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16.1.3.1 LIST OF INDEPENDENT ETHICS COMMITTEE (IEC) OR INSTITUTIONAL REVIEW BOARD (IRB)

ARGENTINA

Study Site Number Independent Ethics Committee or Institutional Review Board Address(es)

1231

Comité Institucional de Revisión de Ensayos Clínicos (C.I.R.E.C.) del Hospital Militar Central

"Cirujano Mayor Dr Cosme Argerich"

Av. Luis María Campos 726, Edificio PACE Piso 5

CABA, 1426 ARGENTINA

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BRAZIL

Study Site Number Independent Ethics Committee or Institutional Review Board Address(es)

1226 CONEP (Comissao Nacional de Etica em Pesquisa)

SRTV 701, Via W 5 Norte, lote D, Edificio PO 700, 3º andar - Asa Norte

Brasilia, DF 70719-040

BRAZIL

Comite de Etica em Pesquisa da Faculdade de Medicina do ABC\Fundacao do ABC-- FMABC

Avenida Lauro Gomes, 2000 - Vila Sacadura Cabral

Santo Andre/SP, 09060-870

BRAZIL

1241 Comite de Etica em Pesquisa do Hospital Santo Antonio /Obras Sociais Irma Dulce

Avenida Luiz Tarquínio, snº, portao 9, 1º andar, sala 1, Roma

Salvador, BA 40414-120

BRAZIL

CONEP (Comissão Nacional de Ética em Pesquisa)

SRTV 701, Via W 5 Norte, lote D, Edificio PO 700, 3° andar -Asa Norte

Brasília/DF, 70719-040

BRAZIL

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GERMANY

Study Site Number 1185	Independent Ethics Committee or Institutional Review Board Address(es) Landesaerztekammer Baden-Wuerttemberg Liebknechtstr. 33 Stuttgart, 70565 GERMANY
1194	Landesaerztekammer Baden-Wuerttemberg Liebknechtstr. 33 Stuttgart, 70565 GERMANY
1195	Landesaerztekammer Baden-Wuerttemberg Liebknechtstr. 33 Stuttgart, 70565 GERMANY
1197	Landesaerztekammer Baden-Wuerttemberg Liebknechtstr. 33 Stuttgart, 70565 GERMANY
1202	Landesaerztekammer Baden-Wuerttemberg Liebknechtstr. 33 Stuttgart, 70565 GERMANY
1203	Landesaerztekammer Baden-Wuerttemberg Liebknechtstr. 33 Stuttgart, 70565 GERMANY

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SOUTH AFRICA

Study Site Number 1229	Independent Ethics Committee or Institutional Review Board Address(es) Pharma Ethics Independent Research Ethics committee 123 Amcor Road, Lyttelton Manor Centurion, 0157 SOUTH AFRICA
1230	Pharma-Ethics (Pty) Ltd 123 Amkor Road, Lyttelton Manor Centurion, 0157 SOUTH AFRICA
1246	Pharma-Ethics (Pty) Ltd 123 Amkor Road, Lyttelton Manor Centurion, 0157 SOUTH AFRICA
1247	Pharma-Ethics (Pty) Ltd 123 Amkor Road, Lyttelton Manor Centurion, 0157 SOUTH AFRICA

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TURKEY

	Independent Ethics Committee or Institutional Review Board Address(es)
1205	Kocaeli Üniversitesi Klinik Arastirmalar Etik Kurulu Kocaeli Üniversitesi Tip Fakültesi Klinik, Arastirmalar Birimi Umuttepe Yerleskesi Kocaeli TURKEY
1207	Kocaeli Üniversitesi Klinik Arastirmalar Etik Kurulu Kocaeli Üniversitesi Tip Fakültesi Klinik, Arastirmalar Birimi Umuttepe Yerleskesi Kocaeli TURKEY
1208	Kocaeli Üniversitesi Klinik Arastirmalar Etik Kurulu Kocaeli Üniversitesi Tip Fakültesi Klinik, Arastirmalar Birimi Umuttepe Yerleskesi Kocaeli TURKEY
1209	Kocaeli Üniversitesi Klinik Arastirmalar Etik Kurulu Kocaeli Üniversitesi Tip Fakültesi Klinik, Arastirmalar Birimi Umuttepe Yerleskesi Kocaeli TURKEY
1210	Kocaeli Üniversitesi Klinik Arastirmalar Etik Kurulu Kocaeli Üniversitesi Tip Fakültesi Klinik, Arastirmalar Birimi Umuttepe Yerleskesi Kocaeli TURKEY
1212	Kocaeli Üniversitesi Klinik Arastirmalar Etik Kurulu Kocaeli Üniversitesi Tip Fakültesi Klinik, Arastirmalar Birimi Umuttepe Yerleskesi Kocaeli TURKEY
1213	Kocaeli Üniversitesi Klinik Arastirmalar Etik Kurulu Kocaeli Üniversitesi Tip Fakültesi Klinik, Arastirmalar Birimi Umuttepe Yerleskesi Kocaeli TURKEY

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Study Site Number Independent Ethics Committee or Institutional Review Board Address(es)

Kocaeli Üniversitesi Klinik Arastirmalar Etik Kurulu

Kocaeli Üniversitesi Tip Fakültesi Klinik, Arastirmalar Birimi Umuttepe Yerleskesi

Kocaeli TURKEY

1217 Kocaeli Üniversitesi Klinik Arastirmalar Etik Kurulu

Kocaeli Üniversitesi Tip Fakültesi Klinik, Arastirmalar Birimi Umuttepe Yerleskesi

Kocaeli TURKEY

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UNITED STATES

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1001	NYU Langone Grossman School of Medicine IRB
	One Park Ave, 6th Fl New York, NY 10016
	UNITED STATES
1002	Western Institutional Review Board
	1019 39th Ave., SE, Ste 120
	Puyallup, WA 98374 UNITED STATES
1003	Western Institutional Review Board
	1019 39th Ave SE, Ste 120
	Puyallup, WA 98374
	UNITED STATES
1005	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200
	Cary, NC 27513
	UNITED STATES
1006	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200
	Cary, NC 27513 UNITED STATES
	UNITED STATES
1007	Cincinnati Children's Hospital Medical Center IRB
	3333 Burnet Ave, MLC 5020 Cincinnati, OH 45229
	UNITED STATES
1000	
1008	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200 Cary, NC 27513
	UNITED STATES

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Study Site Number 1009	Independent Ethics Committee or Institutional Review Board Address(es) Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1011	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1012	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1013	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1015	WCG IRB 1019 39th Ave Se, Ste 120 Puyallup, WASHINGTON 98374 UNITED STATES
1016	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1018	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES

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Study Site Number 1019	Independent Ethics Committee or Institutional Review Board Address(es) Copernicus Group IRB 5000 CentreGreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1021	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1022	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1024	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1027	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1028	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1030	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES

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Study Site Number 1036	Independent Ethics Committee or Institutional Review Board Address(es) Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1037	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1038	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1039	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1042	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1044	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1046	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES

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Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1047	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200
	Cary, NC 27513 UNITED STATES
1048	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1052	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1054	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1055	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1056	Copernicus Group Institutional Review Board 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1057	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES

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Study Site Number 1066	Independent Ethics Committee or Institutional Review Board Address(es) Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1068	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1071	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1072	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1073	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1077	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1079	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES

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Study Site Number	
1080	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513
	UNITED STATES
1081	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200
	Cary, NC 27513 UNITED STATES
1082	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200
	Cary, NC 27513 UNITED STATES
1083	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200 Cary, NC 27513
1004	UNITED STATES
1084	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200
	Cary, NC 27513 UNITED STATES
1085	Copernicus Group IRB 5000 CentreGreen Way, Ste 200
	Cary, NC 27513 UNITED STATES
1087	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200 Cary, NC 27513
	UNITED STATES

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Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1088	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1089	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1090	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1091	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1092	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1093	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1094	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES

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Study Site Number 1095	Independent Ethics Committee or Institutional Review Board Address(es) Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1096	Copernicus Group IRB 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1097	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1098	Copernicus Group Institutional Review Board 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1101	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1107	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1109	Copernicus Group IRB 5000 CentreGreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES

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Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es) WCG IRB 1019 39th Ave Se, Ste 120 Puyallup, WASHINGTON 98374 UNITED STATES
1111	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1112	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1114	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1116	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1117	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1118	Copernicus Group Institutional Review Board 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES

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Study Site Number Independent Ethics Committee or Institutional Review Board Address(es)

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1120	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200
	Cary, NC 27513
	UNITED STATES
1121	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200
	Cary, NC 27513
	UNITED STATES
1122	WESTERN INSTITUTIONAL REVIEW BOARD
	1019 39th Ave S.E, Ste 120
	Puyallup, WA 98374
	UNITED STATES
1123	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200
	Cary, NC 27513
	UNITED STATES
1124	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200
	Cary, NC 27513
	UNITED STATES
1125	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200
	Cary, NC 27513
	UNITED STATES
1126	Kaiser Permanente Northern California Institutional Review Board
	1800 Harrison St, 10th Fl
	Oakland, CA 94612
	UNITED STATES

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Study Site Number 1127	Independent Ethics Committee or Institutional Review Board Address(es) Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1128	Copernicus Group IRB 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1129	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1130	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1131	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1133	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1134	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES

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Study Site Number 1135	Independent Ethics Committee or Institutional Review Board Address(es) Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1136	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1139	WESTERN INSTITUTIONAL REVIEW BOARD 1019 39th Ave SE, Ste 120 Puyallup, WASHINGTON 98374-2115 UNITED STATES
1140	WESTERN INSTITUTIONAL REVIEW BOARD 1019 39th Ave S.E, Ste 120 Puyallup, WA 98374 UNITED STATES
1141	Western Institutional Review Board 1019 39th Ave SE, Ste 120 Puyallup, WASHINGTON 98374 UNITED STATES
1142	Copernicus Group IRB 5000 CentreGreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1145	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES

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Study Site Number 1146	Independent Ethics Committee or Institutional Review Board Address(es) Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1147	WCG IRB 1019 39th Ave Se, Ste 120 Puyallup, WASHINGTON 98374 UNITED STATES
1149	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1150	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1152	Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1156	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1157	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES

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Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1161	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513
	UNITED STATES
1162	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1163	Copernicus Group IRB 5000 CentreGreen Way, Ste 200 Cary, NORTH CAROLINA 27513 UNITED STATES
1166	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1167	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1168	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1169	Lehigh Valley Health Network/Institutional Review Board/Research Participant Office 1255 S Cedar Crest Blvd, Ste 3200 Allentown, PA 18103 UNITED STATES

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Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1170	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200
	Cary, NC 27513 UNITED STATES
	ONTED STATES
1171	Copernicus Group Institutional Review Board
	5000 Centregreen Way, Ste 200
	Cary, NORTH CAROLINA 27513
	UNITED STATES
1174	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200
	Cary, NC 27513
	UNITED STATES
1177	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200
	Cary, NC 27513
	UNITED STATES
1178	Copernicus Group Institutional Review Board
	5000 CentreGreen Way, Ste 200
	Cary, NC 27513
	UNITED STATES
1179	Copernicus Group IRB
	5000 Centregreen Way, Ste 200
	Cary, NORTH CAROLINA 27513
	UNITED STATES
1204	Western Institutional Review Board
	1019 39th Ave SE, Ste 200
	Puyallup, WA 98374-2115
	UNITED STATES

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Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)

1218 Indian Health Service National IRB

5600 Fishers Ln, MS 09E10D Rockville, MARYLAND 20857

UNITED STATES

Johns Hopkins Bloomberg School of Public Health

615 N. Wolfe St, Rm E1100 Baltimore, MARYLAND 21205

UNITED STATES

Navajo Nation Human Research Review Board

Window Rock Blvd, Administration Bldg #2, Division of Health, P.O. Box 1390

Window Rock, ARIZONA 86515

UNITED STATES

Johns Hopkins Bloomberg School of Public Health

615 N. Wolfe St, Rm E1100 Baltimore, MARYLAND 21205

UNITED STATES

1220 Navajo Nation Human Research Review Board

Window Rock Blvd, Administration Bldg #2, Division of Health, P.O. Box 1390

Window Rock, ARIZONA 86515

UNITED STATES

Johns Hopkins Bloomberg School of Public Health

615 N. Wolfe St, Rm E1100 Baltimore, MARYLAND 21205

UNITED STATES

1221 Johns Hopkins Bloomberg School of Public Health

615 N. Wolfe St, Rm E1100 Baltimore, MARYLAND 21205

UNITED STATES

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C4591001

Study Site Number Independent Ethics Committee or Institutional Review Board Address(es) Navajo Nation Human Research Review Board Window Rock Blvd, Administration Bldg #2, Division of Health, P.O. Box 1390 Window Rock, ARIZONA 86515 **UNITED STATES** 1223 Yale University Human Research Protection Program (Human Investigation Committee) 25 Science Park, 3rd Fl, 150 Munson St New Haven, CT 06520 **UNITED STATES** 1224 Copernicus Group IRB 5000 Centregreen Way, Ste 200 Cary, NORTH CAROLINA 27513 **UNITED STATES** 1232 Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 **UNITED STATES** 1235 Western Institutional Review Board 1019 39th Ave. SE, Ste 120 Puyallup, WA 98374 UNITED STATES 1248 Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES 1251 Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 **UNITED STATES**

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Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1252	Copernicus Group Institutional Review Board 5000 Centregreen Way, Ste 200
	Cary, NORTH CAROLINA 27513 UNITED STATES
1254	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1258	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1260	Western Institutional Review Board 1019 39th Ave SE, Ste 120 Puyallup, WA 98374 UNITED STATES
1261	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES
1264	Western Institutional Review Board 1019 39th Ave SE, Ste 120 Puyallup, WA 98374 UNITED STATES
1265	Copernicus Group Institutional Review Board 5000 CentreGreen Way, Ste 200 Cary, NC 27513 UNITED STATES

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Study Site Number Independent Ethics Committee or Institutional Review Board Address(es)

1269 Copernicus Group Institutional Review Board

5000 CentreGreen Way, Ste 200

Cary, NC 27513 UNITED STATES

1270 Kaiser Permanente Northern California Institutional Review Board

1800 Harrison St, 10th Fl Oakland, CA 94612 UNITED STATES

CONFIDENTIAL

Pfizer	CT05-GSOP- SD-GL11 1.0		PHASE 1/2/3 CLINICAL STUDY ASSENT TEMPLATE FOR OLDER CHILDREN	SENT	30-Apr-2020
Protocol Nur	Protocol Number: C4591001		Assent Version Date: Phase 2/3, 03Feb2021	2/3, 03Fe	b2021
⊠ Study □ Country □ Site	Language: English	lish	Center ID: Not Applicable	Country	Country: Not Applicable
Assent Deriv	ed From: Older C	hildren Assen	Assent Derived From: Older Children Assent, Phase 2/3, 07Dec2020		

- 11-year-olds through legal age of adulthood. This template is used by informed consent document authors to develop the assent document for
- Do not delete the header at the top of this page until the assent is customized at the country/site-
- instructional green text, and replace all blue text with appropriate language Before sending the assent to the institutional review board (IRB)/independent ethics committee (IEC), remove the header at the top of this page, remove all inapplicable text, remove all
- The assent must be filed in the Pfizer Trial Master File

CT05-GSOP-SD-GL11 Phase 1/2/3/4 Clinical Study Assent Template for Older Children 30-Apr-2020 Sponsor Assent Version Number (Study/Country/Site): Phase 2/3, 03Feb2021 TMF Doc ID: 173.16 (Study); 173.10 (Country/Central); 173.20 (Site)

Page

Pfizer	CT05-GSOP- SD-GL11 1.0	PHASE 1/2 TEMPLA	SD-GL11 1.0 PHASE 1/2/3 CLINICAL STUDY ASSENT	SENT	30-Apr-2020
rotocol Nur	rotocol Number: C4591001		Assent Version Date: Phase 2/3, 03Feb2021	2/3, 03Fe	b2021
Z Study □ Country □ Site	Language: English	lish	Center ID: Not Applicable	Country	Country: Not Applicable
\ssent Deriv	ed From: Older C	hildren Assent	Assent Derived From: Older Children Assent, Phase 2/3, 07Dec2020		

FDA-CBER-2021-5683-0650143

RESEARCH STUDY TO SEE IF A S **SAFE AND WORKS VACCINE AGAINST COVID-19**

Research studies are the way we find out if test medicines or vaccines are safe and if they COVID-19 is safe and if it can help prevent children and adults from getting COVID-19 We are asking if you would like to be in a research study to see if a vaccine to prevent

wants to know if you want to take part in the research study. The study is being done with healthy children and adults and that is why the study doctor

WHY ARE WE DOING THIS STUDY?

We are doing this study to collect information in children and adults to see if the vaccine is safe and if it can help prevent people from getting COVID-19

understand something, just ask us. It is okay to ask questions now and anytime later that you think of them. You can circle or highlight things on this paper you want to know more about. If you don't The study doctor and nurses will explain the study and answer any questions that you have.

If you decide to be in this study, you will be asked to sign this form. Your parent(s) or your guardian(s) will sign another form. You can talk to your parent(s) or your guardian(s) and ask to read the information the study doctor gives them.

WHAT WILL HAPPEN TO ME IF I GO INTO THE STUDY?

at least 6 visits to the study clinic over roughly the next 2 years. arm at your first and second visit and will need to give at least 5 blood samples. There will be be in the study. If you decide to take part in the study you will be given an injection in your The study starts with an appointment with the study doctor and some tests to see if you can

mL looks like please ask the study team and they will be able to show you the tubes they will is 10 mL if you are between 12 to 15 years of age. If you would like to know what 10 mL or 20 another blood sample. This blood sample is 20 mL if you are 16 years of age or above, and it If you get ill with COVID-19 like symptoms you will need to visit the study clinic and give collect the blood in.



CT05-GSOP-SD-GL11 Phase 1/2/3/4 Clinical Study Assent Template for Older Children 30-Apr-2020 Sponsor Assent Version Number (Study/Country/Site): Phase 2/3, 03Feb2021 TMF Doc ID: 173.16 (Study); 173.10 (Country/Central); 173.20 (Site

Protocol No. C4591001/

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Pfizer	CT05-GSOP- SD-GL11 1.0	PHASE 1/2 TEMPLA	CT05-GSOP- PHASE 1/2/3 CLINICAL STUDY ASSENT SD-GL11 1.0 TEMPLATE FOR OLDER CHILDREN	SENT REN	30-Apr-2020
rotocol Nur	rotocol Number: C4591001		Assent Version Date: Phase 2/3, 03Feb2021	2/3, 03Fe	b2021
Z Study Country Site	Language: English	lish	Center ID: Not Applicable	Country	Country: Not Applicable
\ssent Deri∨	ed From: Older C	hildren Assent	\ssent Derived From: Older Children Assent, Phase 2/3, 07Dec2020		

FDA-CBER-2021-5683-0650144

At your first visit, the study doctor or nurse will give you or your parent(s)/ guardian(s) a device (a bit like a mobile phone) or ask to download an application ('app') to smart phone if guardian(s) on how to fill in the electronic diary (also called e-Diary). will be maintained in confidence. The study doctor will show you or your parent(s)/ you or your parent(s)/ guardian(s) have one. The device/app is secure and your information

illness part of the e-Diary on the device or app on their smartphone. The COVID-19 illness e-Diary will prompt you or your parent(s)/ guardian(s) to record any COVID-19 symptoms every guardian(s) to complete the COVID-19 illness part of the e-Diary. you or your parent(s)/ guardian(s) provide an email address) to remind you or your parent(s)/ also receive text messages to your/ their device or your/ their own smartphone, or emails (if 7 days or at any time you have COVID-19 symptoms. You or your parent(s)/ guardian(s) may There are 2 parts to the electronic diary. Everyone will need to complete the COVID-19

be asked to fill in an e-Diary about how you are feeling for 7 days afer your vaccine injections If you are part of a selected group of participants, you or your parent(s)/ guardian(s) will also

If you decide the take part the following will happen:

At your first visit:

- temperature, measure your height and weight, do a physical exam and ask you some Before you are given your injection, the study doctor or nurse will take your questions about your health.
- will be either 20mL or 10 mL depending on your age group) and take a sample trom your nose using a swab (like a Q-tip). The study doctor or nurse will take a blood sample from your arm using a needle (this
- You will then be given an injection into the muscle at the top of your arm.
- will be asked to complete an electronic diary about how you are feeling for 7 days after If you are part of the selected group of participants, you or your parent(s)/ guardian(s)



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\ssent Deriv	/ed From: Older C	hildren Assent	Assent Derived From: Older Children Assent. Phase 2/3, 07Dec2020		

At your second visit:

- temperature and ask you some questions about your health before they give your injection in your arm. You will be given your second injection, the study doctor or nurse will take your
- will be asked to complete an electronic diary about how you are feeling for 7 days after If you are part of the selected group of participants, you or your parent(s)/ guardian(s) the visit.

It is very important that you or your parent(s)/ guardian(s), as appropriate, complete the contact you or your parent(s)/ guardian(s) to check how you are doing e-Diary regularly as instructed. If this was not completed, your study doctor or nurse will

your information private people who are working on this study will see your information. They are required to keep When you visit the study doctor, the study doctor will write down information about you. Only about 20mL (4 teaspoons) or 10 mL (2 teaspoons) depending on yourage group

and will take a blood sample from your arm using a needle. Each blood sample will be either At the other 4 visits the study doctor or nurse will ask you some questions about your health

Pfizer

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П

What are the Study Injections?

no active ingredients in it. injection. A dummy placebo is a pretend vaccine that looks just like the test vaccine buthas There are 2 types of injections in the study. The active study injection and a dummy placebo

decide if you will get the active study injection or the dummy placebo. You and your parent(s)/guardian(s) will not be told which injection you will get. Once the study doctor has checked that it is OK for you to be in the study a computer will

team) can choose which injection you will get. receive the placebo. No one (including you, your parents, your personal doctor or the study For every 1 child/young person who receives the study vaccine, 1 child/young person will

STUDY? WHAT ARE THE POSSIBLE BENEFITS TO ME IF I AGREE TO BE IN THIS

people like you. Because of this, and the fact that you may receive the placebo vaccination, in preventing COVID-19 in the groups of people already studied, but not yet in children/young social distancing and mask use). you still need to follow local recommendations about how to avoid COVID-19 (for example, Vaccination with BNT162b2 (which is active study injection) has been shown to be effective

WHAT ARE THE POSSIBLE UNCOMFORTABLE OR HARMFUL THINGS THAT COULD HAPPEN TO ME IF I AGREE TO BE IN THIS STUDY?

know all the effects that the vaccine, or your participation in this study, may have on you. Please let the study doctor know if you experience any of these things. The study team will monitor you for risks or discomforts during the study. However, the study team does not There is a chance that during the study you could feel pain or feel bad or uncomfortable

The injection could cause pain, swelling, and redness where it is given.

pain in arm, feeling weak or unwell, and severe allergic reaction (anaphylaxis). allergic reaction (symptoms may include rash, itching, hives, and swelling of the face or lips), chills, headache, joint aches, muscle aches, feeling sick (nausea), enlarged lymph glands, Other side effects could include fatigue (tiredness), increased body temperature (fever)



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In addition,

- Taking a blood sample may:
- hurt when the needle goes into your arm.
- 0 cause a red spot or bruise on your arm or your arm might feel sore
- make you feel dizzy.

0

- 0 cause an infection at the place where the needle went into your arm.
- hurtwhen the sample is taken

Taking a swab from your nose may:

- Cause your nose to bleed.
- Cause your mose to bleed.
- You may feel embarrassed by the questions the study doctor or nurse asks you

study doctor everything you are feeling while you are in the study including if you feel unwell. You might also feel other things. Remember to tell your parent(s) or your guardian(s) and the

Pregnancy, Contraceptives and Babies (do I need to use birth control?)

If you are a girl:

If you are pregnant, planning to become pregnant or breast feeding a baby, you cannot be in the study

study doctor may share this information with others who are working on this study. If you think you are pregnant during the study, you must tell the study doctor immediately. The study doctor may ask for information about the pregnancy and the birth of the baby. The

or nurse may also tell your parent(s) or your guardian(s) about the results of the pregnancy the test results show you are pregnant. Depending on the laws of your area, the study doctor you are not pregnant before you are given your injections. The doctor or nurse will tell you if If you have started to have periods, the study doctor or nurse will test your urine to make sure



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\ssent Derived	From: Older Cl	nildren Assent	Assent Derived From: Older Children Assent, Phase 2/3, 07Dec2020		

discuss this with you if it is appropriate to do so. study and for at least 28 days after your second injection. Your study doctor or nurse will If you are sexually active, you must use birth control consistently and correctly during the

If you are a boy:

nurse will discuss this with you if it is appropriate to do so. during the study and for at least 28 days after your second injection. Your study doctor or If you are sexually active, you must use birth control (eg a condom) consistently and correctly

the baby. The study doctor may share this information with others who are working on this immediately. The study doctor may ask for information about the pregnancy and the birth of If you think that you may have gotten a girl pregnant, you must tell your study doctor

WHAT OTHER OPTIONS ARE THERE?

This study is for research purposes only. Your alternative is to not take part in this study.

Taking part is voluntary and you do not have to be in the study if you don't want to.

It is your choice if you want to be in this study or not. No one will be mad if you choose not to part.

about it later, you can stop being in the study. Just tell the study doctor or your parent(s) or your guardian(s) if you want to stop at any time. If you quit the study, you will be asked to don't want to be in it. If you say okay now to being in the study and you change your mind Your doctors or your parent(s) or your guardian(s) cannot make you be in the study if you come in for one last visit.

Pfizer

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WHAT IF I HAVE QUESTIONS?

You can ask questions about the study at any time

You can call the study doctor any time

If you want to ask questions about what it means to be in a research study, you or your parent(s) or your guardian(s) can call [insert IRB/IEC name] (a group of people who review the study to protect your rights) at [insert IRB/IEC number].

For you to be in this study, you and your parent(s) or your guardian(s) must agree to you But it is still up to you if you want to do it.

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Signature of Person Obtaining Assent:

Date:

Time:

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Please check one box below to show whether or not you want to be in this study.

Printed Name of Child/Young Person	No, I do notwantto be in this study.	Tes, I wallt to be III tills study.

Statement of person conducting assent discussion:

Child/Young Person Signature

Time

- I have explained all aspects of the research to the participant to the best of his or her ability to understand.
- Ν. I have answered all questions of the participant relating to this research.
- ယ I believe the participant's decision to enroll or not enroll is voluntary.
- Printed Name of Person Obtaining Assent: dissent pertains to anything being done solely for the purpose of this research. If the participant decides to enroll, the study doctor and study staff agree to respect the participant's physical or emotional dissent at any time during this research when that



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PHASE 1/2/3 CLINICAL STUDY INFORMED CONSENT TEMPLATE

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about whether or not to participate in this study. sure to read through all sections of this consent document before making your decision This Table of Contents describes the different sections of this consent document. Be

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Where can I find additional information about this study or the study results?

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Privacy Supplement

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Key Study Information and Contact Information

doctor, nurses, and others who work with the study doctor. before, during and after you complete the study. The study team includes the study The study team will address any questions, concerns or complaints you may have

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study. This card includes information about the study that will help them treat you. other health care provider if you seek emergency care while you are taking part in this information, including a 24-hour number. Show this card to any doctor, nurse or Information." You also will be given a card with important emergency contact Phone numbers for the study team are listed below under "Study Site Contact

advocate, and/or bioethicist] listed below. the Institutional Review Board or the Independent Ethics Committee, patient rights involved in the study, you may contact [For the site-level ICD, include as appropriate: If you have any general questions about your rights as a study participant, or would like to obtain information from, offer suggestions to, or speak with someone not directly

VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, Name of Study: A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA

[Institution] Study Number:

Sponsor Study Number: C4591001

Name of Company Sponsoring the Study: BioNTech. Pfizer is conducting the study for BioNTech

Name of Principal Investigator (Study Doctor):

Study Site Contact Information:

Contact Person:

Address:

Phone Number (Normal Business Hours):

Phone Number (Off-Hours or Emergency):

[Complete the following entries for the site-level ICD as appropriate.]

[Institutional Review Board or Independent Ethics Committee] Contact Information:

Contact Person:

Address:

Phone Number:



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Patient Rights Advocate:

Contact Person:

Address:

Phone Number:

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Bioethicist:

Contact Person:

Address:

Phone Number:

Brief Summary of this Study

conducting this study. BioNTech is the regulatory sponsor of this study. Funding for this separate companies who are cooperating to perform this study. Pfizer is responsible for to conduct this study. study is provided by BioNTech and Pfizer and [the study doctor/institution] will be paid This is a research study involving both Pfizer and BioNTech. Pfizer and BioNTech are

have quickly started to look for treatments and ways to prevent COVID-19 this disease was found to be a new Coronavirus; and the disease it causes was named rapidly spread to many other countries around the world. In January 2020, the cause of A new respiratory disease appeared in Wuhan, China in December 2019 and has since COVID-19 (Coronavirus disease 2019). Since then, many companies around the World

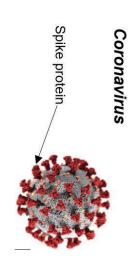
slightly different but work in the same way. The study will also test each of these given to healthy volunteers. The vaccines are given by injection. The vaccines are research study involves 2 investigational vaccines to prevent COVID-19, that will be vaccines at different dose levels (amounts of vaccine). Vaccines help your body to produce antibodies to help you to fight off a disease. This

against COVID-19. We will check how many antibodies you make by taking blood samples and testing them. protein, made by your own body, may help your body to produce antibodies to fight produce some, or all, of the spike protein seen on the outside of the virus. This spike by fatty particles called lipids. They use your own cells' protein making machinery to you ill, instead the vaccines are made up of part of the virus's genetic code, surrounded These vaccines do not contain the whole virus, or the parts of the virus that can make



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gather information to advance science and medicine and does not replace your regular care is to improve or otherwise manage your health, but the purpose of research is to your regular provider <u>and</u> inform the study team, as described later in this document medical care. If you need medical care during your time in the study, you should contact This study is different from your regular medical care. The purpose of regular medical

that you may have about the study. or medical care to which you are entitled. We encourage you to have conversations with whether it is right for you. The study team will work with you to answer any questions your family, caregivers, doctors, and study team about taking part in this study and the study now, and then change your mind later at any time without losing any benefits your regular medical care if you decide not to participate. You can choose to take part in Taking part in this study is voluntary (your choice). There is no penalty or change to

this consent document for your reference You will receive a signed copy of this consent document for your records. Please keep

3. What is the purpose of this study?

will try to see if the vaccine works to prevent COVID-19, as well as: quickly as possible, this study has been separated into 2 phases. In both the phases we vaccine to prevent COVID-19 is an urgent need. To test this investigational vaccine as disease that has spread all over the world and is affecting lots of people); finding a The World Health Organization (WHO) has declared COVID-19 to be a pandemic (a

- Phase 1 where we choose which vaccines at which dose levels are safest and make the most antibodies
- Phase 2/3 where we look at one vaccine at one dose level in lots of people to of antibodies they produce collect even more information about the safety of the vaccines and the amounts

You are being asked to take part in Phase 2/3.

Everyone in Phase 2/3 of the study will receive 2 injections of either: ingredients). In this study the placebo will be salt-water, also known as normal saline (BNT162b2) with those who receive a placebo (a placebo does not contain any active The study will compare the results of the people who receive the study vaccine



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- Study vaccine followed by study vaccine
- Placebo followed by placebo

the same dose, that was chosen based on the results from Phase 1. In Phase 2/3 everyone who receives the study vaccine will receive the same vaccine

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you experience any of the COVID-19 symptoms (explained later in this document). information about your health. You will also be required to contact the study doctor if require you to visit the study doctor to undergo study procedures and to provide The study doctor will determine whether you are eligible for the study. This study will

How long will I participate in this study?

6 to 7 planned times during the study, and any time after you have experienced COVID-19 symptoms and are feeling better in about a month's time. You could be in this study for up to about 26 months. You will need to visit the study site

How many people will take part in this study?

Phase 2/3 of the study up to 43,998 people will take part. Approximately 44,193 healthy people could take part in the 2 phases of this study. In

It is expected that about [number] people will participate in Phase 2/3 of the study at this location.

6. What will happen during this study?

be asked to read and sign this consent document. Before any study procedures begin, or before you begin preparing for the study, you will

be able to take part in the study and the study doctor will explain why this is the case requirements to take part in this study. If you do not meet the requirements, you will not After signing this consent document, the study doctor will check if you meet all of the

Study Vaccines

one (including you, your personal doctor and the study team) can choose this every 1 person who receive the study vaccine, 1 person will receive the placebo. No randomly assigned (like flipping a coin) to receive the study vaccine or placebo. For assignment. Once the study doctor has confirmed you meet the study requirements, you will be

know whether you are receiving the study vaccine or placebo, but the person who gives person that gives you the vaccine will not be able to talk about it with you. In case of you the vaccine will know because the vaccine and placebo do not look the same. This is an 'observer-blind study', which means that you and the study doctor will not However, the syringe will be covered with a label so the contents are not visible and the



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vaccine or placebo. urgent need, the study doctor can learn quickly whether you have received study

site for at least 30 minutes for observation after receiving the study vaccine or placebo. days you receive the study vaccine or placebo, you will be asked to wait at the study your upper arm. Everyone will receive 2 injections, approximately 3 weeks apart. On the The study vaccine or placebo will be given to you through an injection into the muscle in

Overview of Study Procedures and Assessments

come in for extra visit(s) if necessary, to protect your well-being. in this research study. In addition to the visits listed, your study doctor may ask you to The table below lists the tests and procedures or assessments that you will have done

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For people taking part in Phase 2/3, the study doctor or nurse will:

Visit Number	1	2	3	4	5	6
Visit Description	Study Vaccine 1	Study Vaccine 2	1-Month Visit	6-Month Visit	12-Month Visit	24-Month Visit
Ask about Medical history as well as date of birth, sex, race and ethnicity	Х					
Ask about medicines you are currently taking	Х	Х	Х	Х	Х	Х
Perform clinical assessment	Х					
Record latest CD4 count and viral load (for HIV positive participants only)	Х		Х	Х	Х	Х
Measure body temperature	Х	Х				
Measure height and weight	Х					
Urine pregnancy test (if appropriate)	Х	Х				
Ask about other vaccinations you have had	Х	Х	X	Х		
Check you meet all the study requirements	Х	Х				
Check contraceptives (if appropriate)	Х	Х	Х			
Collect blood sample to test antibody levels	~20 mL		~20 mL	~20 mL	~20 mL	~20 mL
Take a nasal swab	Х	Х				
Get the study injection, followed by a 30mins observation period	Х	X				
Give you an e-diary or help you download one	Х					
Vaccination e-diary completion for 7 days (if you are part of chosen group to self-report potential side effects daily for 7 days following each vaccination)	Х	Х				
COVID-19 illness e-diary completion	Х	X	Х	Х	Х	Х
Ask how you are feeling generally	Х	X	Х	Х	Х	Х



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Blood samples for antibody testing

used to test if you already had antibodies against the coronavirus that causes COVIDusing a needle at these visits. vaccination. About 20mL of blood (about 4 teaspoons) will be collected from your arm 19 when you enrolled in the study and may be used to test your antibody levels after You will have blood taken 5 times during the planned visits of the study. This will be

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E-Diary

application ('app') to your smart phone if you have one. The device/app is secure and will either give you a device (a bit like a mobile phone) or ask you to download an At Visit 1, the study team will show you how to fill in an electronic diary (or e-Diary). We your confidentiality will be maintained.

device or your own smartphone, or emails (if you provide your email address) to remind any time you have COVID-19 symptoms. You may also receive text messages to the you to complete the COVID-19 illness part of the e-Diary. Diary will prompt you to record any COVID-19 symptoms (see below) every 7 days or at part of the e-Diary on the device or app on your smartphone. The COVID-19 illness e-There are 2 parts to the e-Diary. Everyone will need to complete the COVID-19 illness

day in the evening with the first day being the day of the vaccination. to complete the vaccination part of the e-Diary for 7 days after each vaccination, once a If you are part of a subset of participants, you will also be instructed by the study team

the thermometer to measure your temperature under your tongue and you will use the You will need to record these measurements in the vaccination part of the e-Diary. measuring device to measure any redness or swelling where the injection was given. You will be given a thermometer and a measuring device to take home. You will use

effects you may have after the injection. If you have any severe symptoms after your schedule an extra visit. vaccination, you should contact your study doctor and the study doctor or nurse may The vaccination part of the e-Diary will also ask other questions about potential side

your study doctor or nurse will contact you to check how you are It is very important that you complete the e-Diary regularly as instructed. If you do not,

Urine pregnancy test

check you are not pregnant before you get the study injection. CT05-GSOP-RF04 7.0 Phase 1/2/3/4 Clinical Study Informed Consent Template (01-Jul-2019) Page:

If you're a woman who is able to have children, you will have a urine pregnancy test to

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What happens if I have positive nasal swab test result?

but will be requested to remain in the study. vaccine as normal. However, if the positive COVID-19 test result is accompanied by potential COVID-19 related symptoms, you will continue to receive the second study causes COVID-19, either at Visit 1 or any time between Visit 1 and Visit 2, but with no medical treatment. If you has a positive nasal swab test result for the coronavirus that to your study doctor, but this will take some time so you should not rely on these for from the Visit 1 and 2 swabs, and all results from the illness visit swabs, will be provided COVID-19 illness – see below) will be tested in a research laboratory. Positive results Nasal swabs obtained during the study (at Visits 1 and 2, and at the time of a potentia potential COVID-19 related symptoms, you will not be given the second study vaccine

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If You Get COVID-19 Symptoms

your usual provider, as well as the study doctor. enough that you would normally see a healthcare professional, please contact Note that this is not instead of your routine medical care. If you feel unwell If you get any of the following you must contact the study doctor straight away.

- A diagnosis of COVID-19
- rever,
- New or increased cough;
- New or increased shortness of breath;
- Chills;
- New or increased muscle pain;
- New loss of taste/smell;
- Sore throat;
- Diarrhea;
- Vomiting.

will be provided to the study doctor once it is available, but this will take some time, and contact your usual provider if you have COVID-19 symptoms and think you need cannot be used to diagnose you with COVID-19. This is why it is important that you coronavirus. We will give you separate instructions about how to take a nose swab care. They will also ask you to take a nose swab or take one from you to check for the the site to talk about how you are feeling and if you have needed any other medical medical care yourself and how to ship the swab to the laboratory if needed. The result from this swab The study doctor may ask you to have a telephone conversation, video call or to visit



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contact your usual provider, and any facility where you are treated, to obtain details and If you are diagnosed with COVID-19, for the purposes of the study, the study doctor will collect medical records: by signing this informed consent document, you agree to this.

test your antibody levels became unwell and you will give another 20 mL (about 4 teaspoons) blood sample to The study doctor will arrange an extra visit to the study site about a month after you

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After the study

through an authorized healthcare professional. you leave the study before receiving the study vaccine, it may be available to you The study vaccine is available only during this study and not after the study is over. If

Are there any special instructions to follow for this study?

and tell them if: It is important you follow all the instructions given to you by the study nurse or doctor

- You don't understand anything about the study
- You are not able to comply with the study requirements
- There are changes in your health
- You take any new medications or receive any other vaccines
- You are going away for a long period
- You wish to take part in another research study

$\dot{\infty}$ What are the possible risks and discomforts of this study?

unwell or uncomfortable and even potentially be serious or life-threatening. All research however, the study team does not know all the effects that the study vaccine may have participants taking part in the study will be watched carefully for any negative effects; Any research has some risks, which may include negative effects that could make you

discussed below. If you take part in this study, the most likely risks or discomforts to happen to you are

this consent document. soon as they occur. Phone numbers for the study team are listed in [Section 1] of It is important that you report to the study team all symptoms and side effects as

Study Vaccine Risks



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countries, about 26 million doses have been distributed. vaccine. In addition, since the vaccine has been approved for emergency use in many included 21,744 people 16 yrs of age and older who have received at least one dose of the Up until the end of 2020, the safety of BNT162b2 has been studied in clinical trials that have

risks have been determined to be caused by BNT162b2 vaccine: Based on the clinical study results, and information gathered during general use, the following

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fatigue (tiredness), increased body temperature (fever, more common after the second dose), chills, headache, joint aches, and muscle aches Very common (occurring in more than 1 in 10 people): injection site pain, injection site swelling

redness Common (between 1 in 10 and 1 in 100 people): feeling sick (nausea), and injection site

Uncommon (between 1 in 100 and 1 in 1,000 people): enlarged lymph glands, allergic reactions feeling weak or unwell. (symptoms may include rash, itching, hives, and swelling of the face or lips), pain in arm, and

Frequency cannot be estimated from available data: severe allergic reaction (anaphylaxis).

based on results from studies of similar vaccines, as well as risks that are currently unknown. As in all research studies, the COVID-19 vaccine may involve risks that might be expected

soon as they occur, whether or not you think they are caused by the study vaccine Therefore, it is important that you report all symptoms and side effects that you experience as

Due to the way in which the study vaccines are made, they cannot cause COVID-19 disease

If I catch COVID-19 disease, could the vaccine make it worse?

received the vaccine than in those that did not. So far this has not been seen with BNT162b2. causes COVID-19), there have been reports of the illness being more severe in the animals that caused by COVID-19 (for example, fever, cough, shortness of breath). remains important for you to contact your study doctor if you develop symptoms that might be For some other vaccines tested in animals against similar viruses (but not the coronavirus that

Placebo Risks

swelling and redness at the site of injection. placebo, some people who received the placebo injection reported pain, bruising having the side effects mentioned above are less likely. In other studies using the same As the placebo injection contains salt-water and no active ingredients, the chances of



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Risks from Study Procedures

Risks and possible discomforts you might have from the study procedures include:

sample collection, you should talk to the study doctor. may faint. If you have a previous history of feeling dizzy or fainting during blood infection around the vein where the blood is collected. You may feel dizzy or include pain from inserting the needle, or less often, swelling, bruising, or **Blood samples:** The risks and possible discomforts involved in taking blood

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may include pain or general discomfort. Sometimes it may cause the nose to Nasal Swabs: The risks and possible discomforts involved in taking nasal swabs

Pregnancy-Related Risks; Use of Birth Control

should not join this study. If you are currently pregnant, plan to become pregnant, or are breastfeeding a child, you

this research study and will help you select the method(s) that is appropriate for you. will discuss with you the methods of birth control that you should use while you are in applies to men as well as women who take part in the research study. The study doctor consistently and correctly for at least 28 days after you receive your last injection. This If you are able to have children and you are sexually active, you must use birth control method and may review this with you at each of your research study visits The study doctor will also check that you understand how to use the birth control

control during the research study, you should tell the study doctor immediately. pregnant. may be withdrawn from the research study if you stop using birth control or you become becomes pregnant during the research study, or you want to stop your required birth Birth control methods, even when used properly are not perfect. If you or your partner

Pregnancy Follow-up

If you or your partner become pregnant during the study, up until 6 months after you last study injection, please tell the study doctor **immediately**. Please also tell the doctor who agree, this information will be provided to BioNTech/Pfizer for safety follow-up study. The study doctor will ask if you/your partner or your pregnancy doctor is willing to will be taking care of you/your partner during the pregnancy that you took part in this provide updates on the progress of the pregnancy and its outcome. If you/your partner

9 What are possible benefits of this study?



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and the fact that you may receive the placebo vaccination, you still need to follow local the groups of people already studied, but not yet in people like you. Because of this, recommendations about how to avoid COVID-19 (for example, social distancing and Vaccination with BNT162b2 has been shown to be effective in preventing COVID-19 in

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What will happen to my blood and nasal swab samples?

complete may be used for additional research related to the development of products destroyed. In addition to testing for this study, any samples left over after the study is may be kept for up to 15 years after the study ends, at which time they will be will not know who you are. Some of the samples may be stored for future testing and sample will be labeled with a code so that the laboratory workers testing the samples No testing of your DNA will be performed. Your blood and nasal swab samples will be used only for scientific research. Each

samples will remain the property of BioNTech/Pfizer and may be shared with other performed. You will not be told of additional tests, nor will you receive results of any of researchers as long as confidentiality is maintained and no testing of your DNA will be Any data already collected from those samples will still be used for the study. The You may request that your samples, if they can be identified, be destroyed at any time

What other choices do I have if I do not join this study?

study. This study is for research purposes only. Your alternative is to not take part in this

<u>1</u>2. What happens if I am injured during this study?

For mandatory research injury language, < click here > (retain this link in the study-level country-level ICD. ICD). The country-specific research injury language must be included verbatim in the

What if I join this study and then change my mind?

stopping or decide to stop so that you can end participation in the study in the safest any benefits to which you are entitled. Tell the study doctor if you are thinking about stop participating at any time. Your decision will not affect your regular medical care or If you agree to participate and then change your mind for any reason, you are free to

While you are participating, the study team will tell you in a timely manner if new continuing in this study. If you decide to withdraw from the study, you may be asked to information is learned during the course of the study that could change your mind about



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the study vaccine continue to participate in the study procedures even though you would no longer receive

If you agree to continue with the study, information about your health will continue to be collected as described in [Section 6].

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study team will explain what other procedures or discussions would occur. If you decide to stop participating in this study, you must notify the study doctor. The

Sometimes the study doctor or BioNTech/Pfizer may decide to take you out of the study (even if you do not agree) if:

- You are unable or unwilling to follow the instructions of the study team;
- The study doctor decides that the study is not in your best interest or that you are no longer eligible to participate; or
- protect your rights), or by a government or regulatory agency. independent ethics committee (IEC) (a group of people who review the study to The study is stopped by BioNTech/Pfizer, the institutional review board (IRB) or

consent document. It describes what happens to your personal information (including your biological samples) and how it may be used if you withdraw from the study. The study team will give you a Privacy Supplement, which is considered part of this

What will I have to pay for if I take part in this study?

study-related procedures, or study visits. You will not need to pay for any of the study vaccines (COVID-19 Vaccine or placebo),

Will I be paid for taking part in this study?

amounts; and reimbursement schedule; note whether receipts are required]. study. You will be reimbursed by [enter, as applicable, method of reimbursement; (for example, parking, meals, travel) that you have as a result of taking part in this you complete, you will be reimbursed by the study site to cover reasonable expenses You will not receive any payment for taking part in this study. However, for each visit

BioNTech/Pfizer may use information resulting from the study to develop products or processes from which they may make a profit. There are no plans to pay you or provide products or processes that are developed using information from the study. you with any products developed from this research.BioNTech/Pfizer will own all

Pfizer

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<u>1</u>6. What will happen to my personal information?

that the Privacy Supplement follows this consent document, after the signature section. verbatim. Any requested changes must be approved by Clinical Development Legal. Note <click here> for language to be inserted into this section. This text must be inserted

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study results? Where can I find additional information about this study or the

at any time most, the Web site will include a summary of the results. You can search this Web site required by U.S. Law. This Web site will not include information that can identify you. At A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as

https://www.clinicaltrialsregister.eu/ study results, when available, may also be found on www.pfizer.com and

database soon after they become available using the following EU trial number for the study: [insert trial number]. outcome. To the extent possible, you will be able to access these summaries in the EU at [insert link to the database]. This information will be provided no matter what the study's In addition, a plain summary of the study results will be made available in the EU database

sites, please ask a member of the study team. These Web sites are in English only. If you need assistance understanding these Web

accordance with applicable law, but will <u>not</u> be given to your family, your employer or study results may be given to you or your doctor (if different from the study doctor) in when all participants have completed the study. At that time, certain of your individual BioNTech/Pfizer will provide the study doctor with information about the study results any insurance company.

exploratory research to specific individuals, including you. BioNTech/Pfizer does not If any exploratory research is done, it may not be possible to link any results from that your doctor (if different from the study doctor). plan to return information from any exploratory research to you, the study doctor, or

18. Signatures

Agreement to Participate and to Process Data

and understand this consent document for the study described above and have CT05-GSOP-RF047.0 Phase 1/2/3/4 Clinical Study Informed Consent Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site)

I confirm I have read (or, if I cannot read, a study team member has read to me)

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study and to decide whether or not to participate consent document. I also have had an opportunity to ask about the details of the had the opportunity to ask questions. I have had enough time to review this

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- N I have read and understand the Privacy Supplement. I understand that taking part within and outside my country of residence for health care, medical research analysis and reporting) of my personal information, as explained in the Privacy in the study will require the processing (including collection, use, transfer, storage and/or regulatory purposes. Supplement. I understand and agree to the processing of my personal information
- I understand that taking part is voluntary and that I am free to stop taking part in longer be traceable to me, may have already been used, or may have been given that my biological samples may not be able to be destroyed because they may no laws and regulations and to maintain the integrity of the study. I also understand processing, my personal information held at that time may be kept to comply with legal rights will not be affected. However, even if I withdraw my consent to at any time. I do not need to give any reason and my regular medical care and this study or to withdraw my consent to the processing of my personal information a third party
- I agree to the study team accessing my medical history, including information from medical records and test results and any medical treatment I receive during the care providers treating me for access to such information. course of the study, and if necessary, contacting my doctor or any other health
- I understand that BioNTech/Pfizer and/or others working with or on behalf of personal information. the study and any other research. I agree that they may have access to my information about me generated at the study site or collected by the study team for committees (IECs), and regulatory agencies may need access to personal BioNTech/Pfizer, institutional review boards (IRBs) or independent ethics
- <u>က</u> I do not give up any of my legal rights by signing this consent document. I have been told that I will receive a signed and dated copy of this document
- I agree to take part in the study described in this document.

Printed name of participant

Signature of participant

Date of signature[§]



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(If no legally acceptable representative is used)

§Participant must personally date their signature

Person Obtaining Consent:

Printed Name of the Person Conducting the Consent Discussion

Date of signature

Consent Discussion †

Signature of the Person Conducting the

document during the same discussion when the participant signs the consent document. investigator to conduct the informed consent process, must sign and date the consent †The investigator, or an appropriately qualified and trained person designated by the

Pfizer

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PRIVACY SUPPLEMENT

PRIVACY SUPPLEMENT

data privacy language must be included verbatim in the country-level ICD. Any requested changes must be approved by Clinical Development Legal. Supplement, < click here > (retain this link in the study-level ICD). The country-specific For mandatory country-specific data privacy language to be inserted in this Privacy

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stored? Who will use my personal information, how will they use it, and where will it be

finalisationJ Mandatory study language – retain the below paragraph and delete this green text before

that are uploaded will be temporary and removed from the secure system after the BioNTech/Pfizer and/or BioNTech/Pfizer representatives can review and verify study systems maintained by a third party engaged by BioNTech/Pfizer so that records that include information that directly identifies you may be uploaded to secure records, including health records, maintained by the study team at your study site. Your Any personal information collected about you during this study will be entered into Some of the uploaded records will be kept for XX years. The remaining records



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Protocol Number: C4591001 ICD Derived From: Study Country Site Language: English CT05-GSOP-RF04 7.0 Parent ICD, Phase 2/3, 08Dec2020 PHASE 1/2/3 CLINICAL STUDY INFORMED CONSENT TEMPLATE Center ID: Not Applicable 03Feb2021 ICD Version Date: Parent ICD, Phase 2/3, **Country:** Not Applicable 01-Jul-2019

Table of Contents

about whether or not to participate in this study. sure to read through all sections of this consent document before making your decision This Table of Contents describes the different sections of this consent document. Be

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(1)

16. What will happen to my child's personal information?

Where can I find additional information about this study or the

Signatures

Privacy Supplement

<u>1</u>∞

study results?

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Key Study Information and Contact Information

includes the study doctor, nurses, and others who work with the study doctor. may have before, during and after your child complete the study. The study team The study team will address any questions, concerns or complaints you or your child

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study. This card includes information about the study that will help them treat your child other health care provider if your child seeks emergency care while taking part in this information, including a 24-hour number. Show this card to any doctor, nurse or Phone numbers for the study team are listed below under "Study Site Contact Information." You also will be given a card with important emergency contact

appropriate: the Institutional Review Board or the Independent Ethics Committee directly involved in the study, you may contact [For the site-level ICD, include as would like to obtain information from, offer suggestions to, or speak with someone not If you have any general questions about your child's rights as a study participant, or patient rights advocate, and/or bioethicist] listed below.

VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, Name of Study: A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA

[Institution] Study Number:

Sponsor Study Number: C4591001

Name of Company Sponsoring the Study: BioNTech. Pfizer is conducting the study for BioNTech

Name of Principal Investigator (Study Doctor):

Study Site Contact Information:

Contact Person:

Address:

Phone Number (Normal Business Hours):

Phone Number (Off-Hours or Emergency):

[Complete the following entries for the site-level ICD as appropriate.]

[Institutional Review Board or Independent Ethics Committee] Contact Information:

Contact Person:

Address:

Phone Number:



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Patient Rights Advocate:

Contact Person:

Address:

Phone Number:

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Bioethicist:

Contact Person

Address:

Phone Number:

2. Brief Summary of this Study

comparing an investigational (study) vaccine against a placebo (injection with no active ingredient) to see if the vaccine can prevent COVID-19. The vaccine is given by You are being asked to allow your child to take part in a research study that involves

separately provide their consent to continue taking part in the study. request, would not be shared with you unless required by local law. Also, if your child will also be able to decide not to take part for confidential reasons, which, if they meet privately with a member of the study team to ask confidential questions. Your child assent document similar to this consent document. They may have an opportunity to child may give assent verbally, or they may be asked to print or sign their name on an to verify your child's agreement (called "assent") to take part in this study. Your reaches the legally recognized age of majority (adulthood) during the study, they must Depending on your child's age, mental status and local laws, the study team may need

is healthy and over the age of 12. You are being asked to allow your child to be in this research study because your child

study is provided by BioNTech and Pfizer and [the study doctor/institution] will be paid conducting this study. BioNTech is the regulatory sponsor of this study. Funding for this separate companies who are cooperating to perform this study. Pfizer is responsible for to conduct this study. This is a research study involving both Pfizer and BioNTech. Pfizer and BioNTech are

have quickly started to look for treatments and ways to prevent COVID-19 this disease was found to be a new Coronavirus; and the disease it causes was named rapidly spread to many other countries around the world. In January 2020, the cause of A new respiratory disease appeared in Wuhan, China in December 2019 and has since COVID-19 (Coronavirus disease 2019). Since then, many companies around the World

research study involves 2 investigational vaccines to prevent COVID-19, that will be CT05-GSOP-RF047.0 Phase 1/2/3/4 Clinical Study Informed Consent Template (01-Jul-2019)

Vaccines help your body to produce antibodies to help you to fight off a disease. This

Pfizer

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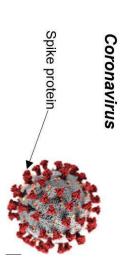
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different dose levels (amounts of vaccine). different but work in the same way. The study will also test each of these vaccines at given to volunteers. The vaccines are given by injection. The vaccines are slightly

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antibodies to fight against COVID-19. We will check how many antibodies your child machinery to produce some, or all, of the spike protein seen on the outside of the virus surrounded by fatty particles called lipids. They use a persons cells' protein making your child ill, instead the vaccines are made up of part of the virus's genetic code makes by taking blood samples and testing them. This spike protein, made by your child's body, may help your child's body to produce These vaccines do not contain the whole virus, or the parts of the virus that can make



time in the study, you should contact your regular provider and inform the study team, medical care is to improve or otherwise manage your child's health, but the purpose of as described later in this document. replace your child's regular medical care. If your child needs medical care during their research is to gather information to advance science and medicine and does not This study is different from your child's regular medical care. The purpose of regular

child. The study team will work with you to answer any questions that you may have family, friends, doctors, and study team about this study and whether it is right for your which you or your child are entitled. We encourage you to have conversations with your then change your mind later at any time without losing any benefits or medical care to about the study. penalty or change to you or your child's regular medical care if you decide not to allow Allowing your child to taking part in this study is voluntary (your choice). There is no your child to participate. You can choose to let your child take part in the study now, and

this consent document for your reference You will receive a signed copy of this consent document for your records. Please keep

What is the purpose of this study?

disease that has spread all over the world and is affecting lots of people); finding a vaccine to prevent COVID-19 is an urgent need. To test this investigational vaccine as The World Health Organization (WHO) has declared COVID-19 to be a pandemic (a



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will try to see if the vaccine works to prevent COVID-19, as well as: quickly as possible, this study has been separated into 2 phases. In both the phases we

make the most antibodies Phase 1 where we choose which vaccines at which dose levels are safest and

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Phase 2/3 where we look at one vaccine at one dose level in lots of people to of antibodies they produce collect even more information about the safety of the vaccines and the amounts

Your child is being asked to take part in Phase 2/3.

ingredients). In this study the placebo will be salt-water, also known as normal saline. Everyone in Phase 2/3 of the study will receive 2 injections of either: (BNT162b2) with those who receive a placebo (a placebo does not contain any active The study will compare the results of the people who receive the study vaccine

- Study vaccine followed by study vaccine
- Placebo followed by placebo

the same dose, that was chosen based on the results from Phase 1. In Phase 2/3 everyone who receives the study vaccine will receive the same vaccine at

will require your child to visit the study doctor to undergo study procedures and to the study doctor if your child experience any of the COVID-19 symptoms (explained provide information about their health. You/your child will also be required to contact The study doctor will determine whether your child is eligible for the study. This study later in this document).

4 How long will my child participate in this study?

study site 6 or 7 planned times during the study. Your child will also need to visit the from those symptoms approximately in a month's time. study site if they experience COVID-19 symptoms and again after they have recovered Your child could be in this study for up to about 26 months and will need to visit the

How many adults and children will take part in this study?

Approximately 44,193 volunteers could take part in the 2 phases of this study

2000 will be of 12 to 15 years of age and the remaining will be above the age of 16 In Phase 2/3 of the study up to 43,998 volunteers will take part, in which approximately

6. What will happen during this study?



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to read and sign a similar document. you will be asked to read and sign this consent document. We may also ask your child Before any study procedures begin, or before your child begins preparing for the study

they will not be able to take part in the study and the study doctor will explain why this is the requirements to take part in this study. If your child does not meet the requirements, After signing this consent document, the study doctor will check if your child meets all of

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Study Vaccines

team) can choose this assignment. child will be randomly assigned (like flipping a coin) to receive the study vaccine or the placebo. No one (including you, your child, your child's personal doctor or the study placebo. For every 1 volunteer who receives the study vaccine, 1 volunteer will receive Once the study doctor has confirmed your child meets the study requirements, your

who gives your child the vaccine will know because the vaccine and placebo do not look the same. The syringe will be covered with a label so the contents are not visible and urgent need, the study doctor can learn quickly whether your child received study will not know whether your child will receive the study vaccine or placebo. The person vaccine or placebo. the person that gives your child the vaccine will not be able to talk about it. In case of This is an 'observer-blind study', which means that you, your child and the study doctor

will be asked to wait at the study site for at least 30 minutes for observation. apart. On the days your child receives the study vaccine or placebo, you and your child muscle of the upper arm. All volunteers will receive 2 injections, approximately 3 weeks The study vaccine or placebo will be given to your child through an injection into the

Overview of Study Procedures and Assessments

come in for extra visit(s) if necessary, to protect their well-being. research study. In addition to the visits listed, the study doctor may ask your child to The table below lists the tests and procedures or assessments that will be done in this

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For people taking part in Phase 2/3, the study doctor or nurse will:

Visit Number	1	2	3	4	5	6
Visit Description	Study Vaccine 1	Study Vaccine 2	1-Month Visit	6-Month Visit	12-Month Visit	24-Month Visit
Ask about Medical history as well as date of birth, sex, race and ethnicity	Х					
Ask about medicines your child is currently taking	Х	Х	Х	Х	Х	Х
Perform clinical assessment	X					
Record latest CD4 count and viral load (for HIV positive volunteers only)	Х		Х	Х	Х	X
Measure body temperature	Х	Х				
Measure height and weight	Х					
If your child is female and started her periods, she will be asked to provide a urine sample for a pregnancy test.	Х	Х				
Ask about other vaccinations your child has had	Х	X	Х	Х		
Check your child meets all the study requirements	Х	Х				
If needed, we will discuss with your child about appropriate birth control	X	X	Х			
Collect blood sample to test antibody levels ^a	~20 mL/ ~10 mL		~20 mL/ ~10 mL	~20mL/ ~10 mL	~20 mL/ ~10 mL	~20 mL/ ~10 mL
Take a nasal swab	X	X				
Get the study injection, followed by a 30mins observations period	X	X				
Give you/your child an e-diary or help you/your child download one	X					
Vaccination e-diary completion for 7 days (if your child is part of a chosen group to report potential side effects daily for 7 days following vaccination)	Х	Х				



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For people taking part in Phase 2/3, the study doctor or nurse will:

Visit Number	1	2	3	4	5	6
Visit Description	Study Vaccine 1	Study Vaccine 2	1-Month Visit	6-Month Visit	12-Month Visit	24-Month Visit
COVID-19 illness e-diary completion	Х	X	X	X	Х	Х
Ask how your child is feeling generally	X	X	X	X	Х	X

Abbreviations: HIV = human immunodeficiency virus; e-diary = electronic diary.

a. 20 mL is to be collected from participants ≥16 years of age; 10 mL is to be collected from participants 12 to 15 years of age.



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Blood samples for antibody testing

after vaccination. If your child is 16 years of age or above, about 20 mL of blood (about be used to test if they already had antibodies against the coronavirus that causes will be collected from their arm using a needle at the above specified visits if your child is between 12 to 15 years of age, about 10 mL of blood (about 2 teaspoons) 4 teaspoons) will be collected from their arm using a needle at these visits. Alternatively COVID-19 when they enrolled in the study and may be used to test their antibody levels Your child will have blood taken 5 times during the planned visits of the study. This will

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E-Diary

not require similar level of support from their parent(s)/ legal guardian(s). Therefore, diary on behalf of younger age group children, whilst children in older age group might e-Diary). themselves older age group children (e.g. 16 years or above) are expected to complete the e-diary At Visit 1, the study team will show you or your child how to fill in an electronic diary (or Parent(s)/ legal guardian(s), as appropriate, will be required to complete the e-

device/app is secure, and your child's confidentiality will be maintained download an application ('app') to smart phone if you or your child has one. The We will either give you/ your child a device (a bit like a mobile phone) or ask to

receive text messages to the device or your/your child's own smartphone, or emails (if days or at any time your child has COVID-19 symptoms. You or your child may also you/they provide your/their email address) to remind you/your child to complete the Diary will prompt you/your child to record any COVID-19 symptoms (see below) every 7 part of the e-Diary on the device or app on their smartphone. The COVID-19 illness e-There are 2 parts to the e-Diary. Everyone will need to complete the COVID-19 illness COVID-19 illness part of the e-Diary.

the study team to complete the vaccination part of the e-Diary for 7 days after each If your child is part of a subset of participants, you/ your child will also be instructed by vaccination vaccination, once a day in the evening with the first day being the day of the

use the measuring device to measure any redness or swelling where the injection was your child will use the thermometer to measure temperature under the tongue and will the e-Diary You/your child will be given a thermometer and a measuring device to take home. You/your child will need to record these measurements in the vaccination part of

effects your child may have after the injection. If your child has any severe symptoms The vaccination part of the e-Diary will also ask other questions about potential side



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or nurse may schedule an extra visit. after vaccination, you/your child should contact your study doctor and the study doctor

as instructed. If this was not completed, your study doctor or nurse will contact you/ your It is very important that you/your child, as appropriate, complete the e-Diary regularly child to check how your child is doing.

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Urine pregnancy test

sample to check she is not pregnant before given the study injection. If your child is female and has started her periods, she will be asked to provide a urine

What happens if my child has positive nasal swab test result?

second study vaccine but will be requested to remain in the study. accompanied by potential COVID-19 related symptoms, they will not be given the the second study vaccine as normal. However, if the positive COVID-19 test result is from the Visit 1 and 2 swabs, and all results from the illness visit swabs, will be provided Visit 2, but with no potential COVID-19 related symptoms, they will continue to receive coronavirus that causes COVID-19, either at Visit 1 or any time between Visit 1 and your child's medical treatment. If your child has a positive nasal swab test result for the to your study doctor, but this will take some time so you should not rely on these for COVID-19 illness – see below) will be tested in a research laboratory. Positive results Nasal swabs obtained during the study (at Visits 1 and 2, and at the time of a potential

If Your Child Gets COVID-19 Symptoms

away. Note that this is not instead of routine medical care. If your child feels contact your usual provider, as well as the study doctor. unwell enough that you would normally see a healthcare professional, please If your child gets any of the following you must contact the study doctor straight

- A diagnosis of COVID-19;
- Fever;
- New or increased cough;
- New or increased shortness of breath;
- Chills;
- New or increased muscle pain;
- New loss of taste/smell;
- Sore throat;
- Diarrhea;
- **Vomiting**



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once it is available, but this will take some time, and cannot be used to diagnose the laboratory if needed. The result from this swab will be provided to the study doctor or the study team may take a swab to check for the coronavirus. We will give you/your medical care. The study team will also ask you to help your child to take a nose swab, to visit the site to talk about how they are feeling and if they have needed any other has COVID-19 symptoms and think your child needs medical care COVID-19. This is why it is important that you contact your usual provider if your child child separate instructions about how to take a nose swab and how to ship the swab to The study doctor may ask you/your child to have a telephone conversation, video call or

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you agree to this. obtain details and collect medical records: by signing this informed consent document will contact your child's usual provider, and any facility where you child is treated, to If your child is diagnosed with COVID-19, for the purposes of the study, the study doctor

10 mL (about 2 teaspoons) of blood sample, as appropriate, to test their antibody levels became unwell and your child will need to give another 20 mL (about 4 teaspoons) or The study team will arrange an extra visit to the study site about a month after your child

After the study

through an authorized healthcare professional. you leave the study before receiving the study vaccine, it may be available to you The study vaccine is available only during this study and not after the study is over. If

Are there any special instructions to follow for this study?

doctor and tell them if: It is important you and your child follow all the instructions given by the study nurse or

- You don't understand anything about the study
- You /your child are not able to comply with the study requirements
- There are changes in your child's health
- Your child takes any new medications or receive any other vaccines
- You or your child are going away for a long period
- Your child wishes to take part in another research study

\odot What are the possible risks and discomforts of this study?

child unwell or uncomfortable and even potentially be serious or life-threatening. All Any research has some risks, which may include negative effects that could make your research participants taking part in the study will be watched carefully for any negative



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effects; however, the study team does not know all the effects that the study vaccine may have on your child.

If your child takes part in this study, the most likely risks or discomforts are discussed

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effects as soon as they occur. Phone numbers for the study team are listed in It is important that you/your child report to the study team all symptoms and side [Section 1] of this consent document.

Study Vaccine Risks

vaccine. In addition, since the vaccine has been approved for emergency use in many included 21,744 people 16 yrs of age and older who have received at least one dose of the Up until the end of 2020, the safety of BNT162b2 has been studied in clinical trials that have countries, about 26 million doses have been distributed

risks have been determined to be caused by BNT162b2 vaccine: Based on the clinical study results, and information gathered during general use, the following

chills, headache, joint aches, and muscle aches. fatigue (tiredness), increased body temperature (fever, more common after the second dose), Very common (occurring in more than 1 in 10 people): injection site pain, injection site swelling

redness Common (between 1 in 10 and 1 in 100 people): feeling sick (nausea), and injection site

feeling weak or unwell. Uncommon (between 1 in 100 and 1 in 1,000 people): enlarged lymph glands, allergic reactions (symptoms may include rash, itching, hives, and swelling of the face or lips), pain in arm, and

Frequency cannot be estimated from available data: severe allergic reaction (anaphylaxis).

based on results from studies of similar vaccines, as well as risks that are currently unknown. As in all research studies, the COVID-19 vaccine may involve risks that might be expected

experiences as soon as they occur, whether or not you think they are caused by the study Therefore, it is important that you/ your child report all symptoms and side effects that your child

Due to the way in which the study vaccines are made, they cannot cause COVID-19 disease

If my child catches COVID-19 disease, could the vaccine make it worse?

causes For some other vaccines tested in animals against similar viruses (but not the coronavirus that COVID-19), there have been reports of the illness being more severe in the animals that CT05-GSOP-RF04 7.0 Phase 1/2/3/4 Clinical Study Informed Consent Template (01-Jul-2019)



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symptoms that might be caused by COVID-19 (for example, fever, cough, shortness of breath) remains important for you/ your child to contact your child's study doctor if your child develop received the vaccine than in those that did not. So far this has not been seen with BNT162b2.

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Placebo Risks

swelling and redness at the site of injection placebo, some volunteers who received the placebo injection reported pain, bruising having the side effects mentioned above are less likely. In other studies, using the same As the placebo injection contains salt-water and no active ingredients, the chances of

Risks from Study Procedures

Risks and possible discomforts from the study procedures include:

- blood sample collection, you should talk to the study doctor. or may faint. If your child has a previous history of feeling dizzy or fainting during infection around the vein where the blood is collected. Your child may feel dizzy include pain from inserting the needle, or less often, swelling, bruising, or **Blood samples:** The risks and possible discomforts involved in taking blood
- may include pain or general discomfort. Sometimes it may cause the nose to Nasal Swabs: The risks and possible discomforts involved in taking nasal swabs

Pregnancy-Related Risks; Use of Birth Control

they should not join this study. If your child is currently pregnant, plans to become pregnant, or is breastfeeding a child,

applies to males as well as females who take part in the research study. The study appropriate for them. The study doctor will also check that your child understands how in this research study. The study doctor will help your child select the method that is doctor will discuss with your child the methods of birth control that they should use while consistently and correctly for at least 28 days after they receive their last injection. study visits. to use the birth control method and may review this with them at each of their research If your child is able to have children and is sexually active, they must use birth control

birth control or they become pregnant. partner becomes pregnant during the research study, or if they want to stop their Birth control methods, even when used properly are not perfect. If your child or their <u>immediately</u>. Your child may be withdrawn from the research study if they stop using required birth control during the research study, they should tell the study doctor



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Pregnancy Follow-up

and its outcome. If your child/their partner agree, this information will be provided to their pregnancy doctor is willing to provide updates on the progress of the pregnancy the doctor who will be taking care of your child/their partner during the pregnancy that after their last study injection, please tell the study doctor immediately. Please also tell If your child or their your partner become pregnant during the study, up until 6 months BioNTech/Pfizer for safety follow-up. your child took part in this study. The study doctor will ask if your child/their partner or

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What are possible benefits of this study?

Vaccination with BNT162b2 has been shown to be effective in preventing COVID-19 in the groups of people already studied, but not yet in the case of your child. Because of distancing and mask use). this, and the fact that your child may receive the placebo vaccination, they still need to follow local recommendations about how to avoid COVID-19 (for example, social

<u>10</u>. samples? What will happen to my child's blood and nasal swab

testing and may be kept for up to 15 years after the study ends, at which time they will samples will not know who your child is. Some of the samples may be stored for future No testing of your child's DNA will be performed. is complete may be used for additional research related to the development of products be destroyed. In addition to testing for this study, any samples left over after the study Each sample will be labeled with a code so that the laboratory workers testing the Your child's blood and nasal swab samples will be used only for scientific research.

researchers as long as confidentiality is maintained, and no testing of your child's DNA will be performed. You and your child will not be told of additional tests, nor will you or time. Any data already collected from those samples will still be used for the study. The samples will remain the property of BioNTech/Pfizer and may be shared with other your child receive results of any of these tests You may request that your child's samples, if they can be identified, be destroyed at any

this study? What other choices do I have if I do not want my child to join

study. This study is for research purposes only. The only alternative is to not take part in this

<u>1</u>2. What happens if my child is injured during this study?

Pfizer

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country-level ICD. ICD). The country-specific research injury language must be included verbatim in the For mandatory research injury language, < click here > (retain this link in the study-level

Can I withdraw my child from the study?

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can end participation in the study in the safest way. the study doctor if you are thinking about stopping or decide to stop so that your child child's regular medical care or any benefits to which you/your child is are entitled. Tell participation in the research study at any time. Your decision will not affect your or your You are free to withdraw your consent for your child and discontinue their

they would no longer receive the study vaccine. information is learned during the course of the study that could change your mind about While your child is participating, the study team will tell you in a timely manner if new your child continuing in this study. If you decide to withdraw your child from the study, your child may be asked to continue to participate in the study procedures even though

collected as described in [Section 6]. If your child continues with the study, information about their health will continue to be

doctor. The study team will explain what other procedures or discussions would occur. If you decide to stop your child participating in this study, you must notify the study

study (even if you do not agree) if: Sometimes the study doctor or BioNTech/Pfizer may decide to take your child out of the

- You/your child are unable or unwilling to follow the instructions of the study team;
- The study doctor decides that the study is not in your child's best interest or that they are no longer eligible to participate; or
- protect your rights), or by a government or regulatory agency. independent ethics committee (IEC) (a group of people who review the study to The study is stopped by BioNTech/Pfizer, the institutional review board (IRB) or

consent document. It describes what happens to your child's personal information the study. The study team will give you a Privacy Supplement, which is considered part of this (including biological samples) and how it may be used if you withdraw your child from

What will I have to pay for if my child takes part in this study?

study-related procedures, or study visits. You will not need to pay for any of the study vaccines (COVID-19 Vaccine or placebo),

<u>1</u>5. Will my child be paid for taking part in this study?



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reasonable expenses (for example, parking, meals, travel) that you have as a result of each visit you/your child completes, you will be reimbursed by the study site to cover required]. reimbursement; amounts; and reimbursement schedule; note whether receipts are taking part in this study. You will be reimbursed by [enter, as applicable, method of You will not receive any payment for your child taking part in this study. However, for

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or provide you/your child with any products developed from this research. from the study. BioNTech/Pfizer will own all products or processes that are developed using information processes from which they may make a profit. There are no plans to pay you/your child BioNTech/Pfizer may use information resulting from the study to develop products

<u>6</u>. What will happen to my child' personal information?

verbatim. Any requested changes must be approved by Clinical Development Legal. Note that the Privacy Supplement follows this consent document, after the signature section. <click here> for language to be inserted into this section. This text must be inserted

17. Where can I find additional information about this study or the study results?

child. At most, the Web site will include a summary of the results. You can search this required by U.S. Law. This Web site will not include information that can identify your Web site at any time. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as

https://www.clinicaltrialsregister.eu/. study results, when available, may also be found on www.pfizer.com

outcome. To the extent possible, you will be able to access these summaries in the EU study: [insert trial number]. database soon after they become available using the following EU trial number for the at [insert link to the database]. This information will be provided no matter what the study's In addition, a plain summary of the study results will be made available in the EU database

sites, please ask a member of the study team. These Web sites are in English only. If you need assistance understanding these Web

when all participants have completed the study. At that time, certain of your child's study doctor) in accordance with applicable law, but will not be given to your family, your individual study results may be given to you or your child's doctor (if different from the employer or any insurance company. BioNTech/Pfizer will provide the study doctor with information about the study results



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not plan to return information from any exploratory research to you/your child, the study exploratory research to specific individuals, including your child. BioNTech/Pfizer does If any exploratory research is done, it may not be possible to link any results from that doctor, or your doctor (if different from the study doctor).

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☆ Signatures

Agreement to Participate and to Process Data

- 1. I confirm I have read (or, if I cannot read, a study team member has read to me) and understand this consent document for the study described above and have consent document. I also have had an opportunity to ask about the details of the study and to decide whether or not to participate had the opportunity to ask questions. I have had enough time to review this
- Ŋ I have read and understand the Privacy Supplement. I understand that taking part analysis and reporting) of my child's personal information, as explained in the in the study will require the processing (including collection, use, transfer, storage medical research and/or regulatory purposes. personal information within and outside my country of residence for health care Privacy Supplement. I understand and agree to the processing of my child's
- I understand that taking part is voluntary and that I am free to stop my child taking time may be kept to comply with laws and regulations and to maintain the integrity withdraw my consent to processing, my child's personal information held at that already been used, or may have been given to a third party. to be destroyed because they may no longer be traceable to my child, may have of the study. I also understand that my child's biological samples may not be able regular medical care and legal rights will not be affected. However, even if I personal information at any time. I do not need to give any reason and my child's part in this study or to withdraw my consent to the processing of my child's
- 4 I agree to the study team accessing my child's medical history, including child receive during the course of the study, and if necessary, contacting my information from medical records and test results and any medical treatment my child's doctor or any other health care providers treating my child for access to such information.
- I understand that BioNTech/Pfizer and/or others working with or on behalf of committees (IECs), BioNTech/Pfizer, institutional review boards (IRBs) or independent ethics and regulatory agencies may need access to personal



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my child's personal information.	team for the study and any other research. I agree that they may have access to	information about my child generated at the study site or collected by the study

<u>ල</u> I do not give up any of my child's legal rights by signing this consent document. I have been told that I will receive a signed and dated copy of this document.

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I agree for my child to take part in the study described in this document

term required per local regulation (country-level). In the section below, the term "legally acceptable representative" should be replaced with the

acknowledge that (Please check one of the following): consenting adult providing permission for this child ð participate ⊒. the study, I

- ☐ I am the biological or adoptive parent of the child.
- I am the legal guardian or legally acceptable representative of the child

representatives available to give permission, and they disagree about allowing the acceptable representative must be obtained. If there are two parents/guardians/legally acceptable [If neither option below is checked, then the consent of the second parent/guardian/legally participate in the study, the child should not be enrolled unless that disagreement can be child to

I also acknowledge that (Please check one of the following):

- \square I have sole legal responsibility for the care and custody of the child
- for example, he/she is on active military duty or is incarcerated). "not reasonably available" when he/she cannot be reached by phone/mail/email because, study OR (2) deceased, unknown, incompetent, or not reasonably available (someone is child (for example, biological parent, adoptive parent, or legal guardian or representative) is (1) aware of and agrees with my granting permission for this child to participate in the $\hfill\square$ The other adult(s) with whom I share legal responsibility for the care and custody of the

Printed name of parent/guardian/legally acceptable representative

Signature of parent/guardian/legally acceptable representative

Date of signature[§]



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Printed name of person conducting the consent discussion

CONSENT TO TAKE PART IN STUDY

decision of the first parent/guardian/legally acceptable representative the consent process and there is reason to believe that he/she may disagree with the parent/guardian/legally acceptable representative is (or would like to be) involved in acceptable representative if (1) required by the IRB/IEC; (2) required by local law (e.g., [Include the statements and signature lines below for a second parent/guardian/legally divorced and have shared custody of the child); or (3) the second

Consent of Second Parent/Guardian/Legally Acceptable Representative:

acknowledge that (Please check one of the following): As the consenting adult providing permission for this child to participate in the study, I

	Signature of parent/guardian/legally acceptable representative Date of signature§
Person Obtaining Consent:	Derson Obtaining Consent:

Signature of person conducting the consent discussion[†]

Date of signature

respective signatures Participant/parent/guardian/legally acceptable representative must personally date their



CT05-GSOP-RF047.0 Phase 1/2/3/4 Clinical Study Informed Consent Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version (Study) Parent, Phase 2/3, 03Feb2021

21 of 23 Page:

FDA-CBER-2021-5683-0650191

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[†] The investigator, or an appropriately qualified and trained person designated by the investigator same discussion when the participant's parent/guardian/legally acceptable representative signs to conduct the informed consent process, must sign and date the consent document during the the consent document.

Pfizer

CT05-GSOP-RF04 7.0 Phase 1/2/3/4 Clinical Study Informed Consent Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version (Study) Parent, Phase 2/3, 03Feb2021

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PRIVACY SUPPLEMENT

PRIVACY SUPPLEMENT

data privacy language must be included verbatim in the country-level ICD. Any requested changes must be approved by Clinical Development Legal. Supplement, < click here > (retain this link in the study-level ICD). The country-specific For mandatory country-specific data privacy language to be inserted in this Privacy

Who will use my child's personal information, how will they use it, and where will it be stored?

finalisation] Mandatory study language – retain the below paragraph and delete this green text before

the study is over so that BioNTech/Pfizer and/or BioNTech/Pfizer representatives can review and verify be uploaded to secure systems maintained by a third party engaged by BioNTech/Pfizer records that are uploaded will be temporary and removed from the secure system after into records, including health records, maintained by the study team at your study site. Any personal information collected about you/your child during this study will be entered You/your child's records that include information that directly identifies you/your child may Some of the uploaded records will be kept for XX years. The remaining

Pfizer

TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site)
Sponsor Consent Version (Study) Parent, Phase 2/3, 03Feb2021

CT05-GSOP-RF047.0 Phase 1/2/3/4 Clinical Study Informed Consent Template (01-Jul-2019)

Protocol No: C4591001

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Pfizer	CLINICAL STUDY INFORMED CONSENT ADDENDUM	ADDENDUM	ED CONS	SENT	Page: 1 of 6
Protocol Number:	Associated ICD Version Date	rsion Date:	ICD Addendum Version Date:	dum Vers	ion Date:
C4591001	Adult and Parent ICD (03Feb2021) and Older Children Assent (03Feb2021)	(03Feb2021) and t(03Feb2021)	03Feb2021		
Study ☐Site ☐ Lar	Language: English	Center ID: Not Applicable	oplicable	Country:	Country: Not Applicable

A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS INFORMED CONSENT ADDENDUM FOR

Protocol Number: C4591001

refers to the study participant. In this informed consent addendum, "you" always refers to the study participant. If you parent/guardian/legally acceptable representative, please remember that "you"

above. This addendum is part of the consent procedure. It has been written to provide still applies know. All other information in the main consent form not addressed in this addendum procedures and the recent update to vaccine study risks section that you will want to you with additional information on your new schedule of study visits, tests, You have already signed a consent form to participate in the research study mentioned

Administration of BNT 162b2 to Participants Originally Assigned to Placebo

this consent document before commencing any new set of study-related procedures willingness to receive the BNT162b2 vaccine, you are now being asked to read and sign study. Since it is confirmed that you received placebo, and you have expressed vaccine (active study vaccine) if you received placebo during the earlier part of the You were asked by the study site whether you would consider receiving BNT162b2

will not be able to receive the vaccine and the study doctor will explain why this is the requirements to receive BNT162b2 vaccine. If you do not meet the requirements, you After signing this consent document, the study doctor will check if you meet all the

study site for at least 30 minutes for observation after receiving the vaccine injection will be given into the muscle in your upper arm and will be asked to wait at the BNT162b2 vaccine, you will receive 2 Once the study doctor has confirmed you meet the study requirements injections, approximately 3 weeks apart. The to receive

Pfizer	CLINICAL ST	CLINICAL STUDY INFORMED CONSENT ADDENDUM	ED CONS	SENT	Page: 2 of 6
Protocol Number: C4591001	Associated ICD Version Date: Adult and Parent ICD (03Feb2021) and Older Children Assent (03Feb2021)	and	ICD Addendum Version Date: 03Feb2021	dum Vers	ion Date:
Study Site L	Language: English	Center ID: Not Applicable	oplicable	Country:	Country: Not Applicable

Overview of Study Procedures and Assessments:

may ask you to come in for extra visit(s) if necessary, to protect your well-being for the remaining duration of the study. In addition to the visits listed, your study doctor The table below lists the tests and procedures or assessments that you will have done

teaspoons) will be collected from your arm using a needle at Visit-1. You may have blood taken once and this will be used to against coronavirus that causes COVID-19. About 20mL of blood (about 4 test if you already had

For placebo participants receiving BNT162b2, the study doctor or nurse will:

Visit Number	_	2	ယ	4	51
Visit Description	BNT162b2 Vaccine 1	BNT162b2 Vaccine 2	1-Month Telephone Visit	6-Month Telephone Visit	18-Month Telephone Visit
Obtain urine pregnancy test (if appropriate)	×	×			
Check contraceptives (if appropriate)	×	×			
Ask about medicines you are currently taking	×	×	X	X	×
Record latest CD4 count and viral load (for HIV positive participants only)	×		×	×	×
Check you meet all the study requirements	×	×			
Collect blood sample to test antibody levels ^a	~20 mL				
Take a nasal swab	×	×			
Get the study injection, followed by a 30mins observation period	×	×			
COVID-19 illness e-diary completion	×	×	X	X	×
Ask how you are feeling generally	×	×	×	×	
Request to return the e-diary or assist to delete the app					×

Only if the sample was not taken as part of the study in last 7days

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Pfizer	CLINICAL STUDY INFORMED CONSENT ADDENDUM	UDY INFORM ADDENDUM	ED CONS	SENT	Page: 3 of 6
rotocol Number:	Associated ICD Version Date:	rsion Date:	ICD Addendum Version Date	dum Versi	ion Date:
4591001	Adult and Parent ICD (03Feb2021) and Older Children Assent (03Feb2021)	(03Feb2021) and (03Feb2021)	03Feb2021		
	Language: English	Center ID: Not Applicable	oplicable	Country:	Country: Not Applicable
□Country □Site					

QP

Key Reminders

- COVID-19 but you still need to follow local recommendations about how to Vaccination with BNT162b2 has been shown to be effective in preventing COVID-19 (for example, social distancing and mask use).
- Diary regularly as instructed. If you do not, your study doctor or nurse will contact It is also very important that you continue to complete the COVID-19 Illness e you to check how you are.

Study Vaccine Risks

dose of the vaccine. In addition, since the vaccine has been approved for emergency use in many countries, about 26 million doses have been distributed. Up until the end of 2020, the safety of BNT162b2 has been studied in clinical trials that have included 21,744 people 16 yrs of age and older who have received at least one

Based on the clinical study results, and information gathered during general use, the following risks have been determined to be caused by BNT162b2 vaccine:

swelling, fatigue (tiredness), increased body temperature (fever, more common after the second dose), chills, headache, joint aches, and muscle aches Very common (occurring in more than 1 in 10 people): injection site pain, injection site

redness. Common (between 1 in 10 and 1 in 100 people): feeling sick (nausea), and injection site

pain in arm, and feeling weak or unwell. reactions (symptoms may include rash, itching, hives, and swelling of the face or lips), Uncommon (between 1 in 100 and 1 in 1,000 people): enlarged lymph glands, allergic

Frequency cannot be estimated from available data: severe allergic reaction (anaphylaxis).

currently unknown. expected based on results from studies of similar vaccines, as well as risks that are As in all research studies, the COVID-19 vaccine may involve risks that might be

experience as soon as they occur, whether or not you think they are caused by the study vaccine Therefore, it is important that you report all symptoms and side effects that you

Pfizer	CLINICAL STUDY INFORMED CONSENT	ADDENDUM	ED CONS	SENT	Page : 4 of 6
Protocol Number: C4591001	Associated ICD Version Date: Adult and Parent ICD (03Feb2021) and Older Children Assent (03Feb2021)	rsion Date : (03Feb2021) and :(03Feb2021)	ICD Addendum Version Date: 03Feb2021	dum Versi	ion Date:
⊠Study Lan Country □Site	Language: English	Center ID: Not Applicable		Country:	Country: Not Applicable

Due to the way in which the study vaccines are made, they cannot cause COVID-19

If I catch COVID-19 disease, could the vaccine make it worse?

if you develop symptoms that might be caused by COVID-19 (for example, fever, cough, severe in the animals that received the vaccine than in those that did not. So far this has coronavirus that causes COVID-19), there have been reports of the illness being more For shortness of breath). not been seen with BNT162b2. It remains important for you to contact your study doctor some other vaccines tested in animals against similar viruses (but not the

taking part in this research study, please sign below before agreeing to continue. If after receiving this information you agree to continue Please take as much time as you need to ask questions from the research study team

SIGNATURES:

- I have read the information in this addendum to the informed consent document.
- answered to my satisfaction. I have had an opportunity to ask questions and all of my questions have been
- study. I have been given enough time to decide whether or not I want to continue in the
- I voluntarily agree to continue taking part in this study.
- l do not give up any of my legal rights by signing this consent document.
- I have been told that I will receive a signed and dated copy of this document.

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\triangleright
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\succeq
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NATURE LINE TO BE COMPLETED FOR AN ADULT PARTICIPAN
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SIGNATURE LINE(S) TO BE COMPLETED FOR A CHILD PARTICIPANT:

Signature of participant

Date of signature[§]

Pfizer	CLINICAL STUDY INFORMED CONSENT ADDENDUM	UDY INFORM ADDENDUM	ED CONS	ĒNT	Page: 5 of 6
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Study Langu Country □Site	Language: English	Center ID: Not Applicable	oplicable	Country: N	Country: Not Applicable
As the consenting adult providing permission for this child to participate in the study, acknowledge that (Please check one of the following):	It providing permis se check one of th	ssion for this che following):	nild to parti	cipate in	the study, I
\Box I am the biolo	\square I am the biological or adoptive parent of the child.	arent of the chi	ld.		
□ I am the legal	\square $\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	y acceptable re	presentativ	e of the c	hild.
also acknowledge that (Please check one of the following):	t (Please check on	e of the following	ng):		
☐ The other ad	☐ The other adult(s) with whom I share legal responsibility for the care	I share legal i	responsibili	ity for the	e care and
custody of the guardian or rep	custody of the child (for example, biological parent, adoptive parent, or legal guardian or representative) is (1) aware of and agrees with my granting permission for this child to participate in the study OR (2) deceased unknown	e, biological pa (1) aware of a pate in the stur	irent, adop	tive parei with m	nt, or legal y granting unknown
incompetent, or when he/she ca	incompetent, or not reasonably available (someone is "not reasonably available" when he/she cannot be reached by phone/mail/email because, for example,	ailable (someo	ne is "not re il/email be	easonably cause, fo	/ available" r example,
he/she is on activ	he/she is on active military duty or is incarcerated).	is incarcerated	·		

Signature of Parent/ Guardian / Legally Acceptable Representative Date of signature[§]

Printed Name of Parent / Guardian / Legally Acceptable Representative

Consent of Second Parent/Guardian/Legally Acceptable Representative:

acknowledge that (Please check one of the following): As the consenting adult providing permission for this child to participate in the study, I

□ I am the biological or adoptive parent of the child

 \square I am the legal guardian or legally acceptable representative of the child

Signature of Parent / Guardian / Printed Name of Parent / Guardian Legally Acceptable Representative Legally Acceptable Representative Relationship to study participant Date of signature

CT05-GSOP-RF07 3.0 Addendum ICD Template (01-Jun-2016)
CONFIDENTIAL
TMF Doc ID: 173.15 (Study); 173.09 (Country/Central); 173.24 (Site)

Pfizer	CLINICAL STUDY INFORMED CONSENT ADDENDUM	UDY INFORM ADDENDUM	ED CONS	ŠĖNT	Page: 6 of 6
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⊠Study □Country □Site	Language: English	Center ID: Not Applicable		Country:	Country: Not Applicable

signature, include appropriate signature line. If local IRB/IEC permits assent of older children to be obtained by the co-

Signature of the Person Conducting the Date of signature Consent Discussion †	Printed Name of the Person Conducting the Consent Discussion	Signature of legally acceptable representative PERSON OBTAINING CONSENT	Printed name of legally acceptable representative and relationship	Signature of Child
ature		Date of signature [§]		Date of signature [§]

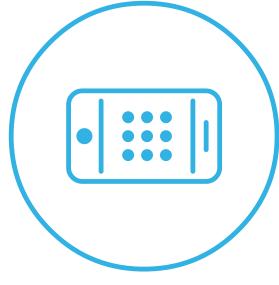
§Participant/parent/guardian/legally acceptable representative must personally date their

acceptable representative signs the addendum. document during the same interview when the participant/parent/guardian/legally investigator to conduct the informed consent process, must sign and date the consent †The investigator, or an appropriately qualified and trained person designated by the



C4591001-Post-12-July-2020





rialMax App™ Site User Guide TrialManager®

Document version: 5
Template version: 12
02NOV2020

Document index: A-1426-0086-5150UG

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IMPORTANT POINTS

incorrect date and time when it is turned back on again. If this current time zone happens, send data from the device and it will sync to your not in use. If the device battery runs flat, it might have an ensure the device(s) are charged at least once per week, even if Keep devices charged at all times – when stored at site, please

FDA-CBER-2021-5683-0650202

- mobile phone service or Wi-Fi is available the App as long as the device is charged, in an area where there is Data will send automatically each time the participant logs into
- each clinic visit. Participants should bring their assigned device with the App to
- the participant is at the study clinic Participant setup should occur on the day of vaccination, whilst
- select the same to remember first log in to the TrialMax device. Please recommend Each participant will be able to set their own PIN code when they code for each device as it will be easier for them to them to
- sent via a text message if a mobile phone number is provided the participant if their email address is provided during setup or opportunity to print this once; however, it will also be emailed to activation information for the participant. You will only have the done on a computer with a printer, as you will need to print the When setting up a participant for the study, make sure this
- To receive SMS notifications in the notifications' section for more details US, please refer to 'Setting up
- Use the TrialManager web portal to regularly monitor participant data for the study

- It is their available storage below: the event the participant does not have the free space or does not want to make that space available. The participant may check properly. Please provide a provisioned device to the participant in participant's personal device to allow the TrialMax app to function recommended to leave 0.5GB of free storage space on the
- iPhone: Select 'Settings'->'General'->'iPhone Storage'
- \circ Android: Select 'Settings' ->'Device Care'->'Storage'
- If you cannot find help in this guide, then please call the Helpdesk.

3311	Logistics PIN Code
7777	Logistics Access PIN Code
1234	Default Participant
PIN Code	Role

TrialManager Website URL

http://trialmax.crfhealth.net/c4591001-Post-12-July-2020

TrialManager login details will be sent to you via email

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Signant Health Overview

Signant Health is the provider of the eCOA (electronic Clinical to it simply as the "App". Helpdesk support. TrialMax App is the brand name, but we will refer comprises the components as displayed below, along with 24/7 Outcome Assessment) system for this study. The eCOA system

Data entered by Participant into the App

App to Signant Data sent from Health servers

monitors and study team Data available for sites, in web portal and TrialManager



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TRIALMANAGER®

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2 Helpdesk

or TrialManager website You may call the Helpdesk for any issue related to the TrialMax App,

FDA-CBER-2021-5683-0650209

Please have the following information ready when you call:

- The study protocol number: C4591001-Post-12-July-2020
- Helpdesk Priority PIN: 19
- Signant Health project code: A-1426-0086
- Your site number
- The participant number (if applicable
- The specific problem



.1 Helpdesk Operating Hours

The Helpdesk is available 24 hours a day, 365 days a year.

business day. Helpdesk will contact you as soon as possible, at the latest by next voicemail If you are unable to reach an agent when you call, you can also leave a 9 send an email giving your contact information. The

2.2 Helpdesk Telephone Numbers

Country Nur	Number
USA (1) 8	(1) 866 402 1154
Helpdesk Priority Code 19	

operator charges might be applied if calling from a mobile phone. Note: Toll Free numbers are free from a landline; however local

2.3 Helpdesk Email Address

For non-urgent issues, you can contact the Helpdesk by email:

C4591001-Post-12-July-2020_TM@support.signanthealth.com

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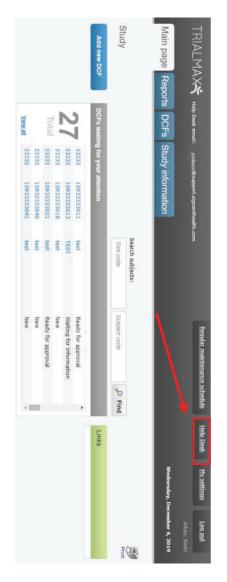
communication via email. participant's identity might be unintentionally revealed during **Note:** Do not share this email address with participant. The

Helpdesk Web Chat via TrialManager

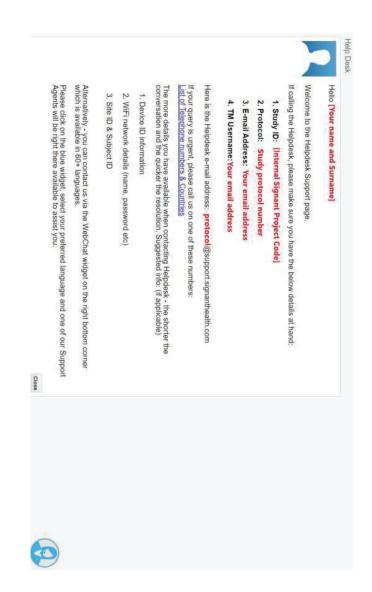
The Helpdesk Web-chat is available via the TrialManager Portal.

Helpdesk Web-chat can be accessed via the steps below:

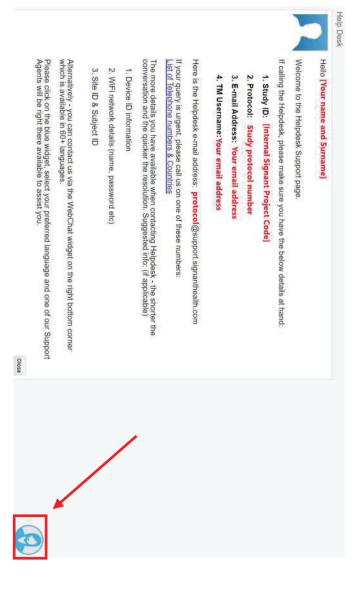
Please click the Help Desk button in the upper right corner of your screen.



2) You will see a welcome will be pre-filled page where all the texts highlighted in red



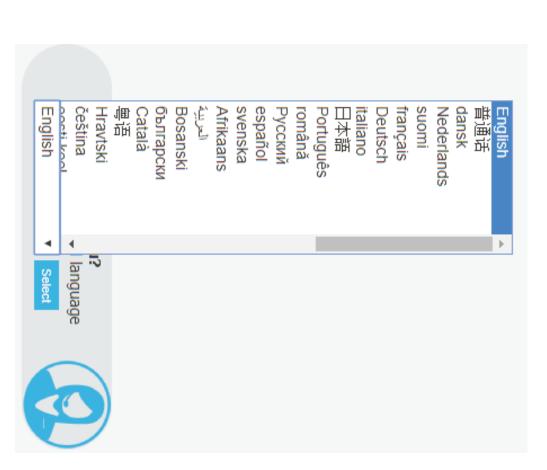
3 You can open the web-chat, available in 60+ languages, by clicking live chat with one of our Support Agents. the blue widget in the lower left corner of the screen to start your

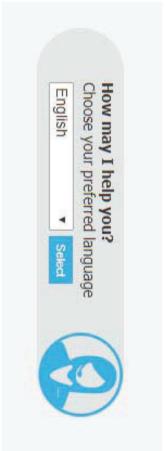


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4 Once you click on this widget, you will be able to select your preferred language from the drop-down menu.





5) agent. After button, then you will be connected to the next available support necessary information in the below screen and click the Continue selecting your language, you will need to complete the



Fields with an asterisk (*) are required.

Health Helpdesk specialist, who will discuss your issue with you Once you click on "Continue", you will be connected to the Signant

If the ticket number is not entered, it will be counted as 2 separate call into the web chat to ensure the background information is linked that you enter the Ticket Number you received from your telephone Please note that if a telephone call has already been placed make sure

Providing feedback about Helpdesk performance

as it helps us continuously improve to exceed your expectations level of your satisfaction from the provided service. This is important, Each time you request support from the Helpdesk, you can rate the

FDA-CBER-2021-5683-0650214

You can provide the feedback in 2 ways:

- scale 0 to 5, where 5 is awesome and 0 poor. you can remain on the line and rate your experience on the Each time you have spoken to the Helpdesk on the phone
- email, enabling you to evaluate the service or reject the When your request has been completed, you will receive resolution of the incident.

Please accept the resolution by rating your service experience, where 0 is poor and 10 is awesome

Or reject to reopen the case

Kind regards,

Jason

Signant Health Service Desk



shorter with every further use (IT profile information needs only to be provided once). The form is a bit longer when you use it the first time take you to a form, where additional information can be provided 10), where 0 means poor and 10 awesome. Selecting any rating will To provide feedback, you would click one of the numbered boxes (0and will be

Evaluation form 1st use

Evaluation form consecutive

Submit	Try to solve the problem by myself Just contact support Ask a colleague	When I have a problem with my IT tools, I most likely	I often need help with IT I rarely need help with IT	How would you describe your IT skills	Anything else you want to say?	0 minutes 5 days	0 minutes	Estimate the working time you lost	Hearned something Service was provided proactively	Service personnel's attitude I was informed about the progress	Service personnel's skills Speed of service	Awesome! Let us know why you were so happy?	Please rate your service experience. You chose 10 change
			Submit		Anything else you want to say?	0 minutes 5 days	0 minutes	Estimate the working time you lost	Service was provided proactively Service personnel's skills	I was informed about the progress I learned something	Speed of service Service personnel's attitude	Awesome! Let us know why you were so happy?	Please rate your service experience. You chose 10 Change

average, 6 and below means negative feedback Please remember that only 9 and 10 mean positive feedback, 7-8

before submitting it. You can change your rating on the top of the form any time

S **Equipment**

Supplies for participant

FDA-CBER-2021-5683-0650216

Provisioned device supplies

- installed for mobile data sending. card (this backs up the data for recovery if needed) and a SIM card iOS or Android device), accompanied by an incorporated SD memory Motorola device with TrialMax App installed (if not using personal
- A device charger (power-cord and charging brick)
- TrialMax App sticker with country specific Helpdesk number
- Quick Reference Guide in the participant's language
- Participant card with App activation details to be sent via email or App Activation Guide in the participant's language

Bring Your Own Device supplies

- TrialMax App sticker with country specific Helpdesk number
- Quick Reference Guide in the participant's language
- App Activation Guide in the participant's language
- Participant card with App activation details to be sent via email or

Provisioned Device Basics

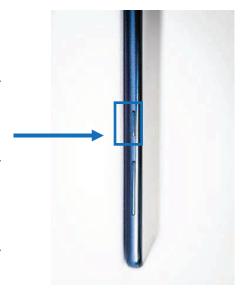


that contains the country specific Helpdesk phone number Each TrialMax App device has a sticker applied to it

technical questions device is not working properly. The Helpdesk Please contact the Signant Health Helpdesk if will assist you or the participant with

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ω ω How to turn on the Provisioned device



The Motorola device is the provisioned device for this study.

Turn the Device on by pressing the

Turn the Device on by pressing the power button on the right side of the device.

If the Device is left on for ten (10) minutes without use, it will hibernate and perform automatic log out.

Press the power button on the side

How to charge the Provisioned Device

indicates the amount of charge remaining in the device the participant with a message that the battery is low, they should the participant to charge the battery every day. If the device prompts display a battery status symbol on the top right side of the screen that charge the device immediately. When the device is powered on it will device has a rechargeable battery. Please remember to instruct

discharged fully, it may take a little time to charge before use participant can use the device while ⇌ S. being charged



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The device will usually fully charge in approximately 2 hours. Connect the power charger cable to the provisioned device.

3.5 Device Navigation



Use your finger to navigate through the device.

Please do not use a stylus or sharp points as these will not function on the device and will damage the screen.

3.6 Additional Site Supplies

- device sticker Quick Reference Guide for the participant and TrialMax App
- App Activation Guide

l TrialManager

investigators, coordinators, monitors and study personnel to view and overall participant compliance and view the participant's Diary data. monitor study progress. TrialManager enables the users TrialManager S. an online, internet-based application used to follow by

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TrialManager supports the following Internet browsers:

- Firefox 33 and up
- Internet Explorer 11 and up
- Chrome 32 and up
- Apple Safari v9 and up

1.1 Functions of TrialManager

the data) sent. Within minutes of sending data, you can view the data (and reports of will need to send their answers to the study database (TrialManager). After answering the questions on the electronic device, the participant

By using TrialManager, you can:

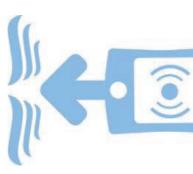
- View the participant's Diary answers
- Monitor participant compliance and other reports
- Monitor the number of days since the participant has completed their Diary
- progression through to closure Data Clarification Forms (DCFs) and monitor their
- changes to forms audit trails for questionnaire entries (including
- Deactivate the participant

login details (which will be sent to your email). Do not share your Note: You should be logging in to TrialManager only with your own

interchangeably throughout the App and TrialManager platforms. password with your colleagues. It is also important to note that while term "Participant" is used to describe the patient in this the terms "Subjects" and "Participants" study,

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Accessing the TrialManager website



All people will have separate access based on their role within the study.

information). Your TrialManager password has no will be emailed TrialMax App. relation to the change change this password at your first login (see Your TrialManager username your TrialManager password for Site personnel PIN codes to you. You will be prompted to and initial password on the How to

then you will be able to use the same Username and Password for each change them manually to match with the rest of your credentials same TrialManager account for older studies, you will not be able to use the Note: If you have Username that started Please and access to TrialManager for another Clinical Study, note that this feature Password after September 1st, for each TrialManager unless is only available for the 2019. If you have

Type the following address into your web browser.

http://trialmax.crfhealth.net/c4591001-Post-12-July-2020



A login window will open. Bookmark this address for easy future access. Next, enter the username and password that was emailed to you.

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How to change your TrialManager password

Screen. There you will find an option to change your password. right-hand corner of the screen or "Change Password" from the Login If you need to change your password, select 'My settings' in the top



in your current password, your new password, and verify your new your new password password by typing it in again. Click the 'Change' button to activate When you decide to change your password, you will be asked to type

Rules for creating new password:

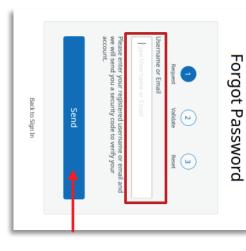
- Must be at least 8 characters.
- Must contain at least one lower case character.
- Must contain at least one upper case character.
- Must contain at least one number.
- Must not contain Unicode characters
- Special characters in password are not necessary.
- Must not contain spaces, line breaks or new lines.

How to Reset your TrialManager Password

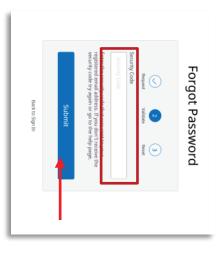
Portal. you are able to reset the password directly within the TrialManager If you have forgotten your password to your TrialManager Account,



From the log in page, select "Forgot Password"



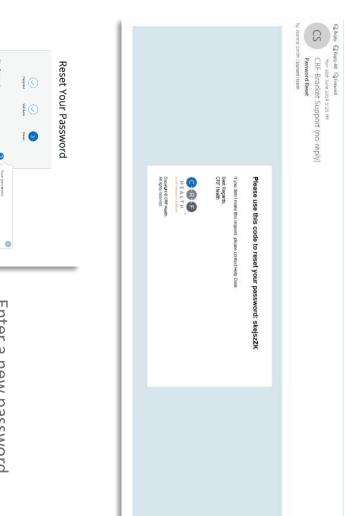
You will be asked to enter your email address so that the system can send you a security code for the password reset



You will be taken to this screen

Check your email inbox and enter the security code, which has been sent to you

This is an example of the email which will be sent to you:





Enter a new password following the guidance on the screen

screen: Once your reset has been successful, then you should see this



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How to request TrialManager access for new team members

should add their information into the 'TrialManager User Order collating requests into 1 email per week and send the updated form to the Signant Health 'TM accounts' In order to request Trial Manager accounts for new team members Form' team

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updates Allow U business days to create new TrialManager accounts/make

directly contacting the Pfizer Study Team via your CRA/Monitor TrialManager requests can be requested 9

How to navigate the TrialManager website

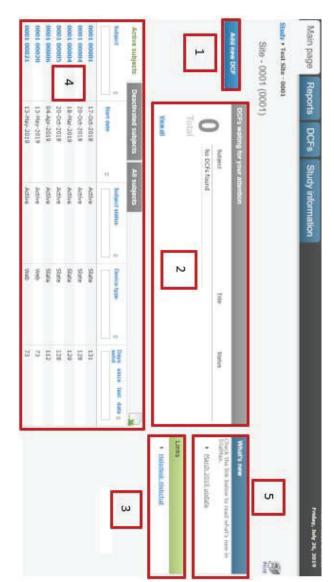
Information' tabs. These are selected by clicking on them. Investigators and Study Coordinators will see several tabs at the top of screen. They are the 'Main Page', 'Reports', 'DCFs', and

The points below highlight the main functions and features of the

- individual participant pages, view open DCFs and navigate to Main Page: View a list of all your participants, the DCF tool, view the latest TrialMax updates
- administrative data Reports: Review, filter, and print information associated site and participants, such as compliance, DCFs, with
- changes for your participants Create, approve, and monitor all requested data
- Study Information: Access supplemental reference such as electronic versions of the Site User Manual and DCF

3.1 Main Page Tab

When you select "Main page" the following screen appears



- With this button, you are able DCFs in TrialManager to add DCFs (see Where to create
- 2 you or anyone else will also need to be approved by a site user for your site that require implement the corrections requested in the DCFs. with DCF particular DCF to see further details displayed. All DCFs created by This section is called the DCF Notice Board and will display all DCFs approval rights. Signant Health your action. Simply click on the title of a will be the one to
- ω hand side of the screen, including the Helpdesk web chat. Some useful web links for the study are displayed on the right-
- all participants at your site The participant list section at the bottom of the screen will display

4

By default, this will display Active participants at the Click on the 'Deactivated subjects' or 'All subjects' to also

- the TrialMax App. view participants that have already been deactivated from
- 0 You are able to sort and filter by any of the column headings by typing into the text boxes below the column headings
- 0 information Clicking on a subject number will take you to more detailed Details Card regarding that participant (see **Participant**
- updates. You can see the latest updates regarding any TrialManager system

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4.4 Add a new participant

Please see 'How to set up a participant in TrialManager'.

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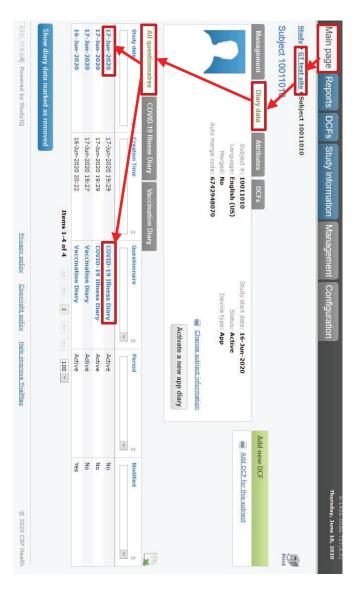
.4.1 Participant Details Card

Upon participant/subject's information card will display: clicking on മ participant from the main page, the



This auto merge code, which is necessary for replacement devices participant status, study start date, <u>≶</u> show details for the device type, participant including: and the participant's language,

forms submitted by the participant on the TrialMax App Below the participant details card, you will be able to review the Diary



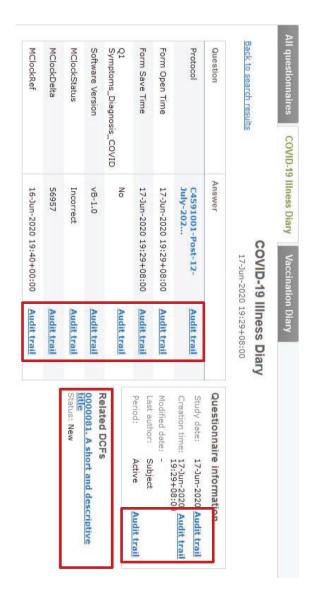
 $\stackrel{\sim}{\mathbb{R}}$ filtered and sorted. Upon selecting a form link the form will open, 'Questionnaire' questionnaires' links to each completed form. tab which contains Each column can be Study, date' and

items items and responses completed by the participant, and administrative displaying such ച SB list of all form data items, including the date and time ച completed the form was questionnaire

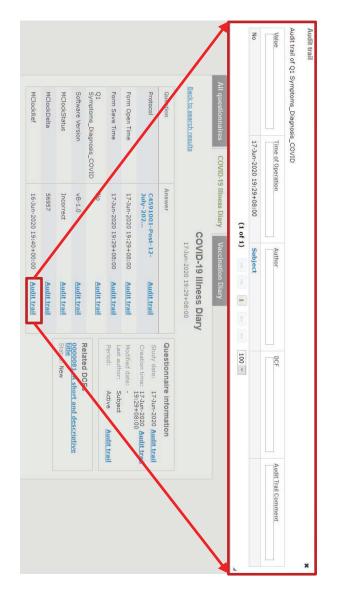
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1.4.2 Data Item Audit Trails

status of the form with a direct link to the DCF itself and the current DCF associated with a questionnaire form, this will be displayed to the right changes were made via the TrialManager DCF tool. If there was review the original values and a full change history of any data item if item from within these form pages. You can use the audit trails to You will also be able to view the audit trails for each questionnaire data a DCF



the data item, and that it has not been modified If only 1 row is displayed, this indicates that this is the original value of the desired item. An audit trail of the item will open displaying a list of original value and any changes, click the 'Audit trail' link to the right of To view the item elements, sorted newest to oldest from top to full audit trail of any available form item, including the bottom.



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The Audit trail column headers are defined as follows:

- Value: the value of the data item itself
- item entry or modification Time of Operation: the date and time associated with the data
- (participant, site, or Signant Health Data Management) Author: the user that committed the associated operation
- to the form DCF: the DCF ID number if a DCF was used to execute a change
- external DCR number (if DCF was not used), or other useful data change Audit Trail Comment: free text field where the Signant Health reference information implementer may post the DCF number, an

the change over the clipboard icon will trigger a pop-up with a brief summary of display a small clipboard icon to its right. Hovering with the mouse Note: if a data item was modified via DCF within TrialManager,

4.5 Reports Tab

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should be reviewed on a regular basis to ensure the participants completing the questionnaires correctly with good compliance 'Reports' tab will contain reports for you to view. These reports

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view these reports initial login of the user. The user may have to logout and log back in to Note: TrialManager reports accessibility may not be available on the

The following reports will be available for this study:

- and a summary of the key metrics Dashboard - Site: personnel with an overview of the situation at their site(s The purpose of this report is to provide
- of the key metrics. the Study team with an overview of the Study and a summary Dashboard - Study: The purpose of this report is to provide
- information of typical inconsistencies in the data such as **Inconsistencies:** The purpose of this report is to provide duplicate participant numbers
- detailed information on each participant Subject Information: The purpose of this report is to provide
- participant for days 1-7, from day 1 up until the current day App Compliance: This report shows the daily compliance by
- days 1-7 following each vaccination. their corresponding severity and any medication taken for have experienced local reactions, systemic events Data Summary: This report shows whether or not participants or fever,
- Severe Reactions Requiring Contact: Displays if participants events or have reported a severe temperature have reported 'Severe' local reactions, 'Severe' systemic

The purpose of this report is to provide the Study team with an overview of the reported symptoms and medications at the sites.

This report provides information with regards to Illness Diary Compliance as well as any cases where subjects reported Covid-19 symptoms.

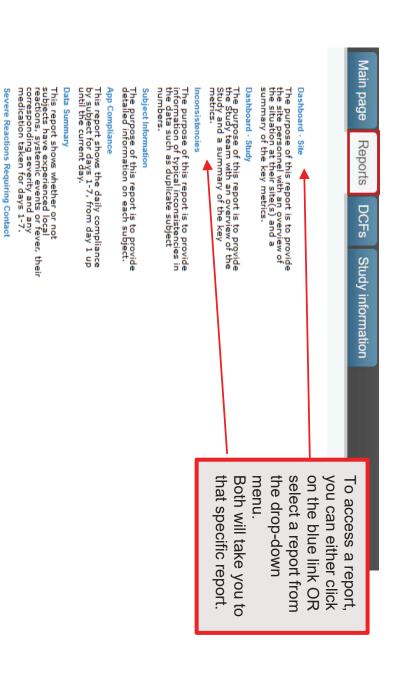
Illness Diary Report

Displays if subjects have reported 'Severe' local reactions, 'Severe' systemic events or have reported severe temperature.

symptoms and medications at the sites. Symptoms Dashboard: The purpose of this report is provide the Study team with an overview of the reported

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subjects reported Covid-19 symptoms Illness Diary Report: This report provides information with regards to Illness Diary Compliance as well as any cases where



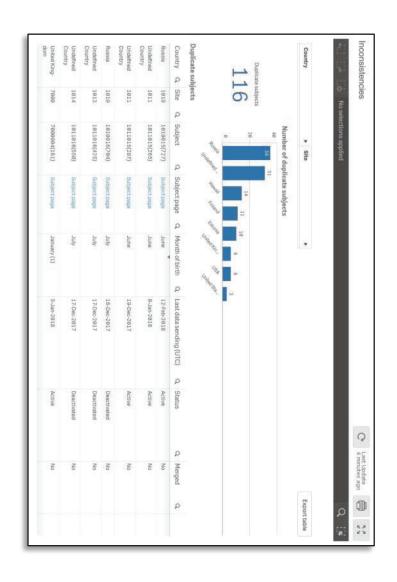
4.6 How To Review Reports

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resolving DCFs completing their questionnaires on schedule) or verify the progress on can verify which study participants are from the study protocol and take corrective action. For example, Graphical visualizations allow you to identify quickly any deviations reports For monitoring about the purposes, state of you can view near real-time, the study right inside still compliant (if they are TrialManager. graphica you

4.6.1 Reports User Guide

example of the Inconsistencies Report. visualizations, Signant Health including Reporting bar charts Solution and data supports tables. മ Below is variety an of



selection automatically. This even works between reports in the same the displayed data in report, all other sections update to filter for the participant Depending drop-down list and allows the user to ask questions about the data These report visualizations are interactive. When you select parts of The report will automatically repopulate number from the drop-down options 9 0 your user role, you can select using the your at the site top criteria and/or of the

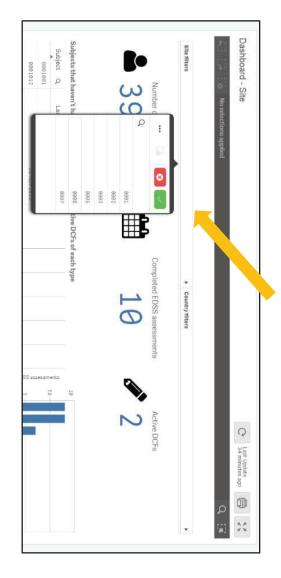
the whole report. selected. Clicking on the drop-down options will automatically filter

.6.2 Hints and Tips for Viewing Reports

from the reports available in the study: key study details. Below are some hints and tips on how to get the best The reports used in this study are designed to give you easy access to

Filtering

below. the drop-down filters appearing at the top of the reports, Reports can be filtered in several ways. One way is by selecting from as shown



filter list without applying the change select the green tick to apply the filter. Select the red cross to close the To use the drop-down filters, select an item or items, from the list and

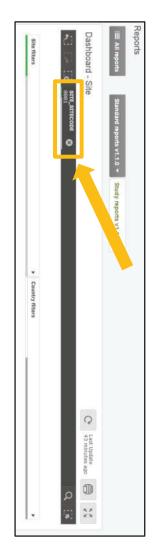
example selecting a participant from a list, or selecting a bar in a chart. Reports can also be filtered by selecting part of a table or chart, for

reports Selecting the icon in column headings can also be used to filter

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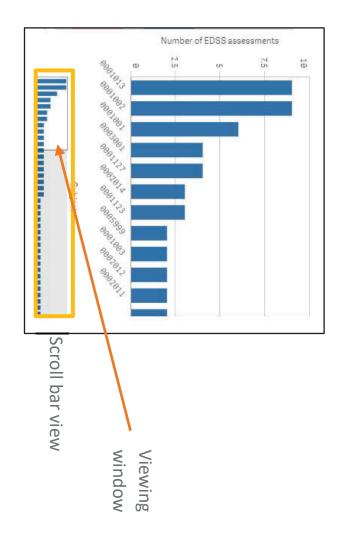
can be seen in the banner at the top of the report. reports viewed, will have this filter applied. All filters that are applied Once a filter selection has been made, all parts of the report and other

top of the screen, as To remove a filter, select the "X" next to the filter in the banner at the per the image below:



Viewing Bar Charts

the main part of the report to the left or right on the scroll bar view to change the data shown in version of the report can be seen. Move the white bars at the same time. When this For bar charts with many data bars, Some reports contain bar charts to display specific data information. is the it may not be case, ص smaller 'scroll possible to view all 'viewing area' bar box



information. Hovering ص bar within ച bar chart <u>≦</u>. display additional

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Viewing Reports with Tables

the the column name with the mouse to view the full name view. If a column name is too wide to be displayed fully, hover over between columns, and resize as required to fit all the columns in the For reports with large tables, you may wish to resize columns to ensure best view in your browser. To do this, simply select the line

you to focus on the columns you require on and dragging a column header into a You can rearrange the order that the columns will appear in by clicking different position, allowing

Select the header to indicate the sorting applied click will sort the report in ascending order, a second click will sort the You can select column headings to sort the report in descending • Export table order. Αn arrow will report by that item. appear on the column



button, where seen, to export information

Standard Report Icons

in the study. The icons seen below can be found at the top left corner of all reports



any report to full screen This icon can be used to expand the viewing area for



This icon will be seen to exit the full screen view





saved, as required. viewed. This pdf copy of the report can be printed or This icon can be used to print to pdf the report being

the report. This icon can be used to reload of the data within

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To will also remain active on other reports **Note:** Any filters applied to one report 'Study reports between reports using the drop-down options 'Standard reports' and switch Ξ. between reports, the selecting same the drop-down list, 'All Reports' you can either option, or return to the you can full list switch

in the 'Study information' tab in Trial on how to use the reports can be found Manager. Further information and video training



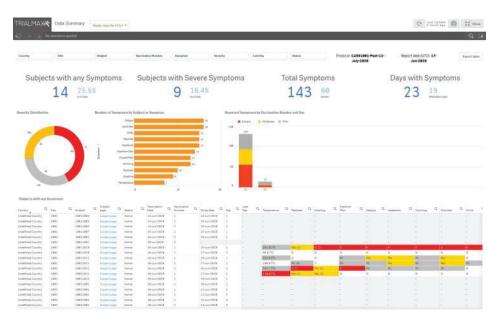
unless specifically removed

4.7 C4591001-Post-12-July-2020 Custom reports

4.7.1 Data Summary Report

This report shows whether or not participants have experienced local reactions, systemic events or fever, their corresponding severity and any medication taken for days 1-7.

Columns will include: "Country", "Site", "Participant", "Participant page" (hyperlink which takes you to the participant page in TrialManager), "Status", "Vaccination Date", "Vaccination Number" (displays the vaccination number entered in the TrialManager), "Study Date" (displays date when diary form was opened. Future/ uncompleted diary dates will appear as [blank]), "Study Day" (fixed column listing '1' – '7' representing each of the study days for each participant), "Temperature", "Injection Site Pain", "Swelling", "Redness", "Fatigue", "Chills", "Diarrhea", "Vomiting", "Headache", "Joint Pain", "Muscle Pain", and "Medication".

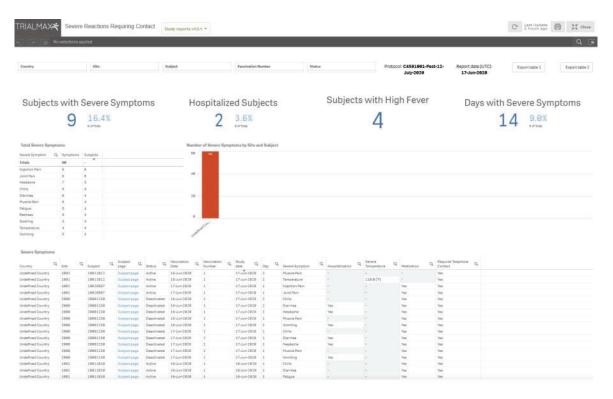


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4.7.2 Severe Reactions Requiring Contact Report

Displays if participant have reported 'Severe' local reactions, 'Severe' systemic events or has reported a severe temperature.

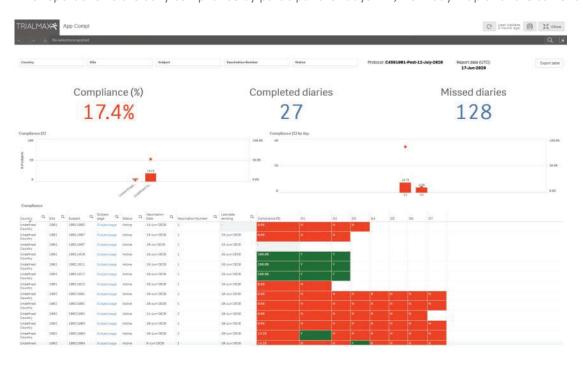
Columns will include: "Country", "Site", "Participant", "Participant page" (hyperlink which takes you to the participant page in TrialManager), "status", "Vaccination number" (displays the vaccination number entered in the TrialManager), "Study date", (displays date when diary form was opened. Future/ uncompleted diary dates will appear as [blank]) "Study Day" (fixed column listing '1' – '7' representing each of the study days for each participant), "Severe Symptoms", "Hospitalization", "Severe Temperature" (Any Temperature higher than 102°F), "Medication", and "Require Telephone Contact".



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4.7.3 Vaccination Diary Compliance Report

This report shows the daily compliance by participant for days 1-7, from day 1 up until the current day.



Columns will include: "Country", "Site", "Participant", "Participant page", "Status", "Vaccination date", "Vaccination number", "Last data sending", & "% Compliance".

Compliance (%): Displays the compliance rate.

D1-D7: represent the study days and will display the status of the participant's diary completion for each day.

Color scheme display for the Compliance (%):

Red: <40%

• Yellow: ≥ 40% - < 80%

• Green: ≥ 80%

Expected diary compliance will follow the standard color-coding scheme and thresholds. For active participants, diary completion expectations will be based on the current date. Once a participant is vaccinated, the participant will be expected to complete the diary every day for 7 days including on the day of the vaccination, for the participant. As each study day passes, the previous study days become expected and should have one diary completed. For deactivated participants, diary completion expectations will be based on the deactivation date. The participant will thus be expected to have completed one diary for each study day starting from the vaccination day and until the day before the Deactivation date. The exception here is that if the participant completed a diary on the day they were deactivated, that day will also be considered as expected.

4.7.4 Symptoms Dashboard Report

The purpose of this report is to provide the Study team with an overview of the reported symptoms and medications at the sites.

Symptom Distribution columns will include: "Symptom", "S" (Severe), "Mo" (Moderate), "Mi" (Mild), & "Total".

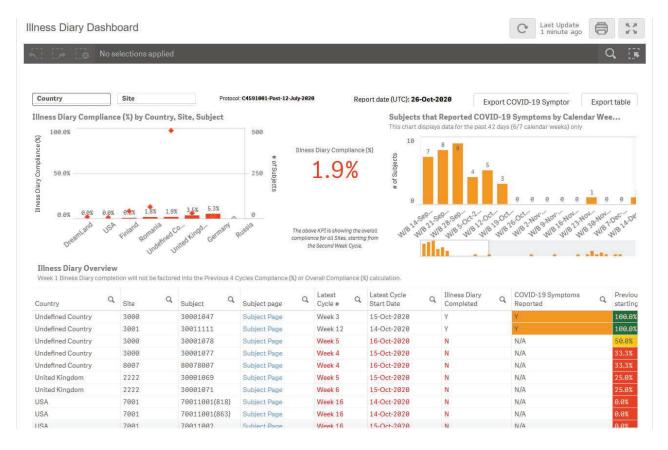


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4.7.5 Illness Diary Report

This report provides information with regards to Illness Diary Compliance as well as any cases where subjects reported COVID-19 symptoms.

Columns will include: "Country", "Site" "Subject", "Subject page" (hyperlink which takes you to the participant page in TrialManager), "Latest Cycle #", "Latest Cycle Start Date", "Illness Diary Completed", "COVID-19 Symptoms Reported", "Previous 4 Cycles Compliance (%) starting from Cycle # 2", "Overall Compliance (%)"

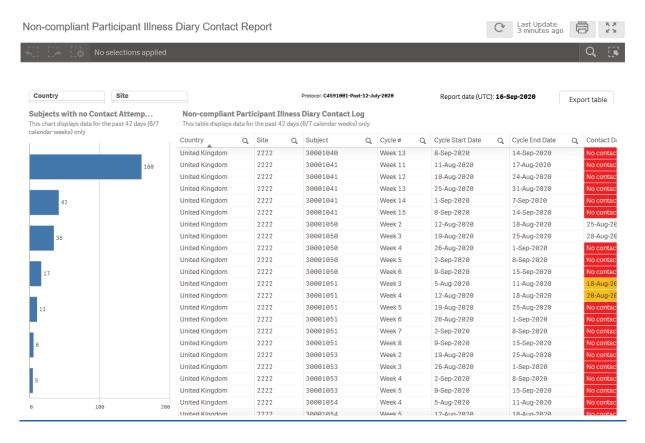


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4.7.6 Non-compliant Participant Illness Diary Contact Report

This report provides information with regards to Non-Compliant Illness Diary subjects and attempts by the site to contact these subjects. The report will display each cycle (7 day period) where a subject has not completed an expected Illness Diary.

Columns will include: "Country", "Site" "Subject", "Cycle #", "Cycle Start Date" "Cycle Start Date "Contact Date (latest)", "Successful Contacts", "Unsuccessful Contacts"



J DATA CLARIFICATION FORM (DCF)

5.1 What is a DCF

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and participant is considered to be the original electronic source data of the study via the site archive. via TrialManager and will be provided to the sites and client at the end Each DCF and its full history are available for review during the study certain data items via the DCF process. The data reported by the This data is very rarely, if ever, changed, however, in some situations TrialManager allows authorized personnel to request modifications to changes are needed. The DCF is the audit trail for data changes

i.2 Types of data changes allowed:

The following data modifications are permitted for this study:

- initial data entered and the corrected data documentation, e.g., telephone contact report detailing the investigational sites responsibility to ensure such changes are systemic increase Changes requested to data previously reported by the participant, i.e., or decrease in the severity of a local reaction or event previously reported on a given day. It is ≕; supported ργ appropriate
- following when previously entered incorrectly: Changes to device set-up information, i.e., corrections to the
- Site number
- Participant number

0

0

- Vaccination number or date of vaccination
- Other administrative changes, i.e.:

0

Merging participant data allows cleaning of data issues that may result and removal of

participants from replacement or multiple devices being issued to

0 inaccurate arising from when the diary device internal clock is Modifying timestamps - allow cleaning of data issues

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Changing participant status

0

deleted, all data will remain in the data When data is modified or duplicate data removed, no data base audit trail. is ever fully

The following data modifications are not permitted for this study:

participant is unable to record their diary. been reported Addition of a form, e.g., addition of a diary that has previously as missed, or if the device tails and

5.3 Where to create DCFs in TrialManager

'Add new DCF' button in TrialManager. You can add a new DCF for any participant where ever you see

participant instance and the specific form will be preselected). from a participant's form view while reviewing data (so the participant page (so the participant instance It is also possible to add a DCF for a specific participant from the will be preselected), or

5.4 How to create a DCF

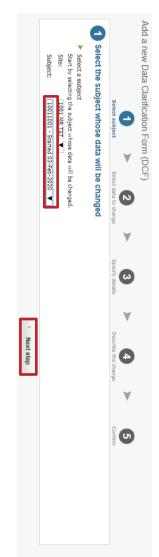
necessary information, where this is required necessary level of information. The system will guide you to select the certain The steps required to complete DCFs, additional steps may be a new DCF are required detailed to provide below. the For

After initiating the DCF SB outlined in Where to DCFs

Select Site and Participant

necessary. entering Note: the the site DCF and Sew participant in the dropdown will not be raised at the participant 9 form level,

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participant details. from the participant level of the correct instance to pre-select the start date (found in the site index). Alternatively, raise the DCF Diary instance) you must select the correct one based on the If there are multiple instances for the participant (i.e. multiple

Select data to change

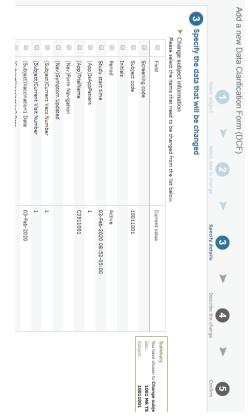
best fits the change, then select 'Next step' to proceed to step 3. as per the example screenshots below. Select the option that Questionnaires. Select the data to be changed, either Participant Information or Based on the selection a further list will appear,

< Previous step	0	0	0	0	0	➤ Then s	0	•	2 Select w First se		Add a new Da
> Next step	Handle duplicate subjects Duplicate subjects will be shown as one subject in listings and reports.	Mark a subject as removed The subject will be hidden from listings and reports. No data will be deleted.	Change subject's site number Move subject to another site.	Change subject status Change subject status to Completed, Discontinued etc.	Change subject information Change subject code, screening code, initials, period, date of birth etc.	Then specify the change that will be made to subject information:	Questionnaires Modify, add or remove questionnaires.	Subject information Change subject information, change site, remove subject, or handle duplicates.	Select what data will be changed First select one of the following:	Select subject Select data to change Specify details Describe the change	Add a new Data Clarification Form (DCF)
							Site: 1001 MR TST Subject: 10011001	Summary You have chosen subject:		Confirm	

Specify details (required for some DCF types)

information may be required Based on the options selected in the previous step, additional

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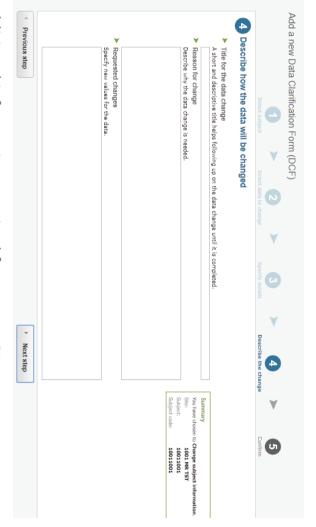


4. Describe the change

much detail as you can provide. When finished, click 'Next step': Fill in the 3 required free text boxes to describe the change, in as

- that describes the change (e.g. 'Update participant Title for the data change: Give the DCF a brief title number').
- 0 the change may be details as possible. If this is not specific, processing Reason for change: Describe the device') Participant number was entered incorrectly on the must be made delayed. This should not simply outline what explicitly, to act as the audit trail. but rather provide issue with many
- X to Y.'). the original value and new value (e.g. 'Please change Specify any values that need to be changed, including Requested changes: Detail the requested changes.

 Ω



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Additional information required for some DCF types

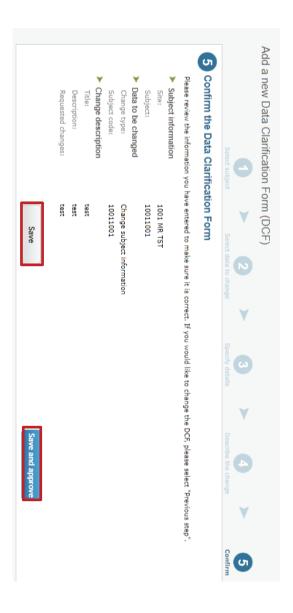
started. cannot be processed without a date when the new status changed in Step 4 (Describe the change). This DCF type include the date of when the participant status has Requesting to change a participant's status: be sure to

(Requested changes). under the Marking a participant should also be marked as 'removed' in Step 4 participant as removed: be sure to specify if forms

5. Confirm

the save before sending to Signant Health Data Management. used if you are sure the data entered in the DCF is correct and you to approve the return to the last step and amend the information. The 'Save you can review the information entered When the DCF has been drafted, you will see a screen where request does not need approve' the information required; button can also be seen if your user role allows DCF request. to be reviewed by anyone or press 'Previous This button should only be and click 'Save' Step'

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change the status of the DCF for processing by the Signant Health Data after pressing either 'Save' or 'Save and approve'. Select 'View DCF' to Management Team, if 'Save and approve' was not selected You will receive a confirmation that the DCF was created successfully

	View DCF
If you would like to view the new DCF, select 'View DCF'. Otherwise select 'Continue'.	would like to view the new l
Thank you! Your DCF was added to the system successfully.	Thank you! Your DCF wa

5.5 Approval of DCFs

When to approve DCFs

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Health can implement a DCF, it must first be approved by the Site. creation process if the user has DCF approval rights. completed separately, once the to have all the necessary and required information. DCFs must be approved once they have been created and confirmed DCF is created, or during Before Signant This the be

How to Approve DCFs

reviewing the DCF Dashboard on the study's TrialManager Main Page notification emails, pending site approval which will include links can be monitored in the to each DCF, weekly 9 DCF by

TrialManager home page by clicking on the DCF title taken directly to the page where the status of the DCF can be changed After clicking the DCF link from the email notification, the user will be can also select the appropriate DCF from DCF Dashboard

approved by the following levels: Before the change requested can be implemented, the DCF must be

approve DCFs approval. Level 1 (Site): The first level of approval is the Site/Investigator Steps below describe how site personnel

necessary information to implement the requested changes Signant Health have Team approval is added once all approvals are received, Level 2 (Service): Finally, Signant Health Data confirmed that the DCF Management includes and

for processing: Follow the instructions below in order to ensure the DCF is approved

Navigate to the DCF and select the 'Approve' button.

Type: Site: Site: 1001 MR TST Subject: Reason for change: Requested changes: Changed fields: Changed fields: Show details Modify DCF	Modify DCF		tus: New	Status Current sta
Type: Change subject's site number Site: 1001 MR TST Subject: 10011001 Reason for change: test Requested changes: test Changed fields: Show details Modify DCF	Modify DCF			24-4-1
Change subject's site number 1001 MR TST 10011001 In for change: test steed changes: test seed fields: Show details Modify DCF	Modify DCF			
Change subject's site number 1001 MR TST 10011001 In for change: test sted changes: test ged fields: Show details				
Change subject's site number 1001 MR TST ct: 10011001 n for change: test steed changes: test Approva	Approve	Show details	Changed fields:	
Change subject's site number 1001 MR TST ct: 10011001 n for change: test	Approve		Requested chang	
Change subject's site number 1001 MR TST 10011001			Reason for chang	
Change subject's site number 1001 MR TST		10011001	Subject:	
Change subject's site number		1001 MR TST	Site:	
		Change subje	Type:	

2 add a comment (optional) and approve the DCF. After entering credentials, ۵ confirmation screen will appear which allows you to and Study Coordinator (DCF) roles can approve you can select approve. Please note only

	Approve	Cancel
		Comment:
		Password: *
		Username: *
	By approving this, I confirm that the information in this Data Clarification Form is true and accurate.	By approving th Clarification For
×	Confirm your approval	Confirm yo

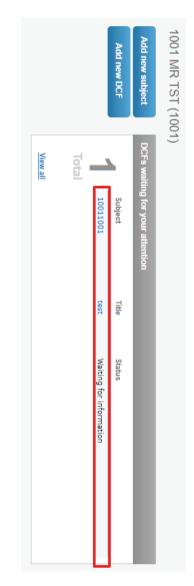


the status in the within the DCF. You can follow the progress by selecting the DCF and checking 'DCF' tab of TrialManager and the comments

5.6 Adding Additional Information to



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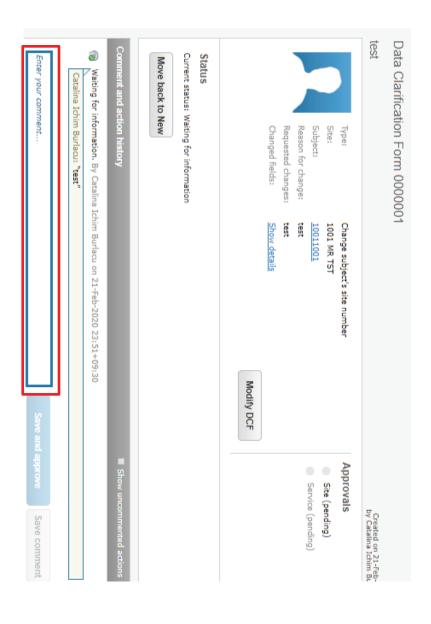
need to answer. The DCFs waiting for information can be found on the Sometimes, 'Main page' 'Waiting for information' tab of the TrialManager DCFs will need additional clarification and will be status with questions that the site will changed

following reasons: DCFs may be placed in a 'Waiting for information' status for the

- DCF wording is unclear
- Wrong type of DCF was selected
- There is missing information that needs to be confirmed

The following steps will be required in order to add comments DCFs in a 'Waiting for information' status:

- for the DCF in the 'Waiting for information' status Click on the Title link to review and read the comment history
- 2 comment. Press the what information is needed, please state this in your with as much detail as possible. If you are still unsure about comment...' text box. Try to respond to all questions raised to be clarified. Enter a clarifying comment in the 'Enter your Review the comments that details the information that needs 'Save comment' button when finished



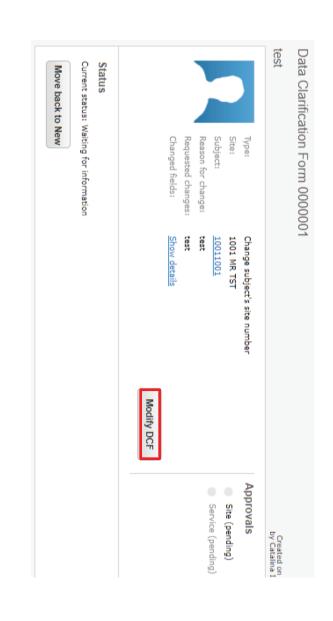
 ω steps outlined in How to Approve DCFs above Once the necessary additional information has been added via comment, the DCF must be approved again. Follow the

the DCF are not clear or do not clearly answer the questions from the Signant Health Data Management Team. moved to a 'Waiting for information' status again if the comments in until no DCFs appear in the DCF Notice Board. Note: The on the Main page – this means that no further action is needed on that You will notice that the DCF no longer appears on the DCF Notice Board DCF. Continue the process with all remaining DCFs in your notice board DCF may be

How to Modify DCFs

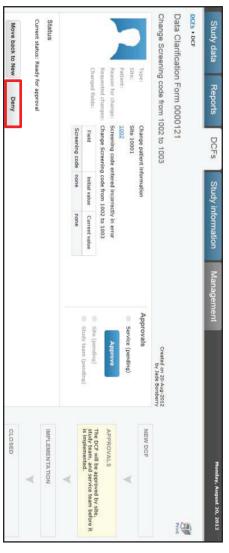
simply selecting the 'Modify DCF' button on the DCF itself. status, the site is able to modify the DCF. This can be accomplished by Until a DCF is either under 'Ready for approval' or any 'Approved'

When making modifications, be sure to save all updates made to the DCF and move to 'Ready for approval' for processing.



How to Cancel/Deny DCFs

approval, by selecting the The site can cancel their entered DCF at any time prior to 'Deny' button on the DCF page their first

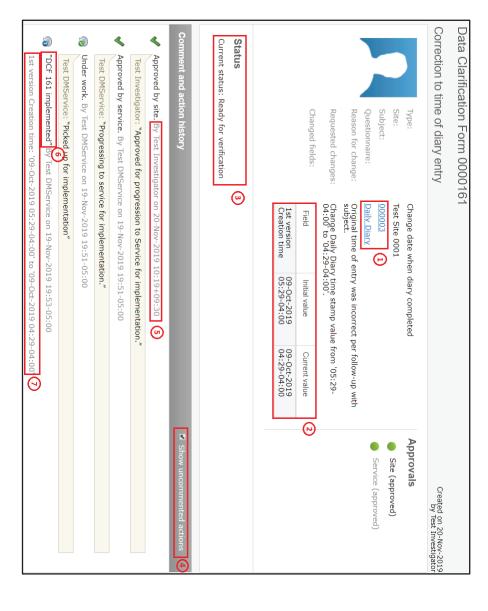


be processed. By selecting the 'Deny' button, this signals to the Signant Health Data Management Team that the change requested in the DCF should not

that are not applicable for your protocol or are duplicate requests Note: The Signant Heath Data Management Team may deny DCFs

Viewing DCF Comment and Action History

displayed in order of oldest to newest, top-to-bottom. actions', and the full history of actions committed in that DCF will be to view the DCF detail. Select the check box, 'Show uncommented 'DCFs' tab, select the sub-tab, committed. To view the latest activity for a DCF, navigate to the A DCF will always retain the full history of all comments and actions 'All', and then click the desired DCF link



follows: elements of the DCF detail view pictured above are defined SB

H under change, as applicable to the DCF Direct links to Participant card and the questionnaire

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- 2 display the data item, DCF has not been implemented yet) present value device, original data selected for change during DCF creation. Changed fields will be displayed if specific and 'Current value' item value (this may match the 'Initial value' captured via the will display the data item's 'Initial value' will display fields 'Field' TrialMax <u>≶</u>.
- ω The current status of the DCF will be displayed
- 4 The of the DCF's history or deselected for a reduced listing. status change can be selected for a comprehensive view Check box to show uncommented actions, such checkbox will default to unchecked when first
- 5 the The committed comment or action name of the individual committing commit timestamp **≦** display next the action and to each

opening the DCF

- 6 Comments entered will display within quotation marks
- 7. display in grey text without quotations Committed changes directly associated with the DCF will

Note: DCF modified once committed comments comment and action history items comprise an audit trail of and actions committed 5 the DCF and cannot

5.8 DCF Timelines and Tips for Success

DCF Timelines

go to "Waiting for information" status, then the implementation time will restart on re-approval of the updated DCF review and implement the request within 5 working days. If a DCF must Once a DCF has been approved, Signant Health Data Management will

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Tips for Success

guidelines on best practices: and cleaned throughout the study. Please find below some important important that all the data that has been uploaded be reviewed

- and approved on an ongoing basis to avoid high volumes of It is highly important that data is reviewed and DCFs DCFs ahead of interim and final database locks are raised
- correctly. numbers, or who may need to be merged, and you should identify participants with potentially incorrect example, the participant you can data esu the to ensure visits are **Inconsistencies** participant report labelled
- 2 required to implement prior to lock dates. Regularly information to provide Signant Health with the information Sites should continuously review any DCFs waiting for more TrialManager Main Page to find any DCFs that need action to waiting for your attention' noticeboard
- $\dot{\omega}$ that all data is uploaded and visible in TrialManager Sites should ensure that all devices at site have
- Please be aware that Signant Health does not review raise DCFs. data

4

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Setting up SMS notifications

9

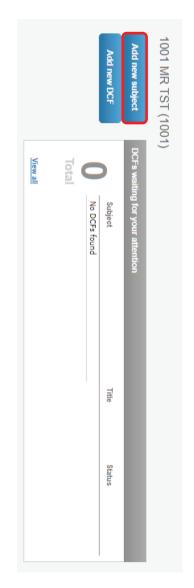
before setting up a participant. they wish to receive this message on. This should be completed participants will need to subscribe with the mobile phone number personal mobile number to receive activation details via SMS. US part of participant setup, you can choose to enter a participant's

the word SUBSCRIBE to phone number 42526. When you opt-in to confirmation of subscription message is received, the participant will To opt-in to receive SMS activation code, send a text message with able to receive SMS activation code service, you will receive a reply confirming your signup. Once

How to set up a participant in TrialManager

participant is at your site for their first study visit and not prior as it is TrialManager for all participants. This must be done when the Participant setup must be performed by site staff through Login to TrialManager to begin. prerequisite for the participant to start entering data in the App.

Select 'Add new subject'



activation details), and Diary reminder time You will then be number time zone, device type, contact information (for receiving and taken to a provide screen where you will need subject information; including to enter the their

		*Required
Only times from 18:00 (6:00 PM) to 22:00 (10:00 PM) are allowed.	06 00 PM	Reminder time (hh:mm):*
e defined time.	The reminder will alert the subject to fill in the diary at the defined time.	The reminder will alert the
		Diary reminder
The subject is encouraged to give both.		** Either mobile phone number or email is required.
(f) Email addresses are kept confidential.		Email address: **
 E. Q. + 1 216 700 700 (Include the country code). Mobile phone numbers are kept confidential. 		Mobile phone number: **
Contact information will be used to install the Study App, and send notifications or reminders to the subject.	used to install the Study App,	Contact information will be
		Contact information
		*Required
	Provisioned device	
⚠ Please answer the required question(2) about subject's study device.	Personal device	Subject will use:*
provisioned device.	Please indicate if the subject will be using a personal or provisioned device.	Please indicate if the subj
		Study device
		* Required
	□ No	complete a vaccination diary?
	© Yes	Will the subject peed to*
Change the time only if the subject lives in a different time zone to the site.	Subject lives in the same time zone	Subject's time zone:*
	English (US) V	Subject language:*
Subject number must be 8 characters long. Last four digits must be within 1001-9999 range.	1001	Subject number: *
		Identification
	ion	1 Enter subject information
2 3 Confirm subject Print subject card information	Subject information Confirm	
)		

Select "Next" once all the required fields have been filled out.

it is important that this information is entered correctly. The participant should Note: Mobile phone number and email address are used by the mobile number to receive the activation code TrialMax system to send an activation code to enter either their personal email address and/or participant. Therefore,

instructions for getting set up with the App. participant card contains their activation code and applicable SubjectCard that is sent to the participant via email/SMS. This participant was created successfully. You will also see displayed You will then receive a message on screen that will confirm that the TrialManager will also display a copy of the participant's card

screen and this should be printed if possible, to make it more convenient for the Code displayed on screen and provide this to the participant. participant. Be sure to write down the Activation





Welcome to the C4591001-Post-12-July-2020 study!

The information below will guide you on how to install the TrialMax App onto your cell phone and how to start using the TrialMax App after the installation.

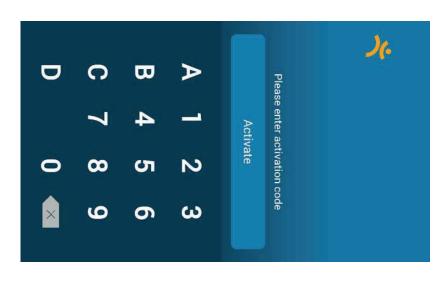
To install the TrialMax App, tap the link in the installation text message (SMS) or email you will receive in a few minutes, and follow the on-screen instructions.

Trial ID: C4591001-Post-12-July-2020

Press "Next" to conclude setup.

.1 How to Activate the App

their subjectt card with the welcome message and activation code, the device (provisioned device) to use in the study. participant should also be When the participant setup is complete and the participant receives provided with a fully charged Motorola



The activation screen is the first screen presented when the provisioned device is turned on. Here, the participant will need to enter the activation code provided in the subject card/ SMS/email message.

the default PIN code '1234' to login for the first time participant will be taken to the login screen where they should enter Once the activation code has been entered appropriately, the

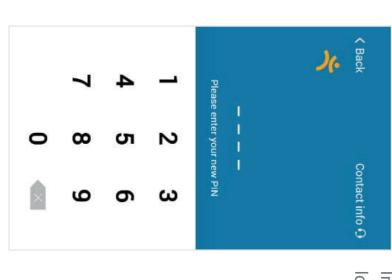
How to setup WiFi on the Provisioned Device

WiFi Settings on the provisioned device please follow these steps WiFi can be configured on the provisioned devices. To access the

- 1. Press the 'home' button on the device
- 2 Next, press the 'gear' symbol in the top right-hand corner of the screen.
- $\dot{\omega}$ Select 'WiFi settings' to display a list of available networks
- 4 Select the appropriate network from the list and enter the the WiFi will connect. password if required. Once the connection is authenticated
- 5 You can then return by clicking the 'home' button, and the App will automatically open

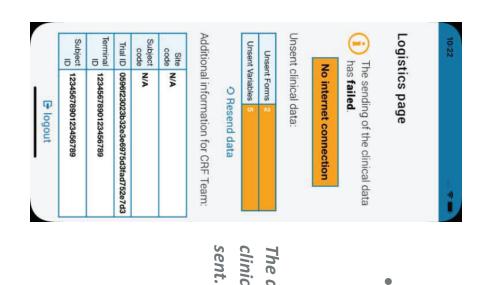
Instructions for reusing the Provisioned Device

for a subsequent participant. To reuse the Provisioned Device for when one participant has finished using the device, it can be setup Signant Health. another participant, all unsent clinical data must first be sent to The App supports the reuse of the Provisioned Devices, meaning that



In order to do this, you will first need to login to the Logistics Page on the device.

- From the login screen, first enter the 'Special Code', 7777 to ready the device for the logistics pIN
- Then enter the 'Logistics PIN', 3311
- Once both PINs have been entered in succession, you will be taken to the Logistics Page



Health unsent clinical data to Signant 'Resend data' to send any From the Logistics Page, select

clinical data has successfully been The device cannot be reset until all



All clinical data has been sent successfully.

Unsent clinical data:

Unsent Variables 0	Unsent Forms 0
0	0

O Reset app

Additional information for CRF Team:

	Subject ID	Terminal ID	Trial ID	Subject code	Site code
₽ logout	1234567890123456789	1234567890123456789	0596f23023b32e3e6975d3fad752e7d3	N/A	N/A

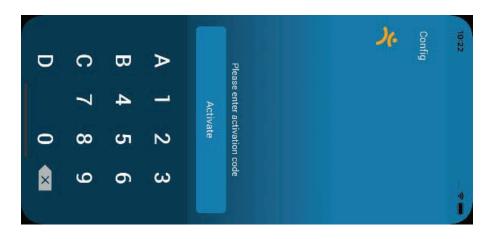
the 'Reset app' button will appear unsent data has successfully been sent, If there is no unsent data, or once all

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the App for the next participant Selecting 'Reset app Button will reset

Unsent clinical data: Additional information for CRF Team: Unsent Forms 0 Subject code Terminal ID 284984800000000000000 Site code 0000 Trial ID 14000000000000049848 ට Resend data O Reset app logout

> sent, then the App can still be reset but all Diary data has successfully been after the data send (due to protocol), Note: if there are new unsent variables



to pre-activated state, ready for another final data sync, then is reset and returns Selecting the participant to be setup reset the App; the App will do one more 'Reset app' Button will

Selecting a TrialMax App PIN

Easily remembered by the user (ex: memorable date)

The TrialMax app has certain restrictions for PIN codes:

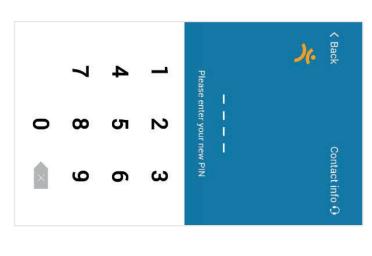
- It cannot be the same as the default PIN code
- It must be four digits
- not be accepted It must not contain running numbers, e.g. 2345, 5678 will
- repeated numbers, e.g. 1111, 2222 will not be accepted It must not contain more than three consecutively

confidential, with only the participant knowing the PIN code The participant should not share their PIN code with anyone, not with study staff. The new PIN code must remain

helpdesk who will be able to reset the PIN code. participant forgets their PIN code, they will need to contact the

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Logging In & Setting Security Question



After the activation code is entered, the participant will be asked to log in to the App. The user will have to enter the default four-digit PIN code (1234) to access the App and will then be prompted to change their PIN to a unique 4-digit PIN.

The participant should not share his/her PIN code with anyone, not even with study staff. The new PIN code must remain confidential, with only the participant knowing the PIN code.

in resetting their PIN code should they forget it during the study. select and answer a security question which will assist the helpdesk Once the participant has changed their PIN, they will be prompted to

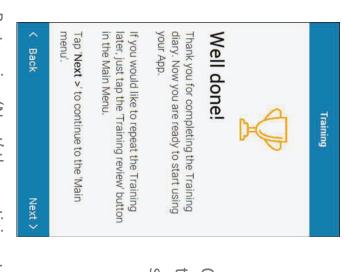
use the App complete, the participant will be led straight into training on how to After PIN code change and security question selection is fully

.4 Training on the TrialMax App

the Diary). the participant can access any other portions of the App (including This initial, mandatory training is required to be completed before

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using the App over the course of the study. well as a sampling training is brief and provides helpful information on App usage of the types of questions they will encounter while



Once the participant has concluded the Training, they will receive this screen confirming their completion.

modify their settings menu of the App where they will be able to complete their Diary and By tapping 'Next' the participant will then be directed to the main

should be performed by the participant only. Site staff will not need Please note — any activities performed while logged into the App to login to the App for any purposes.

7.5 Software Updates

than usual when there is a software update, however a percentage will be displayed on the device indicating progress available update is automatically downloaded when the TrialMax App perform a software update during the course of the study; any Site users/participants do not need to take any special action to opened and logged in. The login process may appear to take longer

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∞ **Managing Participants in TrialManager**

8.1 Participant Card

Upon clicking on a TrialManager, the participant/subject's information card will display: participant number from the main page in



installation This participant status, study group, study start date, <u>≶</u>. show details for the participant, and the status of App including: language

theft, or change in provision device over the course of the study. Here is where you will activate a new App for a participant due to loss,

Activating a new App for an Existing Participant

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activating new Apps for existing participants This section will explain how the participant and site will handle

needed: There are three instances in which a new App activation may be

- If the participant needs a new activation code due to device, loss or theft of device, changing device during the broken
- 2) If the participant has not used their provided activation code occur since the participant is to activate the app as soon as within 72 hours which is the expiration limit. This should not
- ω If the subject is switching between using their personal device and a provisioned device

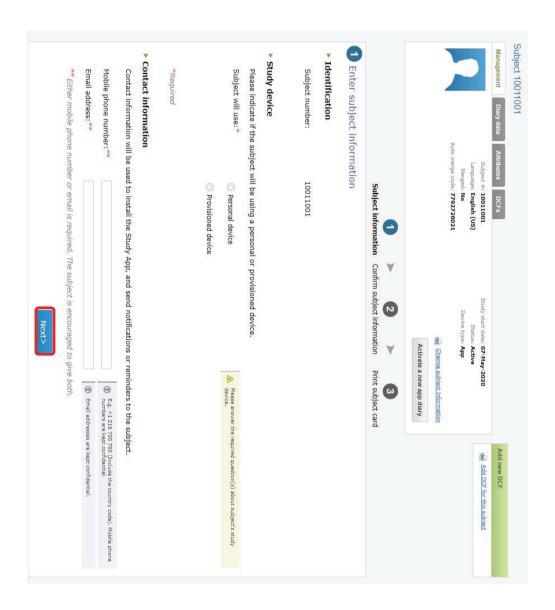
possible at the visit, or

The steps to handle either of these situations are the same

the participant card screen, select the 'Activate a new app diary Login to TrialManager and select the appropriate participant. From button



You will be required to select the participant's mobile phone number and/or email address. Once entered, select 'Next'.



select "Confirm" On the next page, make sure the entered information is correct, then

to make it more convenient for the participant and applicable instructions for getting set up with the App. provided). Participant card that is sent to the participant via email/SMS (if participant was created successfully. You will also see displayed TrialManager will also display a copy of the card which can be printed You will then receive a message on screen that will confirm that the This Participant card contains their new activation code

Press 'Exit' to return to your site in TrialManager.

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Welcome to the C4591001-Post-12-July-2020 study!

The information below will guide you on how to install the TrialMax App onto your cell phone and how to start using the TrialMax App after the installation.

To install the TrialMax App, tap the link in the installation text message (SMS) or email you will receive in a few minutes, and follow the on-screen instructions.

the web browser of your device: If you have not received the text message or email, enter the following internet address into

https://trialmax.crfhealth.net/manager-6.0.0/0B5SAI8.s

After the installation has completed, open the TrialMax App and type in the following code to

5BA-D4B-876-6

Then log in with your temporary PIN provided by your study clinic personnel. You will be asked to change the PIN to a new personal one.

to the TrialMax App installation. During your study clinic visit, the study clinic personnel will help you with any questions related

You must activate the App with the provided activation code during your study clinic visit. If you need any help with the installation, contact your study clinic or the Helpdesk.

If you contact your study clinic or the Helpdesk, you may need to give the following

Participant number: 10012222

Site number: 1001

Trial ID: C4591001-Post-12-July-2020

of this guide and/or activate their App as outlined in the Participant Setup section The participant should then follow the appropriate steps to install

3.3 Management tab

vaccination dates, update Diary reminder times, change participant several options/settings for that participant. Here you can log on the button titled 'Management' will bring you to a page displaying Upon clicking on a participant number from the main page in TrialManager, the participant's information card will display. Clicking language for the App, add or update participant information, and

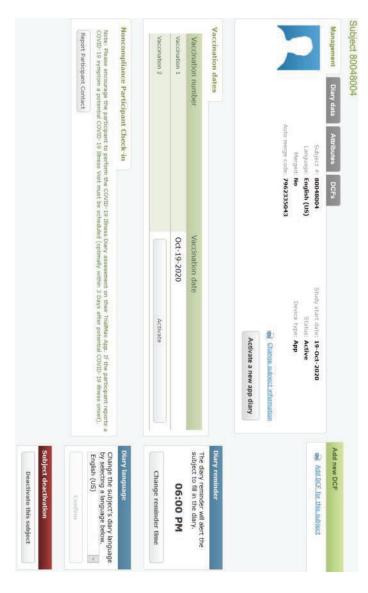
provided in the following sections deactivate a participant from the study. Details for each activity are

.3.1 Activating a New Vaccination

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needs to be set up on TrialManager. The vaccination is automatically vaccinated on 02-Apr-2020. example below, the participant was set up on TrialManager, and activated on the day of a new participant set up, for instance, in the When a participant comes in for the first vaccination the participant

Please be sure this is done before they leave. ** leave the site office, they will NOT be able to complete their Diary. **If their vaccination date is not set in TrialManager before they



appropriate visit. You will then be asked to select the date of the next activation. vaccination. In the example above, Vaccination 2 still requires To activate subsequent diaries, click 'Activate' next to the

3.2 Changing Diary Reminder Time

Site staff have the ability to adjust the time that reminder participant. accessing the 'Management' tab in TrialManager for the particular day (during the post-vaccination periods). This can be modified by notifications will be sent to participants to complete their Diary each

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into the App and selecting 'Information and Settings' from the main 15-minute increments window for reminders to be sent is between 6:00pm and 10:00pm in Reminder' which will allow them to adjust the time. menu screen. This will lead them to several options including 'Diary Additionally, participants may change this on their own by logging The permitted

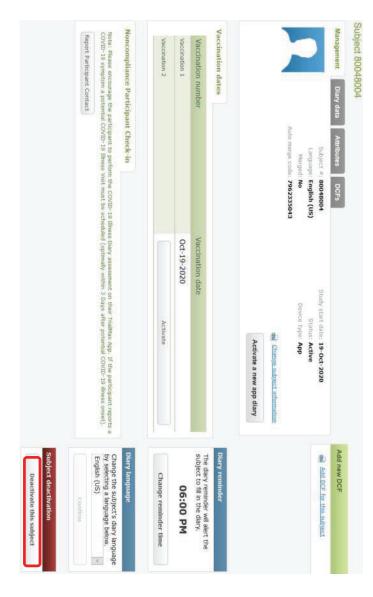
Subject deactivation				
by selecting a language below. English (US)	Note: Please encourage the participant to perform the COVID-19 Illness Diary assessment on their TraMmax App. If the participant reports a COVID-19 symptom a potential COVID-19 illness Visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after potential COVID-19 illness visit must be scheduled (optimally within 3 Days after po	o perform the COVID-19 Illness bi Illness Visit must be scheduled (courage the participant tom a potential COVID-18 ant Contact	Note: Please encourage the COVID-19 symptom a poten Report Participant Contact
Diary language		Ci	Noncompliance Participant Check-in	loncomplian
Change reminder time	Activate			Vaccination 2
06:00 PM	Oct-19-2020	00		Vaccination 1
The diary reminder will alert the subject to fill in the diary.	Vaccination date	Va	number	Vaccination number
Diary reminder			lates	Vaccination dates
	Activate a new app diary			
	ed Change subject information	PUM INELEGICATION OF THE PUMP AND THE PUMP A	AU UI III	
	Status: Active Device type: App	Merged: No		
and Add DCF for this subject	Study start date: 19-Oct-2020	Subject #: 80048004	10)
Add new DCF		butes DCFs	Diary data Attributes	Management
			8004	Subject 80048004

8.4 Deactivating a Participant from the Study

study data. end of study, the participant must be deactivated by the site in Whether the participant needs to be terminated early or has reached TrialManager so that they can no longer login to the App and record

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deactivate the participant and prevent further login to the App. participant' at the very bottom of the page (red header) will TrialManager for the particular participant. This can be handled by accessing the 'Management' tab in Selecting 'Deactivate this



desired action: Upon clicking this button, you will be asked to confirm this is the



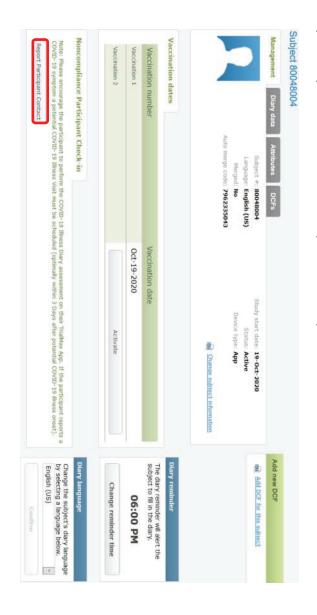
participant. clicking "Cancel" will return you to the management tab for that Selecting "Confirm" will successfully deactivate the participant while

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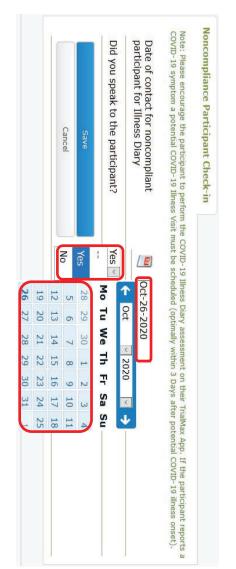
participants who have been deactivated separate tab titled 'Deactivated Subjects' that will list any Participants' tab in your main page of TrialManager. There is a Once deactivated, participants will no longer display on the 'Active

Non-compliance Participant Check-in

participant, and select 'Report Participant Contact' Trial Manager. Access the 'Management' tab for the particular Attempts to contact non-compliant participants can be logged



icon and selecting a date from the calendar, pick from the dropdown whether you spoke with the participant (Yes/No), and then click Enter the date of contact by clicking into the empty box next to the



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page. Participant Contact' tab of the 'Diary data' The attempted contact will now be logged section of the subject under the 'Report



8.6 Participant Travel



All provisioned devices will update the time zone automatically if the participant travels between different time zones.

How to Request Additional Supplies

9

Study Team, as all initial site allocations are predetermined Operating Hours). The request must be approved by the Pfizer/ICON devices than initially allocated in their first shipment), they can request it via the Helpdesk (see Helpdesk phone number in Helpdesk a Site requires device re-supply (for example more provisioned

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reused after one participant has finished using the device IMPORTANT NOTE: Remember that provisioned devices can be

shipments. These will be shipped with standard delivery service Once approved, it will take 5 business days to prepare any additional

shipment label will be provided, along with a Faulty Device Return form to indicate why a replacement is needed broken during use) should be requested via the Replacement device requests (for example for devices that are lost Helpdesk. A return

10 How to return the provisioned devices

Health. At the end of the study ALL devices must be returned to

instructions do not have one. Please see Appendix A for US Logistics device returns country. The UPS driver can bring a manual waybill to the site if local UPS up. If the site does not have a regular pickup, they will have to call their When returning devices to Signant Health, UPS will need to pick them office for a pickup. The UPS number is different in

Health Helpdesk for a form) with the return. Only devices Device you need to return a faulty device Return Form included will be investigated for any unsent data ص completed Faulty Device to Signant Health, make Return Form (refer with a Faulty to Signant

11 Frequently Asked Questions



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Q: Where can I get more help?

this guide or on the participant's Quick Reference Guide or Device please contact your study monitor. about the problem. For any protocol or health-related questions, Label. Please make sure to provide as much information as you can available 24/7 via the phone number provided at the beginning of A: Please contact the Signant Health Helpdesk. The Helpdesk is

How often should the provisioned device be charged?

charger when not in use to keep it fully charged Please be sure to leave the provisioned device plugged into

What do I do if my provisioned device does not switch on?

does not appear, call the Helpdesk. turn the device on. If the home screen with message and App icons Charge the provisioned device for two (2) hours. After charging,

provisioned device. How can the PIN code be retrieved? participant forgot their PIN code and cannot use their

call the helpdesk who will retrieve their original PIN code A: The participant's PIN code can be retrieved. The participant should

Q: How will the participant know how to send | data?

saving study answers App will send data each time the participant logs in, and also when A: The App will do it automatically, as long as the device is online. The

be added later on? A participant forgot to complete their Diary on one day. Can that

within the same day. participant can update their symptoms — both experience and severity No. Data cannot be entered retrospectively. However,

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Q: What should be done if the device is unable to send data

will be saved and automatically sent the next time they use the sent immediately once a connection is established. If the participant please contact helpdesk. device cannot seem to access a connection, please remind them that all data A: As soon as the participant logs into the App, unsent data will be online. If they continue to have issues with data sending

provisioned device? Q: Is the participant able to change the time and/or settings <u>on</u>

automatically be updated. provided date and time, so if the participant travels to a different time other changes to the settings. Also, the device uses and WiFi setup. The participant cannot change the time or make A: The provisioned device is locked to only enable usage of the 9 there are changes 5 daylight savings, the the network time any

country or region? Can the participant send data while away on vacation in another

differences, the time of entry may appear different A: Yes, as long as they can connect to a network. Because of time zone

Q: What happens if the participant forgets to log out of the App?

answers will be deleted from the App at that time automatically log the participant does participant out. Please note not log out of the App, that any unsaved App will

Q: Will the Helpdesk answer questions related to the Diary itself?

contact the site for any vaccine or study-related questions, the participant needs to A: The Helpdesk can provide answers 0 0 Diary functions, but

The participant does not understand the questions. What

If the participant does not understand the questions in the assistance with the questions, please contact your study monitor. Helpdesk cannot answer any health-related questions. For further TrialMax App, you may have to explain what is being asked.

12 **APPENDIX A: US LOGISTICS DEVICE** RETURNS

US Logistics Device Returns

- When returning devices to Signant Health, UPS will need to pick them up
- number is different in each country. If the site does not have a regular pickup, they will have to call their local UPS office for a pickup. The
- any issues with pickup charge. charge to be billed on CRF Health(Signant Health)'s account. Sites with regular pickups will not have how account is set up with UPS) UPS account number 37V198 and postal code 19462 for the pickup When calling for a pickup, the site will need to provide the CRF Health (note CRF not Signant due to
- For returns from USA based sites can request their own return airway bill, quickly and easily. Using this portal sites will be able to choose a pick-up time which best suits their needs. The site address is: this portal sites will be able to choose a pick-up time which best suits their needs

https://row.ups.com/Ship/Ship/StandardShipGuest

- Manual Waybill using the instructions below. The UPS driver can bring a manual waybill to the site if they do not have one. Please complete the UPS
- For returns from outside of the USA or where a commercial invoice is required please email uslogistics@crfhealth.com please include all the information below and a UPS waybill will be emailed
- Protocol Number/CRF Project code:
- Contact number for sender:

Email address of person to be emailed the labels:

0 0 0 0 0

- How many electronic devices are being returned:
- How many boxes will be used for the return of the devices:

APPENDIX B: UK LOGISTICS DEVICE RETURNS

UK Logistics Device Returns

- When returning devices to Signant Health, UPS will need to pick them up.
- If the site does not have a regular pickup, they will have to call their local UPS office for a pickup. The number is different in each country.
- When calling for a pickup, the site will need to provide the CRF Inc Ltd (note CRF not Signant due to issues with pickup charge. pickup charge to be billed on CRF Inc Ldt (Signant) account. Sites with regular pickups will not have any how account is set up with UPS) UPS account number 1F07X9 and postal code CT13 9FG for the
- portal sites will be able to choose a pick-up time which best suits their needs The site address is: For returns from Europe sites can request their own return airway bill, quickly and easily. Using this

- emailed back to you. uklogistics@signanthealth.com please include all the information below and a UPS waybill will be For returns from outside of Europe or where a commercial invoice is required please email
- Protocol Number/CRF Project code:

Name of sender:

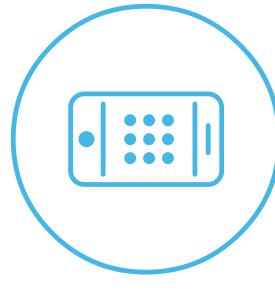
- Contact number for sender: Email address of person to be emailed the labels:

- How many electronic devices are being returned:
- How many boxes will be used for the return of the devices:









Site User Guide rialManager®

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Document index: A-1426-0082-5150UG

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IMPORTANT POINTS

incorrect date and time when it is turned back on again. If this current time zone happens, send data from the device and it will sync to your not in use. If the device battery runs flat, it might have an ensure the device(s) are charged at least once per week, even if Keep devices charged at all times – when stored at site, please

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- mobile phone service or Wi-Fi is available the App as long as the device is charged, in an area where there is Data will send automatically each time the participant logs into
- each clinic visit. Participants should bring their assigned device with the App to
- the participant is at the study clinic Participant setup should occur on the day of vaccination, whilst
- select the same to remember first log in to the TrialMax device. Please recommend Each participant will be able to set their own PIN code when they code for each device as it will be easier for them to them to
- the participant if their email address is provided during setup or during setup. sent via a text message if a mobile phone number is provided opportunity to print this once; however, it will also be emailed to activation information for the participant. You will only have the done on a computer with a printer, as you will need to print the When setting up a participant for the study, make sure this
- To receive SMS notifications in the US, notifications' section for more details please refer to 'Setting up
- Use the TrialManager web portal to regularly monitor participant data for the study

their available storage below: the event the participant does not have the free space or does not want to make that space available. The participant may check properly. Please provide a provisioned device to the participant in participant's personal device to allow the TrialMax app to function It is recommended to leave 0.5GB of free storage space on the

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- 0 iPhone: Select 'Settings'->'General'->'iPhone Storage'
- \circ Android: Select 'Settings' ->'Device Care'->'Storage'
- If you cannot find help in this guide, then please call the Helpdesk.

Logistics PIN Code	Logistics Access PIN Code	Default Participant	Role
4422	8888	1234	PIN Code

http://trialmax.crfhealth.net/c4591001

lanager

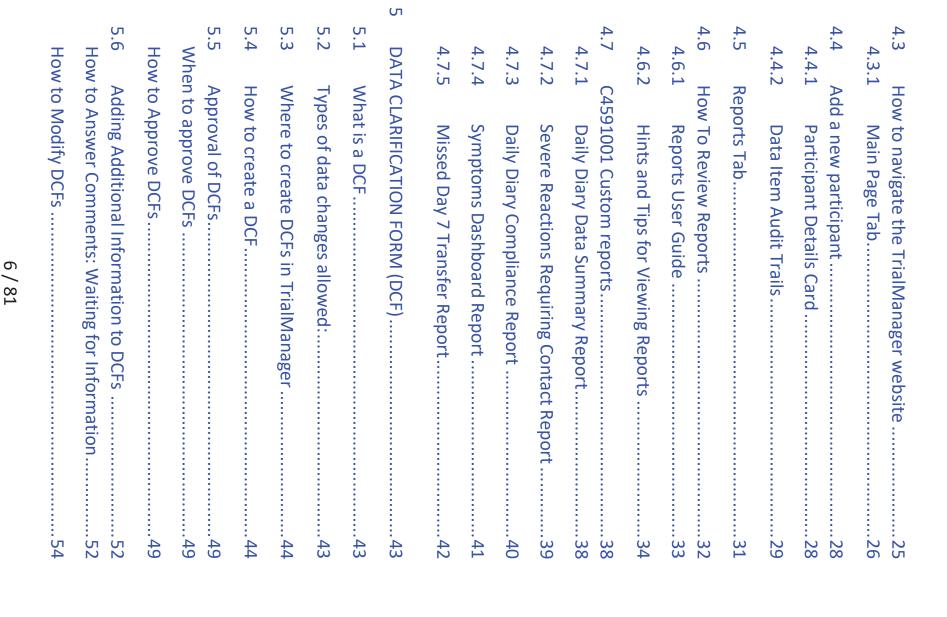
ebsite

TrialManager login details will be sent to you via email

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How to Cancel/Deny DCFs.

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DCF Timelines and Tips for Success

Viewing DCF Comment and Action History

Tips for Success

DCF Timelines

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Frequently Asked Questions.

Signant Health Overview

Signant Health is the provider of the eCOA (electronic Clinical to it simply as the "App". Helpdesk support. TrialMax App is the brand name, but we will refer comprises the components as displayed below, along with 24/7 Outcome Assessment) system for this study. The eCOA system

Data entered by Participant into the App

> App to Signant Health servers

Data sent from

monitors and study team Data available for sites, in web portal and TrialManager



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9 6

D



TRIALMANAGER®

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2 Helpdesk

or TrialManager website You may call the Helpdesk for any issue related to the TrialMax App,

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Please have the following information ready when you call:

- The study protocol number: **C4591001**
- Helpdesk Priority PIN: 19
- Signant Health project code: A-1426-0082
- Your site number
- The participant number (if applicable
- The specific problem



2.1 Helpdesk Operating Hours

The Helpdesk is available 24 hours a day, 365 days a year.

business day. Helpdesk will contact you as soon as possible, at the latest by next voicemail If you are unable to reach an agent when you call, you can also leave a 9 send an email giving your contact information.

2.2 Helpdesk Telephone Numbers

Country	Number
NSA	(1) 866 402 1154
Helpdesk Priority Code	19

operator charges might be applied if calling from a mobile phone Note: Toll Free numbers are free from a landline; however local

2.3 Helpdesk Email Address

For non-urgent issues, you can contact the Helpdesk by email:

C4591001_TM@support.signanthealth.com

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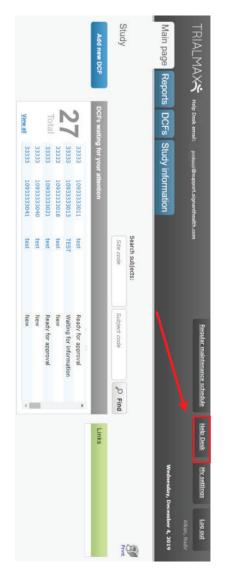
communication via email. participant's identity might be unintentionally revealed during Do not share this email address with participant. The

Helpdesk Web Chat via TrialManager

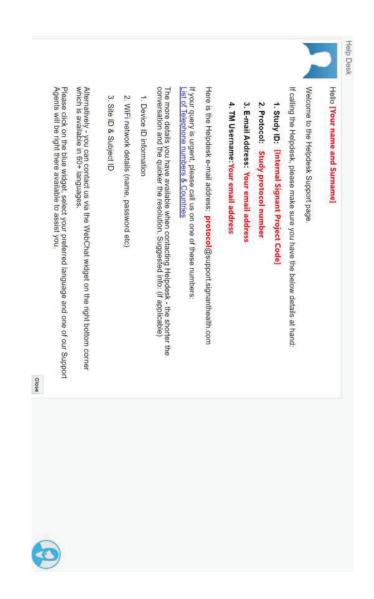
The Helpdesk Web-chat is available via the TrialManager Portal.

Helpdesk Web-chat can be accessed via the steps below:

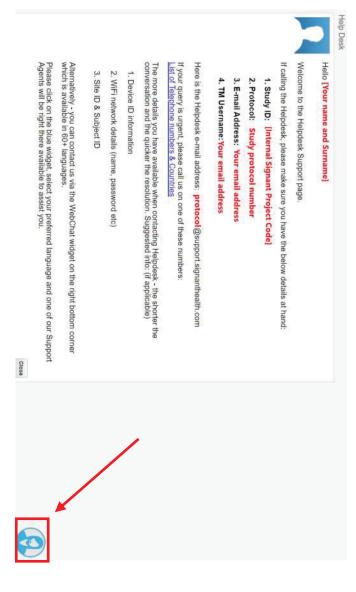
Please click the Help Desk button in the upper right corner of your screen.



2) You will see a welcome will be pre-filled page where all the texts highlighted in red



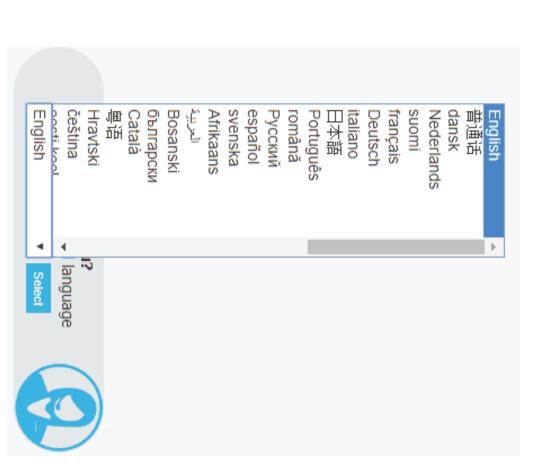
 ω the blue widget in the lower left corner of the screen to start your You can open the web-chat, available in 60+ languages, by clicking live chat with one of our Support Agents.

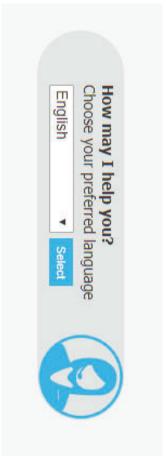


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4 Once you click on this widget, you will be able to select your preferred language from the drop-down menu.





5) agent. After button, then you will be connected to the next available support necessary information in the below screen and click the Continue selecting your language, you will need to complete the



Fields with an asterisk (*) are required.

Health Helpdesk specialist, who will discuss your issue with you Once you click on "Continue", you will be connected to the Signant

If the ticket number is not entered, it will be counted as 2 separate call into the web chat the ensure the background information is linked that you enter the Ticket Number you received from your telephone Please note that if a telephone call has already been placed make sure

Providing feedback about Helpdesk performance

as it helps us continuously improve to exceed your expectations level of your satisfaction from the provided service. This is important, Each time you request support from the Helpdesk, you can rate the

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You can provide the feedback in 2 ways:

- scale 0 to 5, where 5 is awesome and 0 poor. you can remain on the line and rate your experience on the Each time you have spoken to the Helpdesk on the phone
- resolution of the incident. email, enabling you to evaluate the service or reject the When your request has been completed, you will receive

Please accept the resolution by rating your service experience, where 0 is poor and 10 is awesome

Or reject to reopen the case.

Kind regards,

Jason

Signant Health Service Desk



shorter with every further use (IT profile information needs only to be provided once). The form is a bit longer when you use it the first time and will be take you to a form, where additional information can be provided 10), where 0 means poor and 10 awesome. Selecting any rating will To provide feedback, you would click one of the numbered boxes (0-

Evaluation form 1st use

Evaluation form consecutive

Submit	Just contact support Ask a colleague	Try to solve the problem by myself	I help others	I rarely need help with IT I rarely need help with IT	How would you describe your IT skills	Anything else you want to say?	0 minutes 5 days	0 minutes	Estimate the working time you lost	Service was provided proactively	I learned something	Service personnel's attitude I was informed about the progress	Speed of service	Service personnel's skills	Awesome! Let us know why you were so happy?	You chose 10 Change	Please rate your service experience.
				Submit		Anything else you want to say?	0 minutes 5 days	0 minutes	Estimate the working time you lost	Service personnel's skills	Service was provided proactively	I was informed about the progress I learned something	Service personnel's attitude	Speed of service	Awesome! Let us know why you were so happy?	You chose 10 Change	Please rate your service experience.

average, 6 and below means negative feedback. Please remember that only 9 and 10 mean positive feedback, 7-8

before submitting it. You can change your rating on the top of the form any time



S **Equipment**

Supplies for participant

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Provisioned device supplies

- iOS or Android device), accompanied by an incorporated SD memory Samsung device with TrialMax App installed (if not using personal installed for mobile data sending. card (this backs up the data for recovery if needed) and a SIM card
- A device charger (power-cord and charging brick)
- TrialMax App sticker with country specific Helpdesk number
- Quick Reference Guide in the participant's language
- Participant card with App activation details to be sent via email App Activation Guide in the participant's language

Bring Your Own Device supplies

- TrialMax App sticker with country specific Helpdesk number
- Quick Reference Guide in the participant's language
- App Activation Guide in the participant's language
- Participant card with App activation details to be sent via email or

Provisioned Device Basics

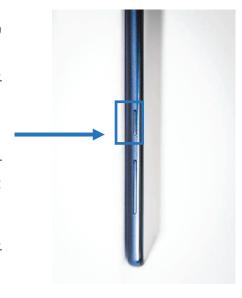


that contains the country specific Helpdesk phone Each TrialMax App device has a sticker applied to it

technical questions agents will assist you or the participant with Please contact the Signant Health Helpdesk if device is not working properly. The Helpdesk

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3.3 How to turn on the Provisioned device



The Samsung device is the provisioned device for this study.

Turn the Device on by pressing the power button on the right side of the device.

If the Device is left on for ten (10) minutes without use, it will hibernate and perform automatic log out.

Press the power button on the side

How to charge the Provisioned Device

the participant with a message that the battery is low, they should the participant to charge the battery every day. If the device prompts indicates the amount of charge remaining in the device display a battery status symbol on the top right side of the screen that charge the device immediately. When the device is powered on it will device has a rechargeable battery. Please remember to instruct

discharged fully, it may take a little time to charge before use participant can use the device while \rightrightarrows S. being charged



.

The device will usually fully charge in approximately 2 hours. Connect the power charger cable to the provisioned device.

3.5 Device Navigation



Use your finger to navigate through the device.

Please do not use a stylus or sharp points as these will not function on the device and will damage the screen.

3.6 Additional Site Supplies

- This Manual
- device sticker Quick Reference Guide for the participant and TrialMax App
- App Activation Guide

l TrialManager

investigators, coordinators, monitors and study personnel to view and overall participant compliance and view the participant's Daily Diary monitor study progress. TrialManager is an online, internet-based TrialManager enables the users application used to follow bγ

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TrialManager supports the following Internet browsers

- Firefox 33 and up
- Internet Explorer 11 and up
- Chrome 32 and up
- Apple Safari v9 and up

.1 Functions of TrialManager

the data) sent Within minutes of sending data, you can view the data (and reports of will need to send their answers to the study database After answering the questions on the electronic device, the participant (TrialManager).

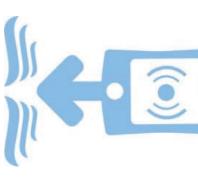
By using TrialManager, you can:

- View the participant's Daily Diary answers
- Monitor participant compliance and other reports
- completed their Daily Diary Monitor the number of days since the participant has
- progression through to closure Data Clarification Forms (DCFs) and monitor their
- changes to forms trails for questionnaire entries (including
- Deactivate the participant

interchangeably throughout the App and TrialManager platforms. password with your colleagues. It is also important to note that while login details (which will be sent to your email). Do not share Note: You should be logging in to TrialManager only with your own term "Participant" is used to describe the patient in this study, **≦** see the terms "Subjects" and "Participants"

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Accessing the TrialManager website



All people will have separate access based on their role within the study.

information). Your TrialManager will be emailed to you. You will be prompted to TrialMax App. relation to the change change this password at your first login (see How to Your TrialManager username and initial password your TrialManager password Site personnel PIN codes password has no for on the more

change them manually to match with the rest of your credentials same Username and Password for each TrialManager unless TrialManager account for older studies, you will not be able to use the TrialManager. then you will be able to use the same Username and Password for each Note: If you have that started Please note that this feature is only available for the access to TrialManager for another Clinical Study, after September 1st, 2019. If you have

Type the following address into your web browser:

http://trialmax.crfhealth.net/c4591001



A login window will open. Bookmark this address for easy future access. Next, enter the username and password that was emailed to you.

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How to change your TrialManager password

Screen. There you will find an option to change your password. right-hand corner of the screen or "Change Password" from the Login If you need to change your password, select 'My settings' in the top



in your current password, your new password, and verify your new your new password. password by typing it in again. Click the 'Change' button to activate When you decide to change your password, you will be asked to type

Rules for creating new password:

- Must be at least 8 characters.
- Must contain at least one lower case character.
- Must contain at least one upper case character.
- Must contain at least one number.
- Must not contain Unicode characters
- Special characters in password are not necessary.
- Must not contain spaces, line breaks or new lines.

Back to Sign In

How to Reset your TrialManager Password

Portal. you are able to reset the password directly within the TrialManager If you have forgotten your password to your TrialManager Account,



From the log in page, select "Forgot Password"

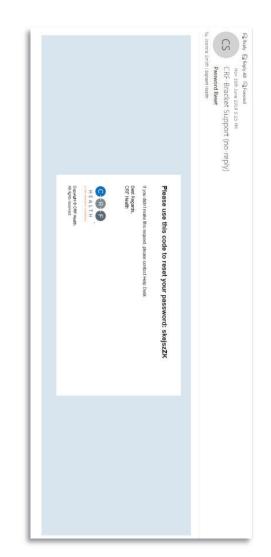


You will be asked to enter your email address so that the system can send you a security code for the password reset

You will be taken to this screen

Check your email inbox and enter the security code, which has been sent to you

This is an example of the email which will be sent to you:





Enter a new password following the guidance on the screen

screen: Once your reset has been successful, then you should see this



How to request TrialManager access for new team members

should add their information into the 'TrialManager User Order collating requests into 1 email per week and send the updated form to the Signant Health 'TM accounts' In order to request TrialManager accounts for new team members

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Allow updates J business days to create new TrialManager accounts/make

directly contacting the Pfizer Study Team via your CRA/Monitor. TrialManager requests can be requested Helpdesk 9

How to navigate the TrialManager website

Information' tabs. These are selected by clicking on them. the screen. They are the Investigators and Study Coordinators will see several tabs at the top of 'Main Page', 'Reports', 'DCFs', and

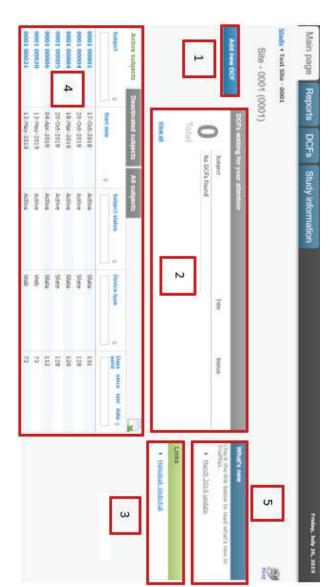
The points below highlight the main functions and features of the tabs:

- individual participant pages, view open DCFs and navigate to Main Page: View a list of all your participants, the DCF tool, view the latest TrialMax updates navigate
- administrative data Reports: Review, filter, and print information associated site and participants, such as compliance, DCFs, and
- changes for your participants Create, approve, and monitor <u>ല</u> requested
- Study Information: Access supplemental reference such as electronic versions of the Site User Manual and DCF content,

.3.1 Main Page Tab

When you select "Main page" the following screen appears:

FDA-CBER-2021-5683-0650310



- \vdash With this button, you are able to add DCFs (see DCFs in TrialManager) Where to create
- 2 for your site that require your action. Simply click on the title of a implement the corrections requested in the DCFs. with DCF you or anyone else will also need to be approved by a site user particular DCF to see further details displayed. All DCFs created by This section is called the DCF Notice Board and will display all DCFs approval rights. Signant Health will be the one to
- ω hand side of the screen, including the Helpdesk web chat. Some useful web links for the study are displayed on the right-
- all participants at your site The participant list section at the bottom of the screen will display

4.

ā By default, this will display Active participants at the Click on the 'Deactivated subjects' or 'All subjects' to also

- the TrialMax App. view participants that have already been deactivated from
- 0 You are able to sort and filter by any of the column headings by typing into the text boxes below the column headings
- 0 information Clicking on a subject number will take you to more detailed **Details Card** regarding that participant (see **Participant**
- updates. You can see the latest updates regarding any Trial Manager system

5

.4 Add a new participant

Please see 'How to set up a participant in TrialManager'.

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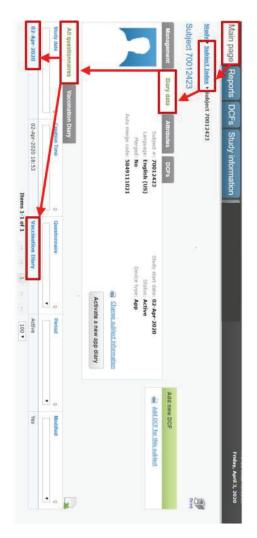
1.4.1 Participant Details Card

Upon participant/subject's information card will display: clicking 9 0 ۵ participant from the main page, the



This auto merge code, which is necessary for replacement devices participant status, study start date, device type, and the participant's <u>≦</u>. show details for the participant including: language,

Diary forms submitted by the participant on the TrialMax App Below the participant details card, you will be able to review the Daily

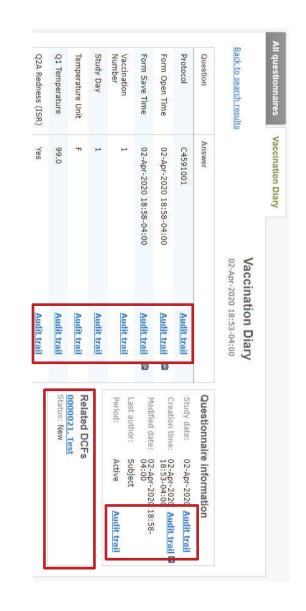


items items and responses completed by the participant, and administrative displaying a list of all form data items, including filtered and 'Questionnaire' questionnaires' such as the sorted. Upon selecting a form link the form will open, links to each completed form. date and time tab which a completed contains Each column can be Study, the questionnaire form was saved date'

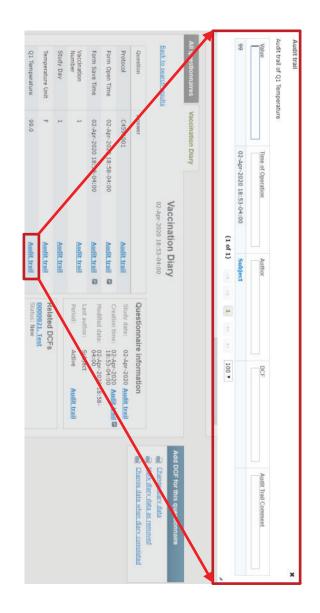
4.2 Data Item Audit Trails

of the form with a direct link to the DCF itself and the current DCF associated with a questionnaire form, this will be displayed to the right changes were made via the TrialManager DCF tool If there was a DCF review the original values and a full change history of any data item if item from within these form pages. You will also be able to view the audit trails for each questionnaire data You can use the audit trails to

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the data the data item, and that it has not been modified If only 1 row is displayed, this indicates that this is the original value of the desired item. An audit trail of the item will open displaying a list of original value and any changes, click the 'Audit trail' link to the right of To view the full audit trail of any available form item, including the item elements, sorted newest to oldest from top to bottom.



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The Audit trail column headers are defined as follows:

- Value: the value of the data item itself
- item entry or modification Time of Operation: the date and time associated with the data
- **Author:** the user that committed (participant, site, or Signant Health Data Management) the associated operation
- to the form DCF: the DCF ID number if a DCF was used to execute a change
- data reference information external DCR number (if DCF was not used), or other useful Audit Trail Comment: free text field where the Signant Health change implementer may post the DCF number, an

the change over the clipboard icon will trigger a pop-up with a brief summary of display a small clipboard icon to its right. Hovering with the mouse Note: if a data item was modified via DCF within TrialManager, it will

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4.5 Reports Tab

The completing the questionnaires correctly with good compliance should be reviewed on a regular basis to ensure the participants 'Reports' tab will contain reports for you to view. These reports

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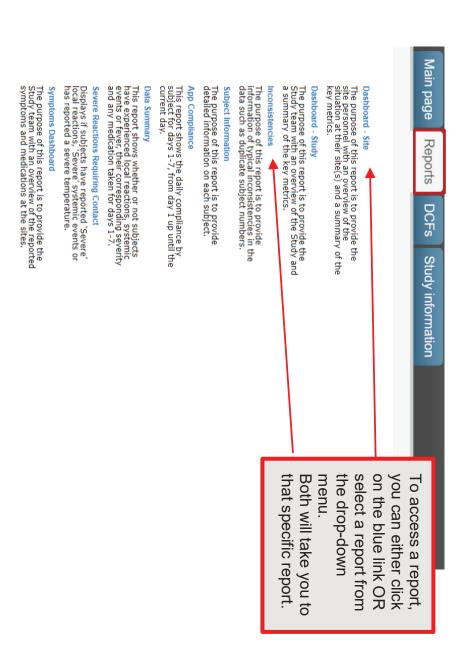
view these reports Note: TrialManager reports accessibility may not be available login of the user. The user may have to logout and log back in to on the

The following reports will be available for this study:

- and a summary of the key metrics site personnel with an overview of the situation at their site(s) **Dashboard - Site:** The purpose of this report is to provide
- the Study team with an overview of the Study and a summary of the key metrics Dashboard - Study: The purpose of this report is to provide
- duplicate participant numbers information of typical inconsistencies in the data such as Inconsistencies: The purpose of this report is to provide
- Subject Information: The purpose of this detailed information on each participant report is to provide
- following each vaccination. participant for days 1-7, from day 1 up until the current day **Compliance:** This report shows the daily compliance
- their corresponding severity and any medication taken for days 1-7 following each vaccination have experienced local reactions, systemic events or fever, **Data Summary:** This report shows whether or not participants
- Severe Reactions: Displays if participants reported a severe temperature. 'Severe' local reactions, 'Severe' systemic events or have have reported

symptoms and medications at the sites Symptoms provide the Study team with an overview of the reported Dashboard: The purpose of this report is

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4.6 How To Review Reports

resolving DCFs completing their questionnaires on schedule) or verify the progress on from the study protocol and take corrective action. For example, Graphical visualizations allow you to identify quickly any deviations reports verify which monitoring about the purposes, study participants state of the you can study are view right inside still compliant (if they near real-time, TrialManager. graphical you

6.1 Reports User Guide

example of the Inconsistencies Report. visualizations, Signant Health including Reporting bar charts Solution and data supports tables. Below variety S an of

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the whole report. selected. Clicking on the drop-down options will automatically filter selection automatically. This even works between reports in the same the displayed data in report, all other sections update to filter for the participant number from the drop-down options Depending drop-down list and allows the user to ask questions about the data These report visualizations are interactive. When you select parts of The report will automatically on your user role, you can select repopulate using your at the site the top of the and/or criteria

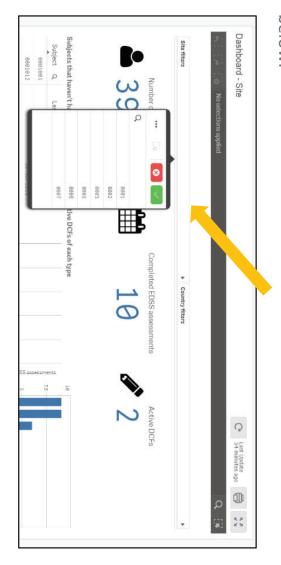
.2 Hints and Tips for Viewing Reports

from the reports available in the study: key study details. The reports used in this study are designed to give you easy access to Below are some hints and tips on how to get the best

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Filtering

below the drop-down filters appearing at the top of the reports, as shown Reports can be filtered in several ways. One way is by selecting from



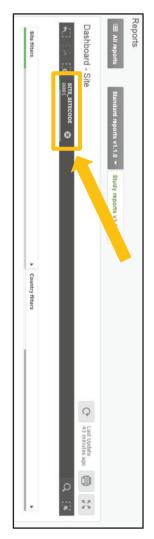
select the green tick to apply the filter. Select the red cross to close the filter list without applying the change To use the drop-down filters, select an item or items, from the list and

example selecting a participant from a list, or selecting a bar in a chart Reports can also be filtered by selecting part of a table or chart, for

reports Selecting the icon in column headings can also be used to filter

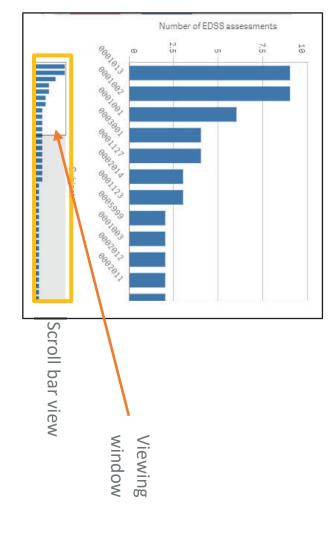
can be seen in the banner at the top of the report reports viewed, will have this filter applied. All filters that are applied Once a filter selection has been made, all parts of the report and other

top of the screen, as per the image below: To remove a filter, select the "X" next to the filter in the banner at the



Viewing Bar Charts

bars the main part of the report. Some reports to the left or right on the scroll bar view to change the data shown in version of the report can be seen. Move the white For bar charts with many data at the same time. contain bar charts to When this bars, S. display specific data information. it may not be the case, ص possible to view all smaller 'viewing 'scroll area' bar' box



information. Hovering over വ bar within $\boldsymbol{\omega}$ bar chart <u>≶</u>. display additional

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10.31

Viewing Reports with Tables

the column name with the mouse to view the full name view. If a between columns, For reports with large tables, you may wish to resize columns to ensure best view in column name is too wide to be displayed fully, hover over your and resize as required to fit all the columns in the browser. To do this, simply select line

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you to focus on the columns you require on and dragging You can rearrange the order that the columns will appear in by clicking a column header into a different position, allowing

header to indicate the sorting applied report in descending click will sort the report in ascending order, a You can select column headings to sort the order. An arrow will appear report by that item. second click will sort the on the column



in a table to excel

button, where seen, to export information

Standard Report Icons

in the study. The icons seen below can be found at the top left corner of all reports



any report to full screen This icon can be used to expand the viewing area for



This icon will be seen to exit the full screen view



saved, as required viewed. This pdf copy of the report can be printed or This icon can be used to print to pdf the report being

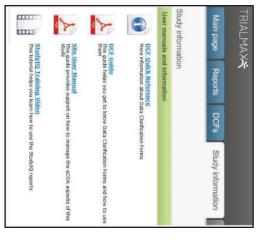
the report. This icon can be used to reload of the data

To 'Study reports'. between reports using the drop-down options 'Standard reports' and reports switch between reports, by selecting the you Reports' can either return to the option, 9 you can full list of switch

Note: Any filters applied to one report will also remain active on other reports viewed in the same drop-down list, unless specifically removed.

Further information and video training

Further information and video training on how to use the reports can be found in the 'Study information' tab in Trial Manager.



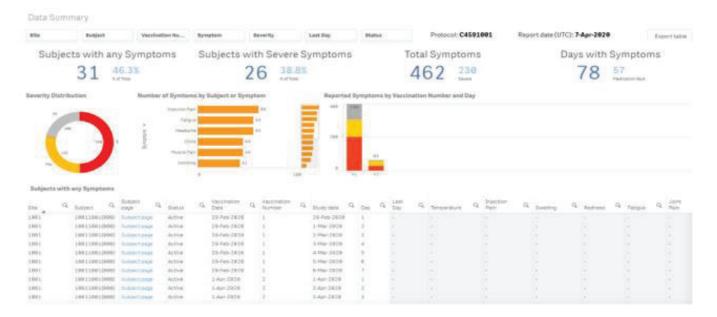
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4.7 C4591001 Custom reports

4.7.1 Daily Diary Data Summary Report

This report shows whether or not participants have experienced local reactions, systemic events or fever, their corresponding severity and any medication taken for days 1-7.

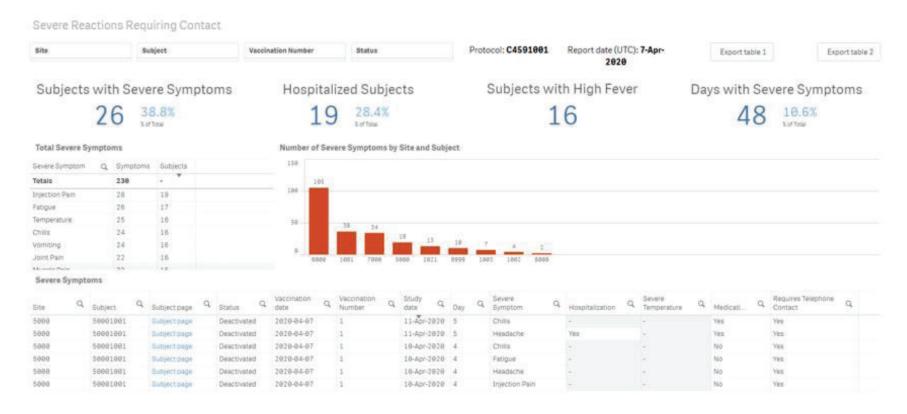
Columns will include: "Site", "Participant", "Participant page" (hyperlink which takes you to the participant page in TrialManager), "Status", "Vaccination Date", "Vaccination Number" (displays the vaccination number entered in the TrialManager), "Study Date" (displays date when daily diary form was opened. Future/ uncompleted diary dates will appear as [blank]), "Study Day" (fixed column listing '1' – '7' representing each of the study days for each participant), "Temperature", "Injection Site Pain", "Swelling", "Redness", "Fatigue", "Chills", "Diarrhea", "Vomiting", "Headache", "Joint Pain", "Muscle Pain", and "Medication".



4.7.2 Severe Reactions Requiring Contact Report

Displays if participant have reported 'Severe' local reactions, 'Severe' systemic events or has reported a severe temperature.

Columns will include: "Site", "Participant"," Participant page" (hyperlink which takes you to the participant page in TrialManager), "Vaccination date", "Vaccination number" (displays the vaccination number entered in the TrialManager), "Study date", (displays date when daily diary form was opened. Future/ uncompleted diary dates will appear as [blank]) "Study Day" (fixed column listing '1' – '7' representing each of the study days for each participant), "Severe Symptoms", "Hospitalization", "Severe Temperature" (Any Temperature higher than 102°F), "Medication", and "Require Telephone Contact".



4.7.3 Daily Diary Compliance Report

This report shows the daily compliance by participant for days 1-7, from day 1 up until the current day.



Columns will include: "Site",
"Participant", "Participant page",
"Status", "Vaccination date",
"Vaccination number", "Last data
sending", & "% Compliance".

Compliance (%): Displays the compliance rate.

D1-D7: represent the study days and will display the status of the participant's diary completion for each day.

Color scheme display for the Compliance (%):

Red: <40%

• Yellow: ≥ 40% - < 80%

Green: ≥ 80%

Expected diary compliance will follow the standard color-coding scheme and thresholds. For active participants, diary completion expectations will be based on the current date. Once a participant is vaccinated, the participant will be expected to complete the diary every day for 7 days including on the day of the vaccination, for the participant. As each study day passes, the previous study days become expected and should have one daily diary completed. For deactivated participants, diary completion expectations will be based on the deactivation date. The participant will thus be expected to have completed one diary for each study day starting from the vaccination day and until the day before the Deactivation date. The exception here is that if the participant completed a diary on the day they were deactivated, that day will also be considered as expected.

4.7.4 Symptoms Dashboard Report

The purpose of this report is to provide the Study team with an overview of the reported symptoms and medications at the sites.

Symptom Distribution columns will include: "Symptom", "S" (Severe), "Mo" (Moderate), "Mi" (Mild), & "Total".

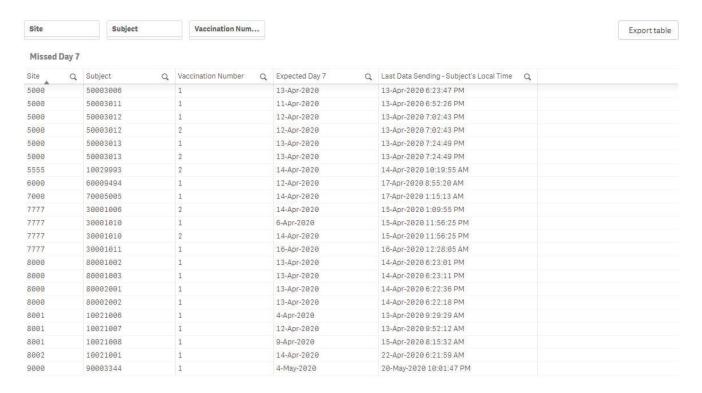


4.7.5 Missed Day 7 Transfer Report

The purpose of this report is to flag any participants who are missing diary data for day 7, following vaccination 1 or vaccination 2, and have not sent data for day 7 or thereafter.

The table will list the site number, participant (subject) number Vaccination number, the date day 7 diary was expected, and the last date and time the participant's App connected to the server (in the participant's local time).

The report can be filtered by: Site number, Subject (participant) number, Vaccination number.



DATA CLARIFICATION FORM (DCF)

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5.1 What is a DCF

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data changes are needed. The DCF is the audit trail for data changes. This data is very rarely, if ever, changed, however, in some situations and participant is considered to be the original electronic source data certain data items via the DCF process. The data reported by the of the study via the site archive. via TrialManager and will be provided to the sites and client at the end Each DCF and its full history are available for review during the study TrialManager allows authorized personnel to request modifications to

5.2 Types of data changes allowed:

The following data modifications are permitted for this study:

- investigational sites responsibility to ensure such changes are initial data entered and the corrected data documentation, e.g., telephone contact report detailing the systemic event previously reported on a given day. It is increase Changes requested to data previously reported by the participant, i.e., or decrease in the severity of a local reaction or ≕; supported bγ appropriate the
- following when previously entered incorrectly: Changes to device set-up information, i.e., corrections to the
- Site number
- Participant number

0

0

- Vaccination number or date of vaccination
- Other administrative changes, i.e.:

0

Merging participant data allows cleaning of data issues that may result and removal of duplicate

- participants from replacement or multiple devices being issued to
- 0 inaccurate arising from when the diary device internal clock is Modifying timestamps - allow cleaning of data issues

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Changing participant status

0

deleted, all data will remain in the data base audit trail. When data is modified or duplicate data removed, no data is ever fully

The following data modifications are not permitted for this study:

the participant is unable to record their daily diary. previously been reported as missed, or if the device Addition of a form, e.g., addition of a daily diary that fails and

Where to create DCFs in TrialManager

'Add new DCF' button in TrialManager. You can add a new DCF for any participant where ever you see the

from a participant's form view while reviewing data (so the It is also possible to add a DCF for a specific participant from the participant instance and the specific form will be preselected). participant page (so the participant instance will be preselected),

5.4 How to create a DCF

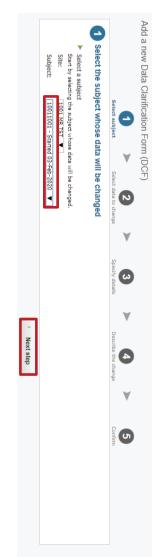
necessary level of information. The system will guide you to select the necessary information, where this is required certain The steps required to complete DCFs, additional steps may be a new DCF are required detailed below. to provide the

After initiating the DCF SB outlined in Where to create **DCFs**

1. Select Site and Participant

necessary. entering Note: 茾 the the site DCF and Sew participant in the dropdown will not be raised at the participant or form level,

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select the participant details. DCF from the participant level of the correct instance to prethe start date (found in the site index). Alternatively, raise the Daily Diary instance) you must select the correct one If there are multiple instances for the participant (i.e. multiple based on

Select data to change

as per the example screenshots below. Select the option that best fits the change, then select 'Next step' to proceed to step 3. Questionnaires. Select the data to be changed, either Participant Information or Based on the selection a further list will appear,

	> Next step	< Previous step
	Handle duplicate subjects Duplicate subjects will be shown as one subject in listings and reports.	0
	Mark a subject as removed The subject will be hidden from listings and reports. No data will be deleted.	0
	Change subject's site number Move subject to another site.	0
	Change subject status Change subject status to Completed, Discontinued etc.	0
	Change subject information Change subject code, screening code, initials, period, date of birth etc.	0
	Then specify the change that will be made to subject information:	➤ Then s
Site: 1001 MR TST Subject: 10011001	Questionnaires Modify, add or remove questionnaires,	0
Summary You have chosen subject:	Subject information Change subject information, change site, remove subject, or handle duplicates.	•
	Select what data will be changed First select one of the following:	2 Select w First se
inge Confirm	Select subject Select data to change Specify details Describe the change	
Y		
	Add a new Data Clarification Form (DCF)	dd a new Da

Specify details (required for some DCF types)

information may be required Based on the options selected in the previous step, additional

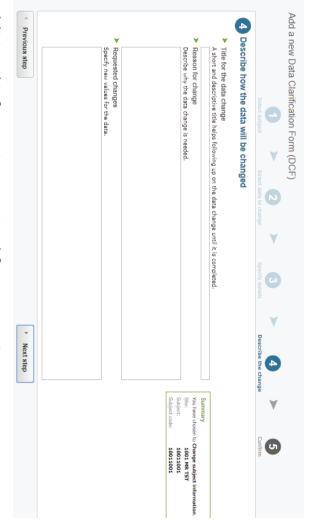


4. Describe the change

much detail as you can provide. When finished, click 'Next step': Fill in the 3 required free text boxes to describe the change, in as

- that describes the change (e.g. 'Update participant Title for the data change: Give the DCF a brief title number).
- 0 the change change may be delayed. This should not simply outline what details as possible. If this is not specific, Reason for change: Describe the device') Participant number was entered incorrectly on the must be made explicitly, to act as the audit trail. but rather provide issue with as processing many
- X to Y.'). the original value and new value (e.g. 'Please change Specify any values that need to be changed, including Requested changes: Detail the requested changes

 Ω



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Additional information required for some DCF types:

started. include the date of when the participant status has cannot be processed without a date when the new status changed in Step 4 (Describe the change). This DCF type Requesting to change a participant's status: be sure to

under the (Requested changes). Marking a participant should also be marked as 'removed' in Step 4 participant as removed: be sure to specify if forms

5. Confirm

the save before sending to Signant Health Data Management. used if you are sure the data entered in the DCF is correct and you to approve the and approve' return to the last step and amend the information. you can review the information entered When the DCF has been drafted, you will see a screen where request does not need to be reviewed by anyone the information required; button can also be seen if your user role allows DCF request. or press 'Previous Step' This button should only be and click 'Save' The



change the status of the DCF for processing by the Signant Health Data pressing either 'Save' You will get a confirmation that the DCF was created successfully after Management Team, if 'Save and approve' was not selected or 'Save and approve'. Select 'View DCF' to

View DCF	If you would like to view the new DCF, select 'View DCF'. Otherwise select 'Continue'.	▲ Than
**	ce to view t	Thank you! Your DCF was added to the system successfully.
	he new DCF	DCF was a
	; select 'Vi	idded to the
	ew DCF'. O	system su
	therwise s	uccessfully
_	elect 'Cont	
Continue	tinue'.	
tinue		

5.5 Approval of DCFs

When to approve DCFs

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Health can implement a DCF, it must first be approved by the Site. creation process if the user has DCF approval rights. Before Signant completed separately, once the to have all the necessary and required information. This DCFs must be approved once they have been created and confirmed DCF is created, or during the may DCF be

How to Approve DCFs

reviewing the DCF Dashboard on the study's TrialManager Main Page notification emails, pending site approval can which will include links to each be monitored in the DCF, weekly 9 DCF by

taken directly to the page where the status of the DCF can be changed After clicking the DCF link from the email notification, the user will be TrialManager home page by clicking on the DCF title can also select the appropriate DCF from DCF Dashboard <u>o</u>n

approved by the following levels: Before the change requested can be implemented, the DCF must be

approve DCFs approval. **Level 1 (Site):** The first level of approval is the Site/Investigator Steps below describe how site personnel can

necessary information to implement the requested changes Signant Health have confirmed Team approval is added once all approvals are received, Level 2 (Service): Finally, Signant Health Data that the DCF Management includes and

for processing: Follow the instructions below in order to ensure the DCF is approved

Navigate to the DCF and select the 'Approve' button.

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/pe: Change subject's site number ite: 1001 MR TST ubject: 10011001 eason for change: test equested changes: test hanged fields: Show details Modify DCF	Change subject's site number 1001 MR TST 10011001 In for change: test sted changes: test ged fields: Show details Modify DCF Approval Site (p		Deny	Move to Waiting for information	Move to Ready for approval Mov	Move to R
Type: Change subject's site number Site: 1001 MR TST Subject: 10011001 Reason for change: test Requested changes: test Changed fields: Show details Modify DCF	Type: Change subject's site number Site: 1001 MR TST Subject: Reason for change: Requested changes: Changed fields: Show details Modify DCF Approval Site (p Site (p Service Modify DCF				us: New	Current stat
Change subject's site number 1001 MR TST 10011001 In for change: test sted changes: test sed fields: Show details Modify DCF	Type: Change subject's site number Site: 1001 MR TST Subject: Reason for change: Requested changes: Changed fields: Show details Modify DCF Approval: Site (p Site (p Site (p) Site (p					Status
Change subject's site number 1001 MR TST 10011001 In for change: test sted changes: test yed fields: Show details	Type: Change subject's site number Site: 1001 MR TST Subject: Reason for change: Requested changes: test Changed fields: Show details Approval Site (p		Modify DCF			
Change subject's site number Approvation of the subject's site number Approvation of the subject's site number and site of the subject's site number Approvation of the subject's site number and subject's site number Approvation of the subject's site number Approvation of the subject's site number Approvation of the subject's site number and subject's site number Approvation of the subject's site number Approvation of the subject's site number and subject's	Type: Change subject's site number Site: 1001 MR TST Subject: Reason for change: Requested changes: test Approval Site (p	Service (pendir		Show details	Changed fields:	
Change subject's site number Approvation 1001 MR TST Site 10011001 on for change: test	Type: Change subject's site number Site: Subject: 1001 MR TST Subject: 10011001 Reason for change: test			test	Requested changes:	
Change subject's site number 1001 MR TST 10011001	Type: Change subject's site number Approval: Site: 1001 MR TST Subject: 10011001	Approve		test	Reason for change:	
Change subject's site number 1001 MR TST	Type: Change subject's site number Approval: Site: 1001 MR TST Site (p			10011001	Subject:	
Change subject's site number	Type: Change subject's site number Approval	Site (pending)		1001 MR TST	Site:	
	St Created on 2 by Catalina Ici	Approvals		Change subject's site number	Type:	

2 Next, Investigator add a comment (optional) and approve the DCF. After entering credentials, you can select approve. a confirmation screen will appear which allows you to and Study Coordinator (DCF) roles can approve Please note only

	Approve	Cancel
		Comment
		Password: *
		Username: *
	By approving this, I confirm that the information in this $\mbox{\it Data}$ Clarification Form is true and accurate.	By approving th Clarification For
×	Confirm your approval	Confirm yo

Information.

ω



the status in the within the DCF. You can follow the progress by selecting the DCF and checking 'DCF' tab of TrialManager and the comments

5.6 **Adding Additional Information to**



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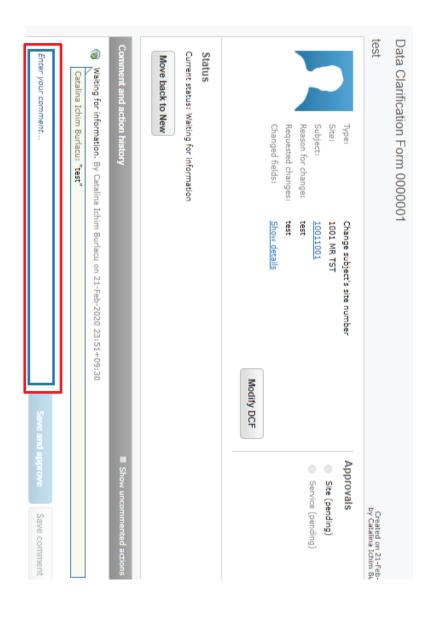
need to answer. The DCFs waiting for information can be found on the Sometimes, 'Main page' 'Waiting for information' status with questions that the site will tab of the TrialManager. DCFs will need additional clarification and will be changed

following reasons: DCFs may be placed in a 'Waiting for information' status for the

- DCF wording is unclear
- Wrong type of DCF was selected
- There is missing information that needs to be confirmed

DCFs in a 'Waiting for information' status: The following steps will be required in order to add comments to

- for the DCF in the 'Waiting for information' status Click on the Title link to review and read the comment history
- 2 what information is needed, please state this in your with as much detail as possible. If you are still unsure about comment...' text box. Try to respond to all questions raised to be clarified. Enter a clarifying comment in the 'Enter your Review the comments that details the information that needs comment. Press the 'Save comment' button when finished



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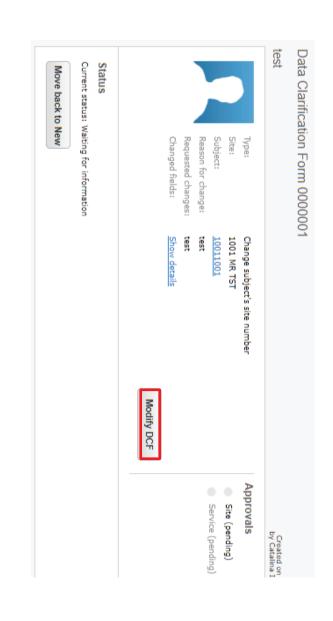
 $\dot{\omega}$ steps outlined in How to Approve DCFs above Once the necessary additional information has been added via comment, the DCF must be approved again. Follow the

Signant Health Data Management Team. the DCF are not clear or do not clearly answer the questions from the moved to a 'Waiting for information' status again if the comments in until no DCFs appear in the DCF Notice Board. Note: The You will notice that the DCF no longer appears on the DCF Notice Board DCF. Continue the process with all remaining DCFs in your notice board on the Main page — this means that no further action is needed on that DCF may be

How to Modify DCFs

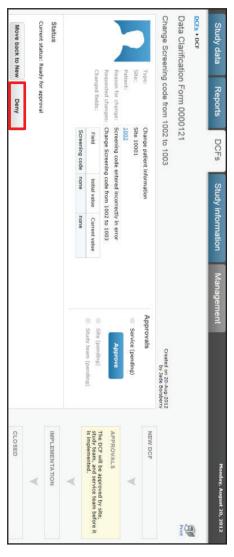
simply selecting the 'Modify DCF' button on the DCF itself. status, the site is able to modify the DCF. This can be accomplished by Until a DCF is either under 'Ready for approval' or any 'Approved'

When making modifications, be sure to save all updates made to the DCF and move to 'Ready for approval' for processing.



How to Cancel/Deny DCFs

approval, by selecting the 'Deny' The site can cancel their entered DCF at any time prior to their first button on the DCF page



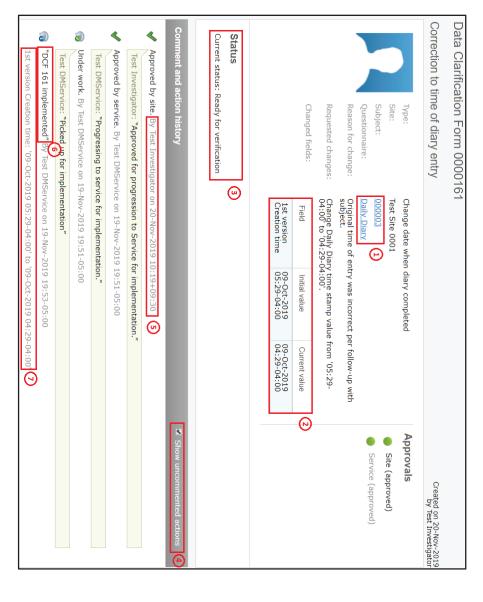
be processed. Management Team that the change requested in the DCF should not By selecting the 'Deny' button, this signals to the Signant Health Data

that are not applicable for your protocol or are duplicate requests Note: The Signant Heath Data Management Team may deny DCFs

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Viewing DCF Comment and Action History

displayed in order of oldest to newest, top-to-bottom. actions', and the full history of actions committed in that DCF will be committed. To view the latest activity for a DCF, navigate to the to view the DCF detail. Select the check box, 'Show uncommented 'DCFs' tab, select the sub-tab, A DCF will always retain the full history of all comments and actions 'All', and then click the desired DCF link



follows: elements of the DCF detail view pictured above are defined

under change, as applicable to the DCF Direct links to Participant card and the questionnaire

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- N DCF has not been implemented yet) present value (this may match the device, and 'Current value' will display the data item's original data display the selected for change during DCF creation. Changed fields will be displayed if specific data item, 'Initial value' item value captured via the TrialMax 'Initial value' will display the fields 'Field' **≦**
- ώ The current status of the DCF will be displayed
- 4 The opening the DCF of the DCF's history or deselected for a reduced listing. status change can be selected for a comprehensive view Check box to show uncommented actions, such checkbox will default to unchecked when
- Ų the committed comment or action The name of the individual committing commit timestamp **≶**. display next the action and to each
- 6 Comments entered will display within quotation marks
- display in Committed changes directly associated with the DCF will grey text without quotations

modified once committed Note: comments DCF comment and action history items comprise an audit trail of and actions committed 5 the DCF and cannot

5.8 DCF Timelines and Tips for Success

DCF Timelines

will restart on re-approval of the updated DCF go to "Waiting for information" status, then the implementation time review and implement the request within 5 working days. If a DCF must Once a DCF has been approved, Signant Health Data Management will

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Tips for Success

guidelines on best practices below: and cleaned throughout the study. Please find below some important important that all the data that has been uploaded be reviewed

- and approved on an ongoing basis to avoid high volumes of It is highly important that data is reviewed and DCFs are DCFs ahead of interim and final database locks raised
- check correctly. numbers, or who may need to be merged, and you should identify participants with potentially incorrect example, the participant data you can esu the to ensure visits are Inconsistencies participant report
- 2 TrialManager Main Page to find any DCFs that need action to required to implement prior to lock dates. Regularly review information to provide Signant Health with the information Sites should continuously review any DCFs waiting for more be taken. 'DCFs waiting for your attention' noticeboard
- ω that all data is uploaded and visible in TrialManager Sites should ensure that all devices at site have sent
- Please be aware that Signant Health does not review data raise DCFs.

4

Setting up SMS notifications

9

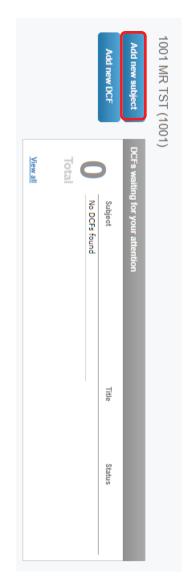
participants will need to subscribe with the mobile phone number personal mobile number to receive activation details via SMS. US As part of participant setup, you can choose to enter a participant's before setting up a participant. they wish to receive this message on. This should be completed

confirmation of subscription message is received, the participant will the word SUBSCRIBE to phone number 42526. When you opt-in to To opt-in to receive SMS activation code, send able to receive SMS activation code service, you will receive a reply confirming your signup. Once a text message with

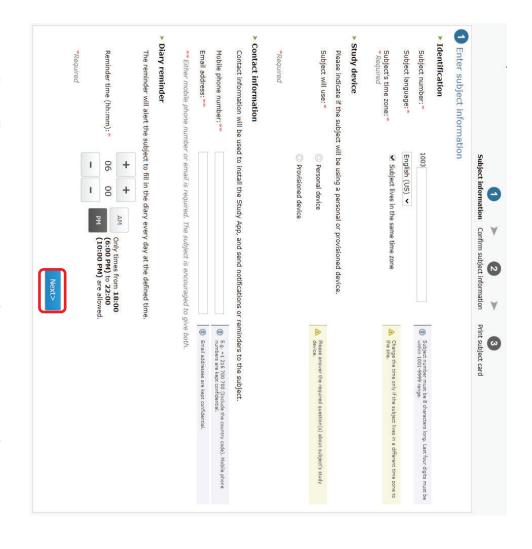
How to set up a participant in TrialManager

a prerequisite Participant setup must be performed by site staff through participant is at your site for their first study visit and not prior as it is TrialManager for all participants. This must be done when the Login to TrialManager to begin. for the participant to start entering data in the App.

Select 'Add new participant'



receiving activation details), and Daily Diary reminder time participant number and You will then be taken to language, time zone, provide വ screen where you will need device participant information; type, contact information (for to including enter the



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Select "Next" once all the required fields have been filled out

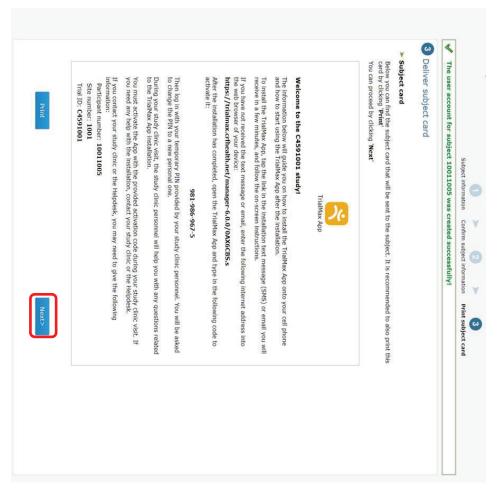
it is important that this information is entered correctly. The mobile number to receive the activation code participant should TrialMax system to send an activation code to participant. Therefore, Note: Mobile phone number and email address are used by the enter either their personal email address and/or

check this information as well, then select "Confirm" the other participant information that has been entered. then select "Confirm". and email address) you have entered. Carefully check the details and review the participant contact information (mobile phone number Next you will see a confirmation screen, where you will be able to This will lead you to another page confirming Carefully

participant was created successfully. You will also see displayed a instructions for getting set up with the App. participant card contains their activation code and applicable Participant Card that is sent to the participant via email/SMS. This You will then receive a message on screen that will confirm that the

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screen and this should be printed if possible, to make it more convenient for the participant. Be sure to write down the Activation Code displayed on screen and provide this to the participant. TrialManager will also display a copy of the participant's card on

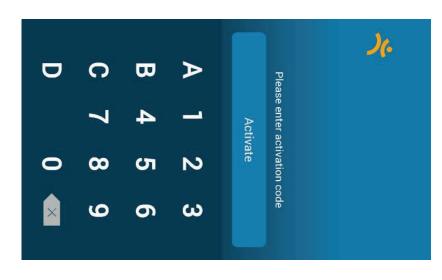


Press "Next" to conclude setup

1 How to Activate the App

the participant should also be provided with a fully charged Samsung their participant card with the welcome message and activation code, device (provisioned device) to use in the study. When the participant setup is complete and the participant receives

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The activation screen is the first screen presented when the provisioned device is turned on. Here, the participant will need to enter the activation code provided in the participant card/
SMS/email message.

the default PIN code '1234' to login for the first time participant will be taken to the login screen where they should enter Once the activation code has been entered appropriately, the

How to setup WiFi on the Provisioned Device

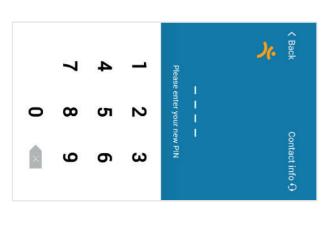
WiFi can be configured on the provisioned devices. To access the WiFi Settings on the provisioned device please follow these steps:

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- Press the 'home' button on the device
- 2.1 the screen. Next, press the 'gear' symbol in the top right-hand corner of
- $\dot{\omega}$ Select 'WiFi settings' to display a list of available networks
- 4 the WiFi will connect. password if required. Once the connection is authenticated, Select the appropriate network from the list and enter the
- 5 You can then return by clicking the 'home' button, and the App will automatically open

Instructions for reusing the Provisioned Device

Signant Health. another participant, all unsent clinical data must first be sent to for a subsequent participant. To reuse the Provisioned Device for when one participant has finished using the device, it can be setup The App supports the reuse of the Provisioned Devices, meaning that



login to the Logistics Page on the device In order to do this, you will first need to

- the the device for the logistics pIN From the login screen, first enter 'Special Code', 8888 to ready
- Then enter the 'Logistics PIN',
- taken to the Logistics Page entered in succession, you will be Once both PINs have been



From the Logistics Page, select 'Resend data' to send any unsent clinical data to Signant Health

The device cannot be reset until all clinical data has successfully been sent.



All clinical data has been sent successfully.

Unsent clinical data:

Unsent Variables 0	Unsent Forms 0
0	0

O Reset app

Additional information for CRF Team:

	Subject ID	Terminal ID	Trial ID	Subject code	Site
₿ logout	1234567890123456789	1234567890123456789	0596f23023b32e3e6975d3fad752e7d3	N/A	N/A

Unsent clinical data:

∂ R	Unsent Variables 2	Unsent Forms 0	
O Resend data	2	0	

Additional information for CRF Team:

O Reset app

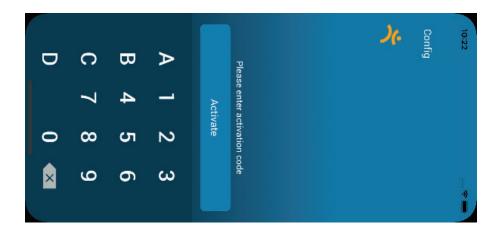
J.€.	Subject ID	Terminal ID	Trial ID	Subject code 119901	Site code 0000
- logout	Subject ID 3049848000000000000000000000000000000000	Terminal ID 28498480000000000040	Trial ID 1400000000000049848	119901	0000

the 'Reset app' button will appear unsent data has successfully been sent, If there is no unsent data, or once all

the App for the next participant Selecting 'Reset app Button will reset

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after the data send (due to protocol), been sent, then the App can still be but all Daily Diary data has successfully Note: if there are new unsent variables



Selecting the 'Reset app' Button will reset the App; the App will do one more final data sync, then is reset and returns to pre-activated state, ready for another participant to be setup

7.2 Selecting a TrialMax App PIN

The TrialMax app has certain restrictions for PIN codes:

Easily remembered by the user (ex: memorable date)

It cannot be the same as the default PIN code

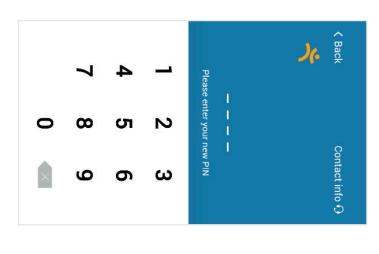
- It must be four digits
 It must not contain runnii
- not be accepted It must not contain running numbers, e.g. 2345, 5678 will
- repeated numbers, e.g. 1111, 2222 will not be accepted It must not contain more than three consecutively

confidential, with only the participant knowing the PIN code The participant should not share their PIN code with anyone, not with study staff. The new PN code must remain

helpdesk who will be able to reset the PIN code If a participant forgets their PIN code, they will need to contact the

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Logging In & Setting Security Question



After the activation code is entered, the participant will be asked to log in to the App. The user will have to enter the default four-digit PIN code (1234) to access the App and will then be prompted to change their PIN to a unique 4-digit PIN.

The participant should not share his/her PIN code with anyone, not even with study staff. The new PIN code must remain confidential, with only the participant knowing the PIN code.

in resetting their PIN code should they forget it during the study. select and answer a security question which will assist the helpdesk Once the participant has changed their PIN, they will be prompted to

use the App complete, the participant will be led straight into training on how to After PIN code change and security question selection is fully

4 Training on the TrialMax App

the Daily Diary). the participant can access any other portions of the App (including This initial, mandatory training is required to be completed before

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using the App over the course of the study. well as a sampling training is brief and provides helpful information on App usage of the types of questions they will encounter while



Once the participant has concluded the Training, they will receive this screen confirming their completion.

and modify their settings. menu of the App where they will be able complete their Daily Diary By tapping 'Next' the participant will then be directed to the main

should be performed by the participant only. Site staff will not need Please note — any activities performed while logged into the App to login to the App for any purposes

7.5 Software Updates

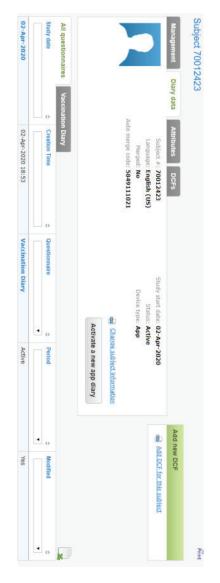
will be displayed on the device indicating progress than usual when there is a software update, however a percentage is opened and logged in. The login process may appear to take longer available update is automatically downloaded when the TrialMax App Site users/participants do not need to take any special action to perform a software update during the course of the study; any

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00 **Managing Participants in TrialManager**

8.1 Participant Card

Upon clicking on a participant number from the main page in TrialManager, the participant/subject's information card will display:



participant status, study group, study start date, and the status of App This installation. <u>\$</u> show details for the participant, including: language,

theft, or change in provision device over the course of the study. Here is where you will activate a new App for a participant due to loss,

8.2 Activating a new App for an Existing Participant

activating new Apps for existing participants This section will explain how the participant and site will handle

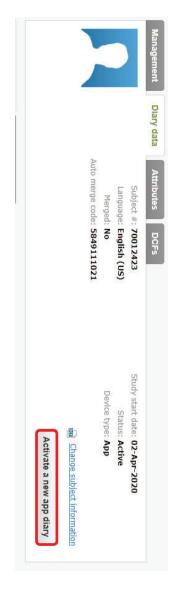
FDA-CBER-2021-5683-0650354

needed: There are three instances in which a new App activation may be

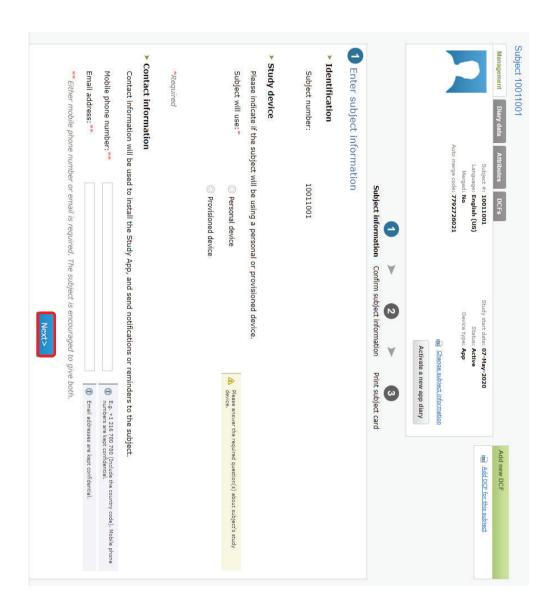
- study, or device, loss or theft of device, changing device during the If the participant needs a new activation code due broken
- 2) If the participant has not used their provided activation code possible at the visit, occur since the participant is to activate the app as soon as within 72 hours which is the expiration limit. This should not
- ω If the subject is switching between using their personal device and a provisioned device

The steps to handle either of these situations are the same

the participant card screen, select the 'Activate a new app diary Login to TrialManager and select the appropriate participant.



and/or email address. You will be required to select the participant's mobile phone number Once entered, select 'Next'



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select "Confirm" On the next page, make sure the entered information is correct, then

to make it more convenient for the participant. and applicable instructions for getting set up with the App TrialManager will also display a copy of the card which can be printed provided). This Participant card contains their new activation code Participant card that is sent to the participant via email/SMS (if participant was created successfully. You will also see displayed You will then receive a message on screen that will confirm that the

Press 'Exit' to return to your site in TrialManager.



Welcome to the C4591001 study!

The information below will guide you on how to install the TrialMax App onto your cell phone and how to start using the TrialMax App after the installation.

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To install the TrialMax App, tap the link in the installation text message (SMS) or email you will receive in a few minutes, and follow the on-screen instructions.

If you have not received the text message or email, enter the following internet address into the web browser of your device:

https://trialmax.crfhealth.net/manager-6.0.0/0AX6CBS.s

After the installation has completed, open the TrialMax App and type in the following code to activate it:

249-7C8-113-2

Then log in with your temporary PIN provided by your study clinic personnel. You will be asked to change the PIN to a new personal one.

During your study clinic visit, the study clinic personnel will help you with any questions related to the TrialMax App installation.

If you contact your study clinic or the Helpdesk, you may need to give the following

You must activate the App with the provided activation code during your study clinic visit. If you need any help with the installation, contact your study clinic or the Helpdesk.

Participant number: 70012423

Trial ID: C4591001

of this guide and/or activate their App as outlined in the Participant Setup section The participant should then follow the appropriate steps to install

Management tab

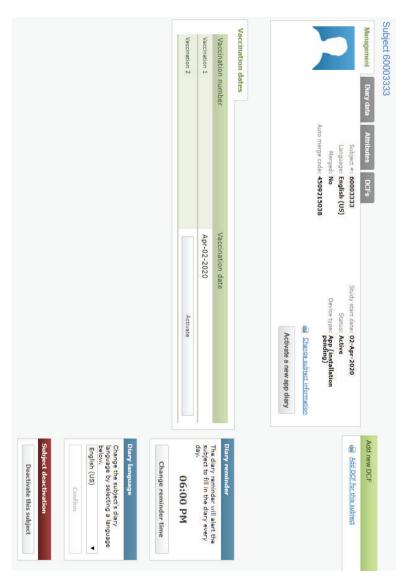
information, and deactivate a participant from the study. Details for vaccination dates, update Daily Diary reminder times, change several options/settings for that participant. on the button titled 'Management' will bring you to a page displaying each activity are provided in the following sections participant language for the App, add or update participant TrialManager, the participant's information card will display. Upon clicking on a participant number from the main page in Here you can log Clicking

8.1 Activating a New Vaccination

vaccinated on 02-Apr-2020. example below, the participant was set up on TrialManager, and activated on the day of a new participant set up, for instance, in the needs to be set up on Trial Manager. The vaccination is automatically When a participant comes in for the first vaccination the participant

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Diary. Please **If their vaccination date is not set in TrialManager before they leave the site office, they will NOT be able to complete their Daily be sure this is done before they leave. **



appropriate visit. You will then be asked to select the date of the vaccination. In the example above, Vaccination 2 still requires To activate subsequent diaries, click 'Activate' activation. next to the next

3.2 Changing Daily Diary Reminder Time

notifications will be sent to participants to complete their Daily Diary Site staff have the ability to adjust the time that reminder participant. by accessing the 'Management' tab in TrialManager for the particular each day (during the post-vaccination periods). This can be modified

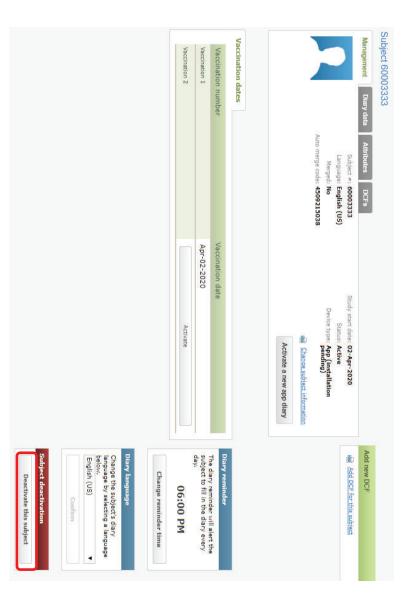
into the App and selecting 'Information and Settings' from the main 15-minute increments window for reminders to be sent is between 6:00pm and 10:00pm in Reminder' which will allow them to adjust the time. The permitted menu screen. This will lead them to several options including 'Diary Additionally, participants may change this on their own by logging

			Vaccination 2	Vaccination 1 Apr-	Vaccination number Vacci	Vaccination dates			Merged: No Auto merge code: 4509215038	Subject #: 60003333 Language: English (US)	Management Diary data Attributes DCFs	
			Activate	Apr-02-2020	Vaccination date		Activate a new app diary	Change subject information	Device type: App (installation pending)	Study start date: 02-Apr-2020 Status: Active		
Subject deactivation Deactivate this subject	Change the subject's diary language by selecting a language below. English (US) Confirm	Change reminder time	06:00 PM	subject to fill in the diary every	Diary reminder					Add DCF for this subject	Add new DCF	

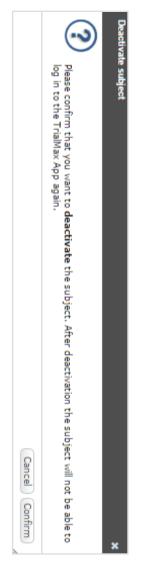
8.4 Deactivating a Participant from the Study

study data. end of study, the participant must be deactivated by the site in TrialManager so that they can no longer login to the App and record Whether the participant needs to be terminated early or has reached

deactivate the participant and prevent further login to the App participant' at the very bottom of the page (red header) will TrialManager for the particular participant. This can be handled by accessing the 'Management' tab in Selecting 'Deactivate this



desired action: Upon clicking this button, you will be asked to confirm this is the



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participant. clicking "Cancel" will return you to the management tab for that Selecting "Confirm" will successfully deactivate the participant while Once deactivated, participants will no longer display on the 'Active

participants who have been deactivated separate tab titled 'Deactivated Participants' that will list any Participants' tab in your main page of TrialManager. There is a

5 Participant Travel



All provisioned devices will update the time zone automatically if the participant travels between different time zones.

9 How to Request Additional Supplies

devices than initially allocated in their first shipment), they can If a Site requires device re-supply (for example more provisioned Team, as all initial site allocations are predetermined Operating Hours). The request must be approved by the Pfizer Study request it via the Helpdesk (see Helpdesk phone number in Helpdesk

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reused after one participant has finished using the device IMPORTANT NOTE: Remember that provisioned devices can

shipments. These will be shipped with standard delivery service Once approved, it will take 5 business days to prepare any additional

shipment label will be provided, along with a Faulty Device Return broken during use) should be requested via the Helpdesk. A return Replacement device requests (for example for devices that are lost form to indicate why a replacement is needed

10 How to return the provisioned devices

Health. At the end of the study ALL devices must be returned to Signant

up. If the site does not have a regular pickup, they will have to call their instructions do not have one. Please see Appendix A for US Logistics device returns country. The UPS driver can bring a manual waybill to the site if they local UPS When returning devices to Signant Health, UPS will need to pick them office for a pickup. The UPS number is different in each

include Device Health Helpdesk for a form) with the return. Only devices with a Faulty If you need to return Return Form included will be investigated for any unsent data മ completed Faulty Device a faulty device to Signant Health, make Return Form (refer to Signant

11 Frequently Asked Questions



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Q: Where can I get more help?

please contact your study monitor. this guide or on the participant's Quick Reference Guide or Device available 24/7 via the phone number provided at the beginning of A: Please contact the Signant Health Helpdesk. The Helpdesk is about the problem. For any protocol or health-related questions, Label. Please make sure to provide as much information as you can

How often should the provisioned device be charged?

charger when not in use to keep it fully charged be sure to leave the provisioned device plugged into the

What do I do if my provisioned device does not switch on?

does not appear, call the Helpdesk. turn the device on. If the home screen with message and App icons A: Charge the provisioned device for two (2) hours. After charging,

provisioned device. How can the PIN code be retrieved? participant forgot their PI code and cannot use their

A: The participant's PIN code can be retrieved. The participant should call the helpdesk who will retrieve their original PIN code

Q: How will the participant know how to send data?

saving study answers. App will send data each time the participant logs in, and also when A: The App will do it automatically, as long as the device is online. The

that be added later on? Q: A participant forgot to complete their Daily Diary on one day. Can

within the same day. participant can update their symptoms – both experience and severity A: No. Data cannot be entered retrospectively. However, the

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Q: What should be done if the device is unable to send data?

device online. If they continue to have issues with data sending will be saved and automatically sent the next time they use the sent immediately once a connection is established. If the participant A: As soon as the participant logs into the App, unsent data will be please contact helpdesk. cannot seem to access a connection, please remind them that all data

provisioned device? Q: Is the participant able to change the time and/or settings <u>o</u>n

provided date and time, so if the participant travels to a different time other changes to the settings. Also, the device uses and WiFi setup. The participant cannot change the time or make automatically be updated. A: The provisioned device is locked to only enable usage of the 9 there are changes 3 daylight savings, the the network time any

country or region? Can the participant send data while away on vacation in another

differences, the time of entry may appear different A: Yes, as long as they can connect to a network. Because of time zone

Q: What happens if the participant forgets to log out of the App?

answers will be deleted from the App at that time automatically log the participant does participant out. Please not log out of the note App, that any unsaved the App will

Will the Helpdesk answer questions related to the **Daily Diary**

0 participant needs to contact the site. functions, but for any vaccine or study-related questions, the A: The Helpdesk can provide answers on how the Daily Diary The participant does not understand the questions. should I do?

If the participant does not understand the questions in the

assistance with the questions, please contact your study monitor. Helpdesk cannot answer any health-related questions. For further TrialMax App, you may have to explain what is being asked. The

APPENDIX A: US LOGISTICS DEVICE RETURNS

US Logistics Device Returns

- When returning devices to Signant Health, UPS will need to pick them up
- number is different in each country. If the site does not have a regular pickup, they will have to call their local UPS office for a pickup. The
- charge to be billed on CRF Health(Signant Health)'s account. Sites with regular pickups will not have any issues with pickup charge. how account is set up with UPS) UPS account number 37V198 and postal code 19462 for the pickup When calling for a pickup, the site will need to provide the CRF Health (note CRF not Signant due to
- For returns from USA based sites can request their own return airway bill, quickly and easily. Using this portal sites will be able to choose a pick-up time which best suits their needs The site address is: this portal sites will be able to choose a pick-up time which best suits their needs

https://row.ups.com/Ship/Ship/StandardShipGuest

- Manual Waybill using the instructions below. The UPS driver can bring a manual waybill to the site if they do not have one. Please complete the UPS
- For returns from outside of the USA or where a commercial invoice is required please email <u>uslogistics@crfhealth.com</u> please include all the information below and a UPS waybill will be emailed
- Protocol Number/CRF Project code:
- Contact number for sender:

0

Email address of person to be emailed the labels:

0

Name of sender:

0 0 0

- How many electronic devices are being returned:
- How many boxes will be used for the return of the devices: