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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Informed Consent Action Network, Plaintiff, v. National Institutes of Health, Defendant.	CV-20-01277-PHX-JJT **NIH'S RESPONSE IN OPPOSITION TO PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT, AND REPLY IN SUPPORT OF NIH'S MOTION FOR SUMMARY JUDGMENT AS TO FOIA REQUEST 54464**

The National Institutes of Health (NIH) submits its Response in Opposition to Plaintiff's Cross-Motion for Summary Judgment and its Reply in Support of NIH's Motion for Summary Judgment. The Opposition is supported by the Memorandum of Points and Authorities, controverting Statement of Facts filed herewith, and all matters of record.

I. INTRODUCTION

On June 2, 2020, NIH searched for records responsive to Plaintiff Informed Consent Action Network (ICAN)'s FOIA Request 54464. The request sought safety and efficacy data regarding the clinical trial of Moderna's experimental vaccine mRNA-1273. As of the date of the search, only Phase I of the clinical trial was up and running. The trial was called "Phase I, Open-Label, Dose-Ranging Study of the Safety and Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults." Although Phase I studied the

safety and immunogenicity of the vaccine, it did not study the efficacy of the vaccine.

As part of its search, the agency tasked its Viral Pathogens Clinical Research Program Officer Dr. Paul Christopher Roberts, who oversees the agency's monetary grant for Phase I, to search his work computer for responsive records. As the agency expert most knowledgeable about the nature and status of Phase I, Dr. Roberts searched and located a 1,093-page Safety Summary Report pertaining to Phase I that the agency had received from a non-NIH entity. On November 20, 2020, NIH released the final production of the Report, which contained limited redactions pursuant to FOIA Exemption b(6). NIH has moved for summary judgment because it conducted an adequate search for records and appropriately applied b(6) redactions while releasing all other segregable information.

In its response, ICAN concedes that June 2, 2020 was the proper cut-off date for the search; concedes that Phase I was the only Phase underway at that time; concedes that Dr. Roberts was the appropriate person to conduct the search; and does not challenge the adequacy of where Dr. Roberts looked for records. In addition, ICAN concedes that at least some of the redactions were proper. However, ICAN claims that the term "efficacy" should have been a search term and that the use of the term "Phase I" improperly narrowed the search. In doing so, ICAN erroneously conflates immunogenicity data, which is part of Phase I, with efficacy data, which is not. In addition, ICAN claims that some of the redactions were improper. For instance, it mistakenly argues that some categories of data were withheld (i.e., Study Site and Deviation), when in fact they were not; claims that the redacted patient information does not implicate a patient's privacy interests; and incorrectly argues that the redacted information somehow sheds light on the workings of the NIH, which did not conduct the study or collect and store the data from the study prior to the date of the search. Furthermore, ICAN's response suffers from numerous evidentiary deficiencies, rendering its opposition insufficient to defeat NIH's summary judgment motion. Ultimately, NIH has met its burden, whereas ICAN has not.

II. NIH's OPPOSITION TO PLAINTIFF'S CROSS-MOTION

MEMORANDUM OF POINTS AND AUTHORITIES

In deciding a motion for summary judgment, the Court views the evidence and all reasonable inferences therefrom in the light most favorable to the party opposing the motion. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *Eisenberg v. Ins. Co. of N. Am.*, 815 F.2d 1285, 1289 (9th Cir. 1987). Where there are cross-motions for summary judgment, each movant has the burden of presenting supporting evidence that would allow the district court, if appropriate, to direct a verdict in its favor. *High Tech Gays v. Def. Indus. Sec. Clearance Office*, 895 F.2d 563, 574 (9th Cir. 1990). Plaintiff has not met its burden, and thus, its cross-motion should be denied.

A. NIH Did Not "Narrow" the Scope of Request 54464, but rather Conducted a Reasonable Search for Responsive Records.

As part of its search, NIH tasked Dr. Roberts at the Division of Microbiology and Infectious Diseases (DMID) to search for records responsive to Request 54464. *See* Defendant's Statement of Facts (DSOF) 12-15 (deemed admitted[1]). The cut-off date for the search was June 2, 2020. DSOF 16 (admitted), 17 (deemed admitted). The search used the following keywords and phrases: "mRNA-1273", "Phase I", "Moderna", "DMID-20-003" and "safety data reports." DSOF 18 (deemed admitted). Using those terms, the agency located a 1,093-page Safety Summary Report. DSOF 23 (deemed admitted).

Plaintiff concedes that DMID was the appropriate entity and that Dr. Roberts was the correct individual to conduct the search. Dkt. 21 at 8. It also concedes that June 2, 2020 was the appropriate cut-off date for the search. *Id.* at 10. However, Plaintiff contends that by including the term "Phase I" while failing to include the term "efficacy" in the search, NIH improperly narrowed the scope of the search, thereby rendering it inadequate. *See id.* at 7-11. This claim lacks merit.

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[1] Unless otherwise noted, facts that are "deemed admitted" are those for which Plaintiff refused to admit or deny. ICAN fails to comply with LRCiv 56.1(b)(1) and fails to provide evidence to support disputing those facts. Thus, those facts are deemed admitted.

1. The Inclusion of the Search Term "Phase I" Was Reasonable.

ICAN's Request 54464 expressly included the term "Phase I," thus its inclusion in the search was reasonable. DSOF 11 (admitted); DSOF 18 (deemed admitted); 19 (admitting the term was used in the request). Furthermore, the inclusion of "Phase I" did not limit or narrow the search. More terms than just "Phase I" were utilized. DSOF 18 (deemed admitted). For example, the use of the terms "Moderna," "DMID 20-003" and "mRNA-1273" enabled the agency to cast a broad and perfectly adequate search that would catch responsive documents regardless of whether or not they mentioned "Phase I." DSOF 19 (deem admitted, as Plaintiff admitted "mRNA-1273" was included in the Request but failed to cite evidence that would support disputing that it was a broad term that would reasonably capture responsive information); DSOF 20-21 (deemed admitted). Ultimately, the keywords and phrases did not limit the scope of the search. But the actual progression of the vaccine's clinical trial did. As of the date of the search (June 2, 2020), neither Phase II nor III of the trial had begun. DSOF 25 (admitted); *see also*, NIH's Controverting Statement of Facts, Attach. A, Roberts Decl., ¶¶ 10, 13. Because Phase I was the only clinical trial underway at the time of the search, the use of that term could not have improperly narrowed the search.

2. NIH's Decision Not To Use the Term "Efficacy" was Reasonable and Harmless.

Dr. Roberts did not use the term "efficacy" in the search because he knew that only Phase I was underway at that time and that Phase I does not assess the efficacy of the vaccine. DSOF 24-30; Attach. A, Roberts Decl. ¶¶ 10, 13. The omission of that term was therefore reasonable. An agency is not required to search for records that will or may be created or obtained in the future. 45 C.F.R. § 5.24(d). FOIA requires only "a reasonable search for records, not a perfect one." *Hamdan v. DOJ*, 797 F.3d 759, 772 (9th Cir. 2015). In addition, given that the search also included the terms "mRNA-1273" and "Moderna" – terms that are broad enough to capture any information about the vaccine – the search was reasonably calculated and therefore adequate.

ICAN admits that "NIH did not possess records regarding subsequent trial phases for mRNA-1273 at the time of the search because the search occurred before subsequent clinical trial phases actually began." DSOF 25 (admitted). However, ICAN contends that some efficacy data may nevertheless have been in existence and therefore should have been captured by the search. This claim lacks merit.

As an initial matter, Plaintiff fails to provide substantive, admissible evidence that this Phase I trial, or indeed any Phase I trial, tracks vaccine efficacy. In the absence of any such evidence, Plaintiff's claims that efficacy data had to have been available at the time of the search are purely speculative and should be disregarded.

Furthermore, NIH has provided ample evidence that no efficacy data was in its possession at the time of the search. The title of the Phase I study indicates that it is a "Study of the Safety and Immunogenicity" of mRNA-1273. DSOF 4 (admitted). The study began on March 16, 2020, and is evaluating different doses of the vaccine for safety and immunogenicity, i.e., the doses' ability to induce an immune response in study volunteers. Attach. A, Roberts Decl., ¶ 6. In contrast, efficacy studies show the extent to which a vaccine provides a beneficial result under ideal conditions, wherein one group of people are given a vaccine and the incidence of disease in that group is compared to that of another group of people who do not receive the vaccine. DSOF 24, Ex. 1, ¶¶ 22-24 (deem admitted for failure to cite to admissible evidence in attempt to dispute fact); *see also* Attach. A, Roberts Decl., ¶ 7; Attach. B, Articles; Attachs. D-E.

As to mRNA-1273, efficacy data did not start being collected or assessed until Phase III of the clinical trial, which began on July 27, 2020. DSOF 25 (admitted); Attach. A, Roberts Decl., ¶ 8. Notably, the Phase III trial is entitled "A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled **Study to Evaluate the Efficacy**, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older." Attach. A, Roberts Decl., ¶ 8 (emphasis added); Attachs. D-E. The fact that efficacy is not part of the Phase I trial is further supported by the attached "FDA Briefing Document Moderna COVID-19 Vaccine," dated December 17, 2020. Attach E. The

report explains that while Phases I and II are studying safety and immunogenicity, Phase III is studying efficacy and safety of the vaccine. *Id.* at p. 12; *see also id.* at p. 9 (describing safety data accumulated in Phase I and II). Thus, the exclusion of the term efficacy from the search was both reasonable and harmless.

3. ICAN's Claim That NIH Possessed Efficacy Data is Speculative and Wrong.

ICAN attempts to establish that efficacy data must have existed at the time of the search by citing to a press release issued by Moderna on May 18, 2020. Dkt. 22-2. Its reliance on this press release is misplaced and insufficient. The press release is entitled "Moderna Announces Positive Interim Phase 1 Data for its mRNA Vaccine (mRNA-1273) Against Novel Coronavirus," and discusses the doses administered, adverse effects and immunogenicity data. *Id.* It states that, "mRNA-1273 was generally safe and well tolerated, with a safety profile consistent with that seen in prior Moderna infectious disease vaccine clinical studies." *Id.* This press release does not address efficacy at all. Indeed, the term "efficacy" only appears in the "Forward Looking Statement," which states that the "efficacy of mRNA-1273 has not yet been established." *Id.*

As the agency has explained, Phase I evaluates the ability of different doses to induce an immune response in study volunteers, and the press release focuses on that evaluation. *See* Attach. A, Roberts Decl., ¶ 6; Dkt. 22-2. As Dr. Roberts attests, the "Phase I trial does not evaluate the efficacy of the vaccine." Attach. A, Roberts Decl., ¶ 7. He explains:

> *Vaccine efficacy data shows the extent to which a vaccine can protect against an infection or disease. Efficacy studies are done by giving one group of people a vaccine and comparing the incidence of disease in that group to that of another group of people who do not receive the vaccine. If there is more disease in one group than the other, there are efficacy analyses that can be performed to determine if this occurred by chance or was because the vaccine protected against the infection (or symptoms, or hospitalizations, etc. – whatever was chosen for a given study).*

Id. The efficacy of mRNA-1273 is in fact being assessed in the Phase III trial, which

began on July 27, 2020, after NIH conducted the search. Attach. A, Roberts Decl., ¶ 8.

Nevertheless, ICAN argues that the press release's reference to "seroconversion, binding antibody levels, neutralizing antibody titers, immunogenicity data, immune response" and "a mouse challenge model" reflect efficacy data and thus indicate that "the Phase I trials collected efficacy data, and that NIH knew about this." Dkt. 23, ¶¶ B17-22 (disputed). Not so. As an initial matter, ICAN fails to present any admissible evidence to support it contention as to what constitutes efficacy data or what NIH supposedly knew about the existence of efficacy data as of the date of the search. *See, e.g.*, Dkt. 23, ¶ B17 (disputed) (claiming "[a]ll of these topics fall under the umbrella of efficacy" but citing only to the press release, which does not support this contention). On that basis alone, this argument should be disregarded.

Furthermore, NIH provides ample evidence that Phase I does not track or evaluate efficacy and that the terms listed above instead address a vaccine's ability to induce an immune response in study participants. DSOF 24, Ex. 1 ¶¶ 22-24; Attach. A, Roberts Decl., ¶¶ 9-12; Attach. B, D-E. As Dr. Roberts attests:

> *There are many examples where a vaccine can induce an immune response, but does not protect against the disease. That is to say, there are vaccines that have demonstrated immunogenicity but not efficacy. HIV vaccines are a good example of this. HIV vaccines can generate an immune response but do not protect the person – they are immunogenic but not effective.*

Attach A, Roberts Decl., ¶ 9. In short, ICAN erroneously conflates immunogenicity data with efficacy data.

Finally, even if Moderna had information that ICAN would consider to be efficacy data, that is insufficient to show that *the agency* had possession of that information or that NIH's search for records was improper. No NIH trial sites were operating to test the vaccine before June 2, 2020. Attach. A, Roberts Decl., ¶ 10. The information NIH had as of June 2, 2020 was in the cumulative Safety Summary Report it had received from a non-agency entity, and that is what NIH has produced. *Id.*, ¶¶ 10-11.

B. NIH's Limited Redactions Were Proper.

ICAN claims certain information has been withheld when, in fact, it has been released; appears to argue that by redacting some patient information, any remaining patient privacy interest is effectively erased; and broadly claims without support that the redacted information may shed light on the workings of the NIH. Dkt. 21 at pp. 7, 11-18. As discussed in NIH's motion and further addressed below, the information at issue was drawn directly from each patient's medical records. Redactions were applied to limited portions of the Report's appendices and conform with industry standards requiring the de-identification and anonymization of individual patient data. Moreover, the same data, which is collated and analyzed in a format that protects the patients' privacy interests, *has* been released. Finally, the redacted information sheds no light on NIH's activities. The redactions are therefore proper.

1. ICAN Does Not Challenge the Redaction of Each Patient's Personal Identification Number, But Mistakenly Claims that "Deviation" and "Study Site" Data Was Withheld.

ICAN's motion, filed December 11, 2020, references only two productions NIH made on October 29 and November 9, 2020, and asserts that "myriad redactions" were made pursuant to FOIA Exemption 6. Dkt. 21 at 7. Notably, ICAN fails to indicate that the final production of the Report and its Appendices occurred on November 20, 2020. *Id.* In addition to emailing the production directly to Plaintiff's counsel, NIH attached it as an exhibit to its Motion for Summary Judgment. *See* Attach. F, NIH cover letter to disclosure, dated Nov. 20, 2020; Dkts. 19-7 through 20-4; DSOF 35 (ICAN admits disclosure).

In the 312-page Report, NIH redacted the "Subject ID" data on only two pages. *See* Dkt. 19-7 at pp. 34, 36. All other data in the Report – including adverse event, age, deviation, and alternative etiology data – was produced without redaction in a format that appropriately anonymizes each individual patient. *See* Dkt. 19-7; DSOF 45-46, 52, 57, 62 (deem admitted for failure to cite to any evidence in attempting to dispute facts); DSOF 68 (deemed admitted); Attach. C, Beigel Decl., ¶¶ 7- 9.

In its briefing, ICAN admits that the Subject ID is a patient's individual medical record identification number, *see* DSOF 37, and does not challenge the redaction of that information throughout the Report and its Appendices. Dkt. 21 at p. 12 ("Nor does ICAN challenge the redaction of the Subject IDs."). However, ICAN claims that NIH has improperly withheld "Deviation" data in Appendices G1 and G2, and "Study Site" data in Appendix G2. Dkt. 21 at pp. 17-18. In fact, as is apparent in the exhibits filed with NIH's motion, this information has been released without redaction. *See* Dkt. 20-4 at pp. 199-205 (showing no redactions of that data); Dkt. 20-4 at p. 205 (listing, Emory Children's Center as the study site); *see also* NIH's Controverting Statement of Facts, B33-35. ICAN's claims therefore lack merit and/or are moot.

2. Patients Have a Non-Trivial Privacy Interest in their Medical Information and That Interest is Protected According to Industry Standards.

The redacted information that remains at issue is found in the Appendices under the following headings: "Adverse Event," "If Not Related, Alternative Etiology," "Age," "Comments," "Reasons for Deviation" and "Deviation Resolution." Dkt. 19-7 through 20-4. Out of ten Appendices to the Report, these redactions are found in only three of them, i.e, App. B, E, and G1. *See* Dkt. 20-6, *Vaughn* Index (providing page citations for each category of redactions). In addition, although ICAN argues that NIH redacted all data in the "Comments," "Reasons for Deviation" and "Deviation Resolution" columns in Appendix G1, dkt. 21 at p. 17, this is not the case. In fact, the majority of the data in those columns has been released. *See* Dkt. 20-4 at pp. 199-205. Thus, ICAN overstates the amount of information that has been withheld.

In addition, ICAN's argument that a patient has no privacy interest in information pulled from his or her own medical record is unavailing. ICAN argues that, because patient names are not provided and the Subject IDs are redacted, the other redacted data "does not implicate a personal privacy interest." Dkt. 21 at p. 13. However, the redaction of information does not erase a patient's privacy interest, and NIH need only show that the

privacy interests at stake constitute "some nontrivial privacy interest in nondisclosure." *Cameranesi v. U.S. Dep't of Def.*, 856 F.3d 626, 637 (9th Cir. 2017). Such interests encompass a range of "concerns relating to an 'individual's control of information concerning his or her person.'" *Lahr v. Nat'l Transp. Safety Bd.*, 569 F.3d 964, 974 (9th Cir. 2009) (quoting *Reporters Comm. for Freedom of the Press*, 489 U.S. at 763 (1989)). "An individual's interest in controlling the dissemination of information regarding personal matters does not dissolve simply because that information may be available to the public in some form." *Painting Indus. of Haw. Mkt. Recovery Fund v. U.S. Dep't of the Air Force*, 26 F.3d 1479, 1484 (9th Cir. 1994).

Here, ICAN admits that the patients are not NIH employees, but rather private parties. *See* DSOF 36. In addition, the redacted information clearly impacts a patient's control of information concerning his or her personal matters. The redactions were applied to patients' medical diagnoses, the cause of a medical condition, age, and medical history – all of which are contained in the patients' medical files – and constitute individual patient data (IPD) typically treated as private information. *See* Dkt. 20-5 (discussing need for de-identification and anonymization of IPD in clinical studies). Indeed, under the HIPAA Privacy Rule, *see* 45 C.F.R. § 164.514, identifiers including patient characteristics, "reported adverse events, medical history . . . and other comments" . . . "must be removed for . . . datasets to be considered de-identified." Dkt 20-5 at p. 6, 10.

"Adverse Event" data is a patient's medical diagnosis that is written by the medical provider at the clinic directly into the patient's medical record. DSOF 41 (deem admitted for ICAN's failure to cite to any admissible evidence in attempt to dispute fact); DSOF 42 (deemed admitted). The "If Not Related, Alternative Etiology" data consists of the cause of the patient's health condition that is deemed unrelated to the vaccine. DSOF 48 (deem admitted for failure to cite to admissible evidence or to refute that that information was pulled directly from the medical record). "Age" data provides a patient's exact age in a table listing patients who obtained abnormal laboratory results. DSOF 54 (deem admitted for failure to cite evidence). In addition, the redacted "Comments" and sporadic redactions

of "Reasons for Deviation" and "Deviation Resolution" data are medical notations about each patient's medical history. DSOF 59 (deemed admitted). As a result, a non-trivial privacy interest is implicated in this data, and its redaction protects the patients' personal information. *See* Attach. C, Beigel Decl., ¶ 9.

Moreover, the agency appropriately protects the patient's privacy interest while allowing the release of the data through the de-identification and anonymization process. Specifically, the redacted information is provided elsewhere in the Report and Appendices. *See* DSOF 45-46 (deem admitted for failure to cite to admissible evidence), 52 (deem admitted as ICAN's statement is non-responsive and cites no evidence), 57 (deem admitted for failure to cite to admissible evidence), 62 (deem admitted for failure to cite to admissible evidence), 68 (deemed admitted). For example, "for a participant reporting an [adverse] event of 'throbbing pain inside my head behind my eye,' that phrase is captured in the database but was redacted, but is also coded in the report as 'headache,' which is not redacted." Attach. C, Beigel Decl., ¶ 9. This process enables NIH "to convey the information, while preserving the anonymity and privacy interests of the participants . . . ." *Id.* Moreover, it is undisputed that this method of de-identification and anonymization conforms to industry standards. *Id.*; DSOF 49 (deemed admitted); Dkt. 20-5.

3. Release of the Redacted Data Would Shed No Light on the NIH's Activities.

In addition to the need to protect the patient's personal information, the release of the redacted information would shed no light on the workings of the NIH. It is undisputed that NIH did not provide direct care and treatment to patients prior to June 2, 2020 and did not collect the data from each patient; rather Kaiser Permanente and Emory University did. DSOF 44 (deem admitted for failure to cite to any evidence), 61 (deemed admitted), 67 (deemed admitted). *See also* Attach. A, Roberts Decl., ¶ 10. As such, the content of the Report sheds no light on the acts or omissions of the agency itself. The Report was created by a non-NIH entity and does not contain any data collected by NIH or any analysis conducted by NIH. Attach. A, Roberts Decl., ¶ 11; DSOF 10 (deemed admitted). Rather,

NIH received a copy of the Report and merely had it in its possession on the date of the search. DSOF 28 (deemed admitted).

ICAN argues that the redacted information "would serve to shed light on NIAID's and NIH's actions with regard to developing, purchasing, promoting, recommending, approving or licensing, and potentially mandating a COVID-19 vaccine." Dkt. 21 at 14. However, none of the redacted information contains information *specific to NIH*. And regardless of the accuracy of ICAN's claim that people may be forcibly vaccinated, the only evidence it provides in support pertains to actions taken by the New York Bar Association and the New York Assembly. *See* Dkt. 23, ¶¶ B5-6. It is the public's interest in the federal agency, not the general public or state entities, that governs the public interest analysis. *Cameranesi*, 856 F.3d at 637. Furthermore, ICAN provides no evidence to support a finding that the redacted information addresses the development, purchasing, promoting, recommending, approving or licensing of the vaccine. Indeed, it is Moderna that issued the press release upon which ICAN relies, it is Moderna that applied for Emergency Use Authorization to distribute the vaccine, and it is the Food and Drug Administration (not NIAID or NIH) that approved or licensed the vaccine. *See* Dkt. 23, ¶ 4. Broadly pointing to the impact that the pandemic has had upon our society is insufficient to satisfy ICAN's burden to show that the specific "information sought is likely to advance [the public's] interest." *Cameranesi*, 856 F.3d at 637. Although "the *only* relevant public interest in the FOIA balancing analysis is the extent to which disclosure of the information sought would she[d] light on an agency's performance of its statutory duties or otherwise let citizens know what their government is up to," *id.* at 640-41, the redacted information that ICAN seeks is simply "information about other private parties held in the government's files." *Painting Indus. of Hawaii Mkt. Recovery Fund*, 26 F.3d at1484. Accordingly, ICAN fails to meet is burden.

C. <u>Plaintiff's Evidence is Insufficient to Warrant a Verdict in Its Favor.</u>

ICAN's motion suffers from numerous evidentiary deficiencies, such that no verdict in its favor should issue. As discussed more fully in NIH's Controverting Statement of

Facts, ICAN propounds numerous facts that, among other things: are irrelevant to the issues before this Court, *see, e.g.*, Dkt. 23, ¶¶ B5-6; actually consist of legal argument, without citation to admissible evidence, *id.*, ¶ B18 (citing NIH's brief rather than admissible evidence); and/or misstate the record and are not supported by the record, *id.*, ¶ B35 (citing NIH's *Vaughn* Index, which does not show the alleged withholding, while failing to cite to Dkt. 20-4 at p. 205, which shows the data was released).

Viewing such evidence and construing all reasonable inferences therefrom in the light most favorable to the party opposing the motion, *Anderson*, 477 U.S. at 255, ICAN has not met its own burden of presenting supporting evidence that would allow the district court to direct a verdict in its favor. *High Tech Gays*, 895 F.2d at 574. Thus, its cross-motion should be denied.

III. NIH'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT.

A. ICAN Fails to Raise a Genuine Issue of Material Fact Sufficient to Defeat NIH's Motion.

A principal purpose of summary judgment is "to isolate and dispose of factually unsupported claims . . . ." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). Summary judgment is appropriate against a party who "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Id.* at 322. The party opposing summary judgment may not rest upon mere allegations or denials of a party's pleadings, but must set forth specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e); *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 585-88 (1986); *Brinson v. Linda Rose Joint Venture*, 53 F.3d 1044, 1049 (9th Cir. 1995).

As discussed in the prior section, ICAN's attack on the adequacy of the search and the limited redactions is wholly unsupported by admissible evidence. In addition, its attempt to challenge NIH's statement of facts is unavailing. As an initial matter, ICAN does not challenge the admissibility or accuracy of the evidence NIH cites in support of its

Statement of Facts. *See* Dkt. 23 at pp. 1-8 (responses to DSOF 1-69). In addition, ICAN fails to admit or deny many facts, in contravention of LRCiv 56.1(b). *See, e.g.*, *id.* at DSOF 5, 8, 10, 12-15, 17 (in part), 18, 20-21, 22 (in part), 23, 28-31, 33, 39-40, 42, 49, 59, 61 (in part), 65, 66 (in part), 67 (in part), 68. In the absence of any response and failure to put forth evidence in opposition, those facts are deemed admitted. In other instances, ICAN attempts to dispute a fact, but fails to cite any admissible evidence in support. *See, e.g.*, Dkt. 23, DSOF 61 (citing without specificity to its cross-motion, which is not evidence); DSOF 62 (broadly claiming that the anonymized adverse event data under the heading "MedDRA Preferred Term" was not the same as the redacted adverse event data, but citing no evidence in support of its claim). Yet still, ICAN makes claims that are unsupported by the cited evidence or flatly refuted by NIH's evidence. For instance, in response to DSOF 46, ICAN claims that the number of days after vaccination that an adverse event occurred could not be determined from the anonymized data. Dkt. 23, DSOF 46. In fact, that information *is* produced in unredacted format in various places throughout the Report. *See, e.g.*, Dkt. 19-8 at p. 49 (indicating a patient suffered a mild fever and moderate feverishness, fatigue, myalgia, and headache on Post Dose Day 2); Dkt. 19-10 at p. 65 (indicating a patient suffered moderate pain and induration/swelling on Post Dose Day 1). These deficiencies, among many others, render its opposition insufficient to defeat NIH's summary judgment motion.

B. NIH Has Met Its Burden.

Whereas Plaintiff has provided insufficient evidence, NIH has provided detailed information in a *Vaughn* Index, declarations from individuals with personal knowledge of the matters at issue, and other documentation in support of its contentions. Dkt. 19-20. The "affiants are knowledgeable about the information sought and the affidavits are detailed enough to allow the court to make an independent assessment of the government's claim." *Lion Raisins v. U.S. Dept. of Agric.*, 354 F.3d 1072, 1079 (9th Cir. 2004). Furthermore, NIH has provided specific, admissible evidence outlining the scope of the

clinical trial that was underway at non-NIH clinics as of the day the search was conducted; detailing the reasons for the limited redactions; and demonstrating that the same data was nevertheless produced in a way that protected the patient information in accordance with industry standards. Dkt. 19-20.

NIH has met its burden. *See discussion*, Dkt. 18. "When the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita,* 475 U.S. at 586 (footnote omitted). ICAN's evidence is "merely colorable or is not significantly probative," *Anderson*, 477 U.S. at 249-50, thus summary judgment should be granted.

IV. CONCLUSION

NIH properly searched for and redacted information responsive to Request 54464. In making limited redactions, NIH weighed the individuals' privacy interest in their personal medical information against the public interest, and released all segregable information. The redacted information does not directly reveal the operations or activities of NIH, thus no public interest would be served by its release. NIH therefore respectfully requests that the Court grant it Motion for Summary Judgment and deny ICAN's motion.

Respectfully submitted this 8th day of January 2021.

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CERTIFICATE OF SERVICE

I hereby certify that on January 8, 2021, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to the following CM/ECF registrant(s):

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