

**1.3.4 FINANCIAL CERTIFICATION AND DISCLOSURE – SUMMARY NOTE**

In accordance with 21 CFR Part 54 and *Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators* (Final, February 2013), Pfizer Inc. is submitting financial disclosure information on the Covered Studies listed in Table 1. The financial disclosure information covers the time period from the start of the study through one year after the completion of the study<sup>i</sup>.

Please note that this disclosure reports information for clinical investigators as that term is defined in 21 CFR Part 54. Accordingly, it may vary from an investigator list compiled from Forms FDA 1572 or listed in study reports.

<b>Table 1. LIST OF COVERED STUDIES (Pfizer Sponsored)</b>			
<b>PROTOCOL NUMBER</b>	<b>PROTOCOL NAME</b>	<b>DISCLOSURE START DATE</b>	<b>DISCLOSURE CUT-OFF DATE</b>
C4591001	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	29-Apr-2020	25-Mar-2021

All investigators are assessed for equity interest, significant payments of other sorts, other compensation by the sponsor and propriety interest. All significant payments of other sorts are checked via internal Pfizer procedures.

In accordance with 21 CFR Part 54 and the FDA Guidance, payments made under a clinical study agreement for the cost of conducting the clinical trial are not considered financial interests or arrangements subject to certification or disclosure. Nonetheless, given the extensive public interest in the COVID-19 vaccine program and in the interest of continued transparency with respect to the COVID-19 vaccine study, Pfizer Inc. wishes to share with FDA that the principal investigator at Site 1231 (Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich in Argentina) has (b) (6)

(b) (6)

(b) (6)

profits from conducting the clinical trial. Pfizer does not know the exact amount of profit

(b) (6), but even at the highest end, the per-patient costs under the clinical study

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agreement at this site are within the range of the per-patient costs that Pfizer pays clinical trial sites in Argentina and elsewhere.

#### **Certification - FORM FDA 3454 Summary**

Certification, using [FORM FDA 3454](#), that none of the financial interests or arrangements described in 21 CFR Part 54 exists, is provided for 1,782 of the 1,793 clinical investigators who participated in the covered study listed above<sup>ii</sup>.

Pfizer Inc. has identified 0 clinical investigators who were full-time or part-time employees of the sponsor of the covered study. Due Diligence activities were required for 4 of the clinical investigators.

#### **Disclosure - FORM FDA 3455 Summary**

A consolidated [FORM FDA 3455](#), Disclosure Statement, is provided to report on each clinical investigator who, or whose spouse or dependent child, had disclosable financial interests in and/or arrangements with any sponsor of any of the covered clinical studies listed in the above Table 1 of Covered Studies. The Summary Table provided within the FORM FDA 3455 on Page 1 lists the clinical investigators and the study for which each reached the disclosure threshold for Significant Payment of Other Sorts. The details of each disclosure are reported on the subsequent pages.

7 of the 1,793 clinical investigators listed in the study report had financial information to disclose, which represents 0.39% of the total number of all clinical investigators<sup>ii</sup> who participated in the study.

All Investigator Initiated Research Grants associated with clinical investigators are paid directly to the Institution rather than to the individual clinical investigator.

Information regarding Pfizer's efforts to eliminate bias for the covered studies is described in a separate [Bias Statement](#) in Module 1, Section 1.3.4.

**1.3.4 FINANCIAL CERTIFICATION AND DISCLOSURE – SUMMARY NOTE**

In accordance with 21 CFR Part 54 and *Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators* (Final, February 2013), BioNTech SE is submitting financial disclosure information on the Covered Studies listed in Table 1. The financial disclosure information covers the time period from the start of the study through one year after the completion of the study<sup>iii</sup>.

Please note that this disclosure reports information for clinical investigators as that term is defined in 21 CFR Part 54. Accordingly, it may vary from an investigator list compiled from Forms FDA 1572 or listed in study reports.

<b>Table 2. LIST OF COVERED STUDIES (BioNTech SE Sponsored)</b>			
<b>PROTOCOL NUMBER</b>	<b>PROTOCOL NAME</b>	<b>DISCLOSURE START DATE</b>	<b>DISCLOSURE CUT-OFF DATE</b>
BNT162-01	A MULTI-SITE, PHASE I/II, 2-PART, DOSE-ESCALATION TRIAL INVESTIGATING THE SAFETY AND IMMUNOGENICITY OF FOUR PROPHYLACTIC SARS-COV-2 RNA VACCINES AGAINST COVID19 USING DIFFERENT DOSING REGIMENS IN HEALTHY AND IMMUNOCOMPROMISED ADULTS	22-Apr-2020	23-Oct-2020

All investigators are assessed for equity interest, significant payments of other sorts, other compensation by the sponsor and propriety interest.

**Certification - FORM FDA 3454 Summary**

Certification, using [FORM FDA 3454](#), that none of the financial interests or arrangements described in 21 CFR Part 54 exists, is provided for 41 of the 41 clinical investigators who participated in the covered study listed above<sup>iv</sup>.

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BioNTech SE has identified 0 clinical investigators who were full-time or part-time employees of the sponsor of the covered study. Due Diligence activities were required for 0 of the clinical investigators.

Information regarding BioNTech SE's efforts to eliminate bias for the covered studies is described in a separate [Bias Statement](#) in Module 1, Section 1.3.4.

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<sup>i</sup> This reporting timeframe begins with the **Disclosure Start Date** and ends with the **Disclosure Cut-off Date + One Year**. However, if the **Disclosure Cut-off Date + 1 Year** falls later than the **Report Date** of the FDA Forms 3454 and 3455, then the **Report Date** is used as the end date for the disclosure reporting timeframe.

<sup>ii</sup> This number represents all the investigators listed on the form and is not unique. Some investigators may have participated in more than one study and multiple financial disclosure forms may have been collected for a single investigator.