1.3.4 FINANCIAL CERTIFICATION AND DISCLOSURE – BIAS STATEMENT

Protocol Number: C4591001

Study Title: 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

STEPS TAKEN TO MINIMIZE THE POTENTIAL FOR BIAS

The above-referenced trial was conducted according to ICH Good Clinical Practices. The study was conducted according to Pfizer SOPs.

Other processes used to minimize potential bias are as follows:

- The facilities performing the safety and efficacy evaluations were determined to be acceptable based on appropriate certification or historical performance and/or qualifications and credentials.
- Electronic diaries were used to collect patient reported outcomes, to ensure real time completion of outcomes questionnaires.
- Subjects were allocated randomly to vaccine group through use of an Interactive Response System.
- An independent external data monitoring committee (DMC), operating under a written charter, reviewed unblinded safety data on a weekly basis during Phase 2/3 and was responsible for the review of the efficacy interim analysis.
- Ongoing accrual of protocol-defined cases was monitored in a blinded manner and, when sufficient cases were available, the unblinded analysis was performed by a limited number of individuals who are not involved in ongoing conduct of the study (statistical team supporting the DMC).
- Microbiological confirmation of cases by Polymerase Chain Reaction (PCR) was performed by individuals blinded to treatment allocation in a central laboratory.
- An independent unblinded submissions team separate from the study team, operating under a written charter, analyzed defined endpoints for regulatory submissions (EUA, MAA). Analyses were stored on restricted sites. Access to the restricted sites was governed by charter and tracked.
- Investigator trial sites were monitored frequently.

- The validity of the data collected during the study was confirmed by standard monitoring procedures.
- During the course of processing, analyzing and reporting data from clinical trials, Pfizer applied procedures (e.g., querying data through electronic edit checks and clinical reviews) designed to ensure that errors were eliminated.
- Appropriate statistical methods were employed by use of an approved statistical analysis plan.
- The study report was reviewed by the Sponsor's Quality Control Group.