## TRANSFER OF OBLIGATIONS

In compliance with 21 CFR 312.52, Table 1 below lists the Sponsor responsibilities\* that were transferred from BioNTech SE to Pfizer Inc. in the conduct of the C4591001 clinical study, with the specific obligations that were transferred. Any obligation not provided in the written description below shall be deemed not to have been transferred.

Table 1. Sponsor Obligations Transferred to Pfizer Related to the Conduct of Study C4591001

NAME AND ADDRESS	STUDY(S) CONTRACTED	OBLIGATIONS ASSUMED / TRANSFERRED
Pfizer Inc. 445 Eastern Point Road, Groton, CT 06340 United States	C4591001	21 CFR 312.50 Ensuring that the investigation is conducted in accordance with the approved investigational plan, the approved protocol and Good Clinical Practice (GCP)
		21 CFR 312.53(a) Selecting investigators with qualified training and Experience
		21 CFR 312.53(c) Obtaining information from investigators, including a signed investigator statement (Form FDA 1572); curriculum vitae; financial disclosure information required under 21 CFR 54
		21 CFR 312.53(d) Selecting monitors qualified by training and experience
		21 CFR 312.55(a) Providing investigators with the information they need to conduct the investigation properly
		21 CFR 312.55(b) Informing investigators of new observations with respect to adverse events and safe use
		21 CFR 312.56(a) Ensuring proper monitoring of the clinical trial
		21 CFR 312.56(b) Secure compliance or discontinue shipments from investigators found not to comply with signed agreement (FDA 1572), the general investigational plan, or other requirements under 21 CFR 312
		21 CFR 312.56(c) Review and evaluate evidence of safety and effectiveness of drug

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NAME AND ADDRESS	STUDY(S) CONTRACTED	OBLIGATIONS ASSUMED / TRANSFERRED
		21 CFR 312.56(d) Ensure discontinuation of the study if the drug presents an unreasonable and significant risk to study subjects; notification to FDA and IRB of discontinuation
		21 CFR 312.57 Maintenance of records and reports
		21 CFR 312.59 Drug accountability (e.g. record of shipment, receipt, method of disposal); ensuring all unused drug is returned or properly disposed of
		Responsible for maintaining an effective IND and ensuring that FDA is promptly informed of: 1) reportable adverse effects or risks with respect to the drug; 2) significant changes to the protocol; 3) addition(s) of new investigators; 4) annual reviews

<sup>\*</sup>Where applicable, contractors who performed clinical supplies manufacturing, packaging, labeling and/or testing are noted in Module 3 Section P.3.1 of the IND and are, therefore, not included in Table 1.