Transfer of (IND) Regulatory Obligations

Sponsor Name:	ModernaTx, Inc.
Sponsor Address:	200 Technology Square Cambridge, MA 02139
IND#:	19745
Protocol Number:	mRNA-1273-P301
Title of Study(ies):	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

As allowed for under 21CFR 312.52, the Sponsor hereby transfers certain obligations pertaining to their clinical study to a contract research organization (CRO), PPD Development, LP, a Delaware limited partnership. The obligations transferred are as follows:

Obligation and/or Task	Moderna	PPD
Responsible for all communications to and from the FDA	X	
Review all information relative to the safety of the drug, especially adverse event information derived from clinical investigations conducted under the IND	X	
Promptly prepare IND safety reports for all serious adverse experiences requiring expedited reporting	X	
Promptly submit IND safety reports for all serious adverse experiences requiring expedited reporting	X	
Notify promptly all participating investigators of all IND safety reports		X
Maintain an effective IND with respect to the investigations to include timely submission of protocol amendments, information amendments, IND safety reports, and annual reports	X	
Regarding the conduct of clinical studies and obligations described in 21CFR Part 312, Subpart D. Selection of qualified investigators	X	
Selection of qualified monitors	X	X
Ensuring proper monitoring of the clinical investigations		X
Obtaining information from the Investigator before allowing the trial to begin, e.g., Signed and completed Form FDA-1572, CV of Principal Investigator Note: PPD will only be collecting Clinical Trial Agreements for non-COVID-19 Prevention Network (CoVPN) sites. PPD will not be collecting Clinical Trial Agreements for CoVPN sites as NIAID has agreements with and pay these sites but PPD will receive confirmation in writing that each CoVPN site sub-award has been executed.		X
Control of investigational drug to include: • Shipping drug only to participating investigators • Maintaining adequate records of receipt, shipment, or other disposition of drug • Assuring return or any previously approved alternative disposition of drug upon the discontinuation or termination of a study	X	X
Providing investigators with appropriate information to properly conduct the investigation, e.g., protocol and investigator brochure		X
Ensuring the investigation is conducted according to the investigational plan and protocol contained in the IND	X	X

Obligation and/or Task	Moderna	PPD
Keeping each participating Investigator informed of new observations made known to the Sponsor and PPD Development about the drug, particularly with respect to safe use of the drug		X
Retention of records showing receipt, shipment, or other disposition of the investigational drug to the Investigator for 2 years after a marketing application is approved, or if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified. Note: The Sponsor's obligation under 312.57 is separate and distinct from the Investigator's obligations, under 21CFR 312.62, to retain records of drug disposition and use in subjects for a 2 year period. PPD Development is not assuming responsibility for the Investigator's obligations under 312.62	X	X

Address of CRO: PPD, Inc.
929 North Front Street
Wilmington, NC 28401-3331

PPD Contact: (b) (6)
(b) (6)
Telephone: (b) (6)
Facsimile: (b) (6)

Sponsor Signature: Carlota Vinals Digitally signed by Carlota Vinals Date: 2020.07.31 14:33:19 -04'00' Date:

Title:

PPD Signature: (b) (6) Date: 31 JUL 2020

Title: (b) (6)