Transfer of US FDA Regulatory Obligations for Investigational Pharmaceutical and Biologic Products Under an Investigational New Drug (IND) Application (21 CFR 312)

Sponsor:	ModernaTX, Inc.	**Project Code:**	FZA89935
Product:	mRNA-1273	**IND Number:**	19745
Indication:	active immunization to induce protective immunity against acute respiratory disease associated with the SARS-COV-2 virus	**Protocol Number:**	mRNA-1273-P301

Regulatory Obligation	Reference	Obligation Assigned to: Sponsor	IQVIA
B. Informing investigators and FDA			
1. Inform participating investigators of new safety information about the study drug	21 CFR 312.55 (b);	☒	☐
2. Notify participating investigators of all serious, unexpected adverse drug reactions	21 CFR 312.32 (c);		
a. Preparation of Investigator Alert Letters		☒	☐
b. Distribution of Investigator Alert Letters		☒	☐
3. Notify FDA in a written IND safety report of all serious and unexpected adverse drug reactions	21 CFR 312.32 (c);		
a) Preparation of IND safety report		☐	☒
b) Notification to FDA (phone/fax or written)		☐	☒

The sponsor hereby transfers to IQVIA the responsibilities indicated above under the column titled "Obligation Assigned to IQVIA." Obligations will transfer upon the execution of the work order authorizing those activities to begin.

ModernaTX, Inc
Sponsor

Carlota Vinals
Signature

Digitally signed by Carlota Vinals
Date: 2020.11.05 16:29:09 -05'00'

Carlota Vinals
Printed Name

VP, Head of Regulatory Strategy ID
Title

Date

IQVIA

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(b) (6)
I approve this document
November 6, 2020 | 8:53:03 AM PST

(b) (6)

(b) (6)
Printed Name

Director, (b) (6)
Title

November 6, 2020
Date