

RECORD OF TELECON

Submission ID:
19745

Office:
OVRR

Title: *Human Coronavirus, (2019-nCoV; Pre-fusion Spike protein; Lipid Nanoparticles; messenger RNA-1273) Vaccine*

Sponsor: *ModernaTX Inc*

Telecon Date/Time: 20-AUG-2021 05:06 PM

Initiated by FDA?: Yes

Email?: Yes

Author: SUDHAKAR AGNIHOTHRAM

Entered in BIRAMS: 21-AUG-2021 11:05 AM

Last Revised: 21-AUG-2021 11:05 AM

Purpose: INFORMATION REQUEST (IR)

FDA Participants:
SUDHAKAR AGNIHOTHRAM

Sponsor Participants:
CARLA VINALS
MICHELLE OLSEN

Amendments: None

Summary of Discussion:

Attachement containing Shell tables sent and requested sponsor fill in and submit a MS word copy with the clinical module to BLA 125752.

Signature: _____