

Version 9 9-Dec-20 [Replaces V8, 02DEC2020]					
Module	Section	Content	SN#	Date of submission (or estimate)	Submitted to IND or EUA
Module 2	2.4	Preclinical Safety and Efficacy Information	SN0012	Available now in IND to review ahead of EUA Submission	IND
Module 2	(b) (4)	mRNA Vaccine Platform Info	SN0001 letter to crossref.	Available now to review ahead of EUA Submission	IND
Module 3	3.2.S and 3.2.P	Incorporation of (b) (4)	SN0025	Available now to review ahead of EUA Submission	
Module 3	3.2.S and 3.2.P	Scale A Drug Substance PPQ information conducted at ModernaTX, Inc. (Norwood, MA) consisting of: (b) (4) scale for CX-024414, (b) (4) (b) (4) for mRNA-1273 LNP.	SN0041 SN0039 SN0039	Available now in IND to review ahead of EUA Submission	IND
Module 3	3.2.S and 3.2.P	Initial Scale B Drug Substance PPQ information conducted at Lonza Biologics (Portsmouth, NH) consisting of (b) (4) for CX-024414	SN0041	Available now in IND to review ahead of EUA Submission	IND
Module 3	3.2.S and 3.2.P	Scale A Drug Product PPQ information conducted at Catalent Biologics, LLC (Bloomington, IN) representing a fill/finish output of (b) (4) (b) (4)	SN0039	Available now in IND to review ahead of EUA Submission	IND
Module 3	3.2.A.1	3.2.A.1- Facilities and Equipment (ModernaTX, Inc)	SN0039	Available	IND
Module 3	3.2.A.1	Letter of authorization to cross reference 3.2.A.1 of (b) (4) held by Catalent Indiana, LLC	SN0041	Available	IND
Module 3	3.2.A.1	3.2.A.1- Facilities and Equipment (Catalent)	SN0070	Available	IND

Module 3	3.2.S and 3.2.P	Analytical methods descriptions, validation summaries and documentation to support CX-024414 mRNA, (b) (4) and mRNA-1273 LNP	SN0053	Available now in IND to review ahead of EUA Submission	IND
Module 4	4.2.1.3	Safety Pharmacology Report	SN0001	Available now in IND to review ahead of EUA Submission	IND
Module 4	4.2.3.7.2	Immunotoxicity Study	SN0012	Available now in IND to review ahead of EUA Submission	IND
Module 5	5.3.5.1	Phase 2 and 3 Protocols, Ph3 SAP, DSMB meeting minutes	SN0033-Ph2 Protocol Amd3 SN0036-Ph3 SAP SN0042-Ph3 Protocol Amd4 SN0047-DSMB minutes SN0055-DSMB minutes	Available now in IND to review ahead of EUA Submission	IND
Module 5	5.3.1.4	Qualification and Validation of ELISA Method	SN0036	Available now in IND to review ahead of EUA Submission	IND
-	-	DMID 20-0003_02JUL_ImmunoSummaryReport	Cross Ref to DMID IND #19635	Available now to review ahead of EUA Submission	IND
-	-	DMID 20-0003_26OCT_SafetySummaryReport	Cross Ref to DMID IND #19635	Available now to review ahead of EUA Submission	IND
Module 1	1.19	pre-EUA Submission Meeting Request/Briefing Document	SN0063	4-Nov	IND

Module 3	3.2.S	First GMP lots for Initial Scale B Drug Substance Process (b) (4) (ModernaTX, Inc) consisting of (b) (4) (b) (4) for mRNA-1273 LNP.	SN0066	9-Nov	IND
		First GMP lots of Final Scale B Drug Substance for Process (b) (4) (ModernaTX, Inc.) consisting of (b) (4) (b) (4)			IND
Module 3	3.2.A.1	SN0067: 3.2.A.1- Facilities and Equipment (Lonza Biologics, Inc.)	SN0067	11-Nov	IND
Module 3	3.2.A.1	Letter of authorization to cross reference 3.2.A.1 of (b) (4) held by Lonza Biologics, Inc.	SN0067	11-Nov	IND
Module 5		P201 SAP; P301 Draft Blinding Plan	SN0068	11-Nov	IND
Module 1 and Module 5		Moderna proposal for datasets supporting EUA (M1), P301 Final Blinding Plan (M5)	SN0069	13-Nov	IND
Module 3	3.2.S and 3.2.P	First PPQ lot for Scale B Drug Product information (Ompi Vials) conducted at Catalent Biologics, LLC (Bloomington, IN) representing a fill/finish output of (b) (4)			IND
		First comparability lot for Final Scale B Drug Substance Process (b) (4) (ModernaTX, Inc) consisting of (b) (4) (b) (4) for mRNA-1273 LNP.	SN0070	16-Nov	IND
		Initial Scale B Drug Substance PPQ information for Process (b) (4) (ModernaTX, Inc) consisting of (b) (4) (b) (4) mRNA-1273 LNP			IND
Module 5	5.3	P301 TFLs: Efficacy Tables and Figures (from Day 49 median Data snapshot)	SN0071	16-Nov	IND

Module 1 and Module 5		Response to questions regarding bio-assays; Validation reports	SN0073	18-Nov	IND
Module 3	3.2.S and 3.2.P	Response to Request for Information from October 6 and November 9	SN0077	24-Nov	IND
Module 5	5.3	P201 TFLs	SN0078	24-Nov	IND
Module 1	1.11	CBER requested SMQ tables	SN0079	25-Nov	IND
Module 5	5.3	P301 TFLs: Safety Tables (from Nov 11 Day 49 median Data snapshot)	SN0080	27-Nov	IND
Module 1	1.11	DMID Phase 1 Study 20-0003 20-0003 Safety Summary Report (dated 26 Oct 2020)  DMID Phase 1 Study 20-0003 Immunogenicity Summary Report (dated 29 Oct 2020)  20-0003 Immunogenicity Summary Report (dated 24 Sep 2020)	SN0080	27-Nov	IND
Module 5	5.3	P301 datasets	SN0080	27-Nov	IND
Module 1	1.19	EUA Submission (based on Day 49 median Data snapshot)	SN0001	30-Nov	EUA
Module 3	3.2.S and 3.2.P	First PPQ lot for Final Scale B Drug Substance Process (b) (4) (ModernaTX, Inc) consisting of (b) (4) (b) (4) for mRNA-1273 LNP.	SN0081	30-Nov	IND

		First Comparability lot for Final Scale B Drug Substance Process (b) (4) (Lonza) consisting of (b) (4) (b) (4) for mRNA-1273 LNP.			
Module 2	2.5	Module 2.5 containing data from Phase 1, 2, and 3 -Analysis of the clinical study data from P301 (1st pre-specified interim analysis (IA) of the primary efficacy endpoint), P201 (primary, secondary and exploratory through Day 57) and Phase 1 DMID 20-0003 data (with reference to the reports submitted in October). - Benefit-Risk Assessment	SN0001	30-Nov	EUA
Module 1	1.11.3	RTQ death	SN0082	2-Dec	
Module 1	1.11.3	sensitivity analysis (RFI rec'd 25Nov, 27Nov)	SN0083	3-Dec	IND
Module 1	1.11.2	RTQ Non-clinical question (RFI rec'd 01Dec)	SN0083	3-Dec	IND
Module 2	2.4, 2.6	Module 2.4 and 2.6	SN0084	4-Dec	IND
Module 4	4.2	All Mod 4 study reports + DART Study Audited Draft Report	SN0084	4-Dec	IND
Module 1	1.14.1.3	Updated Fact Sheets and PI	SN0002	4-Dec	EUA
Module 1	1.11.4	EUA Submission Table V8	SN0003	4-Dec	EUA
Module 5	5.3.5.1	Final analysis TFLs: Efficacy	SN0003	4-Dec	EUA
Module 1	Module 1.19	VRBPAC Briefing Document	SN0003	4-Dec	EUA
Module 1		PVP	SN0003	4-Dec	EUA

Module 1	1.11.3	Response to comments regarding pregnancy and active surveillance studies; response to comments regarding clinical topics	SN0003	4-Dec	EUA
Module 1	1.11.3	Responses to multiple information requests: – Response to Request for Information: EUA27073 #0001-01Dec – Subject Demographics and Other Baseline Characteristics: EUA27073 #0001-05Dec – Response to Comments Regarding Clinical Datasets: EUA 27073 #0004-03Dec -Response to Comments Regarding Summaries for Clinical Laboratory-Safety #0005-04Dec – Response to Information Request – Summary of Severe-COVID-19 by Subject: EUA 27073 #0006-05Dec 1.11.3 – Response Comments Regarding Adverse events: EUA 27073 #0007 Q1-2-05Dec	SN0004	6-Dec	EUA
Module 5	5.3.5.1	Baseline Demographics and Characteristics by Age Group: EUA 27073 #0001-05Dec  mRNA-1273-P301 Severe Covid19 MW Forms: EUA 27073 #0006-05Dec	SN0004	6-Dec	EUA
Module 5	5.3.5.1	Final analysis datasets	SN0005	7-Dec	EUA
Module 5	5.3.5.1	CRFs	SN0006	7-Dec	EUA
Module 1	1.11.3	Final Analysis CBER Requested tables and executive summary	SN0006	7-Dec	EUA
Module 5	5.3.5.1	Final analysis TFLs: Safety	SN0006	7-Dec	EUA
Module 1	1.6.2	List of VRBPAC attendees (response to EUA request for information)	SN0006	7-Dec	EUA

Module 5	5.3.5.1	P201 and P301 list of investigators (response to EUA request for information)	SN0006	7-Dec	EUA
Module 1	1.3.4	Form 3454 associated with IR#2	SN0007	7-Dec	EUA
Module 1	1.11.3	Response to comments: IR#7 Q 4 and 5; IR#8;	SN0007	7-Dec	EUA
Module 5	5.3.5.1	3 Medwatch forms associated with IR#8; SAE listing IR#8	SN0007	7-Dec	EUA
Module 1	1.14.1.1	Artwork: Vial label and carton	SN0007	7-Dec	EUA
Module 1	1.6.2	Updated VRBPAC BD	SN0008	8-Dec	EUA
Module 1	1.14.1.3	Draft PI- sections 11-21, clean and redline	SN0009	8-Dec	EUA
Module 1	1.11.3	Response to comments: -items 3-5 EUA IR#8 -items 1-3 EUA IR#9	SN0009	8-Dec	EUA
Module 3	3.2.S and 3.2.P	Additional manufacturer of plasmid (Aldevron), (b) (4) at Catalent at Scale B (b) (4) PPQ, fill line already filed); Information on Catalent (b) (4) in 32A1 {Catalent}; (b) (4) (b) (4)	SN0085	8-Dec	IND
Upcoming Submissions					
Module 1	1.6.2	VRBPAC Slide Deck- draft	-	11-Dec	EUA

Module 3	3.2.S and 3.2.P	Final Scale B Drug Substance comparability information for Process (b) (4) (ModernaTX, Inc) consisting of (b) (4) for mRNA-1273 LNP. Final Scale B Drug Substance information for Process (b) (4) (ModernaTX, Inc) consisting of (b) (4) mRNA.	-	targeted for 12/11/2020	IND
		Scale B Drug Product PPQ comparability information conducted at Catalent Biologics, LLC (Bloomington, IN) representing a fill/finish output of (b) (4) (Initial report); CCIT data for SiO2 vials; Aldevron 32A1 facility information	-		IND
Module 3	3.2.S and 3.2.P	Scale B Drug Product PPQ information conducted at Catalent Biologics, LLC (Bloomington, IN) representing a fill/finish output of (b) (4) (Updated report); (b) (4) (b) (4) CCIT data for Corning vials; Lonza PO 32A1 facility information; updates for (b) (4) stability	-	targeted for 12/14/2020	IND
Module 3	3.2.S and 3.2.P	Batch Analysis and CofA data for all mRNA-1273 DP and mRNA-1273 LNP available for EUA	-	targeted for 12/17/2020	IND
Module 3	3.2.S and 3.2.P	Batch Analysis and CofA data for all mRNA-1273 DP and mRNA-1273 LNP available for EUA	-	targeted for multiple submissions through 12/31/2020	IND
Module 3	3.2.S	First PPQ lot for Final Scale B Drug Substance Process (b) (4) (Lonza) consisting of (b) (4) for mRNA-1273 LNP.	-	w/o 01/11/2021	IND
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