

Version 8 2-Dec-20 [Replaces V7, 30Nov2020]					
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	Scale A Drug Substance PPQ information conducted at ModernaTX, Inc. (Norwood, MA) consisting of: (b) (4) 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) (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)	SN0039	Available now in IND to review ahead of EUA Submission	IND
Module 3	3.2.S and 3.2.P	Analytical methods descriptions, validation summaries and documentation to support CX-024414 mRNA, (b) (4) 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

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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)			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)	SN0070	16-Nov	IND
		First comparability lot for Final Scale B Drug Substance Process (b) (4) (ModernaTX, Inc) consisting of (b) (4) (b) (4) (b) (4) for mRNA-1273 LNP.			IND
		Initial Scale B Drug Substance PPQ information for Process (b) (4) (ModernaTX, Inc) (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

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Module 1 and Module 5		Response to questions regarding bioassays; Validation reports	SN0073	18-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	
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) 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) 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		Fact Sheets and PI	SN0084	12/4/2020 by 10am	
Module 1		RTQ death	SN0082	2-Dec	
Module 1		sensitivity analysis (RFI rec'd 25Nov, 27Nov)	SN0083	3-Dec	IND
Module 1		RTQ Non-clinical question (RFI rec'd 01Dec)	SN0083	3-Dec	IND

Upcoming Submissions					
Module 2		Module 2.4 and 2.6	-	Target 04Dec- Date TBC	IND
		EUA Submission Table V8	-	4-Dec	EUA
Module 5	5.3.5.1	Final analysis TFLs: Efficacy	-	4-Dec	EUA
Module 4		All Mod 4 study reports + DART Study Audited Draft Report	-	4-Dec	EUA
Module 1	Module 1.19	VRBPAC Briefing Document	-	4-Dec	EUA
Module 1		PVP	-	12/4/2020 maybe 05Dec	EUA
Module 5	5.3.5.1	CRFs	-	7-Dec	EUA
Module 1 and Module 5	1.11 and 5.3.5.1	Final analysis TFLs: Safety Final Analysis CBER Requested tables	-	7-Dec	EUA
Module 5	5.3.5.1	Final analysis datasets	-	7-Dec	EUA
Module 1		Label Artwork	-	7-Dec	
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)		targeted for 12/7/2020	IND
Module 3	3.2.S and 3.2.P	Final Scale B Drug Substance 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 12/17/2020	IND
		Scale B Drug Product PPQ information conducted at Catalent Biologics, LLC (Bloomington, IN) representing a fill/finish output of (b) (4)	-		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 IND