



TEMP-0016: Clinical Study Audit Plan – mRNA-1273-P301

Version Number	2.0	This plan version is:	<input type="checkbox"/> Initial
Version Date	08 December 2020		<input checked="" type="checkbox"/> Updated

Clinical Study Profile

Study Number:	mRNA-1273-P301	Study Title:	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
Investigational Product:	mRNA-1273 SARS-CoV-2 Vaccine		
Indication:	COVID-19		
Study Phase:	Phase III	Planned number of participants:	30,000
Planned number of sites:	99	Regions involved:	USA

Planned Audit Activities:

Document Audits

Are document audits needed for this study?	Yes <input type="checkbox"/> (explain in Rationale below) No <input checked="" type="checkbox"/>
Rationale and additional comments (please provide justification if document audits are not required or if a specific document audit is not to be performed)	At the time of audit plan creation, the study had already started screening and enrollment; corresponding forms and documentation had already been finalized.

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Site Audits

Target Coverage (%)	~10-15%	Number of Audits planned:	~10-15
Rationale and additional comments	To ensure adequate oversight of quality at Clinical Investigator Sites conducting the clinical trial. Note – additional site audits (routine and/or for cause) may be added if deemed necessary.		

Planned Quarter	PI	Site	Site No.	Location
Q3 2020	Hachigian	Benchmark Research	US310	Sacramento, CA
Q4 2020	McGettigan	Quality of Life Medical Research Center	US319	Hunt, AZ
Q4 2020	Rankin	Accel Research Site	US322	Deland, FL
Q4 2020	Gay	University of North Carolina at Chapel Hill	US369	Chapel Hill, NC
Q1 2021	TBD	TBD	TBD	TBD
Q1 2021	TBD	TBD	TBD	TBD
Q1 2021	TBD	TBD	TBD	TBD
Q1 2021	TBD	TBD	TBD	TBD
Q2 2021	TBD	TBD	TBD	TBD
Q2 2021	TBD	TBD	TBD	TBD
Q2 2021	TBD	TBD	TBD	TBD
Q2 2021	TBD	TBD	TBD	TBD
Q3 2021	TBD	TBD	TBD	TBD
Q3 2021	TBD	TBD	TBD	TBD

Vendors

Vendor	Service	Location	Audit Required? (Y/N)*	Plan rationale and additional comments
PPD	CRO	929 N. Front St., Wilmington, NC 28401	Yes	<i>Majority of study activities have been outsourced to PPD.</i>
IQVIA	Safety Management	4820 Emperor Blvd., Durham, NC 27703	Yes	<i>Requalification audit scheduled for 4Q2020.</i>

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(b) (4)

PPD Vaccines Laboratory	BioA Laboratory Services	2244 Dabney Rd., Richmond, VA 23230	Yes	<i>Requalification audit due 4Q2020</i>
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(b) (4)

*** If No, please provide rationale in Comments Section**

Study Oversight Audit

Is a study oversight audit needed for this study?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Rationale and additional comments <i>(please provide justification regarding decision to conduct/not to conduct an oversight audit)</i>	Due to the importance of this study in terms of its contribution and significance to the biologics license application for mRNA-1273 and likelihood of regulatory authority inspection a study oversight audit is warranted.

Study Audit Description	Planned Quarter
Interim	Q1 2021
Final	Q4 2021

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Trending: Where more than three or four investigator site audits are performed, trending of the audit observations will be performed and issued as Study Audit Summary Reports, (SASRs). Please describe the proposed frequency of the trending and issuing of SASRs.

Audit observation trending, and corresponding SASRs, will be compiled after completion of the first three audits. Thereafter, trending and corresponding SASRs will be compiled after completion of every third audit, continuing until all investigator site audits have been completed.

Document History

Date	Reason for Change
1.0	Initial Version
2.0	Periodic Update

Quality Representative

Name: Alex McCord **Title:** Associate Director, RDQ
08-Dec-2020 | 15:21 EST

Signature:  DocuSigned by:
Alex McCord
Date: (dd/mmm/yyyy)
Signer Name: Alex McCord
Signing Reason: I am the author of this document
Signing Time: 08-Dec-2020 | 15:21 EST

Approved by: 50214FA1B1A345F6B9661E33676E5C39
Name: (b) (6) **Title:** (b) (6)
08-Dec-2020 | 12:47 PST

Signature:  **Date:** (dd/mmm/yyyy)

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