

16.1.8 Audit Certificates (if available)

Investigator or Location	Audit Type	Audit #	Date
R&D Quality Vendor Audit	Routine (Remote)	GCP-VEN-2021-001	26 Jan 2021 to 28 Jan 2021
Cynthia Gay, MD Site 369	Routine Clinical Investigator Site Audit	NA	28 Oct 2020 to 29 Oct 2020
Bruce Rankin, DO Site 322	For-Cause Clinical Investigator Site Audit	NA	22 Oct 2020 to 23 Oct 2020
Dr. John McGettigan, Jr., MD Site 319	Routine Clinical Investigator Site Audit	NA	14 Oct 2020 to 15 Oct 2020
Dr. Greg Hachigian, MD Site 310	Routine Clinical Investigator Site Audit	NA	23 Sep 2020 to 24 Sep 2020



200 Technology Square
Cambridge, MA 02139

R&D QUALITY VENDOR AUDIT CERTIFICATE

Audit Number:	GCP-VEN-2021-001	
Audit Type:	Routine (Remote)	
Vendor Name:	PPD	
Vendor Address:	3900 Paramount Parkway Morrisville, NC 27560	
Key Contact(s)	(b) (6)	
Audit Date(s):	26-28 Jan 2021	
Name of Auditor(s):	(b) (6)	
Auditor Signature:	<small>DocuSigned by:</small> (b) (6) <small>22B5ED97EE0742B...</small>	3/24/2021
	Completed by	Date

This is to certify an audit was conducted for the above company against applicable Moderna Standard Operating Procedures and FDA regulations (as applicable), in addition to compliance with the ICH-GCP Guidelines and other current international and / or national regulations.

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FDA-CBER-2022-1614-0666900



RDQ AUDIT CERTIFICATE

Audit Type: Routine Clinical Investigator Site Audit

Protocol Number: mRNA-1273-P301

Protocol 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

Investigator / Site #: Cynthia Gay, MD / Site 369

Address: University of North Carolina at Chapel Hill
160 Dental Circle
Chapel Hill, NC 27514

Auditor(s): Steve Barry, Associate Director, RDQ
Lorrie Anderson, Director, RDQ
Kaitlin Bova, Manager, RDQ

Audit Date(s): 28-29 October 2020

This certificate confirms an independent GCP Quality Assurance audit was conducted at the above investigator site. The audit was conducted to assess compliance with applicable regulations, ICH GCP guidelines, and the study protocol and associated study documents.

Steven Barry

DocuSigned by:

Steven Barry

12-Nov-2020 | 09:46 EST

Auditor Name

Signature

Signer Name: Steven Barry

Signing Reason: I am the author of this document

Signing Time: 12-Nov-2020 | 09:46 EST

Date (dd/mmm/yyyy)

(RDQ Rep if contract auditor involved)

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Research & Development Quality (RDQ), Moderna

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Katie Bova

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Moderna

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Steven Barry

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12-Nov-2020 | 09:46

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RDQ AUDIT CERTIFICATE

Audit Type: For-Cause Clinical Investigator Site Audit

Protocol Number: mRNA-1273-P301

Protocol 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

Investigator / Site #: Bruce Rankin, DO / Site 322

Address: University Clinical Research-Deland, LLC
d/b/a Accel Research
860 Peachwood Drive
Deland, FL 32720

Auditor(s): Alex McCord, Associate Director, RDQ
Steve Barry, Associate Director, RDQ

Audit Date(s): 22-23 October 2020

This certificate confirms an independent GCP Quality Assurance audit was conducted at the above investigator site. The audit was conducted to assess compliance with applicable regulations, ICH GCP guidelines, and the study protocol and associated study documents.

Alex McCord / Steve Barry
Auditor Name / Signature

29 Oct 2020
Date (dd/mm/yyyy)

(RDQ Rep if contract auditor involved)

Research & Development Quality (RDQ), Moderna

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CQA AUDIT CERTIFICATE

Audit Type: Routine Clinical Investigator Site Audit

Protocol Number: mRNA-1273-P301

Protocol 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

Investigator / Site #: Dr. John McGettigan, Jr., MD / Site 319

Address: Quality of Life Medical & Research Center, LLC
5390 E. Erickson Drive
Tucson, AZ 85712, USA

Auditor(s): Alex McCord, Associate Director, R & D Quality
Lorrie Anderson, Director, R & D Quality

Audit Date(s): 14-15 October 2020

This certificate confirms an independent GCP Quality Assurance audit was conducted at the above investigator site. The audit was conducted to assess compliance with applicable regulations, ICH GCP guidelines, and the study protocol and associated study documents.

Alex McCord / Alex McCord
Auditor Name / Signature

20 Oct 2020
Date (dd/mmm/yyyy)

(CQA Rep if contract auditor involved)

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CQA AUDIT CERTIFICATE

Audit Type: Routine Clinical Investigator Site Audit

Protocol Number: mRNA-1273-P301

Protocol 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

Investigator / Site #: Dr. Greg Hachigian, MD / Site 310

Address: Benchmark Research
4345 Arden Way
Sacramento, CA 95864

Auditor(s): Alex McCord, Associate Director, R & D Quality
Steven Barry, Associate Director, R & D Quality

Audit Date(s): 23-24 September 2020

This certificate confirms an independent GCP Quality Assurance audit was conducted at the above investigator site. The audit was conducted to assess compliance with applicable regulations, ICH GCP guidelines, and the study protocol and associated study documents.

Alex McCord / Alex McCord
Auditor Name / Signature

01/04/2020
Date (dd/mm/yyyy)

(CQA Rep if contract auditor involved)

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