

16.1.8 Audit Certificates (if available)

Investigator or Location	Audit Type	Site #	Date
Keith Vrbicky, MD United States	Site Audit	203	13-14 July 2020
David Enszy, MD United States	Site Audit	204	15-16 July 2020
Darrell Herrington, DO United States	Site Audit	207	20-21 August 2020



TEMP-0020: Audit Certificate template

CQA AUDIT CERTIFICATE

Audit Type: Routine Clinical Investigator Site Audit

Protocol Number: mRNA-1273-P201

Protocol Title: A Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of MRNA-1273 SARS-COV-2 Vaccine in Adults Aged 18 Years and Older

Investigator / Site #: Keith Vrbicky, MD / Site 203

Address: Meridian Clinical Research, LLC
1410 N. 14th Street, Suite 5
Lincoln, NE 68701, USA

Auditor(s): (b) (6)
Alex McCord, Assoc Director, GCP/GLP/GVP QA

Audit Date(s): 13-14 July 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

03/Jul/2020
Date (dd/mmm/yyyy)

(CQA Rep if contract auditor involved)

Quality Assurance, Moderna

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TEMP-0020: Audit Certificate template

CQA AUDIT CERTIFICATE

Audit Type: Routine Clinical Investigator Site Audit

Protocol Number: mRNA-1273-P201

Protocol Title: A Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of MRNA-1273 SARS-COV-2 Vaccine in Adults Aged 18 Years and Older

Investigator / Site #: David Enszt, MD / Site 204

Address: Meridian Clinical Research, LLC
330 Dakota Dunes Blvd, Suite 400
Dakota Dunes, SD, USA

Auditor(s): (b) (6)
Alex McCord, Assoc Director, GCP/GLP/GVP QA

Audit Date(s): 15-16 July 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

03/Aug/2020
Date (dd/mm/yyyy)

(CQA Rep if contract auditor involved)

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CQA AUDIT CERTIFICATE

Audit Type: Directed Clinical Investigator Site Audit

Protocol Number: mRNA-1273-P201

Protocol Title: A Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of MRNA-1273 SARS-COV-2 Vaccine in Adults Aged 18 Years and Older

Investigator / Site #: Darrell Herrington, DO / Site 207

Address: Benchmark Research
3605 Executive Drive
San Angelo, TX

Auditor(s): (b) (6)
Alex McCord, Assoc Director, GCP/GLP/GVP QA

Audit Date(s): 20-21 August 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

28/Sep/2020
Date (dd/mm/yyyy)

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