



Pfizer Regulatory Quality Assurance

Audit Certificate

I, the undersigned, confirm and certify that the following investigator site audit activities were performed.

Study C4591001

Sixteen (16) investigator site audits were performed between 29-Apr-2020 and 14-Nov-2020 for Study C4591001 Phase 2/3*.

Investigator Name	Center Number	Country	Dates of Audit	Type of Audit	Name of Auditor
Mulligan, Mark Joseph	1001	United States	27 Jul 2020 to 30 Jul 2020	Routine	Jefferies, Maria
Neuzil, Kathleen Maletic	1002	United States	10 Aug 2020 to 13 Aug 2020	Routine	Cutler, Robert
Seger, William Michael	1042	United States	10 Aug 2020 to 13 Aug 2020	Routine	Popelca, Bogdan
Rankin, Bruce Glenn	1109	United States	18 Aug 2020 to 21 Aug 2020	Routine	Patel, Frederic
Zerbini, Cristiano Augusto de Freitas	1226	Brazil	24 Aug 2020 to 27 Aug 2020	Routine	Tewes, Elisabeth
Polack, Fernando Pedro	1231	Argentina	27 Aug 2020 to 03 Sep 2020	Routine	Mohr, Andrea
Raad, George Louis	1079	United States	01 Sep 2020 to 04 Sep 2020	Routine	Jefferies, Maria
Arora, Samir	1091	United States	14 Sep 2020 to 17 Sep 2020	Routine	Samuels, Marilyn
Patel, Suchet R.	1077	United States	29 Sep 2020 to 02 Oct 2020	Routine	Tewes, Elisabeth
Fried, David L.	1124	United States	05 Oct 2020 to 07 Oct 2020	Non-Routine	Cutler, Robert
Winkle, Peter John	1135	United States	12 Oct 2020 to 14 Oct 2020	Non-Routine	Cutler, Robert
Polack, Fernando Pedro	1231	Argentina	13 Oct 2020 to 20 Oct 2020	Non-Routine	Mohr, Andrea
Reynolds, Steven H.	1149	United States	16 Oct 2020 to 20 Oct 2020	Non-Routine	Cutler, Robert
Rankin, Bruce Glenn	1109	United States	19 Oct 2020 to 22 Oct 2020	Non-Routine	Oprisko, Cheryl
Nell, Haylene	1247	South Africa	26 Oct 2020 to 29 Oct 2020	Routine	Tewes, Elisabeth
Koch, Mark	1128	United States	03 Nov 2020 to 06 Nov 2020	Non-Routine	Cutler, Robert

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***Site 1001 and 1002 audited as part of Phase 1**

Approver:

Cecilia Gabarain
Senior Director, Regulatory Quality Assurance

Robert N Cutler

7997eefb-6feb-4dbc-a232-c15936633467

REASON: I attest to the accuracy and integrity of this document.

19 Nov 2020
13:28:049-0500

Cecilia Gabarain

6809829b-f9ec-4ac9-bc23-e28cfba721dc

REASON: I approve this document.

20 Nov 2020
10:12:039-0500

090177e195a22bb6\Approved\Approved On: 03-Dec-2020 07:03 (GMT)

MSB

Validation Report as of: 20 Nov 2020 10:14:010-0500

1



Subject CN MSB
Subject DN EMAILADDRESS=operations@msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email operations@msbdocs.com
Serial # 103155442024134641897105422308128156249
Issuer DN CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time 20 Nov 2020 10:12:039-0500

- The Certificate chain was successfully built to a Trusted Root Certificate.
- The Signer's identity is valid.
- The Document has not been modified since the signature was applied.

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FDA-CBER-2021-5683-0029192

Audit Trail Report

Date	User	Document	Action	Details
19 Nov 2020 13 09:007-0500	Christine Mina		Started	The custodian composed the ePak successfully. User UU D : a3b2e181-3aee-4aea-b101-ec31853d0033 User Email : christine.mina@pfizer.com
19 Nov 2020 13 09:007-0500	Robert N Cutler		RequestSent	Sign request sent to ePak recipient. User UUID : 7997eebf-6feb-4dbc-a232-c15936633467 User Email : robert.cutler@pfizer.com
19 Nov 2020 13 27:054-0500	Robert N Cutler	C4591001 Phase 2_3 Audit Cert 19-Nov-2020.pdf	DocumentViewed	Document viewed by signer. User UUID : 7997eebf-6feb-4dbc-a232-c15936633467 User Email : robert.cutler@pfizer.com Document UU D : dd1d3c42-4215-4faf-843f-b1d1d2d5c436
19 Nov 2020 13 28:050-0500	Robert N Cutler	C4591001 Phase 2_3 Audit Cert 19-Nov-2020.pdf	SignerTagFilled	The signer filled Time Stamp. Value: 19 Nov 2020 13 28:049-0500 User UUID : 7997eebf-6feb-4dbc-a232-c15936633467 User Email : robert.cutler@pfizer.com Document UU D : dd1d3c42-4215-4faf-843f-b1d1d2d5c436
19 Nov 2020 13 28:050-0500	Robert N Cutler	C4591001 Phase 2_3 Audit Cert 19-Nov-2020.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: None User UUID : 7997eebf-6feb-4dbc-a232-c15936633467 User Email : robert.cutler@pfizer.com Document UU D : dd1d3c42-4215-4faf-843f-b1d1d2d5c436
19 Nov 2020 13 28:050-0500	Christine Mina		EPakStateChanged	The ePak progressed to the next workflow state . User UU D : a3b2e181-3aee-4aea-b101-ec31853d0033 User Email : christine.mina@pfizer.com
19 Nov 2020 13 28:050-0500	Christine Mina		RequestSent	Sign request sent to ePak recipient. User UU D : a3b2e181-3aee-4aea-b101-ec31853d0033 User Email : christine.mina@pfizer.com
20 Nov 2020 10:11:005-0500	Cecilia Gabarain	C4591001 Phase 2_3 Audit Cert 19-Nov-2020.pdf	DocumentViewed	Document viewed by signer. User UUID : 6809829b-f9ec-4ac9-bc23-e28cfba721dc User Email : ceciliabeatriz.gabarain@pfizer.com Document UU D : dd1d3c42-4215-4faf-843f-b1d1d2d5c436
20 Nov 2020 10:12:040-0500	Cecilia Gabarain	C4591001 Phase 2_3 Audit Cert 19-Nov-2020.pdf	SignerTagFilled	The signer filled Time Stamp. Value: 20 Nov 2020 10:12:039-0500 User UUID : 6809829b-f9ec-4ac9-bc23-e28cfba721dc User Email : ceciliabeatriz.gabarain@pfizer.com Document UU D : dd1d3c42-4215-4faf-843f-b1d1d2d5c436
20 Nov 2020 10:12:040-0500	Cecilia Gabarain	C4591001 Phase 2_3 Audit Cert 19-Nov-2020.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: None User UUID : 6809829b-f9ec-4ac9-bc23-e28cfba721dc User Email : ceciliabeatriz.gabarain@pfizer.com Document UU D : dd1d3c42-4215-4faf-843f-b1d1d2d5c436
20 Nov 2020 10:12:040-0500	Christine Mina		Completed	The ePak completed the workflow successfully custodian. User UU D : a3b2e181-3aee-4aea-b101-ec31853d0033 User Email : christine.mina@pfizer.com

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