

Study ID and title:	H-34 DELTA Revision
Date:	04/02/2025
Site:	101 - Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Principal Investigator:	Dr. Jerzy Bialcki

From: Aissa Benyattou NAMSA CSM
To: LimaH34 TMF

Subject: H-34 DELTA REVISION Delay for finalizing the monitoring report for site 101

Issue:
The reports for the following visits listed in the table below signed with delay. The timelines for the finalization of visit report are 10 business days, as per Monitoring Plan V1.1 15/Sept/2021. Timeline for report finalization was not respected for the following monitoring visits:



	Visit #: 1	Visit #: 2	Visit #: 3	Visit #: 4	Visit #: 5	Visit #: 7
MV date	18/11/2021	03/02/2022	09/06/2022	04/11/2022	17/05/2023	26/09/2024
Report Signed on	07/12/2021	18/02/2022	28/06/2022	21/11/2022	28/06/2023	21/10/2024
Report should be signed per M plan	02/12/2021	17/02/2022	23/06/2022	18/11/2022	31/05/2023	10/10/2024
Delay per day	3	1	3	1	20	7

Resolution:
Ensure compliance with the monitoring plan for future visits.

Author

Aissa Benyattou NAMSA CSM

Name/Title

Signed by:

 Signer Name: Aissa Benyattou
Signing Reason: I am the author of this document
Signing Time: 04-Feb-2025 | 10:32 EST
C5BBD1694F3B412FAEB05C4686CD069E

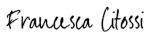

Signature

Date

Approver

Francesca Citossi Lima Manager

Name/Title

Firmato da:

 Nome firmatario: Francesca Citossi
Motivo per la firma: Approvo il documento
Ora firma: 04-Feb-2025 | 16:35 CET

Signature

10372FDFF8B54BDE8D56FA131AAAF8CA
Date

☐ For filling in Trial Master File

Certificate Of Completion

Envelope Id: B1D85E27-A41D-4459-BB42-6EF3B94A32C4

Status: Completed

Subject: Complete with Docusign: Lima H34_Note to file_Late finalization of IMV Report-Signed .pdf

Source Envelope:

Document Pages: 1

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Aissa Benyattou

AutoNav: Enabled

abenyattou@namsa.com

Envelopeld Stamping: Enabled

IP Address: 86.170.144.218

Time Zone: (UTC-05:00) Eastern Time (US & Canada)

Record Tracking

Status: Original

2/4/2025 10:28:18 AM

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abenyattou@namsa.com

Location: DocuSign

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2/4/2025 10:36:04 AM

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Signer Events

Signature

Timestamp

Aissa Benyattou

abenyattou@namsa.com

Clinical Study Mgr.

NAMSA

Security Level: Email, Account Authentication (Required)

Aissa Benyattou

Signature Adoption: Pre-selected Style

Signature ID:

C5BBD169-4F3B-412F-AEB0-5C4686CD069E

Using IP Address: 86.170.144.218

Sent: 2/4/2025 10:31:37 AM

Viewed: 2/4/2025 10:31:54 AM

Signed: 2/4/2025 10:32:26 AM

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Not Offered via DocuSign

Francesca Citossi

francesca.citossi@limacorporate.com

Security Level: Email, Account Authentication (Required)

Firmato da:

Francesca Citossi

Nome firmatario: Francesca Citossi
Motivo per la firma: Approvo il documento
Ora firma: 04-Feb-2025 | 16:35 CET

10372FDF8B54BDE8D56FA131AAAF8CA

Sent: 2/4/2025 10:31:38 AM

Viewed: 2/4/2025 10:35:29 AM

Signed: 2/4/2025 10:36:01 AM

Signature Adoption: Pre-selected Style

Signature ID:

10372FDF-F8B5-4BDE-8D56-FA131AAAF8CA

Using IP Address: 88.32.201.178

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Accepted: 2/4/2025 10:35:29 AM

ID: f408966a-8e2b-405a-a76d-3c8fb7525298

In Person Signer Events

Signature

Timestamp

Editor Delivery Events

Status

Timestamp

Agent Delivery Events

Status

Timestamp

Intermediary Delivery Events

Status

Timestamp

Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	2/4/2025 10:31:38 AM
Certified Delivered	Security Checked	2/4/2025 10:35:29 AM
Signing Complete	Security Checked	2/4/2025 10:36:01 AM
Completed	Security Checked	2/4/2025 10:36:01 AM
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