

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

Signed by:

 Aissa Benyattou

Signer Name: Aissa Benyattou

Signing Reason: I am the author of this document

Signing Time: 04-Feb-2025 | 10:32 EST

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Date

Approver

Francesca Citossi Lima Manager

Firmato da:

 Francesca Citossi

Nome firmatario: Francesca Citossi

Motivo per la firma: Approvo il documento

Ora firma: 04-Feb-2025 | 16:35 CET

Name/Title

Signature

Date

10372FDFF8B54BDE8D56FA131AAAF8CA

For filling in Trial Master File

Note to file list

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Certified Delivery Events	Status	Timestamp
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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
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