

Note to File 05

Date: July 16th 2025
Study ID and title: H-34 DELTA REVISION CUP


Subject: Removal of FU visits from eCRF following protocol amendment

Following the recent protocol amendment (CIP 05 November 2024 v. 2.0), all FU visits at 3 years, 4 years and 5 years have been removed from the electronic Case Report Form (eCRF). Consequently, any patient data that had already been entered into the eCRF for these visits has been deleted to ensure consistency with the updated protocol requirements.


This action was taken to maintain data integrity and compliance with the amended study design. No further data entry related to the removed visits will be permitted in the eCRF.

This note is intended to document the rationale and actions taken in response to the protocol amendment.

Author

Role	Signature	Date
ACLD	<div>Signed by: <i>Ilaria Ciani</i>  Signer Name: Ilaria Ciani Signing Reason: I am the author of this document Signing Time: 16/7/2025 17:06 CEST 706777279D5145EDA32B5EC3D9FCFFA</div>	16/7/2025 17:06 CEST

Approval

Role	Signature	Date
RCMI	<div>Firmato da: <i>Francesca Citossi</i>  Nome firmatario: Francesca Citossi Motivo per la firma: Ho esaminato il documento Ora firma: 21/7/2025 10:24 CEST 10372FDF8B54BDE8D56FA131AAAF8CA</div>	21/7/2025 10:24 CEST

Certificate Of Completion

Envelope Id: 75A7A4B8-6F85-4C7E-BBEF-6C0CB8311B60
 Subject: Complete with Docusign: 20250606_NTF_05_FU deletion eCRF.pdf
 Source Envelope:
 Document Pages: 1
 Certificate Pages: 2
 AutoNav: Enabled
 Envelopeld Stamping: Disabled
 Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna

Status: Completed
 Envelope Originator:
 Ilaria Ciani
 Via Nazionale 52
 Villanova di San Daniele, Udine 33038
 ilaria.ciani@enovis.com
 IP Address: 151.16.35.178

Record Tracking

Status: Original
 7/16/2025 5:00:45 PM
 Holder: Ilaria Ciani
 ilaria.ciani@enovis.com
 Location: DocuSign

Signer Events

Francesca Citossi
 francesca.citossi@enovis.com
 RMCI
 LIMACORPORATE S.p.A
 Security Level: Email, Account Authentication
 (Required)

Signature

Francesca Citossi

Signature Adoption: Pre-selected Style
 Signature ID:
 10372FDF-F8B5-4BDE-8D56-FA131AAAF8CA
 Using IP Address: 93.47.36.144

With Signing Authentication via Docusign password
 With Signing Reasons (on each tab):
 Ho esaminato il documento

Timestamp

Sent: 7/16/2025 5:03:59 PM
 Viewed: 7/21/2025 10:23:53 AM
 Signed: 7/21/2025 10:24:46 AM

Electronic Record and Signature Disclosure:
 Not Offered via Docusign

Ilaria Ciani
 ilaria.ciani@enovis.com
 ACLD
 LIMACORPORATE S.p.A
 Security Level: Email, Account Authentication
 (Required)

Ilaria Ciani

Signature Adoption: Pre-selected Style
 Signature ID:
 70677727-9D51-45ED-AE32-B5EC3D9FCFFA
 Using IP Address: 151.16.35.178

With Signing Authentication via Docusign password
 With Signing Reasons (on each tab):
 I am the author of this document

Sent: 7/16/2025 5:03:59 PM
 Viewed: 7/16/2025 5:04:26 PM
 Signed: 7/16/2025 5:06:24 PM

Electronic Record and Signature Disclosure:
 Not Offered via Docusign

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

Carbon Copy Events	Status	Timestamp
Domizia Baldassi domizia.baldassi@limacorporate.com Security Level: Email, Account Authentication (Required) Electronic Record and Signature Disclosure: Not Offered via DocuSign	<div>COPIED</div>	Sent: 7/16/2025 5:04:00 PM

Witness Events	Signature	Timestamp
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Notary Events	Signature	Timestamp
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Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	7/16/2025 5:04:00 PM
Certified Delivered	Security Checked	7/16/2025 5:04:26 PM
Signing Complete	Security Checked	7/16/2025 5:06:24 PM
Completed	Security Checked	7/21/2025 10:24:46 AM

Payment Events	Status	Timestamps
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