

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	 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 706777279D5145EDAE32B5EC3D9FCFFA	16/7/2025 17:06 CEST

Approval

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

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