

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		

Approval

Role	Signature	Date
RCMI		