Visit Summary

01	Date of this visit: *If for any reason, the entire visit was not completed in1 day, this date should indicate the day the visit began*	__ __ / __ __ / __ __ __ __ (dd/mm/yyyy)
02	Was study product held/discontinued (scheduled or early) at this visit?	☐ Yes ☐ No
03	Did participant exit/terminate the study at this visit?	☐ Yes ☐ No
04	Were any new adverse events (AEs) reported at this visit?	☐ Yes ☐ No
05	Were any new concomitant medications (or changes to concomitant medications) reported at this visit?	☐ Yes ☐ No
06	Were any protocol deviations reported at this visit?	☐ Yes ☐ No
07	*Were any social impacts (benefits or harms) reported at this visit?* *Participants are not asked about social impacts until V9,* ***however they may report an impact unprompted****.*	☐ Yes ☐ No
08	Did the participant sign an updated ICF and/or change their mind about a previous consent addendum? *If yes, update the ICF Summary.*	☐ Yes *(update the ICF Summary)* ☐ No

CRF Completed By: _____ (initials)

CRF Completion Date: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy)