




Visit Summary [V2, V3, V4, V5, V6, V7, V8, V9]

01	Date of visit:  <i>If for any reason, the entire visit was not completed in 1 day, this date should indicate the day the visit began</i>	__ / __ / ____ (dd/mm/yyyy)
02	Was study product held/discontinued (scheduled or early) at this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
03	Did participant exit/terminate the study at this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
04	Were any new adverse events (AEs) reported at this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
05	Were any new concomitant medications (or changes to concomitant medications) reported at this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
06	Were any protocol deviations reported at this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
07	Were any social impacts (benefits or harms) reported at this visit?  <i>While participants are not asked about social impacts at every visit, they may report an impact unprompted.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
08	Did the participant sign an updated ICF and/or change their mind about a previous consent addendum?  <i>If yes, update the ICF Summary.</i>	<input type="checkbox"/> Yes <i>(update the ICF Summary)</i> <input type="checkbox"/> No

CRF Completed By: _____ (initials)

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