SOP 13/V6 Effective Date: 28/04/2021 Validity Date: 10/11/2026

IEC, TMC

AX1-V6/SOP13/V6

Premature Termination / Suspension / Discontinuation Report

Protocol Title: PI:	TMC Project No.:				
E-Mail: Study Site: Sponsor/Funding agency: IEC Approval Date: Date of Last Progress Report Submitted to IEC Please tick the appropriate Premature Termination Suspension Discontinuation Reason for Termination/Suspension/Discontinuation: Study Start Date: Termination / Suspension / Discontinuation Date: Study Participants Termination / Suspension / Discontinuation Date: Study Participants Target accrual of trial (entire study) Total patients to be recruited at TMC (IEC ceiling) Screened: Screened: Finolled: Consent Withdrawn: Reason: (Attach in format below) Withdrawn by PI: Reason: (Attach in format below) Active on treatment: Completed treatment: Patients on Follow-up:	Protocol Title:				
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o Patients on Follow-up:					
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IEC, TMC

o Any other:			
 Any Impaired participants 			
• None			
Physically			
Cognitively			
• Both			
Total number of SAEs reported (if applicable):			
Type of SAEs reported:			
Have any adverse events or outcomes reported to the IEC- ☐ Yes ☐ No ☐ NA			
Have any Protocol deviation/ violation reported to the IEC- ☐ Yes ☐ No ☐ NA			
If yes, please provide the list of reports in tabular form.			
Have there been participant complaints or feedback about the study			
☐ Yes ☐ No ☐ NA If yes Describe			
Had there been any suggestions from the DSMU			
□ Yes □ No □ NA			
If yes, have you implemented that suggestion			
☐ Yes ☐ No ☐ NA Whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., making arrangements for medical care off a research study): ☐ Yes ☐ No ☐ NA If No- provide reasons-			
Summary of Results (if any):			
Budget sanctioned-			
Budget utilized-			
(please enclose UC duly signed by Accounts officer)			
PI Signature: Date:			