

VOICE-C Study-Specific Procedures Manual

Overview of Section Contents and Identification of Current Section Versions

Section Number	Section Title	Current Version Number	Current Version Date	Updates and Comments
19	Household and Community Factors Associated with VOICE Product Adherence Substudy (VOICE-C)	1.0	17 JUN 10	First final version.
19	Household and Community Factors Associated with VOICE Product Adherence Substudy (VOICE-C)	1.1	18 JAN 11	<ul style="list-style-type: none"> • Updated the email address for the VOICE-C management team alias list (throughout) • Section 19.4.2 updated to clarify that a person can only enroll in one group • Section 19.4.3 (Group 1) updated to include guidance to provide participant with VOICE Male Partner Fact Sheet to give to her male partner when permission to contact her partner is granted. • Section 19.5 updated to clarify that VOICE participants may be screened over the phone for VOICE-C if they provide permission to be contacted for this reason during a VOICE visit. • Section 19.6.1 updated to include recommendation that the same staff member carry out all EI for a participant; and the same staff who screens Group 1 IDI participant also conducts the interview.

				<ul style="list-style-type: none"> • Section 19.6.2 updated to clarify that the same pseudonym must be used for each FGD for Group 3 participants; an education session may be held prior to the FGD for Group 3 and Group 4 participants; the EI may be audio-recorded • Section 19.9 updated to include more guidance around social harms related particularly to Groups 1 and 2; relatedness categories for AE/social harms updated to reflect updates in DAIDS EAE Manual version 2.0 • 19.11.10 updated to include guidance on filing requirements for internal query reports as well as those received from RTI • Section 19.11.11 updated to clarify that the EI may be audio recorded and the removal of references to the QQC report
19	Household and Community Factors Associated with VOICE Product Adherence Substudy (VOICE-C)	1.2	18 MAY 11	<ul style="list-style-type: none"> • Revised sample size for Group 3 (~20): LoA#1 • Revised sample size for Group 4 (up to 50): LoA#1 • Removal of reference to ‘recruitment waves’ and update to the randomization section as the randomization scheme was modified in February 2011 • Number and timing of Group 3 FGDs modified: LoA#1 • Number and timing of Group 4 FGDs modified: LoA#1 • Number of EIs to be conducted per G1 randomized to EI modified: LoA#1

				<ul style="list-style-type: none"> • Clarification in section 19.4.3 for Group 1 regarding temporary ineligibility if on product hold • Section 19.4.7: Removal of reference to RTI generated screening/enrollment report • Clarification in Section 19.5- Informed Consent around language and documentation • Addition of Sections 19.5.1 and 19.5.2 • Clarification of language requirements for data collection in Section 19.6.2 • Section 19.6.2: Removal of reference to internal monthly report produced by site based on field notes for EI • Update of Visit Codes in Table 19-3 • Clarifications made in Section 19.11.10 • Clarifications made in Section 19.11.11 • Timeframe for uploading Debriefing Reports for FGD/IDI modified to two weeks after data collection • Clarification that all male partner/community activities with field note reports should be logged in the Supplemental Data Collection Log • Removal of some documents as appendices (these can be found under Study Implementation Materials on the VOICE-C website)
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19	Household and Community Factors Associated with VOICE Product Adherence Substudy (VOICE-C)	1.3	25 JUL 11	<ul style="list-style-type: none"> • Updated to reflect LoA#1 changes • Added guidance to Section 19.6.2 on conducting FGDs • Updated clarification on the transcription and translation QC process and staff training
19	Household and Community Factors Associated with VOICE Product Adherence Substudy (VOICE-C)	1.4	26 JAN 12	<ul style="list-style-type: none"> • Revised to reflect CM#04 including update to Group 1 exclusion criteria • Updated Section 19.5 allowing the signing of the Informed Consent to occur on a different day prior to data collection for FGD participants. • Updated Section 19.6.1 regarding interview scheduling and data collection activities of Group 1 EI participants; there will be a minimum of 2 interviews and may be scheduled after the participant's VOICE TEV.