HCHS/SOL Visit 3 Eligibility & Enrollment Report Guide
7/15/2020

General Instructions

The HCHS/SOL Visit 3 Eligibility & Enrollment Report is a multi-purpose tool designed to assist project staff. Key capabilities of the report include the following.

1. Generating a list of participants who can be scheduled for a Visit 3 appointment (see Scenario One).
2. Generating a list of participants who are initially eligible for an ancillary study (see Scenario Two).
3. Identifying the ancillary studies that a single participant is eligible for (see Scenario Three).
4. Determining the ancillary study procedures that must be completed on a single day during an upcoming Visit 3 appointment (see Scenario Four).

Each of these options will generate a report which consists of (1) Participant Information, (2) Recruitment Information, and (3) Ancillary Study Information (see sections below for details).

Scenario One

To generate a list of participants who can be scheduled for a Visit 3 appointment complete the following steps.

1. Select 'Eligibility & Enrollment Report'.
2. Click 'Ok' to generate the report.

Participants listed in the report have been placed into three waves.

- Wave One – Participants who should be contacted first because they completed Visit 1 or Visit 2 earlier than other participants.
- Wave Two – Participants who should be contacted second because they completed assessments in the middle of Visit 1 or Visit 2.
- Wave Three – Participants who should be contacted last because they completed Visit 1 or Visit 2 later than all other participants.

Scenario Two

To generate a list of participants who are initially eligible for an ancillary study complete the following steps.

1. Select 'Eligibility & Enrollment Report'.
2. Select the appropriate study underneath the *Select Studies of Interest* menu option.
3. Click 'Ok' to generate the report.

Most ancillary studies require participants who are initially eligible to meet additional screening criteria. If a participant does not meet those criteria or declines to participate, that information will be listed.

Scenario Three

Prior to contacting a participant about a Visit 3 appointment, it may help to identify the ancillary studies the participant is eligible for. This can be accomplished by completing the following steps.

1. Select 'Eligibility & Enrollment Report'.
2. Select 'Yes' underneath the *Run Report for Single Participant* menu option.
3. Enter the ID of the participant underneath the *Enter ID* menu option.
4. Click 'Ok' to generate the report.

The eligibility status of the participant will be listed under the column for each ancillary study. If a participant has already been contacted about an ancillary study, that information will also be listed.

Scenario Four

Once multiple participants have been scheduled for a Visit 3 appointment on a specific date, it may help to review which ancillary study procedures must be completed on that date. This can be accomplished by completing the following steps.

1. Select 'Eligibility & Enrollment Report'.
2. Select 'Yes' underneath the *Search by Appointment Date* menu option.
3. Enter the appropriate date underneath *Begin Date* and *End Date* within the *Participants scheduled for appointment between* menu option.
4. Click 'Ok' to generate the report.

Each ancillary study the participants agreed to take part in will be listed under the appropriate column.

Participant Information

The first set of fields in the report provide information about the participant.

- ID – The Subject ID of the participant. If the participant has been transferred between field sites, the transfer ID will be provided and the transition between sites will be described.
- Wave – The wave the participant was assigned to for Visit 3.
- Last Names – The last names of the participant. The paternal, maternal, and legal last name will be provided when applicable.
- First Name – The first name of the participant.
- Gender – The gender of the participant.
- Current Age – The age of the participant on the day the report was generated.
- Language – The preferred language of the participant based on information from Visit 2 and Visit 1.
- Proxy at V2 – An indicator specifying whether a proxy was required during Visit 2.
- Safety – A description of safety information that should be considered when scheduling a participant for an appointment or planning for an upcoming appointment. This includes information about whether the participant (1) is pregnant, (2) requires specialized assistance, (3) has a pacemaker or defibrillator, (4) has been informed by a doctor that they have diabetes, or (5) is able to walk a block without help. If there are additional conditions or special circumstances that must be taken into account, then a reminder will be provided to check the Participant Safety Screen form in CDART.
- V1 Date – The date the Visit 1 assessment was completed.
- Years from V1 – The number of years since Visit 1.
- V2 Date – The date the Visit 2 assessment was completed.
- Years from V2 – The number of years since Visit 2.
- V3 Appointment – The date of the Visit 3 appointment if it has been entered in CDART.
- V3 Date – The date the Visit 3 assessment was completed.
- AFU – Information about the annual follow-up. This includes (1) the most recent AFU attempted, (2) the date of the most recent AFU contact attempt, (3) the status of the most recent AFU contact attempt, and (4) whether the AFU was performed over the phone, at a clinic, or during a home visit.

Recruitment Information

The next set of fields provide information about the order in which ancillary studies should be described to the participant. In most situations, this section will be blank so that each site can determine the sequence that is ideal for their staff.

- Priority – If there is a specific ancillary study that project staff should attempt to recruit the participant for, then that study will be listed.
- Sequence – If there is a specific sequence in which the ancillary studies should be described to the participant, then that sequence will be listed.

Standard Ancillary Study Information

The final set of fields provide standard information about each ancillary study.

- Quota – A site-specific description of whether staff should continue recruiting or if enrollment is completed.
- Eligible – If a participant is initially eligible for the study, then the word 'Yes' will be listed. If a participant is not eligible, then the word 'No' will be listed. If a participant is not currently eligible but will be at a later date, then the phrase 'Not yet' will be listed.
- Screened – Most ancillary studies require eligible participants to be screened prior to enrollment. The description of screening efforts varies across studies. Common options include 'Unable to Contact', 'Refused Screening', 'Ineligible', 'Eligible but Refused', and 'Agreed'. If a participant has not been screened, then the field will be blank.
- Appointment – If an appointment for the ancillary study has been entered into CDART, then that date will be displayed. In all other cases, the field will be blank.
- Participation – If a participant has consented to take part in an ancillary study, then the word 'Yes' will be listed. In all other cases, the field will be blank.

Custom Ancillary Study Information

Some ancillary studies have unique requirements that require customized fields. Examples of custom fields include the following.

- Date Eligible – Participants who take part in PASOS, NAFLD, and OJOS must be above a certain age when they enroll in the study. This field indicates the date on which the participant is old enough to enroll.
- Kit Distribution – Participants who take part in GOLD 2 will be given a specimen kit. The date on which the kit was provided to the participant is displayed.
- Kit Return –The date on which the GOLD 2 specimen kit was returned by the participant is displayed. It has not been returned, the field will be blank.