

ASPIRE: Common QCs Across Sites

Eligibility Criteria (ECI-1) CRF

- If a participant rescreens for the study after a failed screening attempt, the *same* ECI-1 CRF from the initial screening attempt must be updated at the participant's second screening visit. (DO not complete a new ECI-1 CRC). All updated items, including the form completion date, must be updated, initialed, dated, and faxed to SCHARP.

Screening Menstrual History (SMH-1) CRF

- Item 4: If the participant's usual maximum number of bleeding days is greater than 99 days, please record '99' in item 4 and provide details in Item 8 as needed.
- Item 6: If the participant is on her menses during her Screening Visit and this item is marked 'ongoing', do not revisit this CRF at a later visit to update this item. We will collect this data on the Baseline Family Planning CRF at the Enrollment Visit

Screening/Quarterly Laboratory Results (SLR-1, QLR-1)

- Item 2c.Creatinine, has two unit options to record the values. Only record the result in the units listed on the source document. If both options are completed, sites will be instructed to line through one option and re fax to SCHARP. The option to record this value in either unit (mg/dL or $\mu\text{mol/L}$) is provided so that sites do not need to calculate unit conversions for this result.

Visit Summary (VS-1)

- If this form is completed at an Interim Visit, note that after Item 5b is completed, there is an instruction to skip Items 6 and 7. Items 6 and 7 should only be completed at scheduled visits.

Completion of Missed Visit (MV-1) CRF and Protocol Deviation Log CRF (PDL-1)

- If a participant misses a scheduled, monthly visit, a Missed Visit (MV-1) CRF should be completed. While this is considered a protocol deviation, a Protocol Deviation Log CRF *does not* need to be completed as well. The MV-1 will document that both the visit was missed and the corrective action plan (Item 3) to address the protocol deviation. If a

PDL-1 is completed for a missed visit, sites should delete the appropriate log page and refax to SCHARP.

Ring Adherence (RA-1) CRF

- If a participant missed her last scheduled monthly visit and was dispensed a ring at her last visit, the participant is considered to have a ring in her possession and item 1 should be marked 'yes'. The remaining items on this form pertain to the previous month only.

Ring Collection/Insertion (RCI-1) CRF

- Pay particular attention to the skip patterns on this form. For example, in Item 2, if the number of used rings collected is "none", "2" or "3", a reason for this collection is required to be specified in Item 2a.
- If a new ring is not dispensed at this visit and item 4a is completed, skip items 5 and 6 and go to item 7. In item 4a, if a participant declines the study ring, ensure that a reason is specified in the line provided. If 1 or more new rings are dispensed to the participant, items 5, 6 and 7 are required.

Specimen Storage (SS-1) CRF

- If Item 2 (Endocervical swab for biomarkers) is marked as 'stored', ensure that there is a response for item 2a "Was blood visible on the swab?" If the swab was 'not required' or 'not stored', record the reason.