**United States-Latin American-Caribbean HIV/HPV-Cancer Prevention Clinical Trials Network (ULACNet) Accrual Quality Improvement Program (AQuIP) Responsibilities**

**Lead Academic Organization (LAO) AQuIP Responsibilities**

1. Monthly submission of each Affiliate Organization’s (AO) AQuIP Accrual report.
   1. The AQuIP Accrual Report is a cumulative report that covers the first month the site is open through the current reporting month.
   2. The AQuIP Accrual Report for each AO should be submitted to the DCP Help Desk ([DCPhelpdesk@dcpais.com](mailto:DCPhelpdesk@dcpais.com)) by the 10th of each month.
   3. Each LAO should designate a staff member to oversee AQuIP Accrual Report submission and any data queries.
   4. The reports may be submitted to TRI in Spanish, Portuguese, or English. The reports will be translated to English by TRI staff.
2. Monthly submission of the Recruitment Journal Study Events spreadsheet.
   1. The recruitment journal study events spreadsheet is a cumulative report completed by the LAO to record any study updates or issues at the LAO or AOs that could positively or negatively affect accrual.
   2. Recruitment Journal Study events may include:
      1. Protocol amendments that may affect accrual. *Updated inclusion/exclusion criteria, a decrease in the number of study visits, an in-office visit is changed to a telephone contact, etc.*
      2. Staffing issues/turnover. *A staff member goes on maternity or medical leave, staff member retires, or issues/delays with training staff members on equipment or procedures.*
      3. Drug/vaccine shipment delays. *Issues at the pharmacy with the distribution of study drug or study vaccine, issue at the sponsor level with study drug or study vaccine availability, etc.*
      4. Clinical holds. *Accrual at the site is on hold for any reason including holds required by the Sponsor, FDA, or Ministry of Health.*
      5. The addition or removal of sites. *A new site is added to the protocol, a site is closed or removed from the protocol because of accrual issues, etc.*
   3. The LAO should submit the Recruitment Journal Study Events spreadsheet by the 10th of each month, or if there are no events that month, an email should be sent to the DCP Help Desk notifying the help desk that there were no events to add for the month.
      1. The Recruitment Journal Study Events spreadsheet is sent to the DCP Help Desk ([DCPhelpdesk@dcpais.com](mailto:DCPhelpdesk@dcpais.com)). The spreadsheet can be included with the monthly accrual report submission.
3. LAO will notify TRI via the DCP Help Desk of any changes to staff that oversee the journal submission.
4. LAO will notify TRI via the DCP Help Desk of any changes to staff that need to be included or removed from the monthly distribution. This includes changes to LAO and AO staff members.

**Affiliate Organization (AO) AQuIP Responsibilities**

1. Monthly completion of the AQuIP Accrual Report.
   1. The completed reports should be emailed, as an attachment, to the LAO (UCSF, Cornell, or Fred Hutchinson) before the 10th of each month.
   2. For each participant, the strategy that was used in the recruitment process and the staff involved are documented.
      1. Try to limit the use of “**J01 – Other**” when completing the recruitment strategy. For example, if the strategy entered is “**Other**”, but the “**Specify**” column notes that the participant was called using a previous study list, the correct category would be “**B05 - Contact from Previous Study**”.
   3. For participants that do not sign consent or sign consent but do not start study intervention, document the reason consent was not signed or the reason study drug was not started.
      1. The reason a participant does not sign the consent or start study intervention can be because they decline participation in the study for any reason, many of which are listed on the “**Reasons Not**” drop-down, or because the participant does not meet eligibility criteria.
      2. A list of the “**Reason(s) Consent NOT Signed”/ “Study Intervention NOT Started**” and the definition for each selection can be found in the “**Reasons Not**” tab of the AQuIP Accrual Report. Please consider all options from the list before making your selection and only use “**Other**” if there is not a more appropriate category to select from.
      3. The comments field can be used to add any additional information regarding the participant that does not fit in the “**Specify**” columns.
2. Review and reply to all queries each month.
   1. Each month the AQuIP Accrual report will be reviewed for queries by TRI. If any queries are noted, the AQuIP Accrual Report Query List will be sent to the LAO. The LAO will review the query list with site personnel at the AO. Site personnel will provide the updated information directly to the AQuIP Accrual Report by the next monthly submission.
   2. Please remember to be as complete, up-to-date, accurate, and consistent as possible when filling in the data fields for a participant to avoid queries.