2012 Consortia

Accrual Quality Improvement Online Accrual Reporting System (AQuIP OARS) Refresher Training

Tiana Tower, B.S.
DCP Help Desk Specialist

Technical Resources International (TRI), Inc.
monitoring, auditing and informatics support
Outline

• Review the AQuIP OARS monthly deliverable process, account creation, and maintenance

• Discuss updates to the monthly ZMR deliverable and the AQuIP OARS Pre-screen feature

• Identify the three most common data entry errors resulting in queries
  ➢ How to avoid queries
  ➢ Shortcuts and tips
AQuIP Reporting

Final AQuIP Reports due the 10th of each month

CLOs and POs address queries and submit new accrual data

Reminder sent if not received after 2 business days

Help Desk notifies CLOs of submission acceptance and any new queries

Help Desk reviews new data for completeness and accuracy and queries incomplete data

Help Desk reviews queries from the previous month

CLOs and POs address queries and submit new accrual data

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Monthly Distribution

Final AQuIP Reports due the 10th of each month

Reminder sent if not received after 2 business days

Help Desk reviews queries from the previous month

Help Desk reviews new data for completeness and accuracy and queries incomplete data

Help Desk notifies CLOs of submission acceptance and any new queries

CLOs and POs address queries and submit new accrual data

Help Desk reviews queries from the previous month

Excel Spreadsheets

Zone Monitoring Reports
AQuIP Account Maintenance

• Account inactivity reviewed every 90 days
• User instructed to log into AQuIP OARS within 30 days
• Deactivation if inactivity persists
• Contact DCP Help Desk for account activation
Dear CLO Lead Coordinator,

Thank you for submitting your Accrual Report via AQuIP OARS. Please find the attached annotated accrual zone monitoring report and OARS export.

During our review, we identified records that require review and correction. Accrual and Journal Event data queries are now created, displayed, addressed, verified, and resolved within OARS. Please access the AQuIP OARS Query List to address data corrections before the 10th of next month. The CLO/PO corrections will be reviewed/resolved the following month by the OARS administrator at the DCP Help Desk.

The following sites have not submitted a Recruitment Journal Study Event in the past month:

<table>
<thead>
<tr>
<th>CLO/PO</th>
<th>Date of Most Recent Study Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>Month Day, Year</td>
</tr>
<tr>
<td>Site 2</td>
<td>Month Day, Year</td>
</tr>
<tr>
<td>Site 3</td>
<td>Month Day, Year</td>
</tr>
</tbody>
</table>

To capture the factors that may have favorably or unfavorably impacted accrual (or potentially may do so in the future), please enter a Study Event into AQuIP OARS OR respond to this email including any recruitment activity from the previous month and the DCP Help Desk will enter the data into AQuIP OARS on the site’s behalf.

Quick Tips: Try using Ctrl+F for each PID to locate each record. This may help you quickly find the applicable record.

For questions or support please contact the DCP Help Desk at dcphelpdesk@dcpis.com or 1-844-901-4357.

Kind regards,

Casey Deans
DCP Help Desk
Updating Recruitment Journal Data

Add Study Event

- Study Event Start Date: 10/07/2019
- Study Event End Date: 11/07/2019
- Study Event: AIR - Staff issues: CLO Staff Turnover/ Availability
- Study Event Description: Change in PI
- POs Affected: Division of Cancer Prevention PO

OR

Email:

Subject: Accrual Zone Report for Protocol # (Agent/Organ), MM/YYYY

Dear CLO Lead Coordinator,

Thank you for submitting your Accrual Report via AQUIP-OARS. Please find the attached annotated accrual report.

During our review, we identified records that require review and correction. Accrual and Journal Event data should be addressed, verified, and resolved within OARS. Please access the AQUIP OARS Query List to address data corrections.

CLO/P0 corrections will be reviewed/resolved the following month by the OARS administrator at the DCP Help Desk.

The following sites have not submitted a Recruitment Journal Study Event in the past month:

<table>
<thead>
<tr>
<th>CLO/P0</th>
<th>Date of Most Recent Study Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>Month Day, Year</td>
</tr>
</tbody>
</table>
Protocol # (Agent/Organ) - Reasons Not Consented

This report displays the reasons participants did not sign consent.

<table>
<thead>
<tr>
<th>Reason</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decline</td>
<td>1</td>
<td></td>
<td>28</td>
</tr>
<tr>
<td>Surgery Timing</td>
<td>7</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Too Many Procedures or Invasiveness of Procedures</td>
<td>7</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>Passive Decline</td>
<td>6</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Agent Toxicity</td>
<td>8</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Comorbidity/Medical History</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Eligibility Procedure Timing</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Family's Concerns</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Overwhelmed with Recent Diagnosis</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Protocol Eligibility Criterion</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Route, Frequency or Duration of Study Agent Administration</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Insurance</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Lives Out of Area/Patient Not Local</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Medical Research Attitudes</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Medical Scheduling Issues</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy-Related Issue</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Too Many Visits or Length of Appointments</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Color by Site Name:
- Site 1
- Site 2
- Site 3

Number of Participants
Protocol # (Agent/Organ) - Reasons Not Started Intervention

This report displays the reasons participants did not start study intervention.

Color by Site Name

Age

Other

Number of Participants

Site 1
• Optional feature for users to capture data for potential participants

• Establish protocol-specific pre-screen criteria

• Determine if chart is appropriate for continued eligibility screening prior to contact
**Pre-screen Information**

Pre-screen: An individual who meets the protocol-specific preliminary eligibility criteria (as defined by the CLO), and is thus qualified for continued eligibility screening via further review of records prior to contacting that individual.

**Participant ID (PID):**

**Date of Pre-screen:**

**Pre-screen Strategy:**

**Pre-screen Outcome:**

Eligible for Contact, Not Eligible for Contact

**Pre-screen Comments:**
# AQuIP OARS Pre-screen Fields

**Pre-screen Information**

Pre-screen: An individual who meets the protocol-specific preliminary eligibility criteria (as defined by the CLO), and is thus qualified for continued eligibility screening via further review of records prior to contacting that individual.

<table>
<thead>
<tr>
<th>Field</th>
<th>Label</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant ID (PID)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Pre-screen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-screen Strategy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-screen Outcome</td>
<td></td>
<td>Eligible for Contact, Not Eligible for Contact</td>
</tr>
<tr>
<td>Pre-screen Comments</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Pre-screen Information**

Pre-screen: An individual who meets the protocol-specific preliminary eligibility criteria (as defined by the CLO), and is thus qualified for continued eligibility screening via further review of records prior to contacting that individual.

<table>
<thead>
<tr>
<th>Field</th>
<th>Label</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant ID (PID)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Pre-screen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-screen Strategy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-screen Outcome</td>
<td></td>
<td>Eligible for Contact, Not Eligible for Contact</td>
</tr>
<tr>
<td>Reason NOT Eligible for Contact</td>
<td>Reason(s)</td>
<td>+ Add/Edit</td>
</tr>
<tr>
<td>Pre-screen Comments</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Protocol # (Agent/Organ) - Number of Charts Pre-screened

This report displays the number of charts pre-screened by each site for this protocol each month. Please note that recent months will not be displayed if no pre-screens were made.

Color by Site Name:
- Site 1
- Site 2
- Site 3

Number of Charts Pre-screened
Protocol # (Agent/Organ) - Pre-screens Eligible for Contact

This report displays the number of charts pre-screened who were eligible for contact by each site for this protocol each month. Please note that recent months will not be displayed if no charts were eligible for contact.

Date of Pre-screen (Month)
Protocol # (Agent/Organ) - Pre-screen Reasons Not Eligible for Contact

This report displays the reasons the charts pre-screened were not eligible for contact.

- **Prohibited Concomitant Medication**: 2 (Site 1), 12 (Site 2), 13 (Site 3)
- **Comorbidity/Medical History**: 1 (Site 1), 11 (Site 2), 11 (Site 3)
- **Other**: 8 (Site 1), 2 (Site 2), 4 (Site 3)
- **Protocol Eligibility Criterion**: 2 (Site 1), 6 (Site 2), 8 (Site 3)
- **Age**: 5 (Site 1), 5 (Site 2), 5 (Site 3)
- **Prior Cancer**: 4 (Site 1), 1 (Site 2), 5 (Site 3)
- **PI Decision**: 1 (Site 1), 3 (Site 2), 4 (Site 3)
- **Pregnancy Related Issue**: 1 (Site 1), 3 (Site 2), 4 (Site 3)
- **Surgery Timing**: 3 (Site 1), 1 (Site 2), 4 (Site 3)
- **Eligibility Procedure Timing**: 2 (Site 1), 1 (Site 2), 3 (Site 3)
- **Lab Values**: 2 (Site 1), 2 (Site 2)
- **Lack of Targeted Disease, Pathology or Biomarker**: 1 (Site 1), 1 (Site 2), 2 (Site 3)
## Protocol # (Agent/Organ) - Recruitment Summary

This report displays the number of charts screened, pre-screens eligible for contact, participants contacted, signed consent and started intervention by site.

<table>
<thead>
<tr>
<th>Charts Screened</th>
<th>Eligible for Contact</th>
<th>Contacted</th>
<th>Signed Consent</th>
<th>Started Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>30</td>
<td>41</td>
<td>18</td>
<td>12</td>
</tr>
<tr>
<td>Site 2</td>
<td>41</td>
<td>38</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td>Site 3</td>
<td>80</td>
<td>52</td>
<td>47</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td>204</td>
<td>110</td>
<td>101</td>
<td>46</td>
</tr>
</tbody>
</table>
Common Queries

- Missing Recruitment (or Pre-screen) Strategy: 29%
- Change Consent/Intervention Status: 8%
- All Other Queries: 3%
- Protocol Eligibility Criteria Not Listed Above to different Reason: 3%
- No Contacts in > 1 Month (without Journal Entry): 11%
- 'Other' as a Reason(s) Consent NOT Signed/Study Intervention NOT Started: 46%
Common Queries

- Missing Recruitment (or Pre-screen) Strategy: 46%
- Change Consent/Intervention Status: 29%
- 'Other' as a Reason(s) Consent NOT Signed/Study Intervention NOT Started: 3%
- Protocol Eligibility Criteria Not Listed Above to different Reason: 8%
- No Contacts in > 1 Month (without Journal Entry): 11%
- All Other Queries: 3%

Protocol Eligibility Criteria Not Listed Above to different Reason:
Missing Recruitment (or Pre-screen) Strategy Queries

Protocol Staff

AND

Recruitment Strategy

Recruitment Strategies

Include multiple staff when applicable and select the applicable strategy(ies) used. When selecting a protocol staff member as a Recruitment Strategy, please specify the applicable name if possible or enter 'not available' if the name is unknown/not available.

- PROTOCOL STAFF RECRUITMENT
- EXISTING DATABASE
- U.S. POSTAL SERVICE OR EMAIL
- TELEPHONE CALLS
- REFERRAL
- NON-DIGITAL MASS MEDIA
- SOCIAL/DIGITAL MEDIA
- COMMUNITY CONTACTS
- PATIENT ISSUES/CONCERNS
- Other
### Participant Accrual Queries

<table>
<thead>
<tr>
<th>Participating Organization (PO)</th>
<th>Participant ID</th>
<th>Query</th>
</tr>
</thead>
<tbody>
<tr>
<td>Division of Cancer Prevention PO</td>
<td>103456</td>
<td><a href="#">Thank you for providing the Protocol Staff member in the Recruitment Strategies (or Prescreen Strategy) field for this entry. To provide greater recruitment strategy insights, please select an additional Recruitment Strategy to indicate which recruitment strategy was used by the 'Principal Investigator'.</a></td>
</tr>
</tbody>
</table>

**Query Open Date (MM/DD/YYYY):** 10/08/2019
Entering Recruitment Strategies into AQuIP OARS

Add Participant Accrual Information

- **Participant ID (PID):** 104567
- **First Contact Date:** 10/08/2019
- **Recruitment Strategies:** Recruitment Strategies
- **Consent Date/Status:** Consent Date/Status
- **Intervention Start Date:** Intervention Start Date
- **Reason(s) Consent NOT Signed/Study Intervention NOT Started:**
- **Comments:** Comments

[Submit] [Close]
## Entering Recruitment Strategies into AQuIP OARS

<table>
<thead>
<tr>
<th>Status Marker</th>
<th>Participant ID</th>
<th>First Contact Date</th>
<th>Recruitment Strategies</th>
<th>Consent Date/Status</th>
<th>Reason(s) Consent NOT Signed/Study Intervention NOT Started</th>
<th>Intervention Start Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>104567</td>
<td>October 06, 2019</td>
<td>Research Nurse (Jane Smith) Clinic Schedules</td>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Avoiding Missing Recruitment (or Pre-screen) Strategy Queries

Recruitment Strategies

Include multiple staff when applicable and select the applicable strategy(ies) used. When selecting a protocol staff member as a Recruitment Strategy, please specify the applicable name if possible or enter “not available” if the name is unknown/not available.

- PROTOCOL STAFF RECRUITMENT
- EXISTING DATABASE
- U.S. POSTAL SERVICE OR EMAIL
- TELEPHONE CALLS

Appendix A – AQuIP OARS Recruitment Strategies

Include multiple staff when applicable and select the applicable strategy(ies) used. When selecting a protocol staff member as a Recruitment Strategy, please specify the applicable name, if possible, or enter “not available” if the name is unknown/not available.

- Protocol Staff Recruitment (Protocol Staff member involved in recruitment of individual participant)
- Non-Digital Mass Media

- Existing Data
- Social/Digital Media
Common Queries

- Missing Recruitment (or Pre-screen) Strategy: 46%
- Change Consent/Intervention Status: 29%
- ‘Other’ as a Reason(s) Consent NOT Signed/Study Intervention NOT Started: 8%
- Protocol Eligibility Criteria Not Listed Above to different Reason Not: 3%
- No Contacts in > 1 Month (without Journal Entry): 11%
- All Other Queries: 3%
<table>
<thead>
<tr>
<th>Status Marker</th>
<th>Participant ID</th>
<th>First Contact Date</th>
<th>Recruitment Strategies</th>
<th>Consent Date/Status</th>
<th>Reason(s) Consent NOT Signed/Study Intervention NOT Started</th>
<th>Intervention Start Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>✨</td>
<td>104567</td>
<td>October 08, 2019</td>
<td>Research Nurse (John Smith), Clinic Schedules</td>
<td>Not Signed</td>
<td>Other (Lives Out of Area)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Participant Accrual Queries

<table>
<thead>
<tr>
<th>Participating Organization (PO)</th>
<th>Participant ID</th>
<th>Query</th>
</tr>
</thead>
<tbody>
<tr>
<td>Division of Cancer Prevention PO</td>
<td>104567</td>
<td>Please select the Participant Accrual tab, edit the specified record, and revise &quot;Reason Consent NOT Signed/Study Intervention NOT Started&quot; from &quot;Other&quot; to &quot;Lives Out of Area/Patient Not Local&quot; to match the content in the &quot;specify here&quot; field. If this query has not been resolved by the next reporting period, the Help Desk will map the site's entry in the &quot;specify here&quot; field to the appropriate selection from the dropdown list for the site staff to review. If the site does not object, the mapped entry will remain.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10/08/2019</td>
</tr>
</tbody>
</table>
Entering Reason(s) Consent NOT Signed/Study Intervention NOT Started into AQuIP OARS
### Reason Consent NOT Signed or Study Intervention NOT Started Table

**Logistics**
- Non-Medical Scheduling Issues
  - Transport/Commute/Parking
  - Insurance
  - Compensation/Reimbursement
- Lives Out of Area/Patient Not Local

**Study Related Issues**

**Participant Attitude and Concern**

**Other**
<table>
<thead>
<tr>
<th>Reason Consent NOT Signed or Study Intervention NOT Started Table</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select all that apply.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>▶ ELIGIBILITY CRITERIA NOT MET</td>
</tr>
<tr>
<td>▶ LOGISTICS</td>
</tr>
<tr>
<td>▶ STUDY RELATED ISSUES</td>
</tr>
<tr>
<td>▶ PARTICIPANT ATTITUDE AND CONCERN</td>
</tr>
<tr>
<td>▶ Other</td>
</tr>
<tr>
<td>□ Overwhelmed with Recent Diagnosis</td>
</tr>
<tr>
<td>□ Pursuing Alternative Treatment Option</td>
</tr>
<tr>
<td>□ Site Study Accrual Complete</td>
</tr>
</tbody>
</table>
Avoiding ‘Other’ as Reason(s) Consent NOT Signed/Study Intervention NOT Started Queries

<table>
<thead>
<tr>
<th>Reason Consent NOT Signed or Study Intervention NOT Started</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligibility Criteria Not Met</td>
<td>Lab values that fall outside of range specified per protocol.</td>
</tr>
<tr>
<td>Prior Cancer</td>
<td>History of cancer (type &amp;/or diagnosis timing) as specified in protocol exclusion criteria.</td>
</tr>
<tr>
<td>Age</td>
<td>Age falling outside of range specified per protocol.</td>
</tr>
<tr>
<td>Pregnancy-Related Issue</td>
<td>Includes issues pertaining to willingness to adhere to birth control as specified per protocol.</td>
</tr>
<tr>
<td>Allergy to Related Drugs (Specify Here)</td>
<td>History of allergy to study related drug, drug class or those specified in protocol.</td>
</tr>
<tr>
<td>Prohibited Concomitant Medication (Specify Here)</td>
<td>Taking protocol-prohibited medications and unwilling to discontinue, or discontinuation is not medically advised.</td>
</tr>
<tr>
<td>Comorbidity/Medical History (Specify Here)</td>
<td>Any concurrent illness or disorder reported or as documented in the patient record that is excluded in the protocol eligibility criteria.</td>
</tr>
<tr>
<td>Eligibility Procedure Timing (Specify Here)</td>
<td>Protocol required schedule of events does not align with standard of care (SOC) guidelines, medical indication, or insurance requirements. Note: for non-timing related insurance denials please select “Insurance”.</td>
</tr>
<tr>
<td>Surgery Timing</td>
<td>Unwilling to delay procedure/surgery or delay is not medically indicated.</td>
</tr>
<tr>
<td>Lack of targeted disease, pathology or biomarker (Specify Here)</td>
<td>Does not have the targeted disease, condition, or severity of condition. Usually determined after screening procedure(s).</td>
</tr>
<tr>
<td>In decision (Specify Here)</td>
<td>Participation not advised per IR.</td>
</tr>
<tr>
<td>Protocol Eligibility Criteria NOT Listed Above (Specify Here)</td>
<td>Any eligibility criterion not specified in the other “Reasons Not” options above.</td>
</tr>
</tbody>
</table>
Common Queries

- Missing Recruitment (or Pre-screen) Strategy: 46%
- Change Consent/Intervention Status: 3%
- ’Other’ as a Reason(s) Consent NOT Signed/Study Intervention NOT Started: 29%
- Protocol Eligibility Criteria Not Listed Above to different Reason Not: 8%
- No Contacts in > 1 Month (without Journal Entry): 11%

All Other Queries: 3%
No Contacts in > 1 Month (without Journal Entry) Queries

<table>
<thead>
<tr>
<th>Participating Organization (PO)</th>
<th>Study Event Start Date</th>
<th>Query</th>
<th>Query Open Date (MM/DD/YYYY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Division of Cancer Prevention PO</td>
<td>November 22, 2018</td>
<td>Division of Cancer Prevention PO has not made any contacts since August 2019. Please select the Recruitment Journal tab, and provide a Study Event to define any recruitment impediments, if applicable.</td>
<td>11/27/2018</td>
</tr>
</tbody>
</table>
Avoiding No Contacts in > 1 Month (without Journal Entry) Queries
Shortcuts and Tips to AQuIP OARS

• Split screen
• ‘Ctrl’ + ‘F’ for PC and ‘Command + F’ for MAC
• ‘Expand All’
AQuIP Support and Resources

- **AQuIP Website**
  - **Training and Resources Section**
    - AQuIP OARS User Guide
    - AQuIP OARS Pre-screen User Guide
    - AQuIP OARS Training demonstration
- DCP SOP6: Participant Recruitment, Retention and Adherence
- **2012 Clinical Trial Management Website**
- DCP AIS Help Desk
  - [DCPhelpdesk@dcpais.com](mailto:DCPhelpdesk@dcpais.com)