This User Guide provides an introduction to the AQuIP On-line Accrual Reporting System (OARS) for the Division of Cancer Prevention (DCP) Consortia 2012 clinical trials. AQuIP OARS is a system for collecting and reporting study participant level accrual data to DCP on a monthly basis.

Please note:
- For questions, please contact the DCP Help Desk at dcphelpdesk@dcpais.com or 1-844-901-4357

Table of Contents

AQuIP OARS Process Overview ............................................................................................................................................ 1
How to Request Access to AQuIP OARS .................................................................................................................................. 2
Participating Organization (PO) Accrual Reporting ....................................................................................................................... 4
Consortia Lead Organization (CLO) Accrual Reporting .................................................................................................................. 17
How to Submit the Monthly Accrual Report .......................................................................................................................... 29
Frequently Asked Questions ......................................................................................................................................................... 31

AQuIP OARS Process Overview

Accrual and recruitment journaling data entry is done in real time at the accruing PO or CLO. By the 10th of every month the affiliated CLO reviews the POs’ accrual data from the prior month, clarifies and/or modifies as necessary and then submits the data to the DCP Help Desk at TRI. The DCP Help Desk then aggregates the data, performs data integrity checks and sends data queries back to the CLOs for resolution with their respective POs as needed. TRI then generates the AQuIP Zone Monitoring Reports which show how actual accrual rates compare to the projected accrual rate. This accrual performance status helps DCP and CLOs identify the need for strategic modifications. This cycle of reporting and ongoing evaluation occurs each month and is the basis for continuous improvement. Furthermore, all accrual outcomes data are being collected, aggregated, analyzed and mined to find "lessons learned" to apply when developing future protocols and recruitment plans.
How to Request Access to AQuIP OARS

AQuIP OARS accounts may be requested when a protocol has been approved by DCP. A request for AQuIP OARS access is initiated by the CLO since CLOs may differ in how they manage accrual tracking and reporting per DCP SOP 6: Participant Recruitment, Retention and Adherence.

Please contact your CLO Lead Coordinator to submit an access request on your behalf following the instructions below:

1. CLO Lead Coordinator/designee sends an AQuIP OARS access request to the DCP Help Desk confirming the 20 minute AQuIP OARS training webinar and user guide have been reviewed by the individual specified, and therefore has completed the AQuIP OARS training. Please send your requests using the following table format and include all requested information:

<table>
<thead>
<tr>
<th>DCP Protocol Number/Agent/Organ (list each)</th>
<th>First/Last Name</th>
<th>Site Designation (CLO or PO)</th>
<th>Site Name</th>
<th>Confirmation of webinar training (complete)</th>
<th>Confirmation of user guide training (complete)</th>
<th>Email address</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
2. DCP Help Desk submits the CLO’s request to DCP for approval.
3. An AQuIP OARS account is created and credentials are provided within two (2) business days from receipt of DCP’s approval.
   a. The password may be reset by selecting the “Password Reset” button on the “Accrual Report” login page and entering your email address. Next, select the “Password Reset” button to prompt an email notification, which includes a link to change your current password. Please note: this email notification may be sent to your clutter/junk folders.

Please note: Account activity will be reviewed by the DCP auditing and informatics support contractor at Technical Resources International (TRI), Inc. Account holders that have not logged into the system for more than 90 days (approximately 3 months) will be identified as candidates for inactivation. An email will be sent requesting the account holder to login into the system and thereby confirm the account is still needed. Upon confirmation that the account is no longer needed or if no response is received within 30 calendar days of the request for confirmation, the account will be deactivated without further notification. The CLO Lead Coordinator/designee must notify the DCP Help Desk when a CLO or PO user no longer needs access to AQuIP OARS.
4. Once access is granted, select the **Accrual Report** tab.

5. Log into AQuIP OARS using your account credentials provided by the DCP Help Desk and select **Log In**.
Participating Organization (PO) Accrual Reporting

Participating Organizations (PO) are the DCP Consortia accrual sites affiliated with the CLOs. Please note: Jane Doe is used as an example of a PO user to illustrate the AQuIP OARS process below.

1. Once logged in, the Assigned Protocol page appears, listing all protocol numbers assigned to Jane Doe at University of Chemoprevention. In addition, the following columns are displayed:
   - CLO Name
   - Study Status
   - Target Enrollment
   - Total Number of Participants Started Study Intervention

   Please note: All columns, with the exception of the CLO Name, can be sorted in ascending/descending order by clicking on the column header.

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>CLO Name</th>
<th>Study Status</th>
<th>Target Enrollment</th>
<th>Total Number of Participants Started Study Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>CL02016-02-01</td>
<td>Consortia Lead Organization</td>
<td>Active</td>
<td>120</td>
<td>4</td>
</tr>
<tr>
<td>CL02016-04-01</td>
<td>Consortia Lead Organization</td>
<td>Active</td>
<td>80</td>
<td>3</td>
</tr>
</tbody>
</table>

2. To continue, select Protocol **CL020 16-02-01**.
3. Next, the information for Protocol CL02016-02-01 appears along with the following tabs to enter additional data:
   a. **Protocol Information**: Displays the current status for Protocol CL020 16-02-01.
   
   ![Protocol Information Screen]

   **Protocol Information**

   - **Current Reporting Month**: April 2017
   - **Protocol Title**: Randomized Phase X Trial of Agent B in High Risk Individuals
   - **Protocol Number**: CL02016-02-01
   - **Targeted Enrollment**: 120
   - **Total Number of Participants Started Study Intervention**: 4
   - **Projected Accrual Per Month**: 8.00
   - **Projected Completion Date**: June 12, 2018
   - **Study Status**: Active
   - **Study Status Date**: March 27, 2017
   - **Accrual Duration (Months)**: 15
   - **Approved Participating Organizations**:
     - University of Chemoprevention
     - Chemoprevention Institute
   - **Date of First Contact**: March 08, 2017

   b. **Participant Accrual**: Next, select the **Participant Accrual** tab to view, edit, or delete participant information.

   ![Participant Accrual Screen]
The Participant Accrual Page opens. On this page, you can view/edit the following columns:

- **Status Marker**: Each participant accrual record includes a Status Marker reflecting the accrual progression status as either Contacted, Consented, Not on Study or On Study.
- **Participant ID***
- **First Contact Date***
- **Recruitment Strategies**
- **Consent Date/Status***
- **Reasons Consent NOT Signed/Study Intervention NOT Started**
- **Intervention Start Date***
- **Comments**

Please note: * These columns can be sorted in ascending/descending order by clicking on the column header.

### How to Add a New Participant

**Step 1:** Select +Add New Participant on the Participant Accrual page.

**Step 2:** The Add Participant Accrual Information Page appears.
Step 3: Next, enter the **Participant ID**.

![Add Participant Accrual Information](image)

**Please note:** For quality assurance purposes, the *AQuIP OARS System does not allow for duplicate or blank, placeholders and/or participant IDs.* In the event a CLO does not have a standard screening (or placeholder ID) procedure, we offer the following screening/placement ID numbering convention until participants receive a unique ID. The Participant ID # field (PID) should be populated with this screening/placement and replaced with the PID upon study enrollment [by the accruing site]. As this is a recommendation, CLOs are welcome to follow this process or apply the necessary institutional conventions to avoid blank or duplicate IDs.

<table>
<thead>
<tr>
<th>Participant Entered into AQuIP OARS</th>
<th>Participant ID #</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Participant Entered by DCP Institution</td>
<td>DCP Institution Code-01</td>
</tr>
<tr>
<td>Second Participant Entered by DCP Institution</td>
<td>DCP Institution Code-02</td>
</tr>
<tr>
<td>Third Participant Entered by DCP Institution</td>
<td>DCP Institution Code-03</td>
</tr>
<tr>
<td>Example: First Participant Entered by The University of Arizona Medical Center-University Campus</td>
<td>Example: AZ017-01</td>
</tr>
<tr>
<td>Example: Second Participant Entered by The University of Arizona Medical Center-University Campus</td>
<td>Example: AZ017-02</td>
</tr>
</tbody>
</table>

Contact the DCP Help Desk at dcphelpdesk@dcpais.com or by calling 1-844-901-4357 if CLO or PO DCP Institution Code is unknown.
Step 4: If this participant has already been contacted, enter the date by selecting the calendar button.

![Add Participant Accrual Information](image)

Step 5: Next, select the +Add/Edit button to indicate the recruitment strategy used for this participant.

![Add Participant Accrual Information](image)

Step 6: The Recruitment Strategies page appears. Select the recruitment strategy used to contact the participant and fill out/check the displayed options [as needed] for each of the strategies selected. For this example, we selected Telephone Calls and checked the Script Call option.
Please note: each strategy has its own options or fields to check/fill out. To view these options or fields for all Strategies, select Expand All.

Step 7: Select Save to submit your data and to return to the Add Participant Accrual Information page.

Step 8: If the Study Intervention Date is available, select the calendar button and enter a date. Please note users can later enter this information to document any changes.
Step 9: Enter the additional information required [i.e. if a Consent Form has been signed]. If it has not been signed, check the **Consent NOT Signed** box and select the +Add/Edit button.

![Add Participant Accrual Information](image)

Step 10: The **Reason Consent NOT Signed or Study Intervention NOT Started Table** page appears. From the list, select the reason this participant did not sign a consent form and enter the required information. For this example, we selected **Logistics** and checked **Scheduling Conflicts**.

![Reason Consent NOT Signed or Study Intervention NOT Started Table](image)
Step 11: Select **Save** to submit your changes.

Step 12: A message appears indicating the participant was successfully added. Select **OK** to return to the Participant Accrual Information Page.

ii. **How to Edit Information**

Step 1: To update or edit information for existing participants, select the **Edit** button and follow **Steps 1 to 12** in section i.
iii. **How to Delete Information**

Step 1: Select the **Delete** button corresponding to the participant information you wish to remove from the list.

<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>B</td>
<td>March 06, 2017</td>
<td>Mailing List</td>
<td>No</td>
<td>Known History of Non-Compliance</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>March</td>
<td>Mailing List</td>
<td>March 22</td>
<td>Scheduling Conflict</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Step 2: A message appears. To continue, select **Yes, delete it!**

Step 3: A message appears indicating participant accrual was successfully deleted. Select **OK** to return to the **Participant Accrual** page.

---

c. **Recruitment Journal**: This is a place to document activities, events or other factors that may have an effect on study accrual trends (either positive or negative) rather than on a specific participant. Examples might include: changes in staffing, changes in clinic hours, institution-wide events or a change in eligibility criteria. This information will provide insights into accrual patterns and may be useful for future planning.

Step 1: Once the **Participant Accrual** page appears, select the **Recruitment Journal** tab to view and enter Study Event data.
The **Recruitment Journal** page opens. On this page, you can view/edit the following columns:

- Study Event Start Date*
- Study Event End Date*
- Study Event
- Event Description

**Please note:** * These columns can be sorted in ascending/descending order by clicking on the column header.

The Recruitment Journal page opens. On this page, you can view/edit the following columns:

- Study Event Start Date*
- Study Event End Date*
- Study Event
- Event Description

**Please note:** * These columns can be sorted in ascending/descending order by clicking on the column header.

### How to Add a New Study Event

**Step 1:** Select **Add New Study Event** on the **Recruitment Journal** page.

**Step 2:** The **Add Study Event** page appears.

<table>
<thead>
<tr>
<th>Study Event Start Date</th>
<th>Study Event End Date</th>
<th>Study Event</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 08, 2017</td>
<td></td>
<td>A1 - Study Active</td>
<td></td>
</tr>
</tbody>
</table>

**Study Event Start Date:** MM/DD/YYYY  
**Study Event End Date:** MM/DD/YYYY  
**Study Event:** -- Select Study Event --  
**Study Event Description:** Study Event Description
Step 3: Enter the start date and select the Study Event from the pull-down menu. For this example, we selected Protocol Amendment Approval: Eligibility.

Step 4: Select Submit to save your changes.

Step 5: A message appears indicating the recruitment journal entry was successfully added. Select OK to return to the Recruitment Journal page.
ii. **How to Edit Information**  
Step 1: Select the **Edit** button to update or edit information for existing Study Events.

<table>
<thead>
<tr>
<th>Study Event Start Date</th>
<th>Study Event End Date</th>
<th>Study Event</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 05, 2017</td>
<td></td>
<td>A1 - Study Active</td>
<td><img src="image" alt="Edit Button" /></td>
</tr>
</tbody>
</table>

Step 2: The **Edit Study Event** page appears. Enter the required information and select **Submit** to save your changes.

<table>
<thead>
<tr>
<th>Study Event Start Date</th>
<th>Study Event End Date: (If applicable)</th>
<th>Study Event</th>
<th>Study Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/08/2017</td>
<td>04/XX/2017</td>
<td>A1 - Study Active</td>
<td><img src="image" alt="Edit Button" /></td>
</tr>
</tbody>
</table>

Step 3: A message appears indicating the recruitment journal entry was successfully updated. Select **OK** to return to the **Recruitment Journal** Page.

![Success](image)

iii. **How to Delete Information**  
Step 1: Select the **Delete** button corresponding to the study event you wish to remove from the list.

<table>
<thead>
<tr>
<th>March 23, 2017</th>
<th>A4 - Protocol Amendment Submitted to DCP</th>
<th>Edit</th>
<th>Delete</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 05, 2017</td>
<td>A18 - PI Issues: Availability/Change in PI</td>
<td>Edit</td>
<td>Delete</td>
</tr>
</tbody>
</table>
Step 2: A message to confirm deletion appears. To continue select **Yes, delete it!**

![Image of warning message]

Step 3: A second and final message appears indicating the Recruitment Journal entry was successfully deleted. Select **OK** to return to the **Recruitment Journal** page.

![Image of success message]

Step 4: The **Recruitment Journal** page appears. If you wish to add or update another protocol, select **Close** to return to the **Assigned Protocol** page or select **Log Out** to end this session.

![Recruitment Journal page with protocol information and study events]
Consortia Lead Organization (CLO) Accrual Reporting

Consortia Lead Organizations (CLOs) are the five main DCP Consortia clinical trial institutions, which include, Mayo Clinic, MD Anderson Cancer Center, Northwestern, University of Arizona, and University of Wisconsin. Please note, Jane Doe is used as an example of a CLO user to illustrate the AQuIP OARS process below.

1. Log into the AQuIP OARS using your account credentials provided by the DCP Help Desk and select Log in. If you do not have an account, please reference steps 1-5 under How to Request AQuIP OARS Access section.

2. Once logged in, the Assigned Protocol page appears, listing all protocol numbers assigned to each of Jane Doe’s Participating Organizations. In addition, the following columns are displayed:
   - Study Status
   - Target Enrollment
   - Total Number of Participants Started Study Intervention
   Please note: All columns can be sorted in ascending/descending order by clicking on the column header.

3. To continue, select CL02016-02-01.
4. Once you select **Protocol CL02016-02-01**, a reminder appears indicating when the Monthly Report is due. Select **Continue** to proceed to the **Protocol Information** page.

![Protocol Information](image)

**Please note:** Daily reminders for Monthly Report submission appear from the 1st to the 15th of the month.

5. Next, the information for **Protocol CL02016-02-01** appears along with the following tabs to enter additional data:
   a. **Protocol Information**: Displays the current status for **Protocol CL020 16-02-01**.

   ![Protocol Information](image)

   - **Current Reporting Month**: April 2017
   - **Protocol Title**: Randomized Phase II Trial of Agent B in High-Risk Individuals
   - **Protocol Number**: CL02016-02-01
   - **Targeted Enrollment**: 120
   - **Total Number of Participants Started Study Intervention**: 4
   - **Projected Enrollment For Month**: 8.00
   - **Projected Completion Date**: June 12, 2018
   - **Study Status**: Active
   - **Study Status Date**: March 27, 2017
   - **Accrual Duration (Months)**: 15
   - **Approved Participating Organizations**: University of Chemoprevention
   - **Date of First Contact**: March 06, 2017

   b. **Participant Accrual**:
   Step 1: Next, select the **Participant Accrual** tab to view, edit, or delete participant information.

   ![Participant Accrual](image)
Step 2: The Participant Accrual page opens and displays all POs assigned to CLO coordinator Jane Doe and the First Contact Date.

![Participant Accrual page]

Step 3: To continue, select University of Chemoprevention.

![Participant Accrual page for University of Chemoprevention]

The Participant Accrual page for PO University of Chemoprevention opens. On this page, you can view/edit the following columns:

- **Status Marker**: Each participant accrual record includes a Status Marker reflecting the accrual progression status as either Contacted, Consented, Not on Study or On Study.
- **Participant ID**
- **First Contact Date**
- **Recruitment Strategies**
- **Consent Date/Status**
- **Reasons Consent NOT Signed/Study Intervention NOT Started**
- **Intervention Start Date**
- **Comments**

**Please note**: * These columns can be sorted in ascending/descending order by clicking on the column header.
i. **How to Add a New Participant**  
Step 1: Select **Add New Participant** in the Participant Accrual page.

Step 2: The **Add Participant Accrual Information** page appears.

Step 3: Next, enter the **Participant ID**.
Please note: For quality assurance purposes, the AQuIP OARS System does not allow for duplicate or blank, placeholders and/or participant IDs. In the event that a CLO does not have a standard screening (or placeholder ID) procedure, we offer the following screening/placement ID numbering convention until participants receive a unique ID. The Participant ID # field should be populated with this screening/placement and replaced with the PID upon study enrollment (by the accruing site). As this is a recommendation, CLOs are welcome to follow this process or apply the necessary institutional conventions to avoid blank or duplicate IDs.

<table>
<thead>
<tr>
<th>Participant Entered into AQuIP OARS</th>
<th>Participant ID #</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Participant Entered by DCP Institution</td>
<td>DCP Institution Code-01</td>
</tr>
<tr>
<td>Second Participant Entered by DCP Institution</td>
<td>DCP Institution Code-02</td>
</tr>
<tr>
<td>Third Participant Entered by DCP Institution</td>
<td>DCP Institution Code-03</td>
</tr>
<tr>
<td>Example: First Participant Entered by The University of Arizona Medical Center-University Campus</td>
<td>Example: AZ017-01</td>
</tr>
<tr>
<td>Example: Second Participant Entered by The University of Arizona Medical Center-University Campus</td>
<td>Example: AZ017-02</td>
</tr>
</tbody>
</table>

Contact the DCP Help Desk at dcphelpdesk@dcpais.com or by calling 1-844-901-4357 if CLO or PO DCP Institution Code is unknown.

Step 4: If this participant was already contacted, enter the date by selecting the calendar button.

Step 5: Next, select the +Add/Edit button to indicate the recruitment strategy used on this participant.
Step 6: The **Recruitment Strategies** page appears. Select the recruitment strategy used to contact the participant and fill out/check the displayed options [as needed] for each of the strategies selected. For this example, we selected **Telephone Calls** and checked the **Script Call** option.

Please note: each strategy has its own options or fields to check/fill out. To view these options or fields for all strategies, select **Expand All**.

Step 7: Select **Save** to submit your changes and to return to the **Participant Accrual Information** page.
Step 8: If the Study Intervention Date is available, select the calendar button and enter a date. Please note users can later enter this information to document any changes.

Step 9: Enter the additional information required [i.e. if a Consent Form has been signed]. If it has not been signed, select the **Add/Edit** button.

Step 10: The **Reason Consent NOT Signed or Study Intervention NOT Started Table** page appears. From the list, select the reason this participant did not sign a Consent Form and enter the required information. For this example, we selected **Logistics** and checked **Scheduling Conflicts**.
Step 11: Select **Save** to submit your changes.

Step 12: A message appears indicating the participant was successfully added. Select **OK** to return to the **Participant Accrual Information** page.

**Success**

Participant Accrual has been successfully added.

**OK**

---

ii. **How to Edit Information**

**Step 1:** To update or edit information, select the **Edit** button and follow **Steps 1 to 12** in section i.

<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>ABC</td>
<td>April 03, 2017</td>
<td>Script Call,</td>
<td>No</td>
<td>Scheduling Conflicts,</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

iii. **How to Delete Information**

**Step 1:** Select the **Delete** button corresponding to the participant you wish to remove from the list.

<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>A</td>
<td>March 16, 2017</td>
<td>Study Website,</td>
<td>March 17, 2017/Yes</td>
<td></td>
<td>March 20, 2017</td>
<td></td>
</tr>
</tbody>
</table>
Step 2: A message appears. To continue, select Yes, delete it!

![Image of a message with options to cancel or delete]

Step 3: A second message appears indicating participant accrual was successfully deleted. Select OK to return to the Participant Accrual page.

![Image of a success message]

c. **Recruitment Journal**: Once the Participant Accrual page appears, select the Recruitment Journal tab to view and enter study event data.

![Image of a protocol number with tabs for protocol information, participant accrual, recruitment journal, and close]

**Participant Accrual**

**PO: University of Chemoprevention**

- Co: Contacted
- C: Consented
- nS: Not on Study (Consent Not Signed, Ineligible, etc.)
- D: On Study
The Recruitment Journal page opens. On this page, you can view/edit the following columns:
- Study Event Start Date*
- Study Event End Date*
- Study Event
- Event Description
- POs Affected

Please note: * These columns can be sorted in ascending/descending order by clicking on the column header.

i. How to Add New Study Event
   Step 1: Select Add New Study Event in the Recruitment Journal page.

   Step 2: The Add Study Event page appears.
Step 3: Enter the start date and select the Study Event from the pull-down menu. For this example, we selected Accrual on Hold: Interim Analysis Per Protocol and all POs are checked.

Step 4: Select Submit to save your changes.

Step 5: A message appears indicating the recruitment journal was successfully added. Select OK to return to the Recruitment Journal page.
ii. **How to Edit Information**

Step 1: Select the **Edit** button to update or edit information to existing study events.

<table>
<thead>
<tr>
<th>Study Event Start Date</th>
<th>Study Event End Date</th>
<th>Study Event</th>
<th>Event Description</th>
<th>POs Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 08, 2017</td>
<td></td>
<td>A1 - Study Active</td>
<td>Study will remain active.</td>
<td>University of Chemoprevention</td>
</tr>
</tbody>
</table>

Step 2: The **Edit Study Event** page appears. Enter the required information and select **Submit** to save your changes.

Step 3: A message appears indicating the recruitment journal was successfully updated. Select **OK** to return to the Recruitment Journal page.
iii. How to Delete Information

Step 1: Select the Delete button corresponding to the study event you wish to remove from the list.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
<th>Status</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 08, 2017</td>
<td>All - Accrual on Hold: FDA Clinical Hold</td>
<td>Study is now on hold.</td>
<td>University of Chemoprevention</td>
</tr>
<tr>
<td>March 20, 2017</td>
<td>A2 - Site Issues: Drug Shipment Authorization</td>
<td></td>
<td>University of Chemoprevention</td>
</tr>
</tbody>
</table>

Step 2: A message to confirm deletion appears. To continue, select Yes, delete it!

Step 3: A second message appears indicating recruitment journal was successfully deleted. Select OK to return to the Recruitment Journal page.

How to Submit the Monthly Accrual Report

CLO users receive daily reminders from the 1st to the 15th of the month. Please Note: CLO users cannot submit reports after the 15th of each month.
1. Once all the required information is updated or added, select **Submit Monthly Report** in the **Protocol Information** page.

![Protocol Information](image)

2. A message appears indicating the monthly report was successfully submitted. Select **OK** to return to the **Protocol Information** page.

![Success](image)

3. The **Protocol Information** Page appears. If finished, select **Log out**.

![Protocol Information](image)

We welcome your feedback on this Quick Start Guide. Please send your comments to dcphelpdesk@dcpais.com
Frequently Asked Questions

1. **Q:** Who will add/delete POs from AQuIP OARS?
   - **A:** PO and CLO users submit PO changes as Study Events including the Study Event Dates, Type, and Description on the 'Recruitment Journal' tab. The DCP Help Desk will edit the list of POs accordingly.

2. **Q:** Will AQuIP OARS collect pre-contacted data (i.e., data before participant was contacted)?
   - **A:** No, this information is outside the scope of AQuIP OARS data collection, beginning at “First Contact Date” and ending with “Intervention Start Date” or “Reason(s) Consent NOT Signed/Study Intervention NOT Started”

3. **Q:** Where can I find total participants that started study intervention per PO and protocol?
   - **A:** The total number of participants that started study intervention per PO and protocol is not available in the current AQuIP OARS; however, it is under consideration for the next AQuIP OARS iteration.

4. **Q:** How are pending accrual records handled in AQuIP OARS (i.e., participants that have been contacted without consent dates, or consented participants that have not started intervention)?
   - **A:** Accrual records are considered pending when the individual was contacted but has not yet signed consent or started intervention. In these instances, the “Date Consent Signed Date” and/or the “Date Started Study Intervention” are left blank and the “First Contact Date” and “Recruitment Strategy” fields are populated. **Please note:** The DCP Help Desk will query participants that have been pending for more than six (6) months.

5. **Q:** If a participant is identified through a participant registry, but the Principal Investigator (PI) had a key role in the enrolling process, should the PI also be added as a recruitment strategy?
   - **A:** Yes, DCP recommends listing all recruitment strategies used to enroll participants.