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 dchelpdesk@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 ................................................... 31
Frequently Asked Questions ........................................................................ 33

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. Data is modified, as necessary and then submitted to the DCP Help Desk at TRI. The DCP Help Desk aggregates the data, performs data integrity checks, and sends queries back to the CLOs for resolution. The DCP Help Desk 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 collected, aggregated, analyzed, and mined to find "lessons learned" for future protocols and recruitment plans.
How to Request Access to AQuIP OARS

AQuIP OARS accounts are requested when a protocol has been approved by DCP. 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. Additionally, the following information is needed for each individual:

<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>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. DCP Help Desk submits the CLOs’ 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. The password may be reset by selecting the “Password Reset” button on the “Accrual Report” login page and enter 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 is reviewed by DCP auditing and informatics support contractor at Technical Resources International (TRI), Inc. Accounts with no activity for more than 90 days are identified as candidates for inactivation. An email request is sent to the account holder to confirm if access is still needed. Upon confirmation that access is not required or if no response is received within 30 calendar days, the account is deactivated without further notification. 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, Ima Researcher 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 Ima Researcher at Chemoprevention Institute. In addition, the following columns are displayed:
   - CLO Name
   - Study Status*
   - Target Enrollment*
   - Total Number of Participants Started Study Intervention*

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

2. To continue, select Protocol CLO2016-02-01.
3. Next, the information for Protocol CLO2016-02-01 appears along with the following tabs to enter additional data:
   a. **Protocol Information**: Displays the current status for Protocol CLO2016-02-01.

   ![Protocol Information](image)

   **Protocol Information**
   - **Current Reporting Month**: October 2017
   - **Protocol Title**: Randomized Phase X Trial of Agent B in High-Risk Individuals
   - **Protocol Number**: CLO2016-02-01
   - **Targeted Enrollment**: 130
   - **Total Number of Participants Started Study Intervention**: 7
   - **Projected Acrual Per Month**: 8
   - **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](image)
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.

  - Contacted
  - Consented
  - Not on Study (Consent Not Signed, Ineligible, etc.)
  - On Study Intervention

- **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.*

<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>
</table>

When a pending Accrual Record exceeds 90 days, a pop-up reminder appears to update highlighted record. Select the **Continue** button to update pending records highlighted in red.

*The record(s) highlighted below have been in a pending status for greater than 90 days. Please open the highlighted records below and update the Consent Date/Status, Intervention Start Date and/or the Reason(s) Consent NOT Signed/Signed/Study Intervention NOT Started fields as applicable to complete the identified recruitment record(s).*

<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>115</td>
<td>March 14, 2017</td>
<td>Participant Registries,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>111</td>
<td>March 20, 2017</td>
<td>Patient, Patient, Patient</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
i. **How to Add a New Participant**

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

### Participant Accrual

**PO:** University of Chemoprevention

- [ ] Contacted  
- [ ] Consented  
- [ ] Not on Study (Consent Not Signed, Ineligible, etc.)  
- [ ] On Study Intervention

---

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

![Add Participant Accrual Information](image)

**Step 3:** Next, enter the **Participant ID.** A unique PID will be assigned once participant starts study intervention.

![Add Participant Accrual Information](image)

For quality assurance, 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 numbering convention until participants receive a unique ID. Enter these screening/placeholders in the Participant ID # field (PID) and replace them with the accruing site PID upon study enrollment. 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](mailto:dcphelpdesk@dcpais.com) or by calling 1-844-901-4357 if CLO or PO DCP Institution Code is unknown.
Step 4: Enter the **First Contact Date** by selecting the calendar button.

First Contact Date field is required once the Participant ID (PID) is entered.

Step 5: Next, select the **+Add/Edit** button to enter the recruitment strategy used for 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 data and return to the Add Participant Accrual Information page.

Step 8: Next, check the appropriate checkbox under Consent Date/Status. For this example, participant ABC signed the Consent Form on 10/09/2017.
Step 9: If Participant withdraws before screening or is found ineligible for intervention, enter **Reason(s) Consent NOT Signed/Study Intervention NOT Started** field by clicking on the **+Add/Edit** button to proceed. This field is also required if participant declines to sign the Consent Form.

![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. Some reasons may require additional 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.

![Reason Consent NOT Signed or Study Intervention NOT Started Table](image)

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

![Success](image)

**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.

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 appears. 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.

### i. How to Add a New Study Event

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

### Recruitment Journal

```
Protocol Number: CLO2016-02-01

<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 06, 2017</td>
<td>11/01/2017</td>
<td>A1 - Study Active</td>
<td></td>
</tr>
</tbody>
</table>
```

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

### Add Study Event

```
Study Event Start Date: 11/01/2017
Study Event End Date: (If applicable) 11/01/2017
Study Event: -- Select Study Event --
Study Event Description: Study Event Description
```

AQuIP OARS Quick Start Guide for DCP Consortia 2012
Last Updated October, 18 2017
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.

Please Note: If you pick one of the following Study Event(s), you must enter a Study Event Description:
- A0 – Change in Monthly Accrual Rate (provide new monthly accrual rate in the Event Description)
- A3 – Site Open (Provide Date in the Event Type Description)
- A9 – Accrual Hold: Specify in the Event Type Description
- A23 – New recruitment strategy started (Specify in the Event Type Description)
- A28 – Other (Specify in the Event Type Description)

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.

**Success!**

Recruitment journal has been successfully added!

OK

ii. **How to Edit Information**

   Step 1: Select the Edit button to update or edit information for existing Study Events.

   **Recruitment Journal**

<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></td>
</tr>
</tbody>
</table>

   Edit

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

   **Edit Study Event**

   - Study Event Start Date: 03/05/2017
   - Study Event End Date: MM/DD/YYYY
   - Study Event: A1 - Study Active
   - Study Event Description: Study will remain active.

   Submit

   Close

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

   **Success!**

   Recruitment journal has been successfully updated!

   OK
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>Edit</th>
<th>Delete</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 29, 2017</td>
<td>A4 - Protocol Amendment Submitted to DCP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>April 03, 2017</td>
<td>A18 - PI Issues: Availability/Change in PI</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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.

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.
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, Ima Researcher at Consortium Lead Organization 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 Ima Researcher’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 CLO2016-02-01.
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.

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 CL02016-02-01.

   b. Participant Accrual:
      Step 1: Next, select the Participant Accrual tab to view, edit, or delete participant information.
Step 2: The **Participant Accrual** page opens and displays all POs assigned to CLO coordinator Ima Researcher, the First Contact Date, and the Total Number of Participants Started Study Intervention Per Site.

### Participant Accrual

Select a Participating Organization Assigned to this Protocol.

<table>
<thead>
<tr>
<th>Approved PO Name</th>
<th>First Contact Date</th>
<th>Total Number of Participants Started Study Intervention Per Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Chemoprevention</td>
<td>March 08, 2017</td>
<td>4</td>
</tr>
<tr>
<td>Chemoprevention Institute</td>
<td>March 09, 2017</td>
<td>3</td>
</tr>
</tbody>
</table>

Step 3: To continue, select **University of Chemoprevention**.

### Participant Accrual

Select a Participating Organization Assigned to this Protocol.

<table>
<thead>
<tr>
<th>Approved PO Name</th>
<th>First Contact Date</th>
<th>Total Number of Participants Started Study Intervention Per Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Chemoprevention</td>
<td>March 08, 2017</td>
<td>4</td>
</tr>
<tr>
<td>Chemoprevention Institute</td>
<td>March 09, 2017</td>
<td>3</td>
</tr>
</tbody>
</table>

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***
- **Reason(s) 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.
When a pending Accrual Record exceeds 90 days, a pop-up reminder appears to update highlighted record. Select the Continue button to update pending records highlighted in red.

The record(s) highlighted below have been in a pending status for greater than 90 days. Please open the highlighted records below and update the Consent Date/Status and/or the Reason(s) Consent NOT Signed/Study Intervention NOT Started fields as applicable to complete the identified recruitment record(s).

![Continue button]

<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>0297</td>
<td>April 10, 2017</td>
<td>Clinic Schedules</td>
<td>April 11, 2017/Signed</td>
<td></td>
<td>April 12, 2017</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4587</td>
<td>March 30, 2017</td>
<td>Site Coordinator</td>
<td>Specify name</td>
<td>Coordination</td>
<td>Clinic Schedules</td>
<td></td>
</tr>
</tbody>
</table>

i. **How to Add a New Participant**

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

![Add New Participant button]

**Participant Accrual**

PO: **University of Chemoprevention**

- Contacted  - Consented  - Not on Study (Consent Not Signed, Ineligible, etc.)  - On Study Intervention

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

![Add Participant Accrual Information dialog box]

**Participant ID (PID):** Participant ID (PID)

**First Contact Date:** First Contact Date

**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 and Close buttons]
Step 3: Next, enter the **Participant ID**.

For quality assurance, 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 numbering convention until participants receive a unique ID. Enter these screening/placeholders in the Participant ID # field (PID) and replace them with the accruing site PID upon study enrollment. 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](mailto:dcphelpdesk@dcpais.com) or by calling 1-844-901-4357 if CLO or PO DCP Institution Code is unknown.

Step 4: Enter the **First Contact Date** by selecting the calendar button.

**First Contact Date** field is required once the Participant ID (PID) is entered.
Step 5: Next, select the **Add/Edit** button to enter the recruitment strategy used for this participant.

**Add Participant Accrual Information**

- **Participant ID (PID):** ABC
- **First Contact Date:** 10/02/2017
- **Recruitment Strategies:**
  - Recruitment Strategies

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.

![Recruitment Strategies](image1)

Step 8: Next, check the appropriate checkbox [Signed, pending, or declined] and enter the date [if applicable] under **Consent Date/Status**. For this example, participant ABC signed the Consent Form on 10/09/2017.

![Add Participant Accrual Information](image2)
Step 9: If Participant withdraws before screening or is found ineligible for intervention, enter **Reason(s) Consent NOT Signed/Study Intervention NOT Started** field by clicking on the +Add/Edit button to proceed. This field is also required if participant declines to sign the Consent Form.

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.

### 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.

### iii. How to Delete Information

**Step 1:** Select the **Delete** button corresponding to the participant you wish to remove from the list.
Step 2: A message appears. To continue, select Yes, delete it!

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

c. Recruitment Journal: 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
- POs Affected

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

### 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.

Please Note: If you pick one of the following Study Event(s), you must enter a Study Event Description:

- A0 – Change in Monthly Accrual Rate (provide new monthly accrual rate in the Event Description)
- A3 – Site Open (Provide Date in the Event Type Description)
- A9 – Accrual Hold: Specify in the Event Type Description
- A23 – New recruitment strategy started (Specify in the Event Type Description)
- A28 – Other (Specify in the Event Type Description)

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.

![Success Message]

ii. **How to Edit Information**

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

   **Recruitment Journal**

<table>
<thead>
<tr>
<th>Study Event Start Date</th>
<th>Study Event End Date</th>
<th>Study Event</th>
<th>Event Description</th>
<th>P0s 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>

   ![Edit Study Event]

   **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.

![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>Date</th>
<th>Event Description</th>
<th>Status</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 08, 2017</td>
<td>A8 - Acutal 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 - Sita Issues; Drug Shipment Authorization</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

![Confirmation](image)

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

![Success](image)
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 on the Protocol Information page.

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

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?
   o 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)?
   o 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?
   o 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)?
   o 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?
   o A: Yes, DCP recommends listing all recruitment strategies used to enroll participants.