Electronic Data Capture (EDC) - Support

1. How do I get an EDC account or get access to another study?

   IMPORTANT: You must "activate" your EDC account with Canadian Cancer Trials Group for the study you are involved in. In the future if you require access to other studies you will need to be added to the Trial Participants List for EDC access to those studies. Please allow 24-48 hours for the Canadian Cancer Trials Group Central Office to process your request.

   How do I get added to a Trial Participants List?

   - Ripple - Web-based system to create and manage Canadian centre membership as well as create and manage Trial Participants Lists. For more information refer to Ripple Resources.
   - Paper - Participants List and Participants List Change Forms – Forms are available on the trial websites (where applicable).
   - Mango/Remote Roster Management - Web-based system for International...
Partners/Groups to create and manage Trial Participants Lists.

Note: To obtain access to a specific study:

- You require an active Canadian Cancer Trials Group Member Account
- You must be listed on the Trial Participants List

How to obtain a specific study access if you do not already have an active account in the EDC system:

1. Select a PIN via the Password Management System.
2. Once received, the Canadian Cancer Trials Group Central Office will process your request within 24-48 hours and will send you an email with;
   - your Login user name;
   - the activation code that is used to activate your account in EDC;
   - the weblink to the EDC system.

How to obtain a specific study account if you already have an active account in the EDC system:

- Ensure you are listed on the Trial Participants List, you should be assigned EDC access according to your Trial Role; if not please email: roster@ctg.queensu.ca

2. What is the PIN number? Where can I find it?

The PIN number is the 4 digit code you created via the Password Management System. It is your own personal number. For security reasons your PIN must be not be 4 sequential numbers or 4 repeating numbers.

This is a very important number and it should be guarded the same way as a secure password.

This number is required for activating your account. It is also needed in situations where;

- you have forgotten your password and need to generate a new one;
- your account is locked out and needs to be unlocked

If you have lost or forgotten your PIN you may set a new one by using the Set EDC PIN# link via the Password Management System.

If you are unable to reset your PIN, please contact Canadian Cancer Trials Group through their helpdesk system. Or email your request to support@ctg.queensu.ca
3. What is the Activation Code?

The Activation Code is sent to you after you have selected a PIN via the Password Management System. The Canadian Cancer Trials Group Central Office will have processed your request and will have sent an email to you with;

- your Login user name;
- the activation code that is used to activate your account in EDC;
- the weblink to the EDC system.

4. How do I activate my EDC account?

If you have selected a PIN via the Password Management System, here are the steps to activate your account.

1. When you selected your PIN, within 24-48 hours you should receive an email with your Username, an Activation Code and a web link to the EDC system.
2. On the EDC login page, click the Activate New Account link.
3. On the Account Activation Request screen enter the Activation Code (if it is not automatically entered for you) from the email you received. Then enter your PIN number in the required field. **NOTE: if you are using the key pad of your keyboard please ensure the Num Lock is on so that you are entering numbers correctly.**
4. Click Activate Account
5. You should then be taken to the New Password screen.
6. Create your password in the "New password" and "Confirm password" spaces provided. The password must be a minimum of 6 digits long and must contain both letters and numbers. It is case sensitive.
7. Click "Save password and continue". Your password is now valid in the system. It will remain active for 180 days.

From this point forward you will only use the username sent to you and the password you created to access EDC.

After activating the account and creating the password, you will then need to complete the web based e-training for EDC. The link to this training should appear once you have logged in.

What if I cannot activate my account? If you cannot activate your account, please look for any error messages that may appear. If the activation does not work and the activation gets locked out, a new activation code will need to be sent to you. If this happens please contact the Canadian Cancer Trials Group Helpdesk. Please provide details on the issue and any errors or messages you received while trying to activate the account. You can reach the heldesk by clicking here. You can also email them at support.ctg.queensu.ca.

5. The web based E-Training seems to lock up or hang on certain pages

There have been issues where the E-Training has seemed to freeze or hang at certain pages.
People have described it as the page seems to get stuck loading. Example: Page 5 is completed. They click next. It shows loading the next page but it never seems to complete or it stops at a certain percentage.
Some possible solutions to try;

1. Ensure your pop up blocker is turned off. The training uses other windows that a pop-up blocker might stop from loading.
2. Let the page load entirely before trying to skip to another section/page. The page will often need to fully load before it activates other links/buttons.
3. To skip ahead if the page gets stuck, you want to click on the "Menu" tab in the bottom left corner of the training session window. This will bring up the names of all the pages for the training session. Click on the next page (example - page 6 hangs, click on page 7) If that doesn't work try clicking on the page before the one that got stuck, after that page is done loading skip ahead to the page after the one that gets stuck. (example - page 6 hangs, click on page 5) Once the page fully loads go to the menu and click page 6, If you are still stuck, try clicking page 7. As a last resort try going back a series of pages and then rapidly clicking next to get to the page you need to get to.
4. If the problem persists, please try this at another computer. The issue is often local to the PC. By going to another system you remove the possible issues with the first computer. Also, it could be the local network and the system’s ability to pull information across the network.

One of the above solutions usually fixes the problem, and allows you to carry on with the training session. If the issue persists, please contact the Canadian Cancer Trials Group helpdesk by clicking here. You can also email them at support@ctg.queensu.ca.

6. I Forgot my EDC Password. What Can I do? And what are the EDC Password Guidelines?

If you forget your password you can access the system as follows:

1. Access the Login Page by typing the URL address for EDC into your web browsers address bar. The address is https://edc.ctg.queensu.ca.
2. Click on "Forgot Password?". This will take you to the "Lost Account Information Screen".
3. Enter your First Name, Last Name and PIN number and click the "Recover Account" Button. This will take you to the New Password Screen.
4. Enter your password twice in the "New password" and "Confirm password" spaces provided. Please ensure to follow the Password Guidelines: it must be a minimum 6 characters long and must contain numbers and letters.
5. Click "Save password and continue".
6. Click "click here to continue" and you will be granted access into the system.

Note: If you forgot both your password and PIN contact the Canadian Cancer Trials Group Systems Administrator through the Canadian Cancer Trials Group helpdesk by clicking here. Or by email at support@ctg.queensu.ca.
7. My Account is Locked out. What Can I Do?

Note: This is for situations where you have already activated your EDC account and have been using your password. If your password is entered incorrectly 4 times in a row, your account will get locked out. If it that happens you should see a message that the account is locked out.

You can try to unlock the account yourself. To do this you will need the following information:

- Your name;
- Your PIN number

You can then follow these steps;

1. From the EDC login page, click Forgot Password
2. On the Recover Account page enter your first name, last name and the PIN number
3. Click Recover Account
4. You will then be asked to create a new password
5. Once done you will have unlocked the account, created a new password and have been logged into the EDC system. You will now use this newly created password to log into EDC from this point forward until it expires, you change your password or your account gets locked out again.

If you are unable to unlock your account, please contact the Canadian Cancer Trials Group helpdesk by clicking here. Or by email at support@ctg.queensu.ca. Please make sure to include details of the issue, any messages or errors that you have received.

8. I have corrected the data field in EDC, but the query doesn’t seem to disappear

System-generated queries in EDC may be closed automatically once the data is fixed. However, manual queries in EDC (i.e., those manually created by an SC) may stay open until the response has been SC reviewed and then subsequently closed.

9. Drop down menus are very slow or not working at all

There is a known issue with slow or non-functional drop down menus in EDC if you are using Internet Explorer version 6 or earlier. (Other browsers & versions may also be affected) As a first course of action, have your IT Team upgrade your Internet Browser.

10. EDC Training - How do I obtain or print my certificate?

In order to obtain a copy of your EDC training certificate.
Log into EDC at https://edc.ctg.queensu.ca/MedidataRAVE/
In the upper right corner click on My Profile.
On the right hand side under My Profile click on the eLearning link.
Under the Certificate Heading you will see a paper icon.
Click on that icon and a pop up will occur allowing you to save or open your certificate in PDF
format.
You can then print this certificate for your records.

11. EDC Training - How can I re-take the e-training?

In order to re-take the EDC Training.
Log into EDC at https://edc.ctg.queensu.ca/MedidataRAVE/
In the upper right corner click on My Profile.
On the right hand side under My Profile click on the eLearning link.
Under the Start Heading you will see a play button icon.
Click on that icon to re-take the EDC training.

12. Number of Log Lines viewable per Page in Table Forms?

The default setting for viewable log lines in "Table" EDC forms (called "Log Forms") is 20 per screen. While this is satisfactory in most cases, some trials use Log Forms which exceed 20 lines (e.g. daily pill logs for 28-days) and the log table is displayed on 2 pages. If you wish, you may change the default setting, so as to increase the lines visible per screen.

1. From any page in Rave, click on the "my profile" link on the top right of your screen:

2. Under the "my profile" sub-section click the "edit" link.

3. Change the selection in the "Lines per Page" field from 20 to 50 and click "save".
13. Supporting Document Submission to Canadian Cancer Trials Group?

As part of Canadian Cancer Trials Group's data review process it is required that copies of selected Supporting Documents (e.g. diagnostic pathology reports, CT reports etc) be submitted to the Canadian Cancer Trials Group Central Office together with applicable e-CRFs. (please refer to each protocol for details)

1. **You must use your member password** not your EDC/Rave password to upload Supporting Documents.
2. All Supporting Documents must be de-identified before submission to Canadian Cancer Trials Group. Please black out all identifiers such as name and date of birth. The patient's Study ID and initials should be hand-written on the top margin, instead.
3. Supporting Documents may be submitted in one of two ways: hard copies in the mail (majority of studies) and uploaded directly into Medidata RAVE
4. For Supporting Documents sent by mail: print the Supporting Documents reminder Email, complete it (ensure to check all documents being sent on the list provided) and use as a Cover Page for document submission through the mail.
5. For Supporting Documents uploaded onto Medidata RAVE: electronic documents should be directly uploaded into Medidata RAVE following the instructions on the screen; paper documents should be first scanned and then uploaded onto Medidata RAVE.

14. e-CRF submission through the Folder Completion Form?

A Folder Completion Form appears at the bottom of every Canadian Cancer Trials Group Folder (see screen shot below).
1. To access this form (AFTER you have completed the data in all other forms in the folder), click on "Folder Completion" in the left sidebar.

2. Two data entry fields will appear when the form is opened (see screen shot below). Enter the name of the person submitting the folder to Canadian Cancer Trials Group. The date refers to the date all required fields in all forms included in this folder were initially completed.

3. The Folder Completion Form should be done ONCE only and information on it should NOT be changed when/if there are subsequent changes (for example, after queries from Canadian Cancer Trials Group) to data fields in the rest of the folder. This form is meant to indicate the FIRST TIME e-CRF (=folder) was completed and submitted to Canadian Cancer Trials Group.

4. **VERY IMPORTANT:**
   Information in the Folder Completion form must be entered for each fully completed folder that is used for each patient. This information will be used to calculate Forms Reminders, to evaluate timeliness in the Centre Performance Index (CPI - applicable sites) and on monitoring/auditing. Timelines for data submission are outlined in each Canadian Cancer Trials Group protocol. Please ensure the date entered is accurate.

15. **Help and Resources for EDC Studies?**

Can be divided in three categories:

1. General about the RAVE system (i.e. help about the RAVE program rather than the content of the screen or the specific CRF or study being done).
2. Specific to all Canadian Cancer Trials Group studies (i.e. help about processes that have been specifically set up by Canadian Cancer Trials Group and apply generically to all their studies)
3. Specific to a particular Canadian Cancer Trials Group study.

Help resources may apply to the entire study, entire folder, specific page being viewed, or an
<table>
<thead>
<tr>
<th>Individual data field. Here is a list of available EDC resources for Canadian Cancer Trials Group studies:</th>
<th>Resource</th>
<th>Where?</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDC Generic Data Management Guidebook</td>
<td>Posted on trial or Co-Op Group website / Resource Page</td>
<td>Specific to all Canadian Cancer Trials Group studies</td>
<td></td>
</tr>
<tr>
<td>EDC Generic Data Management Guidebook for SAE Reporting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Introduction to SAE Reporting in EDC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RAVE System Help</td>
<td>Link on top right of every RAVE screen</td>
<td>General about RAVE system (page being viewed)</td>
<td></td>
</tr>
<tr>
<td>Folder Instruction Form</td>
<td>Text-only Form. It is the top Form in every Folder</td>
<td>Specific to each Canadian Cancer Trials Group Study and the Folder being viewed (provides folder-specific information)</td>
<td></td>
</tr>
<tr>
<td>Help Text</td>
<td>The questionmark icon (?) shown next to individual data field labels - clicking on it generates a pop up window</td>
<td>Specific to each data field</td>
<td></td>
</tr>
<tr>
<td>Mock e-CRFs</td>
<td>Posted on trial or Co-Op Group website / Resource Page</td>
<td>Specific to each Canadian Cancer Trials Group Study. You may use the Mock e-CRFs to share the e-CRF content with parties who do not have access to RAVE (e.g. local REB/IRB) or to 'get an idea' of what to expect once you log into RAVE</td>
<td></td>
</tr>
<tr>
<td>Study-Specific Supplementary Material / Slide Sets (some studies)</td>
<td>Posted on trial or Co-Op Group website / Resource Page</td>
<td>Specific to each Canadian Cancer Trials Group Study (study-specific important content)</td>
<td></td>
</tr>
</tbody>
</table>

**16. Why are my dropdowns, links or navigation not working in Internet Explorer?**

**If using Internet Explorer 11**

Internet Explorer 11 causes functionality issues with Medidata Rave/EDC. If using Internet Explorer 11 please use Medidata Rave/EDC in Compatibility View. Please go to https://edc.ctg.queensu.ca/ click on the gear icon in the address bar. Select Compatibility View settings. Click Add.
If using Internet Explorer 10
Recent web browser releases Firefox 22 (released June 25, 2013) and Internet Explorer 10 have caused functionality issues with Medidata Rave/EDC. In the interim if you are experiencing functionality issues with Medidata Rave/EDC we recommend using Internet Explorer 8 or Internet Explorer 10 in Compatibility View (click the small broken paper icon in the address bar, see below).

17. EDC/RAVE is slow or unresponsive?

EDC/RAVE has known issues with Internet Explorer 10 and 11. In order to use these browsers please make sure you are running in compatibility mode.

If browser compatibility is not an issue please follow the troubleshooting steps below.

- Clear your browsers cache: Log out of EDC and clear your internet browsers cache. Steps on how to clear browsers cache can be found at Google Chrome, Firefox, Internet Explorer, Safari. Once the cache has been cleared log back into EDC and test navigation.
- Test another page: Navigate to a different url ie. Youtube. Test the load time on a video or page, are you experiencing lag/stutters? Does the website load as it normally would? If the website is slow or unresponsive check with your IT department.
- Restart your computer: Exit EDC and restart your computer completely. If restarting is not an option please make sure all other programs and internet browser tabs are closed. Log into EDC and test navigation.
- Try from another computer: If available try from a different computer within your network.
- Try from a different device: If available try from a different device such as a tablet or mobile phone.

Contact support: If after trying the above methods EDC/Rave is still slow or unresponsive please file a help desk ticket or email support@ctg.queensu.ca with the following information.
Mango / Canadian Cancer Trials Group Website - Support

1. I do not know my Member User ID

You can locate your Member User ID by accessing our Account Management Tool [here](https://www.ctg.queensu.ca). Once on this page please click on Find My Member User ID. You can then enter one of two options your Email Address or your Centre Code and Trial Code. Your Website User Id will then be mailed to you.

2. I do not remember my Member Password

You can reset your Member Password by accessing our Password Management Tool [here](https://www.ctg.queensu.ca). Once on this page please click on Password Reset. You can then enter your Website User ID and your Email Address. Your new temporary password will be e-mailed to you.

3. Where can I find Mango Help documentation

Mango Help documentation is located [here](https://www.ctg.queensu.ca).

WebEx - Support

1. WebEx Instructions - Requirements

- **Important:** If this is your first time using WebEx, WebEx requires you to install a browser plugin. It is highly recommended you use Internet Explorer to access WebEx, other browsers such as Firefox attempt to block the installation of this plugin. **Important:** You should test your computer configuration at least 15 minutes prior to your meeting. The test module checks to make sure your computer meets all of the WebEx requirements. The test module is located [here](https://www.ctg.queensu.ca).
- **Important:** Java must be enabled on your computer for WebEx sessions to work. If you receive a Java warning from WebEx you will need to upgrade or enable Java before you can join a meeting.
2. WebEx Instructions - Join a Meeting

- To join a meeting. Click on the meeting link or copy and paste the link into your browser.
- You will be taken to a welcome screen. Clicking on the More Information button will reveal the telephone numbers and access codes if you are calling into the meeting from a phone.
- Sign into the meeting by entering a display name, email address and clicking on the button Join as Guest.
- **Important**: You will not be able to join a meeting until the scheduled meeting time.

3. WebEx Instructions - Presenter / Presenter Ball

- Once you have joined a meeting the list of attendees will be on the right hand side. The attendee with the ball next to them (known as the presenter ball) is the current presenter.
- The presenter is able to share their desktop with the group. If at any point other attendees need to share their screen. The presenter can drag the ball to the name of the attendee in the list who wishes to share. This attendee now becomes the presenter and can share their screen.
- When the attendee has finished their presentation they can drag the presenter ball to another attendee.

4. WebEx Instructions - Sharing your Desktop

- If you are the presenter you have the ability to share your desktop with the group.
- To share your desktop click on the desktop button or click on Share from the Webex Menu located at the top of your screen.
- When you share your desktop attendees will see what is on your desktop until you stop sharing or are no longer the presenter.
- To stop sharing your desktop. Click on the Stop Sharing icon.

5. WebEx Instructions - Official support links, videos and instructions

Official support links, videos and instructions can be found [here](https://www.ctg.queensu.ca).