



3CTN Reporting Portal User Training

2023



When you first login to V3 your dashboard will be blank. In order to add widgets to your dashboard click **Edit Dashboard**.

| 🕏 edge | A Home | 🖌 Management | Projects | H Sites | Participants | 🗠 Reports | 🔩 Support | 💄 James Schoales 🗸 |
|----------|--------|--------------|----------|---------|--------------|-----------|-----------|--------------------|
| 💄 Dashbo | oard | 🔒 🔒 Ho | ome | | | | | + Edit Dashboard |
| D Notes | | | , inc | | | | | |



- You can click on the sliders to add certain widgets to your dashboard.
- For reporting portal users we recommend the selected widgets in the image to the right.

| Widgets |
|----------------------|
| Notifications |
| Appointments |
| Favourite Projects |
| Newsfeed |
| Add Participants |
| Last Viewed Projects |
| My Reports |
| Delegation Logs |
| My Workflows |
| Release Notes |
| Save 🛇 Cancel |



• Once you click save you can resize and reorganize the widgets.

| <pre> description description</pre> | 🖌 Management 🗎 Projects 🖪 Sites 💄 | Participants 🗠 Reports 🔩 Support | | 💄 James Schoales 🗸 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|----------------------------------------------------------------------|-----------------------------------------------------------------|
| Dashboard Notes | A Home | | | + Edit Dashboard |
| Calendar Documents | ⊘ Last Viewed Projects | ▲ Favourite Projects | ☐ Notifications | * |
| Documents | 3CTN Reporting Y10 for Peds Sites 3CTN Reporting Y10 for Adult Sites 3CTN Reporting Y9 for Adult | (COG) ACNS1422 (COG) ARST1921 3CTN Reporting Y9 for Adult Sites (COG) APEC1621F | Page 1 of 1 Unread Notification Project Site Status Change From Open | Previous Next 2 records returned Date 25/09/2023 21:29 |
| | Sites (CCTG) BLC.5 / ALLIANCE A032001 (AHS) 24541 | (COG) AOST2032 3CTN Reporting Y9 for Ped Sites (CHUQ) CHLOE pancreas | Add Participants Add Participant | |
| | (COG) PEPN2111 3CTN Reporting Y9 for Ped Sites | 3CTN Member Resources (New) | | |



Options Under "My Profile"

- Add default project and project site roles
- Change Password
- Edit Notifications

Options Under "Management> Users"

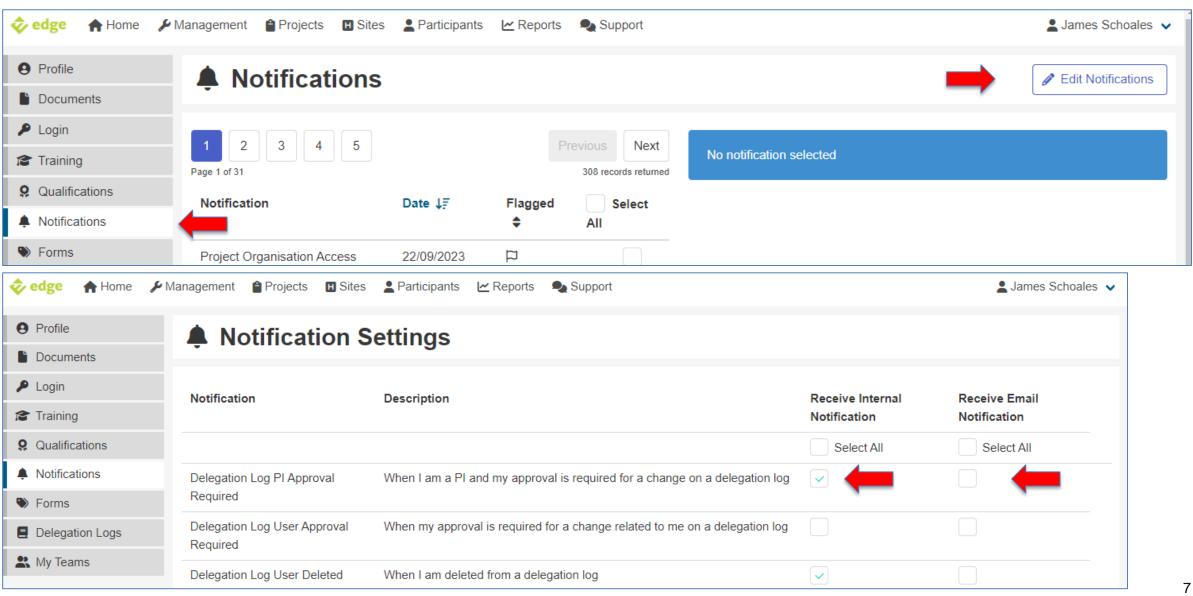
- Change Username
- By default, it is your email. If too long, you can change into a short username



Edit User Profile

| | Management 😭 Projects 🖪 Sites 💄 Participants | 🗠 Reports 🛛 🔍 Support | | 💄 James Schoales 🗸 |
|--------------------------------------------------------------------------------------------|----------------------------------------------|-----------------------|------------------------------------------|--------------------|
| Profile Documents | Sersonal Details | Edit Signature | Professional Details | Contraction Edit |
| Login Training Qualifications Notifications | Full Name Mr James Schoales Gender Male | 5 | Organisation 3CTN Coordinating Centre | |
| S Forms | | | | |
| Delegation Logs My Teams | Contact Details | P Edit | | |
| | Email James.Schoales@oicr.on.ca | | | |
| | Address | P Edit | | |
| | | | | |







Knowledgebase - Tutorial Articles

| 🔩 Support | KnowledgeBase Home / 1 - Getting Started | | | |
|------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| KnowledgeBase | 1.1 - Account Set Up | 1.2 - Your EDGE | 1.3 - Navigating EDGE | |
| VideosRelease Notes | How to manage your EDGE account and gain access | Profile Managing and updating your information in EDGE | Learn how to move around the system with an overview of the system functions and where to get help and support | |
| | 1102 - How to Activate an EDGE Account 1103 - How to Log In and Out of EDGE Securely 1104 - Password Criteria 1105 - Forgotten Your Password? 1106 - How to Reset a User's Password | 1201 - How to Update My Profile 1202 - How to Update Documents in My Profile 1203 - How to Edit Your Login Details 1204 - How to Update Training in My Profile 1205 - How to Update Qualifications in My Profile 1206 - How to Update Notifications in My Profile 1207 - How to Update Forms in My Profile 1208 - Delegation Logs 1209 - My Teams | 1300 - The EDGE Dashboard 1301 - Navigating the Homescreen 1302 - The EDGE Environments 1303 - Notifications 1304 - The Support Tab | |







- CTMS design allows for sharing and collaboration
- Shared (project level) records containing common data can save time for collaborating sites/groups
- Establishing data levels ensures only desired elements are shared without compromising security and privacy





| Site | Administrative data not limited to a given project/trial |
|----------------------|--------------------------------------------------------------------------------------------|
| | |
| Project | General project information available to all sites and research groups |
| | |
| Project Site | Site/Group-specific data related to a given project/trial |
| | |
| Participant Level | Participant level data |



Data Levels – example

| 💠 edge 🔺 Home 🎤 Management 🕋 Projects | 🖪 Sites 💄 Participants 🗠 | Reports 🔍 Support | 💄 James Schoales 🗸 |
|---------------------------------------|--------------------------------|--------------------------------------------------------------|---------------------------------------------------|
| ✓ Search Criteria | Search | | |
| Scope Assigned Projects | 1 2 3 4 Page 1 of 31 | Project level | Project Site level Is Next records returned |
| Title/Short title | (AHS) 24541 | | 3CTN - Cross Cancer Institute (Closed to |
| | Phase I/II Study of Fractional | ted Stereotactic Radiotherapy for Early Stage Non-Small Cell | recruitment - in follow up) |
| Local Reference | Lung Cancer | | Tom Baker Cancer Centre (Closed to recruitment - |
| | Project owner | 3CTN Coordinating Centre | in follow up) |
| | Status | Completed | |
| | Clinical Trials Gov | NCT00888823 | |
| Project Identifiers | Edge ID 11210 | | |
| ▶ Core details | | | |

| 🗞 ed 💏 🛛 🏫 Home 🖌 | Management 🔮 Projects 🖪 Sites 💄 Participants 🗠 Reports 🎭 Support | | 💄 James Schoales 💊 |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-------------------------------|
| t Project Search | (BCC) BEV-DOSE | | * |
| i Overview | Oligican aites to position to | | |
| H Sites | Click on sites to navigate | | |
| Staff | i o your project site level | Audit Mode | Transfer Ownership |
| Documents | | | |
| Forms | Core Details | Identifiers≣ | 🥒 Edit |
| ■ Workflows | | | |
| D Notes | Short Title | EDGE ID | 6936 |
| Finance | (BCC) BEV-DOSE | Clinical Trials Gov | NCT04787289 |
| Organisations | Full Title | Protocol ID | BEV-DOSE |
| S Collaborators | A Comparison of 2 Standard Doses of Bevacizumab in Combination With Chemotheral in Epitrix al Ovarian Cancer - a Pragmatic Trial | | |
| Criteria | Summary | ♥ (⇒ographic IS⇒pe | / Edit |
| Stakeholders | A pragmatic, rearment, study pmps lig 2 stands I dose of anti-clincer | | |
| Statistics | drug called bevacizumab, given in combination with Chemotherapy. The study | Lead Country | Canada |
| Configuration | will be offered to ovarian cancer patients whose d Read more | Geographical Scope | Multi-centre |
| Import Participants | Study Chair | Site Participation Option | Yes, within lead country only |
| Sites Management | Visibility Public | | , " , ", ", ", ", |



Data Levels – Project Site Level

| 1 Sites | H (BCC) BE | V-DOSE | | |
|---------------------------|-------------------------------|-----------------------------------------------|-----------------------------------|----------------------|
| i Overview | BC Cancer – Ab | | | |
| 😵 Staff | | | | |
| Documents | i Overview | | Audit Mode 🔁 C | Clone Site Zwap Site |
| Sorms | | | | |
| ž≣ Workflows | 🗂 Core Detail | idit idit | C pp sval | Sector Edit |
| Notes | | | | |
| Finance | Site Owner | Canadian Cancer Clinical Thats Network (3011) | Approva: rocess | Site Activation |
| Collaborators | Site Parent | BC Cancer | REB Submission Date | 03/06/2023 |
| E Metrics & Clocks | Project Site Status | Open to recruitment (26/07/2023) | Date of REB Approval | 24/09/2023 |
| S Timeline | Site Type | | Date site specific information | |
| Delegation Log | Project Site Number | | Capacity & capability | No |
| 2 Participants | | sites to navigate | assessment required? | |
| - Import Participants | Target Recr. to your p | articipant level | Date site invited by sponsor | |
| Statistics | Actual Recruitment | 4 | Date site selected by sponsor | |
| ✗ Settings | Participant Data Collection P | lan Canada | Date site confirmed by sponsor | |
| e octange | Participant Identifier Type | Local Number | Date site confirmed participation | 03/04/2023 |
| | | | Non-confirmation Status | |



Data Levels – Participant Level

| t Participants i Overview t Safety Reporting | (BCC) BEV-DOSE BC Cancer – Abbotsford (anonymous) | | | |
|------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| AppointmentsFinance | i Overview | | Audit Mo | de Delete Participant |
| FormsDocuments | Le Participant Details | Participant Status | 🥒 Edit S | Status 🧪 Take Off Study |
| | First name Last name Gender Subject ID 123456 Screening ID Project Arm Referring Site Date Referred Comments | Str Pr scree ed Approached Consented Screened Recruited / Randomised | Date This action hap 03/04/2023 03/04/2023 03/04/2023 03/04/2023 03/04/2023 | Actioned by opened elsewhere Schoales, James Schoales, James Schoales, James Schoales, James |
| | Responsible Physician Deceased | S Identifiers | | + Add |



View and Add Trials

Exiting and new trials



View Open Recruiting Portfolio Trials

| 💠 ed 📽 🏫 Home 🌶 Management 🖀 Projects | 🗓 Sites 💄 Participants 🗠 Reports 🧠 Support | 🛓 James Schoales 🗸 |
|---------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| ✓ Search Criteria Scope All Projects | Search Projects All projects Page 1 of 2 | Previous Next 32 records returned |
| Title/Short title | (AHS) 27/ MANTICORE BC - Vancouver (Open to recruitment) A Prospective Study to See if Cardiac Effects of Herceptin Can be Prevented With Standard Heart Medications CancerCare Manitoba - Adults (Project site in setup) |)) |
| Local Reference Project Identifiers Core details | Project owner Canadian Cancer Clinical Trials Network (3CTN) Status Closed to recruitment - in follow up Local reference (AHS) 27/ MANTICORE Clinical Trials Gov NCT01016886 Protocol ID | |
| ✓ Project type | (BB) Another Test | |
| Academic non-portfolio Academic portfolio Commercial non-portfolio Commercial portfolio | Another Test Project owner Hamilton Health Sciences, Juravinski Cancer Centre Status Open to recruitment Clinical Trials Gov 12345678 Edge LD 6943 | |
| | | |
| Closed - COVID-19 Destroyed Follow up on hold - COVID-19 Project setup suspended - COVID-19 Recruitment on hold - COVID-19 Concept | (BCC) BEV-DOSE BC - Vancouver (Open to recruitment) A Comparison of 2 Standard Doses of Bevacizumab in Combination With Chemotherapy in Epithelial Ovarian Cancer - a Pragmatic Trial BC Cancer – Abbotsford (Open to recruitment) Project owner Canadian Cancer Clinical Trials Network (3CTN) BC Cancer – Abbotsford (Open to recruitment) Status Open to recruitment Open to recruitment Clinical Trials Gov NCT04787289 Protocol ID BEV-DOSE | |



- To add a new/missing trial, you can search by selecting All Projects from the Scope dropdown
 - Once found, request involvement

- Once you have access to/added the project:
 - Add your project site
 - Add yourself to the project & project site

Trial Performance Data Entry: Trial Status and Activation Dates



Trial Performance Data Entry

Reporting new Portfolio trial involvement



- Search global projects for your desired Trial
- If found request involvement, notification email will be sent from the system (if you set it up).
- If not found,
 - For portal users, complete the 3CTN Portfolio application form and submit to info@3CTN.ca
 - For current EDGE site, use the "online 3CTN Portfolio application" project attributes
- Once you have added or have been a granted access to the project, you will then need to add your staff and project site to the project.



 If there is an existing project on EDGE and you do not have access, you can navigate to the Organization tab and click Request Involvement

| edge 🔥 Home 🎾 N | anagement 🔒 Projects 🔲 Sites 💄 Particip | pants 🗠 Reports 🔩 Support | | | 💄 Rebecca Xu 🗸 | |
|---------------------|-----------------------------------------|---------------------------|----------------|---------------|----------------|--|
| t Project Search | Over: Alberta Admin Service | tegy" and Brain Injury | | | | |
| | + Organisations | | | | | |
| Stakeholders | Approved | Organisation | Requested date | Approved date | | |
| | ~ | Alberta Admin Services | | 10/11/2015 | | |
| | ~ | Alberta Innovates | | 21/09/2015 | | |



- Once the request is approved, you will need to add yourself and other users at the project level (green banner).
- Select the STAFF tab at the Project level (green banner) and click ADD ME. To add other users, ADD A NEW TEAM or ADD A NEW MEMBER OF STAFF.
- Click the Manage option (if applicable). You can also select a role from a drop-down list if desired.

| t Project Search i Overview | (AHS) 27/ MANTICORE Owner: Canadian Cancer Clinical Trials Net | work (3CTN) | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|-------------|-----------------------|--------------------------------------|-------------------------------------|
| Image: Staff Image: Organisations Image: Staff Image: Staff | Project Staff | | | | + Add me |
| | y staff name 🗎 | | | Include Deleted | Limit To My Organisation |
| (AHS) 27/ MANTICORE Owner: Canadian Cancer Clinical Trials | Network (3CTN) | | | | Previous Next 2 records returned |
| Project Staff | | | + Add a new team + Ad | d a new member of staff | age |
| Filter by staff name | | | Include Dele | ted Users 🗸 Limit To My Organisation | |
| Page 1 of 1 | | | | Previous Next 2 records returned | |
| User | Role | Active | Manage | | |
| Chowdhury, Raisa | | ~ | ~ | | |
| Schoales, Mr James | | ~ | ~ | | 22 |
| | | | | | |



After receiving access to the trial and being added as staff at the project level you will need to add your project site.

Steps

- Go to the project level (green banner) of desired trial
- Click on the "Sites" tab from the left navigation bar
- Click "Add Project Site"
- Choose your site from the "select site" window
- Fill in relevant data and click "save"

Note: To be able to add a site, your organization needs to be involved in the trial and you need to be added as staff to the trial with "**manage**" access.

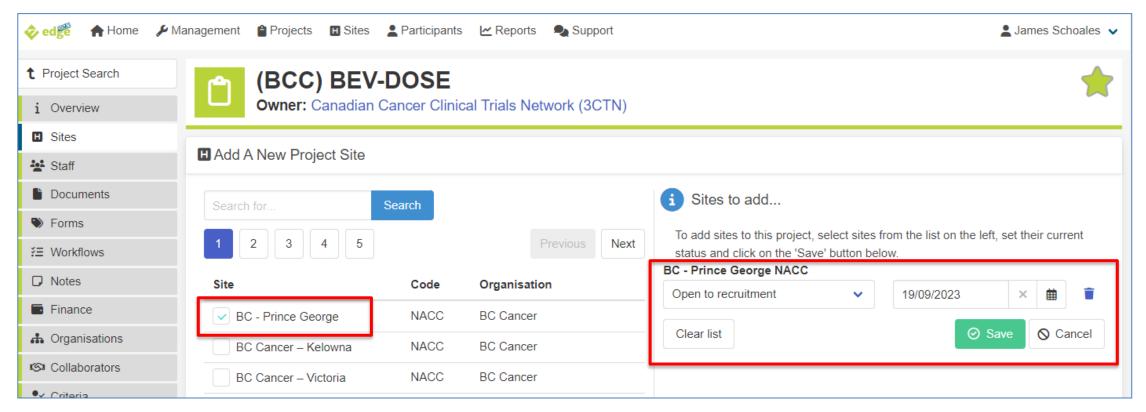


- 1. Go to the project level (green banner) of desired trial
- 2. Click on the "Sites" tab from the left navigation bar
- 3. Click "Add a new project site"

| t Project Search i Overview | (BCC) BEV-DOSE owner: Canadian Cancer Clinical Trials Network (3CTN) | * |
|--------------------------------|-------------------------------------------------------------------------|----------------------------------------------|
| 🖪 Sites | | |
| 🛃 Staff | H Sites | + Add a new project site |
| Documents | | |
| Forms | Filter by site name | Limit To My Organisation |
| žΞ Workflows | | Previous Next |
| Notes | Page 1 of 1 | 2 records returned |



- 4. Choose your site from the list or search
- 5. Fill in relevant data and click "save"





- At the site level, users can manage information related to the specific site
- Update site details (overview), site forms, site process tracking, accrual, staff and site-specific finance. Collaboration with other sites can also be set up here.

| t Sites | H (CCTG) ME.1 | 13 | 1 | | | | | | | | |
|-----------------------|----------------------------------|---------------------------------------------|------------|--|--|--------|-----------------------------------------------|-----------------|--------------|--------------------|--------------|
| i Overview | | nces, Juravinski Cancer Centre | | | | | | | | | |
| 🛃 Staff | | | | | | | | | | | |
| Documents | i Overview | | - | | | | | Audit Mode | ₽ Clone Site | ₽ Swap Site | |
| Sorms | | | | | | | | | | | |
| ž≣ Workflows | 🖞 Core Details | | | | | / Edit | ⊘ Approvals | | | | Section 2017 |
| Notes | | | | | | | | | | | |
| Finance | Site Owner | Canadian Cancer Clinical Trials Network (30 | | | | | Approval Process | Site Activation | | | |
| SI Collaborators | Site Parent | Hamilton Health Sciences, Juravinski Cance | cer Centre | | | | REB Submission Date | 25/09/2016 | | | |
| E Metrics & Clocks | Project Site Status | Open to recruitment (07/10/2016) | | | | | Date of REB Approval | 27/09/2016 | | | |
| S Timeline | Site Type | Recruiting Site Only | | | | | Date site specific information | | | | |
| Delegation Log | Project Site Number | | | | | | Capacity & capability assessment required? | No | | | |
| Participants | Qualified Investigator | | | | | | Date site invited by sponsor | 07/07/2016 | | | |
| - Import Participants | Target Recruitment | 48 | | | | | Date site selected by sponsor | 07/07/2016 | | | |
| Statistics | Participant Data Collection Plan | Canada | | | | | Date site confirmed participation | 03/08/2016 | | | |
| 🖋 Settings | Participant Identifier Type | Local Number | | | | | Date site confirmed by sponsor | 07/07/2016 | | | |
| | | | | | | | Non-confirmation Status | | | | |
| | Milestones | | | | | Sedit | | | | | |
| | | | | | | | | | | | |
| | SIV Date | | | | | | 😤 Key Staff | | | | |
| | Open To Recruitment | 07/10/2016 | | | | | Study Coordinator | | | | |
| | Recruitment End Date (Planned) | | | | | | Rebecca Xu | | | | |
| | Recruitment End Date (Actual) | | | | | | Canadian Cancer Clinical Trials | Network (3CTN) | | | |
| | Closing Date (Planned) | | | | | | | | | | |
| | Closing Date (Actual) | | | | | | | | | | 26 |



- In the project site level select the **STAFF** tab, and then click **ADD TEAM** or **ADD USER**.
- Select role (if applicable) and determine access level for member:
 - > Manage This access allow users to edit any of the data their organization can access (read and write access)
 - Clinical Only clinical access will allow users to see specific patient information. Any staff members at the site level that will be managing patients and patient data to a project will need this access.
 - Key Staff The Key staff feature can be used to identify key members for each project such as the PI, Co-PI, Lead Nurse, CRA etc. They will be listed on the "site details" page.

| 💠 edge 🔺 Home 🎾 | Vanagement 🍵 Projects 🔲 Sites 💄 Participants 🗠 Reports 🔩 S | Support | | | 💄 Rebecca Xu 🗸 |
|----------------------------------------------------|------------------------------------------------------------------|---------|---------------|-----------------------------|---------------------------|
| t Sites i Overview | (CCTG) ME.13 Hamilton Health Sciences, Juravinski Cancer Cent | tre | | | |
| StaffDocuments | Add A New Member Of Staff | | | | |
| Forms ¥Ξ Workflows | Search for Search | | | i Staff to add | |
| Notes | 1 2 | | Previous Next | User Role | Manage Clinical Key Staff |
| Finance Collaborators | User | Active | Access Type | Chang, Jose Please select ~ | |
| E Metrics & Clocks | Anillo, Emma | × | Admin | Clear list | ⊘ Save 🛇 Cancel |

Trial Performance Data Entry: Trial Status and Activation Dates



Trial Performance Data Entry

Updating / Adding trial statuses and activation dates



Project Site Detail Page

| 1 Sites | (BCC) BEV-E | DOSE | | | | | |
|----------------------------------------------------------|----------------------------------|------------------------------------------------|--------|-----------------------------------|-----------------|--------------|--------------------|
| i Overview | BC Cancer – Abbotsf | | | | | | |
| 🛃 Staff | | | | | | | |
| Documents | i Overview | | | | Audit Mode | ₽ Clone Site | ≵ Swap Site |
| Sorms | | | | | | | |
| ž≣ Workflows | 🖞 Core Details | | 🥒 Edit | ⊘ Approvals | | | Delit 🖉 |
| Notes | Site Owner | Canadian Cancer Clinical Trials Network (3CTN) | | Approval Process | Site Activation | | |
| Finance | Site Parent | BC Cancer | | REB Submission Date | 03/06/2023 | | |
| Collaborators | Project Site Status | Open to recruitment (26/07/2023) | | Date of REB Approval | 24/09/2023 | | |
| E Metrics & Clocks | Site Type | | | Date site specific information | | | |
| Timeline | Project Site Number | | | Capacity & capability | No | | |
| Delegation Log Participants | Qualified Investigator | Ms Rebecca Xu | | assessment required? | | | |
| -S Import Participants | Target Recruitment | 5 | | Date site invited by sponsor | | | |
| Statistics | Actual Recruitment | 4 | | Date site selected by sponsor | | | |
| ✤ Settings | Participant Data Collection Plan | Canada | | Date site confirmed by sponsor | | | |
| _ | Participant Identifier Type | Local Number | | Date site confirmed participation | 03/04/2023 | | |
| | | | | Non-confirmation Status | | | |
| | Milestones | | P Edit | | | | |
| | † Wilestones | | ear | 💒 Key Staff | | | |
| | SIV Date | | | , | | | |
| | Open To Recruitment | 25/08/2021 | | James Schoales | | | |
| | Recruitment End Date (Planned) | | | Canadian Cancer Clinical Trials | Vetwork (3CTN) | | |
| | Recruitment End Date (Actual) | | | | | | |
| | Planned completion date | | | | | | |
| | Completion date | | | | | | |
| | | | | | | | |



Project Site Detail Page – Details Section

- 1. Edit For most sections on the project site details page there will be an "Edit" button located to the right of the section header.
 - If you do not see the "Edit" button please make sure that you have "Manage" access to this project site under the Staff Tab.
 - If you have "Manage" access but still don't see the "Edit" button please make sure the project site is "Owned by" your organization.
- Status (Status Date) Your sites status for the project e.g. Open to Recruitment . Note you will need to enter a status date.
- 3. Site target recruitment Your site's expected recruitment over the lifespan of the project, which is set at the beginning of the trial initiation process. Note this target shouldn't change.

|) Core Details | Ed |
|----------------------------------|------------------------------------------------|
| Site Owner | Canadian Cancer Clinical Trials Network (3CTN) |
| Site Parent | BC Cancer |
| Project Site Status | Open to recruitment (26/07/2023) |
| Site Type | |
| Project Site Number | |
| Qualified Investigator | Ms Rebecca Xu |
| Target Recruitment | 5 |
| Actual Recruitment | 4 |
| Participant Data Collection Plan | Canada |
| Participant Identifier Type | Local Number |



Project Site Detail Page

| t Sites i Overview | (BCC) BEV-I BC Cancer – Abbots | | | | | | |
|-----------------------|-----------------------------------|------------------------------------------------|-------------|---------------------------------------------------|-----------------|---------------------|--------------------|
| Staff | | | | | | | |
| Documents | i Overview | | | | Audit Mode | ₽ Clone Site | ₽ Swap Site |
| Forms | | | | | | | |
| ¥∃ Workflows | 🗂 Core Details | | Sedit Sedit | ⊘ Approvals | | | 🥟 Edit |
| Notes | Site Owner | | | America | | | |
| Finance | Site Owner | Canadian Cancer Clinical Trials Network (3CTN) | | Approval Process REB Submission Date | Site Activation | | |
| Collaborators | | BC Cancer | | L | | | |
| E Metrics & Clocks | Project Site Status | Open to recruitment (26/07/2023) | | Date of REB Approval | 24/09/2023 | | |
| C Timeline | Site Type | | | Date site specific information | | | |
| Delegation Log | Project Site Number | | | Capacity & capability assessment required? | No | | |
| Participants | Qualified Investigator | Ms Rebecca Xu | | Date site invited by sponsor | | | |
| Import Participants | Target Recruitment | 5 | | Date site selected by sponsor | | | |
| Statistics | Actual Recruitment | 4 | | Date site confirmed by sponsor | | | |
| 🖌 Settings | Participant Data Collection Plan | Canada | | Date site confirmed participation | 03/04/2023 | | |
| | Participant Identifier Type | Local Number | | Non-confirmation Status | | | |
| | | | | | | | |
| | Milestones | | Sector Edit | Key Staff | | | |
| | SIV Date | | | | | | |
| | Open To Recruitment | 25/08/2021 | | | | | |
| | Recruitment End Date (Planned) | | | James Schoales Canadian Cancer Clinical Trials | Network (3CTN) | | |
| | Recruitment End Date (Actual) | | | | | | |
| | Planned completion date | | | | | | |
| | Completion date | | | | | | |
| | | | | | | | |



By default the "Approvals" section will only show REB and SSI dates. You will need to change the "Approval process" from "REB Approval" to "Site Activation".

| ⊘ Add Approval | | | | | ⊘ Add Approval |
|---------------------------------------------------------------------|---|---|--------|----------|--------------------------------------------------------------------------------------------------------|
| Approval Process REB Approval REB Submission Date | + | | | | Approval Process REB Approval (No approval process) REB Approval |
| 04/06/2023 Date of REB Approval | × | | | | Site Activation 04/00/2023 X Date of REB Approval |
| 25/09/2023 | × | 曲 | | | 25/09/2023 × 🗰 |
| Date site specific information | | | | | Date site specific information |
| | × | | | | × # |
| | | | ⊘ Save | O Cancel | Save Save |



You will now be able to add the "Start Date of Site Activation Process" in the "Date site confirmed participation" data field.

If you will also add your site's REB submission and approval dates in this section.

Note: REB dates are the initial submission and approval dates.

| Approval Process | | | | | |
|--------------------------------------------------------------|------|--------|--------|----------|---|
| Site Activation 🗸 | | | | | |
| REB Submission Date | | | | | |
| 04/06/2023 | × | ₿ | | | |
| Date of REB Approval | | | | | |
| 25/09/2023 | × | | | | |
| Date site specific information | | | | | |
| | × | | | | |
| Capacity & capability assess Date site invited by sponsor | smen | t requ | uired? | | |
| | × | | | | |
| Date site selected by sponsor | | | | | |
| | × | | | | |
| Date site confirmed by sponse | or | | | | |
| | × | | | | _ |
| Date site confirmed participati | on | | | | |
| 04/04/2023 | × | | | | |
| Non-confirmation Status | | | | | |
| Please choose | | ~ | | | |
| | | | ⊘ Save | O Cancel | |

| | adian cer Clinical | roject Site Detail Page | | | | | |
|-----------------------|-----------------------------------------------------------------|------------------------------------------------|--------|---------------------------------------------------|-----------------|---------------------|--------------------|
| t Sites | (BCC) BEV-D | DOSE | | | | | |
| i Overview | BC Cancer – Abbotsf | | | | | | |
| 😫 Staff | · • | | | | · · · · · · · | | |
| Documents | i Overview | | | | Audit Mode | ₽ Clone Site | ≵ Swap Site |
| Forms | 🗂 Core Details | | / Edit | ⊘ Approvals | | | 🖉 Edit |
| ž≡ Workflows | - | | | | | | |
| Finance | Site Owner | Canadian Cancer Clinical Trials Network (3CTN) | | Approval Process | Site Activation | | |
| Collaborators | Site Parent | BC Cancer | | REB Submission Date | 03/06/2023 | | |
| E Metrics & Clocks | Project Site Status | Open to recruitment (26/07/2023) | | Date of REB Approval | 24/09/2023 | | |
| S Timeline | Site Type | | | Date site specific information | | | |
| Delegation Log | Project Site Number | | | Capacity & capability assessment required? | No | | |
| 2 Participants | Qualified Investigator | Ms Rebecca Xu | | Date site invited by sponsor | | | |
| - Import Participants | Target Recruitment | 5 | | Date site selected by sponsor | | | |
| Statistics | Actual Recruitment | 4 | | Date site confirmed by sponsor | | | |
| 🖌 Settings | Participant Data Collection Plan Participant Identifier Type | Canada Local Number | | Date site confirmed participation | 03/04/2023 | | |
| | Participant identifier Type | Local Number | | Non-confirmation Status | | | |
| | | | | I | | | |
| | Milestones | | 🥒 Edit | to Koy Stoff | | | |
| | SIV Date | | | 📲 Key Staff | | | |
| | Open To Recruitment | 25/08/2021 | | | | | |
| | Recruitment End Date (Planned) | 25/00/2021 | | James Schoales Canadian Cancer Clinical Trials | Vetwork (3CTN) | | |
| | Recruitment End Date (Actual) | | | | | | |
| | Planned completion date | | | | | | |
| | Completion date | | | | | | |
| | | | | | | | |



- 1. Edit Clicking "Edit" will open a dialogue box that will enable you to update or add information.
- 2. Open to recruitment Date your site is initially authorized to open to recruitment (dd/mm/yyyy)
- 3. Recruitment end date Date your site is closed to recruitment. (dd/mm/yyyy)





Knowledgebase - Tutorial Articles

| ≽ ed 💏 🛛 🏫 Home 🖌 | 🖌 Management 😭 Projects 🖪 Sites 💄 Pa | articipants 🗠 Reports 🔍 Support | | Lames Schoales |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Support | KnowledgeBase Home / 5 - Managing Projects | s and Projec | | |
| KnowledgeBase | 5.1 Sotting up | 5.2 Managing | 5.2 Managing Project | 5.4 Managing |
| Videos | 5.1 - Setting up Projects | 5.2 - Managing Projects | 5.3 - Managing Project Sites | 5.4 - Managing Projects and Proj |
| Release Notes | Learn how to add Projects to EDGE, including definitions for all fields | Learn about managing all parts of the Project section within EDGE | Learn about managing all parts of the Project Sites section within Projects | Learn about managing Projects an Project Site documents |
| | 5101 - Searching for a Project in EDGE 5102 - Creating a New Project 5103 - Removing Organisational Involvement in a Project 5104 - Deleting a Project 5105 - Managing Project Involvement Requests | 5200 - Project Data Dictionary 5201 - Project Ownership 5202 - How to Add a Chief Investigator to a Project 5203 - How to Transfer Project Ownership 5204 - How to Assign / Unassign a Site from a Project 5205 - How to Manage Staff on a Project 5206 - How to Add Forms and Fields to a Project 5207 - How to Update Fields on a Form 5208 - How to Add a Workflow to a Project 5209 - How to Add a Project Note 5210 - Project and Project Site Finance Overview 5211 - How to Add an Organisation to a Project 5212 - How to Set Up Project | 5300 - Project Site Data Dictionary 5301 - How to Manage Staff on a Project Site 5302 - How to Transfer Ownership of a Project Site 5303 - How to Use the Swap Site Function on a Project Site 5304 - How to Clone a Project Site 5305 - How to Add Forms and Fields to a Project Site 5306 - How to Update Fields on a Form 5307 - How to Add a Workflow to a Project Site 5308 - How to Add a Project Site Note 5309 - Project Site Finance Overview 5310 - How to Set Up a Project Site Collaboration 5311 - Project Site Metrics & Clocks 5312 - Project Site Timeline | 5400 - Documents on Projects and Project Sites 5401 - How to Upload a Document to a Project/Project Site 5402 - How to Update a Document on a Project/Project Site 5403 - How to Upload a New Version of a Document 5404 - How to Delete a Project/Project Site Document |

Reporting and Tracking Patients: How to Manually Enter Patients



Reporting and Tracking Patients

Manually Adding Patients



Patient Reporting – Mandatory Information

Patient Information:

- Subject ID used for patient verification
- Date consented used for multi-staged registration trials
- Date recruited/randomized used to track patient recruitment by quarter

Supplemental, Priority Patient Information (for AYA or Remote trial participants only):

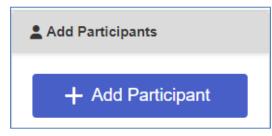
- AYA Patient? (age 15-39) Yes or No
- Remote Patient? Yes or No
- Satellite Site Name Full name of satellite site
- Type of Satellite Site Primary Oncology Site or Closer to Home Healthcare provider
- Initial Date of Remote Trial Access Date patient receives initial trial related care/support at satellite site
- Satellite Site Clinical Trial Conduct Trial conduct being preformed at satellite site
- Remote Access Comments Additional context to help with eligibility evaluation



Manually Adding a Participant - Options

There are **2** ways to manually add participants to EDGE:

1. Using the "Add Participant" button on the home page



2. At the project site level (red banner) of a trial

| t Sites | (BCC) BEV-DOSE | |
|--------------|-----------------------|----------------------------------------------------------------|
| i Overview | Abbotsford Centre | |
| 🐮 Staff | | |
| Documents | 2 Participants | + Add a new participant ▲ Download ∨ 📋 Delete all Participants |
| S Forms | | |
| žΞ Workflows | Filter by participant | All 🗸 |

Note: Both these options require you to have Clinical access to the project site level of the trial and the trial is open to recruitment at your project site level.



Adding a Participant – Participant Details

| Add Participant | |] | | | | | |
|----------------------------------------------------------------------------|------------------------------------|---|--|--|--|--|--|
| Project Sites you have recently recruited to Search Your Clinical Projects | | | | | | | |
| | Project (BCC) BEV-DOSE | | | | | | |
| | You are assigned to these 2 sites: | , | | | | | |
| | Abbotsford Centre | | | | | | |

| La Ado | l Partic | cipant | | | |
|------------------|--------------|-------------|-----------|---------------|--------------|
| 1 Identifiers | 2 Details | 3 Status | Off Study | 5 Comments | 6 Summary |
| Local Numb | er | | | | |
| ID Number | | | | | |
| First Name | | | | | |
| First name | | Optiona | l Fields | | |
| Last Name | | Optiona | | | |
| Last name | | | | | |
| Gender | | | | | |
| Please sele | ect 🗸 | | | | |



Adding a Participant – Participant Details

| | • | • | 6 | 6 |
|----------------------------|-----------|-----------|----------|--------|
| d 2 Identifiers Details | Status | Off Study | Comments | Summar |
| Subject ID | | | | |
| Subject ID | | | | |
| Screening ID | | | | |
| Screening ID | | | | |
| Other ID | | | | |
| Other ID | | | | |
| Project Arms | | | | |
| Search for project arms | Ontiona | | Ŵ | Search |
| Responsible Physician | Optiona | I FIEIUS | | |
| Search for Responsible | Physician | | Ŵ | Search |
| | | | | |
| Referring Site | | | <u>A</u> | Search |
| Referring Site | | | Ŵ | Search |



Adding a Participant – Participant Status Dates

| Add Participant | | | | | | | |
|-----------------------------------------------------|----------------------|--------------|-----|----------------|----------|-----|--------|
| 1 2 3 Identifiers Details Status | 0ff Study Comments S | - 6 Summa | ıry | S Exit Wizard | Previo | ous | > Next |
| Participant transfer is not enabled on this project | Status Date | | | Actioned By | | | |
| Pre-Screened | 28/07/2023 | × | 曲 | James Schoales | Ŵ | Q | ~ |
| Approached | 28/07/2023 | × | ₿ | James Schoales | Ē | Q | ~ |
| Consented | 28/07/2023 | × | | James Schoales | Û | Q | ~ |
| Screened | 28/07/2023 | × | | James Schoales | Ŵ | Q | ~ |
| Recruited / Randomised | 28/07/2023 | × | | James Schoales | ١ | Q | ~ |
| On treatment | | × | | James Schoales | Ŵ | Q | ~ |
| On follow-up | | × | | James Schoales | Ŵ | Q | ~ |
| Completed | | × | | James Schoales | Ŵ | Q | ~ |
| Note: All previous | dates must also | o k | e f | illed in. | < Previo | ous | > Next |



Adding a Participant – Within the Project Site level

| t Sites | H (BCC) BEV-D | OSE | |
|-----------------------|----------------------------------|------------------------------------------------|---------|
| i Overview | Abbotsford Centre | | |
| 😫 Staff | • • • | | _ |
| Documents | i Overview | | Audit M |
| Forms | A B B B | | |
| žΞ Workflows | 🖞 Core Details | | 🥟 Edit |
| D Notes | | | |
| Finance | Site Owner | Canadian Cancer Clinical Trials Network (3CTN) | |
| Collaborators | Site Parent | British Columbia Cancer Agency | |
| E Metrics & Clocks | Project Site Status | Open to recruitment (26/07/2023) | |
| C Timeline | Site Type | | |
| Delegation Log | Project Site Number | | |
| Participants | Qualified Investigator | | |
| - Import Participants | Target Recruitment | 5 | |
| Statistics | Actual Recruitment | 3 | |
| 🖌 Settings | Participant Data Collection Plan | Canada | |
| | Participant Identifier Type | Local Number | |



Adding a Participant – Participant Details

| H (BCC) BEV-DOSE Abbotsford Centre | |
|---------------------------------------|-------------------------|
| Participants | + Add a new participant |
| Filter by participant | [|

| La Ado | l Partic | ipant | | | |
|------------------|--------------|-------------|----------------|---------------|--------------|
| 1 Identifiers | 2 Details | 3 Status | 4 Off Study | 5 Comments | 6 Summary |
| Local Numb | er | | | | |
| ID Number | | | | | |
| First Name | | | | | |
| First name | | Optiona | l Fields | | |
| Last Name | | optiona | | | |
| Last name | | | | | |
| Gender | | | | | |
| Please sele | ect 🗸 | | | | |



Adding a Participant – Participant Details

| | • | • | 6 | 6 |
|----------------------------|-----------|-----------|----------|--------|
| d 2 Identifiers Details | Status | Off Study | Comments | Summar |
| Subject ID | | | | |
| Subject ID | | | | |
| Screening ID | | | | |
| Screening ID | | | | |
| Other ID | | | | |
| Other ID | | | | |
| Project Arms | | | | |
| Search for project arms | Ontiona | | Ŵ | Search |
| Responsible Physician | Optiona | I FIEIUS | | |
| Search for Responsible | Physician | | Ŵ | Search |
| | | | | |
| Referring Site | | | <u>A</u> | Search |
| Referring Site | | | Ŵ | Search |



Adding a Participant – Participant Status Dates

| Add Participant | | | | | | | |
|-----------------------------------------------------|----------------------|--------------|-----|----------------|----------|-----|--------|
| 1 2 3 Identifiers Details Status | 0ff Study Comments S | - 6 Summa | ıry | S Exit Wizard | Previo | ous | > Next |
| Participant transfer is not enabled on this project | Status Date | | | Actioned By | | | |
| Pre-Screened | 28/07/2023 | × | 曲 | James Schoales | Ŵ | Q | ~ |
| Approached | 28/07/2023 | × | ₿ | James Schoales | Ē | Q | ~ |
| Consented | 28/07/2023 | × | | James Schoales | Û | Q | ~ |
| Screened | 28/07/2023 | × | | James Schoales | Ŵ | Q | ~ |
| Recruited / Randomised | 28/07/2023 | × | | James Schoales | ١ | Q | ~ |
| On treatment | | × | | James Schoales | Ŵ | Q | ~ |
| On follow-up | | × | | James Schoales | Ŵ | Q | ~ |
| Completed | | × | | James Schoales | Ŵ | Q | ~ |
| Note: All previous | dates must also | o k | e f | illed in. | < Previo | ous | > Next |

Reporting and Tracking Patients: Bulk Import



Reporting and Tracking Patients

Bulk Import Patients



- Management Tab Import (Bulk Import)
 - Allows admin users to import participants to multiple projects/project sites at once regardless of project or project site status
 - Main drawback is the limited participant information that can be imported
 - Import template can be downloaded and completed
- Project/Project Site Level Import (Detailed Import)
 - Allows users with manager/clinical access import participants to a single project or project site
 - · Import template can be downloaded and filled out
 - Allows the most participant details to be imported (e.g. all workflow status, comments and off study reasons



- In the Management tab click on Participant Import
- Click Download import template to download a .csv import template

| 😫 Users | - Participant Imports + Add a new import |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 😫 Teams | |
| Training Courses | These are surrantly as management level participant imports |
| Projects | There are currently no management level participant imports. If this is your first time importing participants into EDGE, we would recommend <u>a quick tour</u> to help you get started. |
| Documents | |
| Sorms | |
| žΞ Workflows | |
| Finance | |
| ≟≣ Custom Lists | |
| A Organisation | |
| Partnerships | |
| Folder Templates | |
| -Site Import Templates | |
| Bata Collection Plans | |
| - Participant Import | |
| Catalogue | |
| 🛓 Export | |
| | |

Canadian Cancer Clinical Trials Network Bulk Importing – Template Data Fields

• The following data fields (red = mandatory) are available in the import template:

- Project Title
- Site Name
- Identifier Number
- Title
- First name
- Last name
- Date of Birth
- Gender
- Date of Death
- Study ID
- Subject ID
- Screening ID
- Other ID
- Ethnicity
- Participant Type

- Project Arm
- Referring Site
- Responsible Physician
- Screened Date
- Screened By
- Recruited Date
- Recruited By
- Off Study Date
- Off Study By
- Off Study Reason
- Off Study Decision
- Off Study Description
- Off Study Comments
- Patient Comments



- Once you have completed the import template you will need to make sure that it is formatted correctly and saved as a CSV file
- Date format should be dd/mm/yyyy
- Project Site name and Project Short title should match what is in EDGE
- Make sure the Project Site is attached to the trials
- Users/Staff names should be Last Name, First Name



Once Template and CSV are complete, click + Add a new import

| - S Participant Imports | 🛓 Download import template | + Add a new import |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|
| There are currently no management level participant imports. If this is your first time importing participants into EDGE, we would recommend <u>a quick tour</u> to help you get started | | |

- Select your CSV file and click import.
- You will be brought to an Import overview page where you can see what is being imported and can make corrections if there are any errors. Once the import is finalized click + Import Participants

- Participant Import

+ Validate this import +

+ Import Participants



- You can navigate to the project or project site level of the project you are going to import participants to.
- Click Import Participants in the left navigation bar and click Download import template

| t Project Search | (BCC) BEV-DOSE |
|------------------------|------------------------------------------------------------------------------------------------------------------------------|
| i Overview | Owner: Canadian Cancer Clinical Trials Network (3CTN) |
| 🖪 Sites | |
| 💒 Staff | - Participant Imports Add a new import Add a new import |
| Documents | |
| Forms | There are currently no participant imports on this project. |
| ž≣ Workflows | If this is your first time importing participants into EDGE, we would recommend <u>a quick tour</u> to help you get started. |
| Notes | |
| Finance | |
| 🔥 Organisations | |
| Collaborators | |
| よ Criteria | |
| Stakeholders | |
| Statistics | |
| Configuration | |
| -5 Import Participants | |
| Sites Management | |
| E KPIs | |

Cancer Clinical Trials Network Detailed Importing – Template Data Fields (Project Level)

- The following data fields (red = mandatory) are available in the import template:
 - Site Name

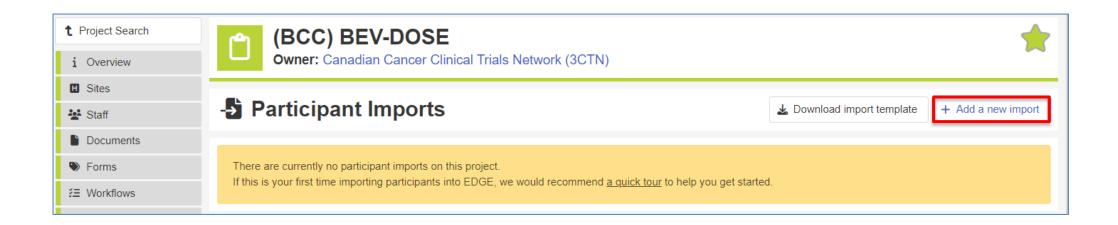
Canadian

- Identifier Number
- Title
- First name
- Last name
- Date of Birth
- Gender
- Date of Death
- Study ID
- Subject ID
- Screening ID
- Other ID
- Ethnicity
- Participant Type
- Project Arm
- Referring Site
- Responsible Physician
- Pre-Screened Date
- Pre-Screened By
- Approached Date

- Approached By
- Consented Date
- Consented By
- Screened Date
- Screened By
- Recruited / Randomised Date
- Recruited / Randomised By
- On treatment Date
- On treatment By
- On follow-up Date
- On follow-up By
- Completed Date
- Completed By
- Off Study Date
- Off Study By
- Off Study Reason
- Off Study Decision
- Off Study Description
- Off Study Comments
- Patient Comments



- You will now have an Excel file with column headers for participant identifiers, details and participant statuses.
- Fill out this Excel template using the participant information you want to import making sure not to skip statuses and save as a CSV file. Then you can go back to the Import Participant tab of the project and upload the CSV file. A similar Import overview page window will open where you can see what is being imported and can make corrections if there are any errors. Once the import is finalized click Import participants.





Bulk Importing – Import File Verification

- Once Import template is set up, ensure:
 - Excel is formatted correctly
 - Saved as a .CSV file
- Date format should be *dd/mm/yyyy*
- **Project Site** name and **Project Short title** should match what is in EDGE
- Make sure the *Project Site* is attached to the trials



Once imported, review the *import preview pane* to verify which patients are being imported and to identify data errors.

| 💠 ed 💏 🛖 Home 🎤 M | anagement 😭 Projects 🔳 Sites 💄 Participants 🗠 Reports 🎭 Support | | | | 🛓 James Schoales 🗸 |
|------------------------------------------|-----------------------------------------------------------------|---------------|-------------------|----------------------|---------------------------|
| Users | - Participant Import | | + \ | /alidate this impo | ort + Import Participants |
| Training Courses | ⊘ Import Details | | | | |
| Projects | | | | | |
| Documents | Filename Test import.csv | Status | Reviewing | | |
| Forms | Date File Uploaded 03/08/2023 Date Import | Rows | 2 in total, 0 i | gnored and 2 are | e valid. |
| ¥∃ Workflows | Performed | | | | |
| Finance | | | | | |
| ¹ ₂ ∃ Custom Lists | ▼ State (All) ~ | | | | |
| 🚓 Organisation | | | | | |
| Real Partnerships | Page size 25 🗸 | | | | Previous Next |
| Folder Templates | Page 1 of 1 | | | | 2 records returned |
| Site Import Templates | Valid Errors | Name | Project | Site | Date Of Birth |
| II Data Collection Plans | ✓ | null, | (BCC) | Abbotsford | • 🖉 📋 |
| - Participant Import | - | null | BEV-DOSE | Centre | |
| Catalogue | \checkmark | null, null | (BCC) BEV-DOSE | Abbotsford Centre | •• |
| 🛓 Export | | nuii | DEV-DUGE | Centre | |

Reporting and Tracking Patients: Priority Patient Reporting



Reporting and Tracking Patients

Priority Patient Reporting



Priority Patient Tracking

Priority patient information will be tracked at the participant level. Patients will have to have been added to the trial beforehand (manually or imported).

Priority Patient Information (filled out for AYA or Remote patients only):

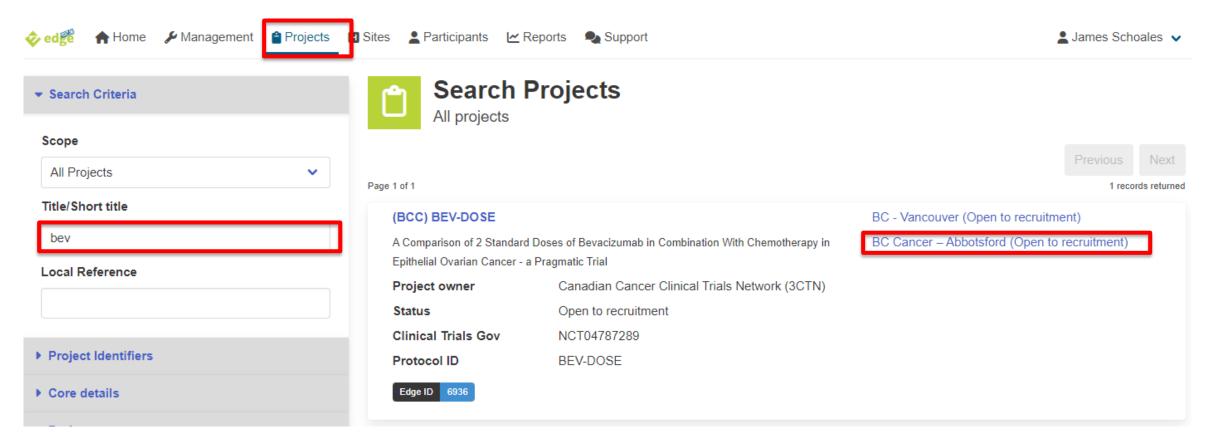
| Data Field | Options |
|---------------------------------------|--------------------------------------------------------------------|
| AYA Patient? (age 15-39) | Yes or No |
| Remote Patient? | Yes or No |
| Satellite Site Name | Full name of Satellite Site |
| Type of Satellite Site | Primary Oncology Site or Closer to Home Healthcare provider |
| Date of Remote Access Initiation | Date patient receives trial related care/support at satellite site |
| Satellite Site Clinical Trial Conduct | Trial conduct being preformed at satellite site |
| Remote Access Comments | Additional context to help with eligibility evaluation |

Definitions available: <u>https://3ctn.ca/files/remote-access-ibf-definition</u>



Priority Patient Tracking - Navigation

- Go to *Projects* tab and search for the trial
- Select your Project Site Name to the right of the trial information





Priority Patient Tracking - Navigation

- At the project site level (red banner) click the patient tab
- Click on patient's "name" to the left of the patient information

| t Sites | (BCC) BEV-DOSE |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| i Overview | BC Cancer – Abbotsford |
| 🐮 Staff | |
| Documents | ▲ Participants+ Add a new participant▲ Download ∨■ Delete all Participants |
| Forms | Name / Identifiers Current Status (All status) |
| žΞ Workflows | Name / Identifiers Current Status (All status) |
| D Notes | Date of Birth × |
| Finance | ⊘ Update results |
| Collaborators | |
| 🛋 Metrics & Clocks | Previous Next |
| S Timeline | Page 1 of 1 6 records returned |
| Delegation Log | Name ↓ Date of Birth Identifiers Study ID Subject ID Screening ID Other ID Current Status \$ Current Status Date ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ ◆ |
| Participants | |
| - Import Participants | (anonymous) 123456 Recruited / 03/04/2023 Randomised |



Priority Patient Tracking – Data Entry

- At the *Participant* level, go to *Forms*
- Select Add a new form





Priority Patient Tracking – Navigation / Data Entry

- Select the *Priority Patient* Form
- Check the box of relevant fields (below is an example of Remote Access Patient reporting by Primary Site) and fill in fields on the right, to complete relevant data

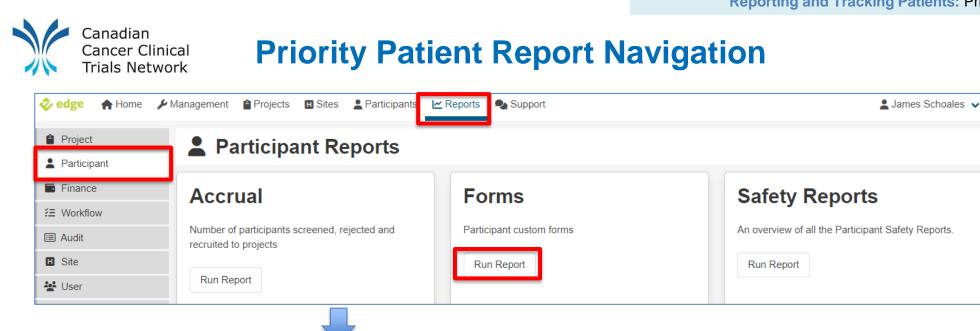
| | | Add A New Form And Field | |
|----------------------------------------------------------------------------------------------------------------------------------------|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Add A New Form And Field | | Form | i Add a New Form and Field |
| Form | | Priority Patient Select All | Remote Patient? |
| (Choose form) | | AYA Patient? (Age 15-39) | Ves |
| (Choose form) Consent/re-consent/randomization timepoints Patient screening Patient Visit Tracking (demo) Priority Patient | menu above. | Remote Patient? Satellite Site Name Type of Satellite Site Date of Remote Access Initiation Satellite Site Clinical Trial Conduct | No RA-1 RA-2 RA-3 Unknown |
| Treatment Period Treatment Period for BMS CA209-451 | ⊘ Save | Primary Site NameTrial Short Title (Remote Access)Remote Access Comments | Satellite Site Name BCC - Prince George |
| | | Save 🛇 Canc | |
| | | | C2H-HCP |



Priority Patient Reporting

- A priority patient report has been created for portal sites
- Date filters are used to limit data to current quarter
- Update the date filters to focus data on quarters being reported
- Run and download report results to MSExcel

| ort Criteria Priority Patient Report ver 2 | | | | | | | O Clear | E Load | Save 3 | Save A |
|--------------------------------------------|------------|-----|--------|------------------------|------------|--------------------------|--------------|--------------------------|-----------------|--------|
| ields | + Add Fi | eld | Filter | rs | | | | | | |
| Project Site Name | Add Filter | × | \$ | Project Type | ls 🗸 | Equal To | | Acad | lemic portfolio | > |
| Project Short Title | Add Filter | × | AND 🗸 | | | | | | | |
| Subject ID | Add Filter | × | \$ | Remote Patient? | ls 🗸 | Like | | ✓ yes | | 2 |
| AYA Patient? (Age 15-39) | Add Filter | × | AND 🗸 | | | | | | | |
| Remote Patient? | Add Filter | × | \$ | Date of Remote Access | Initiation | ls 🗸 | Greater Than | | ✓ 31/03/20 | 22 |
| Date Randomised / Recruited | Add Filter | × | AND 💙 | | | | | | | |
| Date of Remote Access Initiation | Add Filter | × | \$ | Date of Remote Access | Initiation | ls 💙 | Less Than | | • 01/07/20 | 22 |
| Satellite Site Name | Add Filter | × | OR 🗸 | | | | | | | |
| Type of Satellite Site | Add Filter | × | \$ | Project Type | ls 🗸 | Equal To | | Acad | lemic portfolio | : |
| Satellite Site Clinical Trial Conduct | Add Filter | × | AND 💙 | | | | | | | |
| Remote Access Comments | Add Filter | × | | AYA Patient? (Age 15-3 | 9) Is | Like | | ✓ y | es | 3 |
| Project type | Add Filter | × | AND 💙 | | | | | | | |
| | | | | Date Randomised / Rec | ruited Is | ✓ Gre | ater Than | ~ | 31/03/2022 | : |
| | | | AND 🗸 | | | | | | | |
| | | | \$ | Date Randomised / Rec | ruited Is | ✓ Les | s Than | ~ | 01/07/2022 | |



| Participant Forms Re | port | |
|-----------------------------------------------------------------------------------------------------------------|---------------------|----------------------------|
| Report Criteria | | 🛇 Clear 🕞 Load 🗈 Save As |
| Load Query | 8 | |
| priority | Limit To My Queries | |
| Public Name Image: Priority Patient Report ver 2 Image: Priority Patient Report ver 2 | 8 | Note: Report name may vary |



Priority Patient Report Generation

| Participant Forms Report | | |
|----------------------------------------------|--------------|-------------------------------------------------------------------------------------------------------------------------------|
| eport Criteria Priority Patient Report ver 2 | | Sour Save As Save Save As |
| Fields | + Add Field | Filters |
| Project Site Name | Add Filter × | ♦ Project Type Is ▼ Equal To ▼ Academic portfolio × |
| Project Short Title | Add Filter × | AND V |
| Subject ID | Add Filter × | ♦ Remote Patient? Is ✓ Like ✓ yes × |
| ♦ AYA Patient? (Age 15-39) | Add Filter × | |
| Remote Patient? | Add Filter × | ♦ Date of Remote Access Initiation Is ♥ Greater Than ♥ 31/03/2022 × |
| Date Randomised / Recruited | Add Filter × | AND V |
| Date of Remote Access Initiation | Add Filter × | ♦ Date of Remote Access Initiation Is ▶ Less Than ▶ 01/07/2022 |
| Satellite Site Name | Add Filter × | |
| ♦ Type of Satellite Site | Add Filter × | ♦ Project Type Is ▼ Equal To ▼ Academic portfolio × |
| Satellite Site Clinical Trial Conduct | Add Filter × | |
| Remote Access Comments | Add Filter × | ♦ AYA Patient? (Age 15-39) Is ▶ Like ▶ yes |
| ♦ Project type | Add Filter × | |
| | | AND V |
| | | |
| | | |
| eport | | 🕨 Run 🛃 🕹 Download |



3CTN Priority Patient Reporting

- Under Project Site level for the 3CTN Reporting Y9 for Adult Sites, or 3CTN Reporting Y9 for Ped Sites project, as applicable
- Upload your Priority Patient file to the *Priority Patient Reports (site to upload) folder* using *Add file*

| 😫 Staff | | | | | | | | |
|--------------------|------------------------------|----------------------------------------------|-----------------|---------|----------|-----------|--------|-----------------------------------------|
| Documents | Project Site L | Project Site Documents + Add from folder | | | | | | late + Add a new folder |
| Forms | | | | | | | | |
| žΞ Workflows | Root | | | | | | | |
| Notes | Name 🗢 | Uploaded By 🖨 | Uploaded Date 🖨 | Version | Comments | Published | Public | \checkmark |
| Finance | 🕑 🖿 Annual Schedule G | | | | | | | * 🖉 🔟 |
| Collaborators | 💽 🖿 Priority Patient Reports | | | | | | | ‡ |
| 🔳 Metrics & Clocks | 🔄 🖿 M & D from RFA | | | | | | | |
| C Timeline | | | | | | | | * 🧖 📋 |
| Delegation Log | 3 folder(s), 0 file(s) | | | | | | | |
| Participants | | | | | | | | (Select action to perform) \checkmark |



 Once in the folder you can drag and drop the file in the grey box or click on the box to use the file finder widow to choose the desired file. Make sure to check Public to allow 3CTN to see the report.

| Pro | ject Site Docı | uments | | | + Add from folder | template + Add a new folder |
|-----------------|-----------------|---------------------------------------|-----------------------|-------------|-------------------|------------------------------|
| Root / Priority | Patient Reports | | | | | |
| Name 🖨 | Uploaded By 🖨 | Uploaded Date 🖨 | Version | Comments | Published | Public |
| | | | | | | |
| 0 folder(s), 0 | file(s) | | | | | (Select action to perform) M |
| | | | | | | (Select action to perform) V |
| | | · · · · · · · · · · · · · · · · · · · | | | | |
| | | Version | | | | |
| | | Published 🚯 | | |) | |
| | | Public 🚯 | | |] | |
| | | | <u>1</u> | | | |
| | | Choose | a file, or drag one o | r more here | | |

M&D and Schedule G Reporting: M&D Reporting



M&D Reporting

Using EDGE site fields



3CTN Reporting: Y9 (April 2022 – Mar 2022)

| Reporting Obligations | Frequency | | 2022 Onwards Platform |
|------------------------------------|---------------|---------|--------------------------|
| Milestones and Deliverables | Semi-annually | MS Word | 3CTN PORTAL |
| Schedule G: Annual Progress Report | Annually | EXCEL | 3CTN PORTAL |

Project for updating M&D and Annual progress will follow the naming convention **3CTN Reporting** *Fiscal Year Number* for Adult Sites or **3CTN Reporting** *Fiscal Year Number* for Peds Sites.

Examples:





3CTN Reporting – Prefilled information from site M&D

M&Ds can be found at the project site level (Red Banner) of the reporting project under the Forms tab





3CTN Reporting – Site to Complete in Q2 and Q4

| 1 Sites | GROWN Reporting Y10 for Adult Sites | tes | | |
|--------------------|-----------------------------------------------------------|------------------------------------------------|----------------------------------------------------------------------------|----------------------------|
| i Overview | BCC - Surrey | | | |
| 🛃 Staff | | | | |
| Documents | Sorms | | | + Add a new form |
| Forms | Expand All Collapse All | | | |
| žΞ Workflows | ▶ 3CTN M&D Progress - Communications | | | 3CTN Coordinating Centre |
| D Notes | | | | |
| Finance | ▶ 3CTN M&D Progress - Patient Access to Trials | | | 3CTN Coordinating Centre 🥒 |
| Collaborators | | | | |
| E Metrics & Clocks | ▶ 3CTN M&D Progress - PPI Initiatives | | | 3CTN Coordinating Centre |
| C Timeline | ▼ 3CTN M&D Progress - Recruitment | | | 3CTN Coordinating Centre |
| Delegation Log | | | | |
| Statistics | Recruitment Goal 1 Details | Target of 100% above pre-3CTN baseline | | 3 🖉 📋 |
| 🖌 Settings | Recruitment Goal 1 Metrics of Success | By end of Y10, overall recruitment has reached | at least 36% of pre-3CTN baseline (44 patients)- equivalent to 16 patients | 3 🥒 📋 |
| | Recruitment Goal 1 Status | Site to complete and add comments below | Site to complete in Q2 and Q4 | 3 🥒 💼 |
| | Recruitment Goal 1 Comments | | | 3 🖉 🗊 |
| | Recruitment Goal 2 Details | Site Root Cause Analysis | by editing the stat | |
| | Recruitment Goal 2 Metrics of Success | By end of Y10, action items have been develope | ed to increase trial accrual. and adding comm | ents 🤉 🖉 💼 |
| | ✓ Recruitment Goal 2 Status | Site to complete and add comments below | Site to complete in Q2 and Q4 | 3 🖉 🗎 |
| | Recruitment Goal 2 Comments | | | 3 🖉 🗎 |



3CTN Reporting Progress – Site to complete

Once a site has completed the necessary reporting for the quarter, they need to check of that they have completed the reporting under the **3CTN Reporting Progress** form. This informs 3CTN that the site data is ready to be pulled.

| t Sites | H 3CTN Reporting Y10 for | Adult Sites | | |
|--------------------|------------------------------------------------|----------------|------------------|----------------------------|
| i Overview | BCC - Surrey | | | |
| 😫 Staff | | | | |
| Documents | Sorms | | | + Add a new form |
| Forms | Expand All Collapse All | | | |
| ž≣ Workflows | ▶ 3CTN M&D Progress - Communications | | | 3CTN Coordinating Centre 🖉 |
| Notes | | | | |
| Finance | ▶ 3CTN M&D Progress - Patient Access to Trials | | | 3CTN Coordinating Centre 🥒 |
| Collaborators | ▶ 3CTN M&D Progress - PPI Initiatives | | | 3CTN Coordinating Centre |
| E Metrics & Clocks | F 3C IN MaD Progress - PPI Initiatives | | | 3CTN Coordinating Centre |
| S Timeline | ▶ 3CTN M&D Progress - Recruitment | | | 3CTN Coordinating Centre |
| Delegation Log | | | | |
| Statistics | 3CTN M&D Progress - Trial Performance | | | 3CTN Coordinating Centre 🖉 |
| 🖌 Settings | ▶ 3CTN M&D Progress Overall | | | 3CTN Coordinating Centre |
| | | | _ | 3CTN Coordinating Centre |
| | Completed Q1 Report? | Site to select | | 3 🖉 📋 |
| | Completed Q2 Report? | Site to select | Site to complete | 3 🖉 📋 |
| | Completed Q3 Report? | Site to select | Site to complete | 3 🖉 🃋 |
| | Completed Q4 Report? | Site to select | | 3 🥒 📋 |



3CTN Reporting – Site to Complete

Sites are to check off which elements of reporting have been completed

Note: The NA options are to be used when there is no update or nothing to report

M&D and Schedule G Reporting: Schedule G Reporting



Schedule G Reporting

Document Upload



- Schedule G reporting templates will be attached to the Q4 reporting reminder emails
- Sites are to complete the excel template and upload the completed excel to the Annual Schedule G folder at the project site level of the reporting project

| t Sites i Overview | H 3CTN Rep BCC - Abbotsford | orting Y10 f | or Adult Site | S | | | | |
|-----------------------------------------------|----------------------------------------------------------------------|---------------|-----------------|---------|----------|-----------|----------|-------------------------------------|
| Staff Documents | Project Site Documents + Add from folder template + Add a new folder | | | | | | | |
| ♥ Forms送 Workflows | Root | | | | | | | |
| Notes | Name 🖨 | Uploaded By 🖨 | Uploaded Date 🖨 | Version | Comments | Published | Public 🗸 | |
| Finance | 🕑 🖿 Annual Schedule G | | | | | | | * 🖉 🗊 |
| Collaborators | 🕑 🖿 Priority Patient Reports | | | | | | | * 🖉 🔟 |
| E Metrics & Clocks | 💽 🖿 M & D from RFA | | | | | | | ¢ 🖉 🗊 |
| S Timeline | | | | | | | | • |
| Delegation Log | 3 folder(s), 0 file(s) | | | | | | | |
| 2 Participants | | | | | | | (Sele | ect action to perform) \checkmark |



 Once in the folder you can drag and drop the file in the grey box or click on the box to use the file finder widow to choose the desired file. Make sure to check Public to allow 3CTN to see the report.

| | Project Site Documents | | | | | template + Add a new folde |
|------------------|------------------------|-----------------|-----------------------|-------------|-----------|----------------------------|
| ot / Annual Sch | hedule G | | | | | |
| ame 🖨 | Uploaded By 🖨 | Uploaded Date 🖨 | Version | Comments | Published | Public 🗸 |
| | | | | | | |
| folder(s), 0 fil | le(s) | | | | | |
| | | | | | | (Select action to perform) |
| | | | | | | |
| | | Version | | | | |
| | | Published 3 | | | | |
| | | Public 🚯 | | | | |
| | | | | | 9 | |
| | | | <u>1</u> | | | |
| | | Choose | a file, or drag one o | r more here | | |