INTELLIGENT RESEARCH MANAGEMENT™

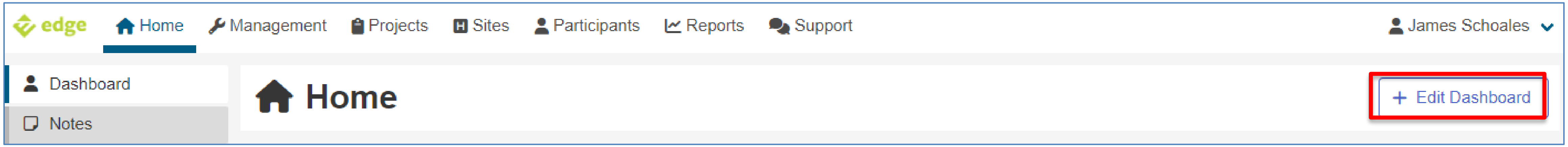
Canadian Cancer Clinical Trials Network

3CTN Reporting Portal User Training

2023

Setting Up Your Dashboard

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



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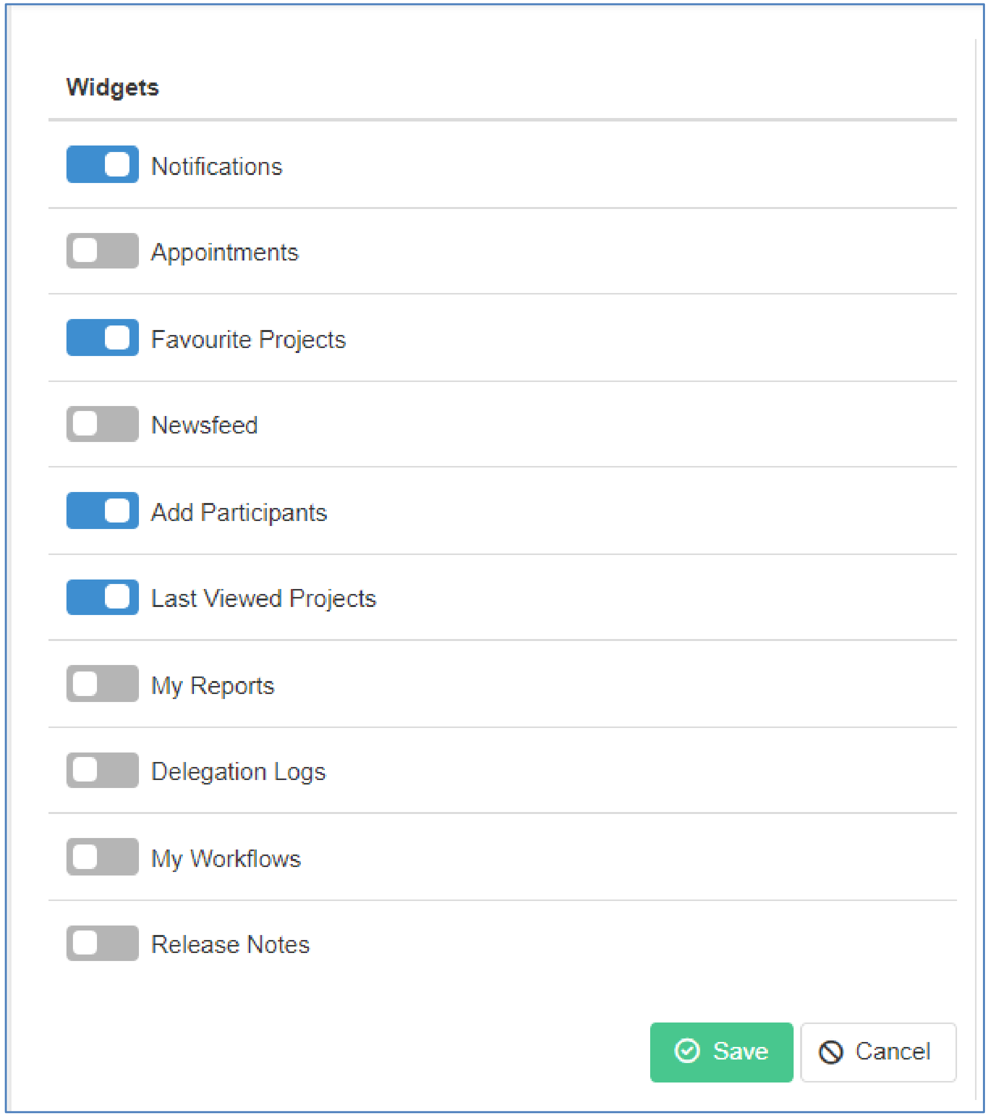
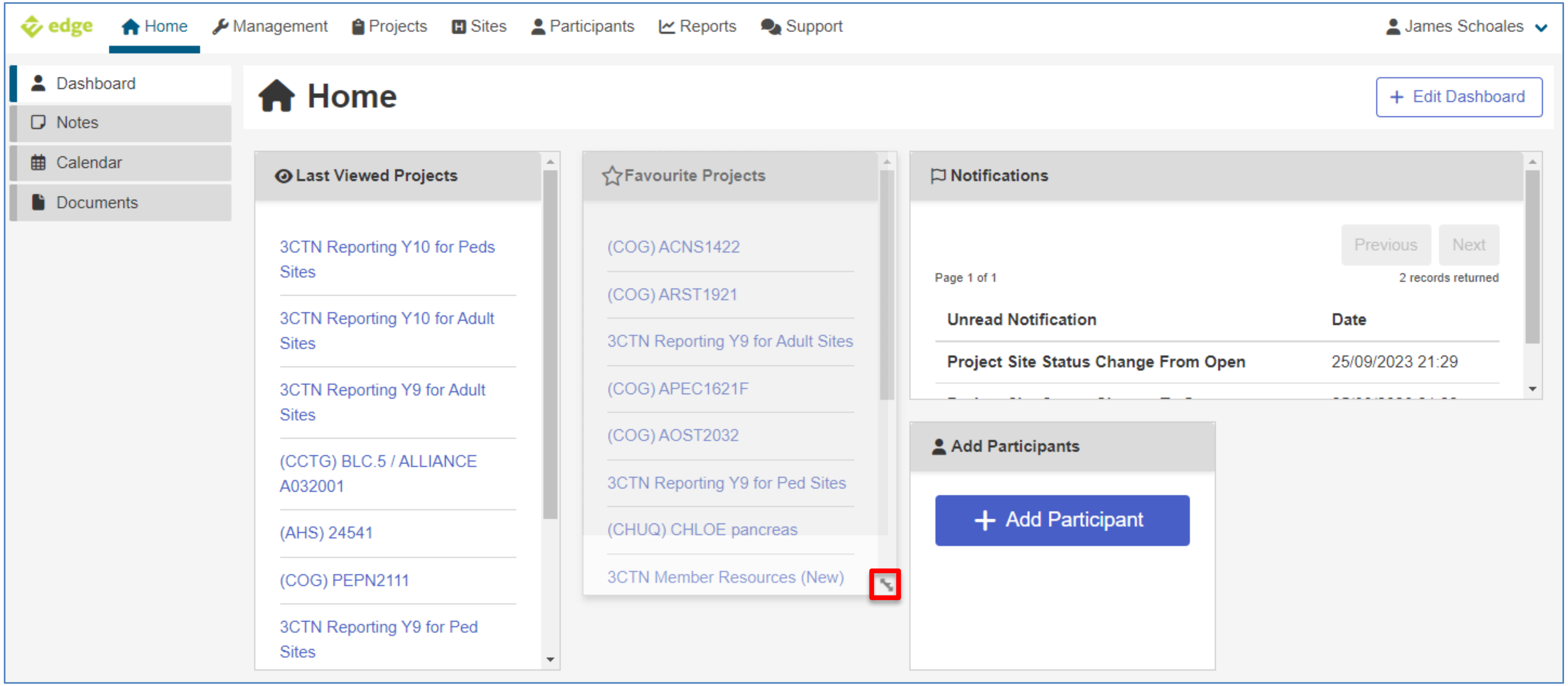
Setting Up Your Dashboard

- 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.



Setting Up Your Dashboard

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



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Setting Up Your User Profile

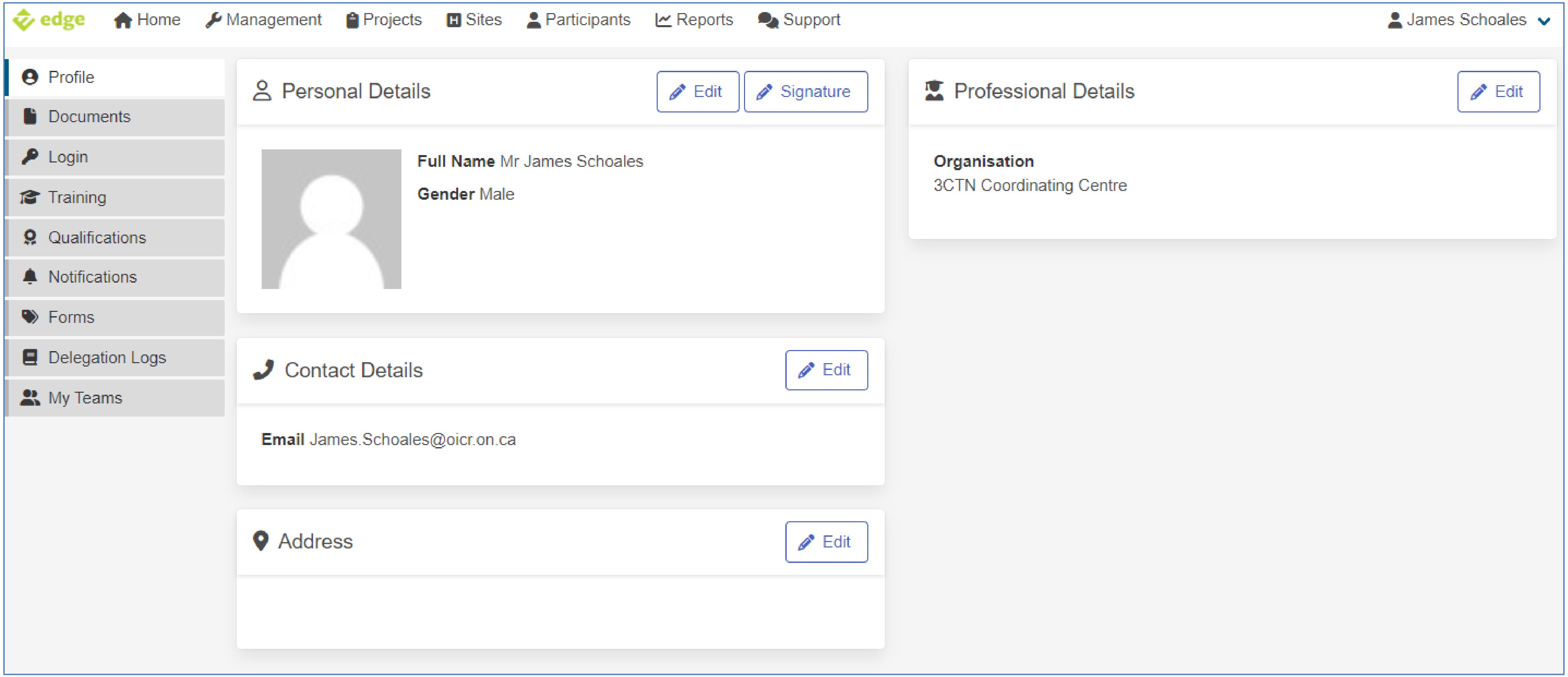
Options Under “My Profile”

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

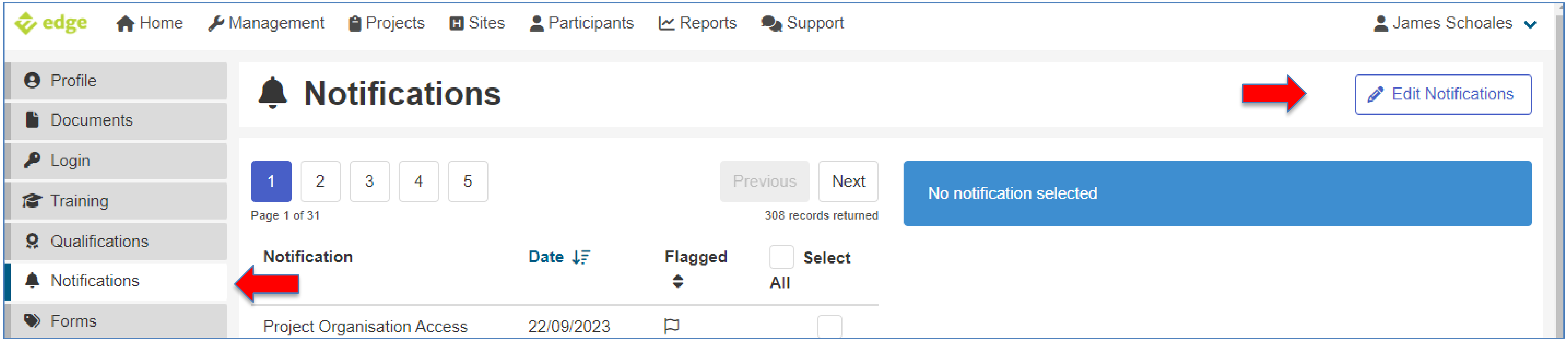
Options Under “Management> Users”

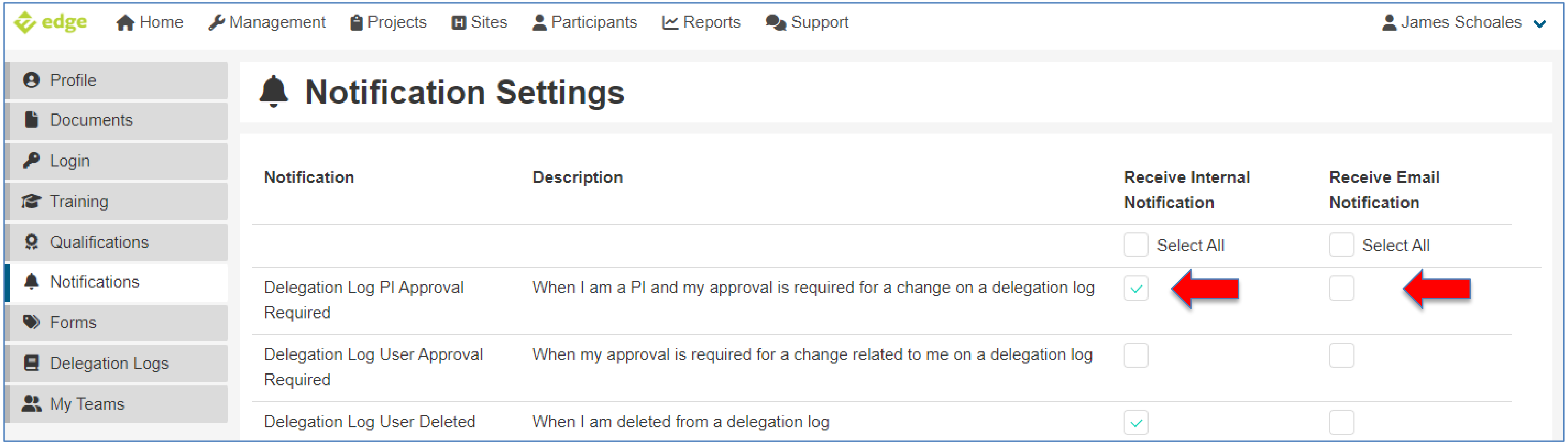
- Change Username
- By default, it is your email. If too long, you can change into a short username

Edit User Profile



Notifications





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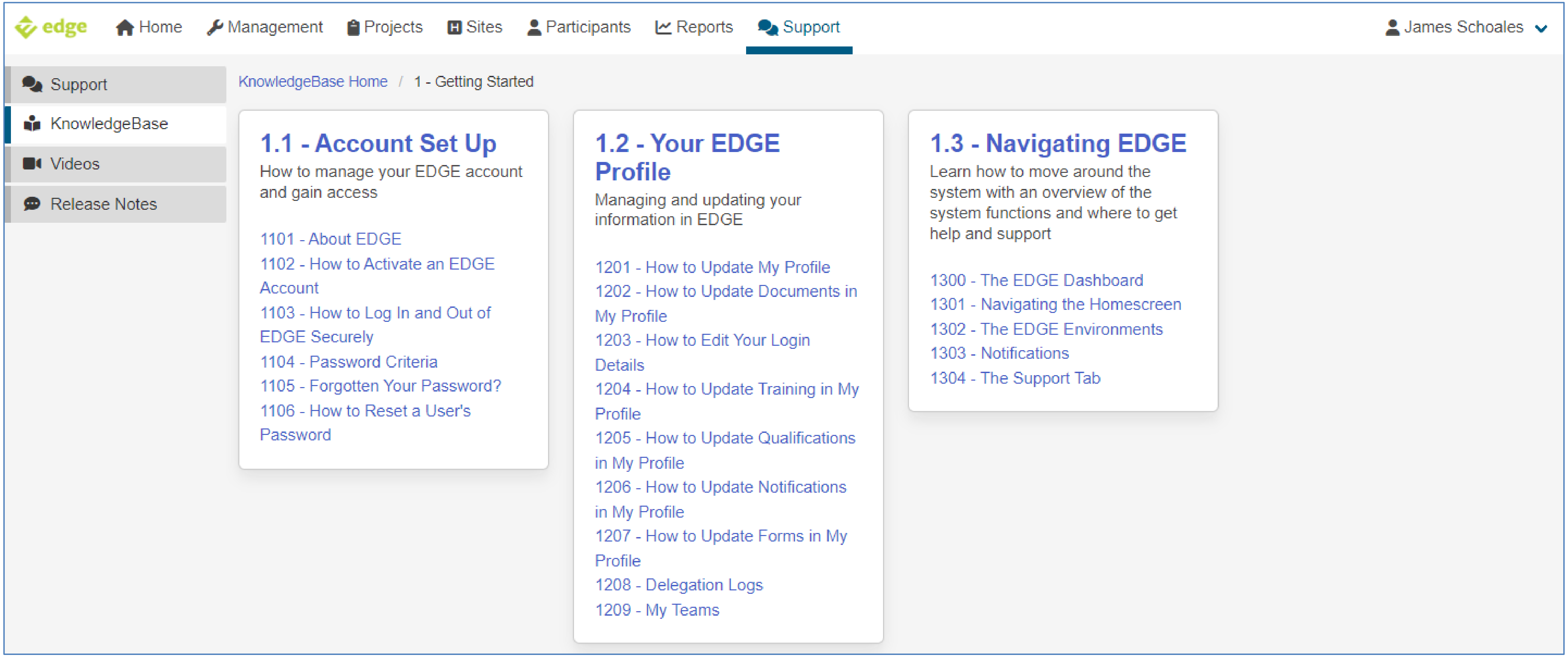
Knowledgebase - Tutorial Articles



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Trial Navigation

Different levels of data

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Why different levels of data?

- 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

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System Data Levels

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

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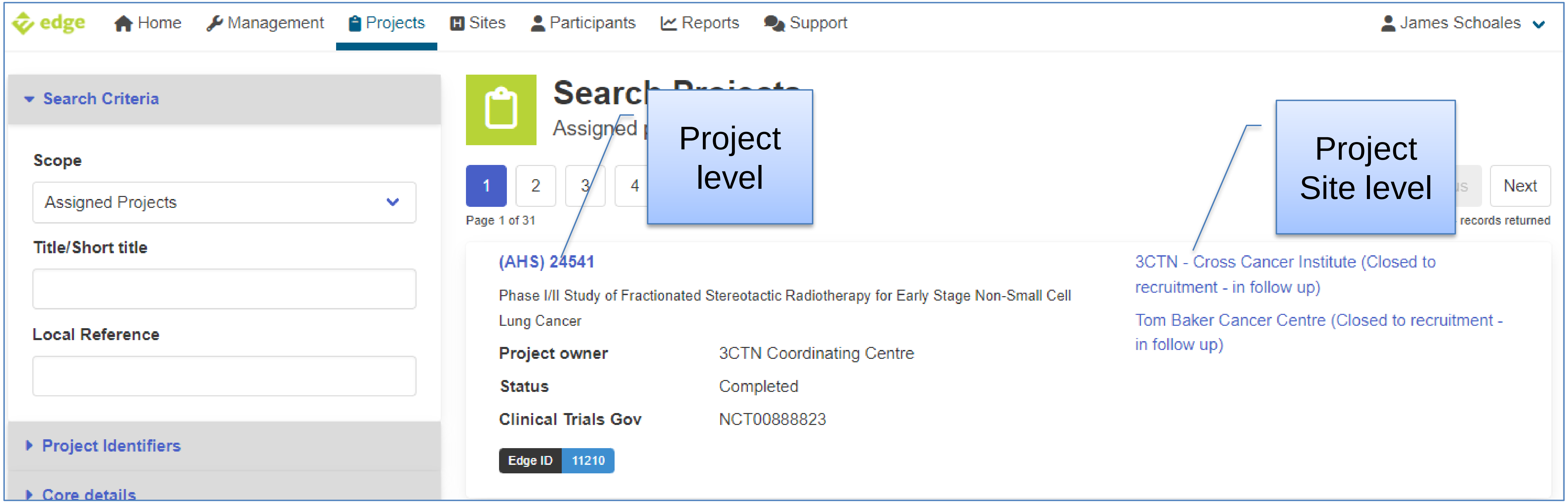
Data Levels – example



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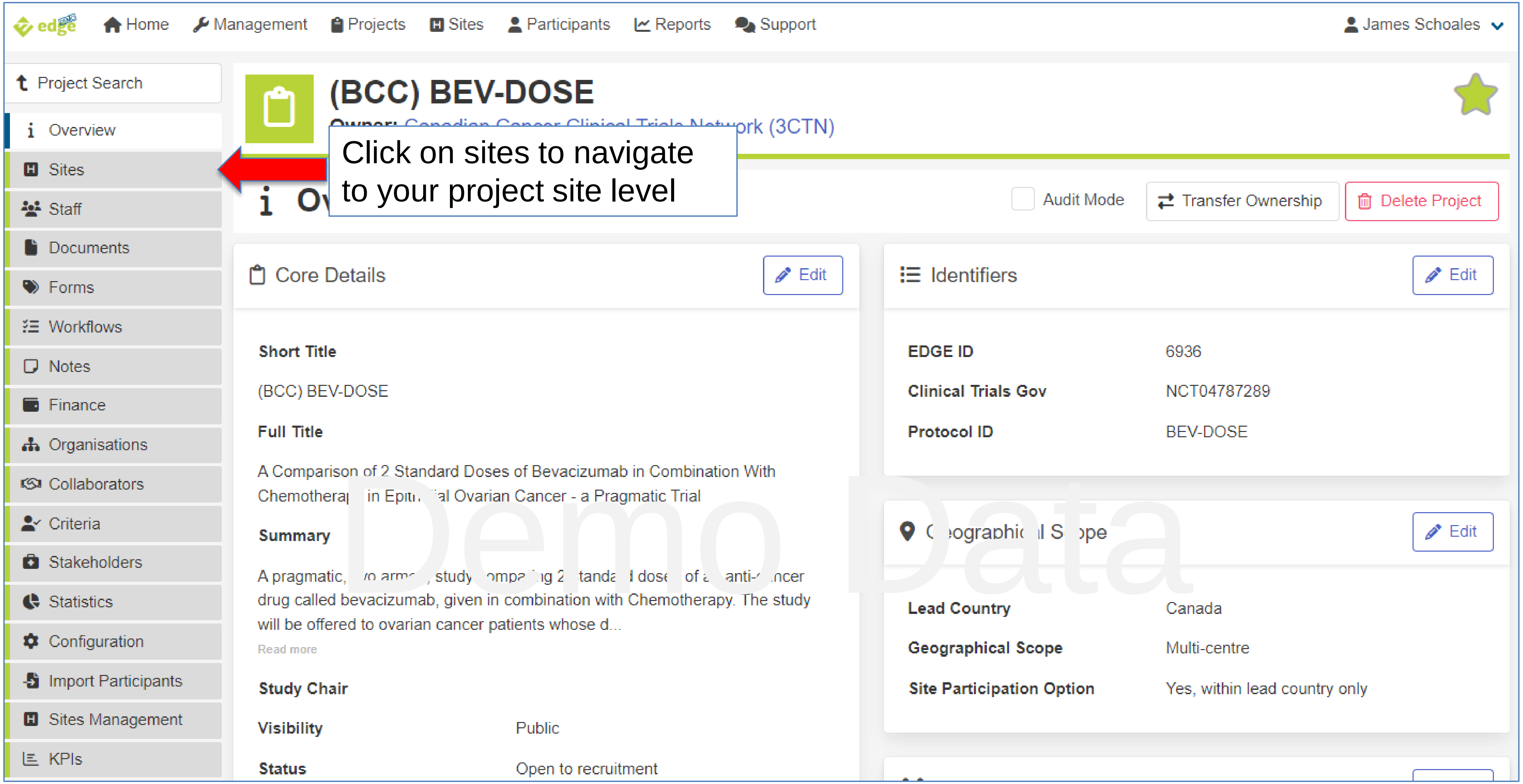
Data Levels – Project Level



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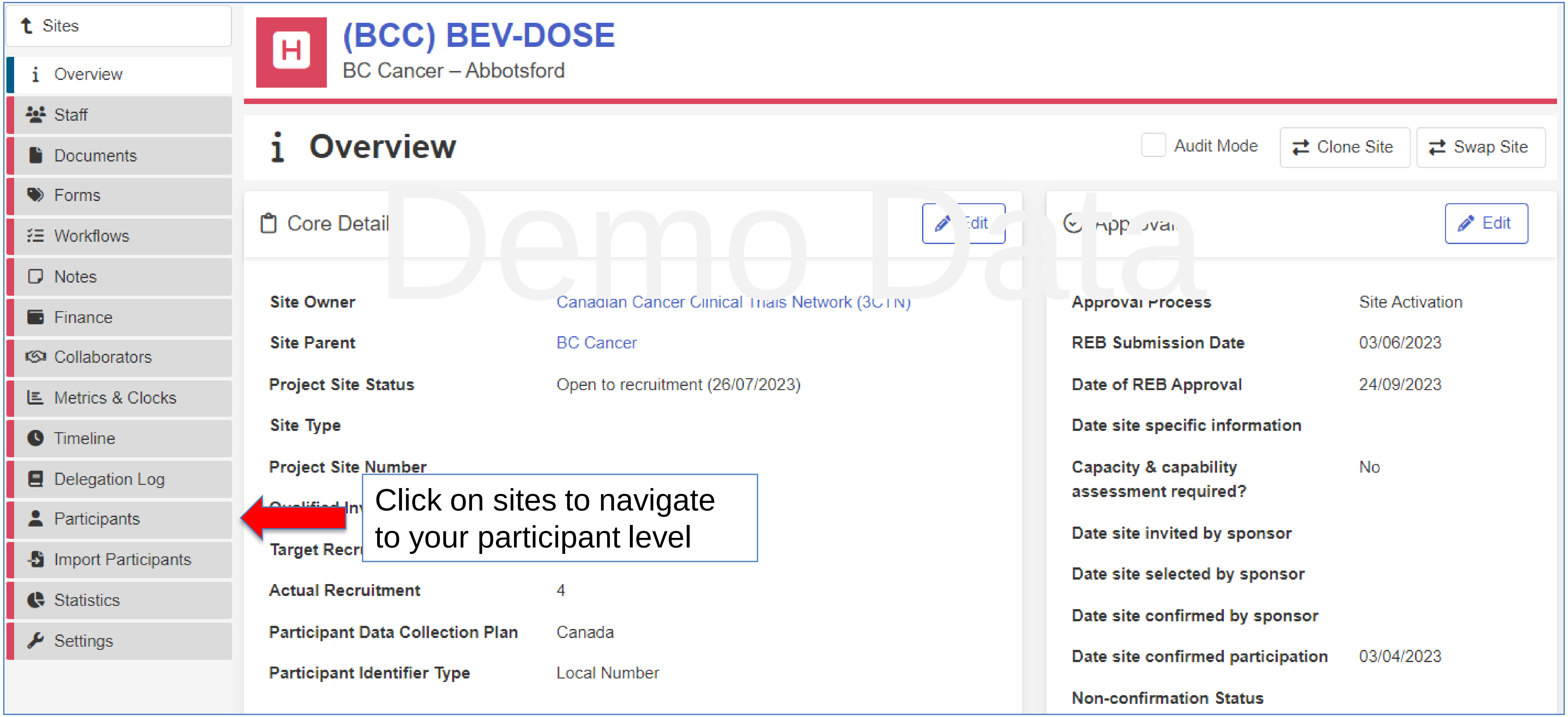
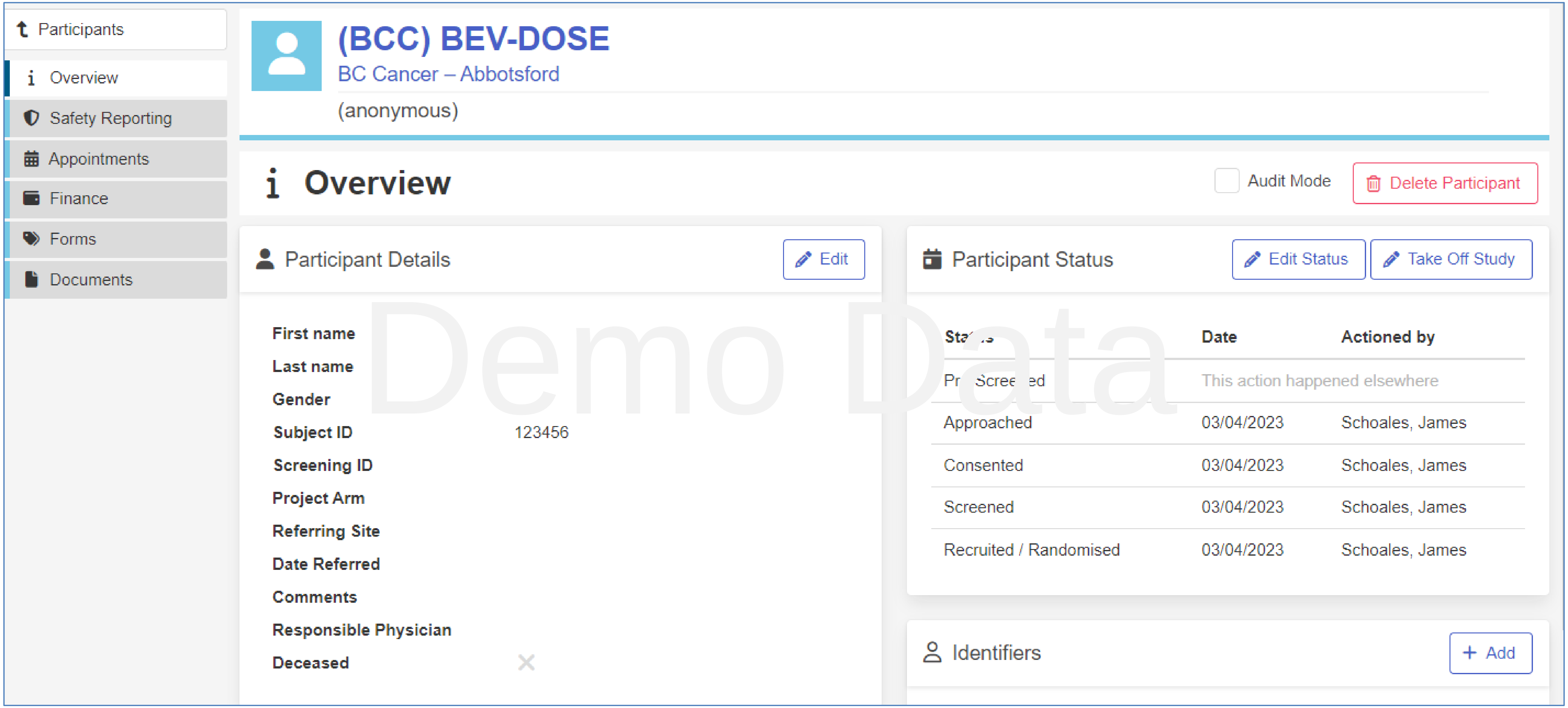
Data Levels – Project Site Level



Data Levels – Participant Level



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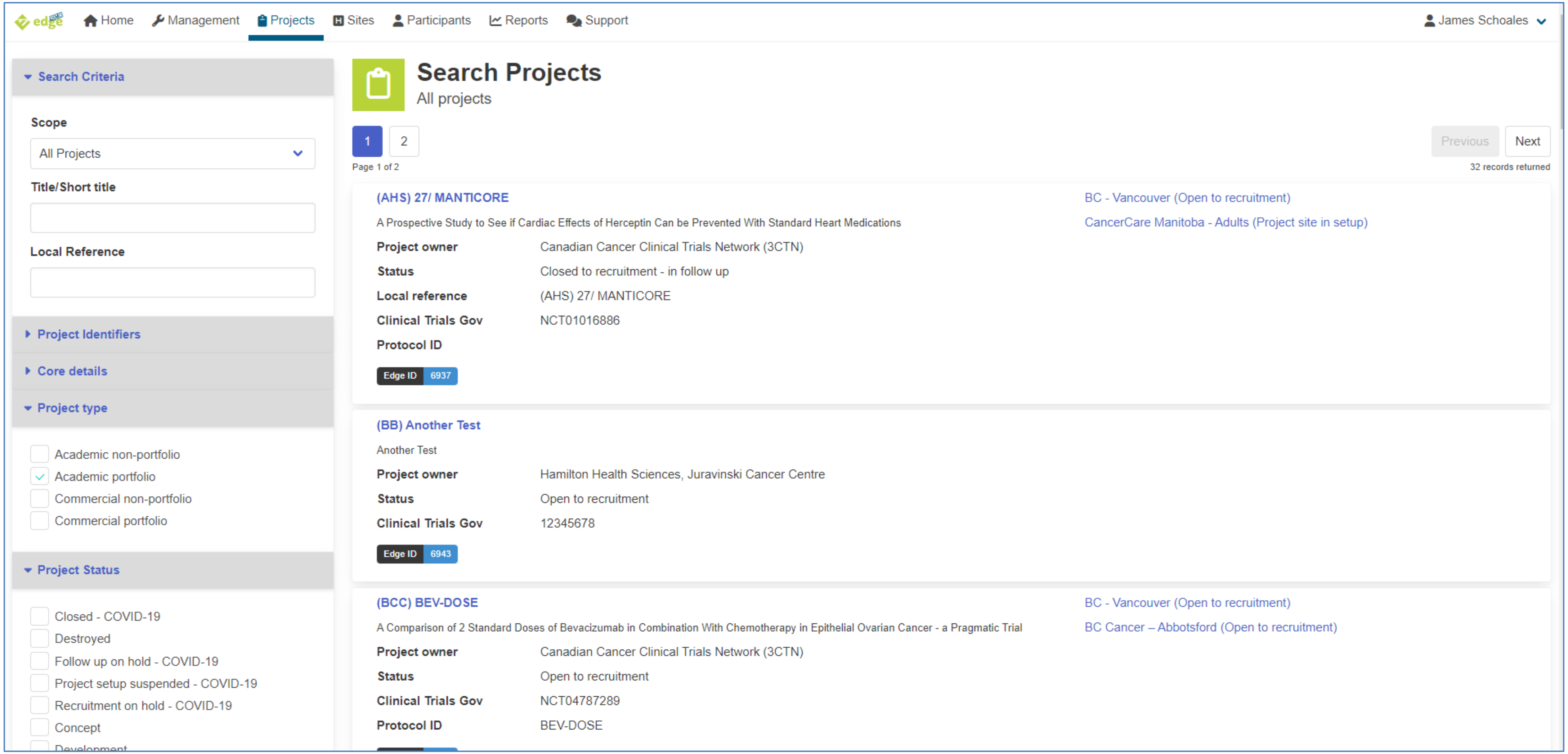
View and Add Trials

Exiting and new trials

View Open Recruiting Portfolio Trials



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ALL(Global) Projects – Search & Add

- 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

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Trial Performance Data Entry

Reporting new Portfolio trial involvement

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Adding a Project to your Organization in EDGE

- 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.

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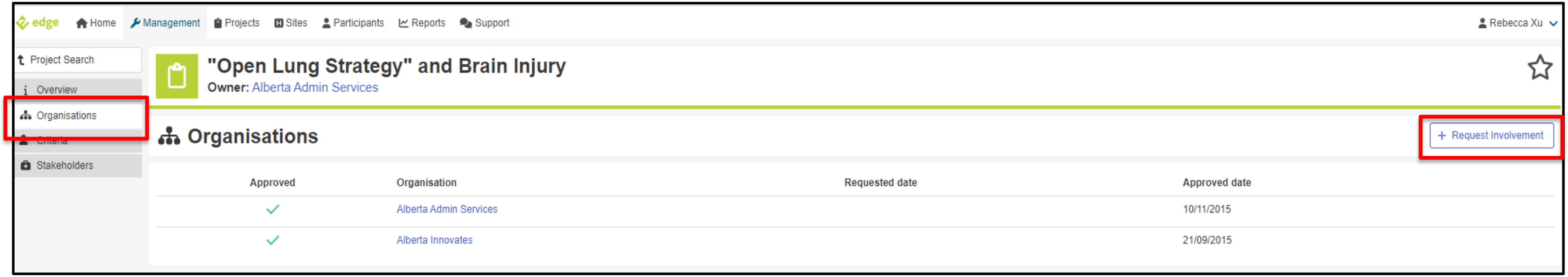
Requesting involvement

- 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**



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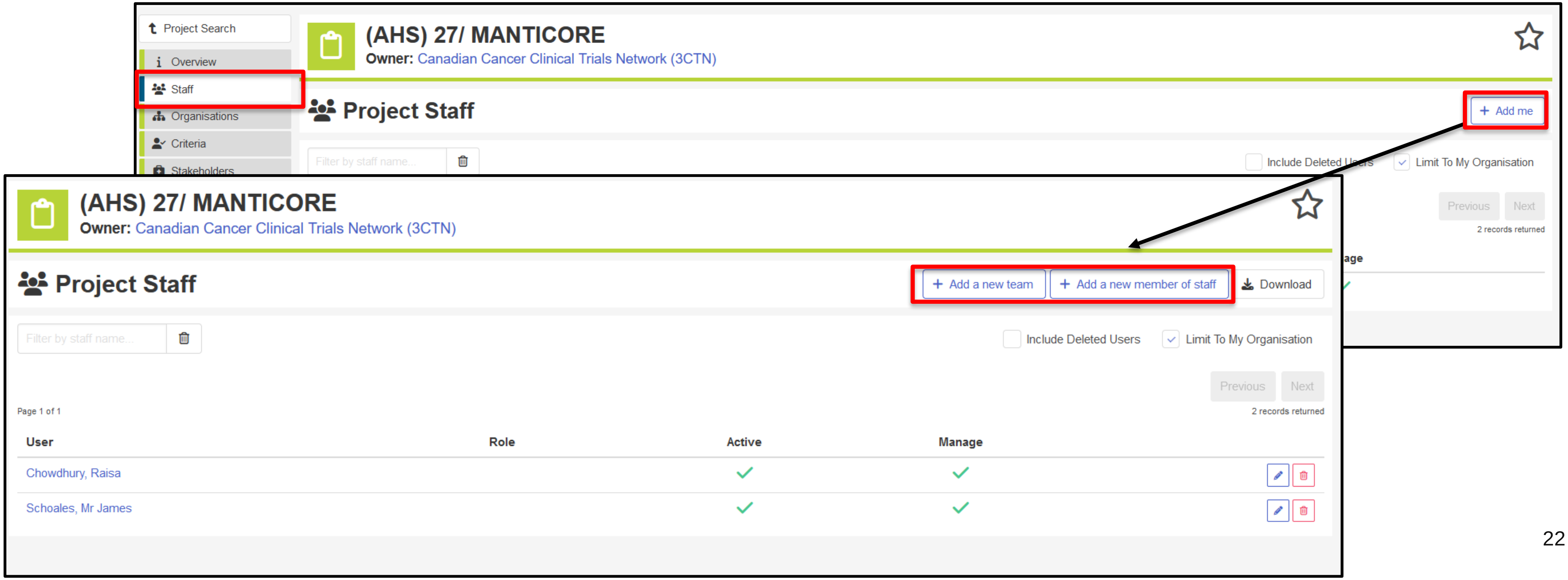
Add users to project

- 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.



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Adding a Site to a Project

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

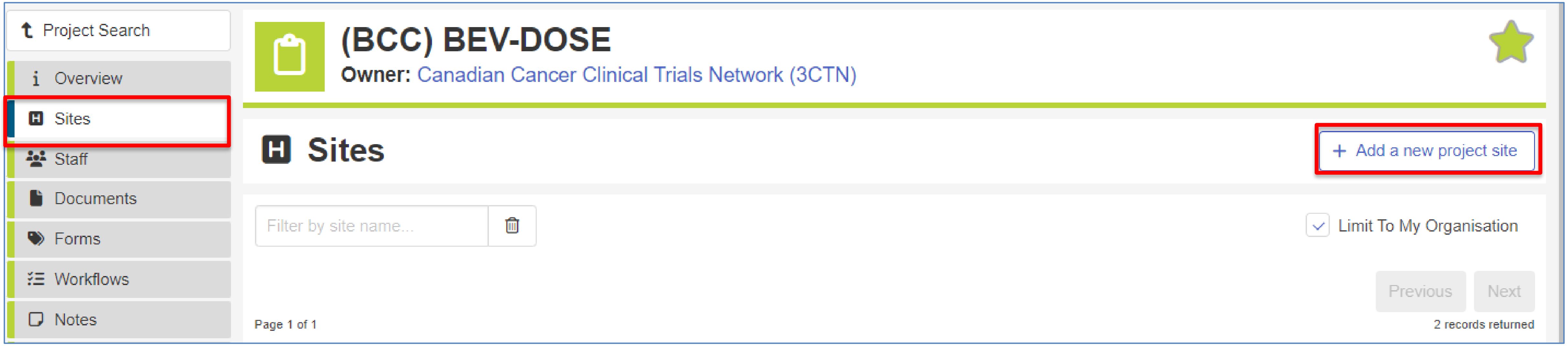
Steps

- 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.

Adding project site

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**"



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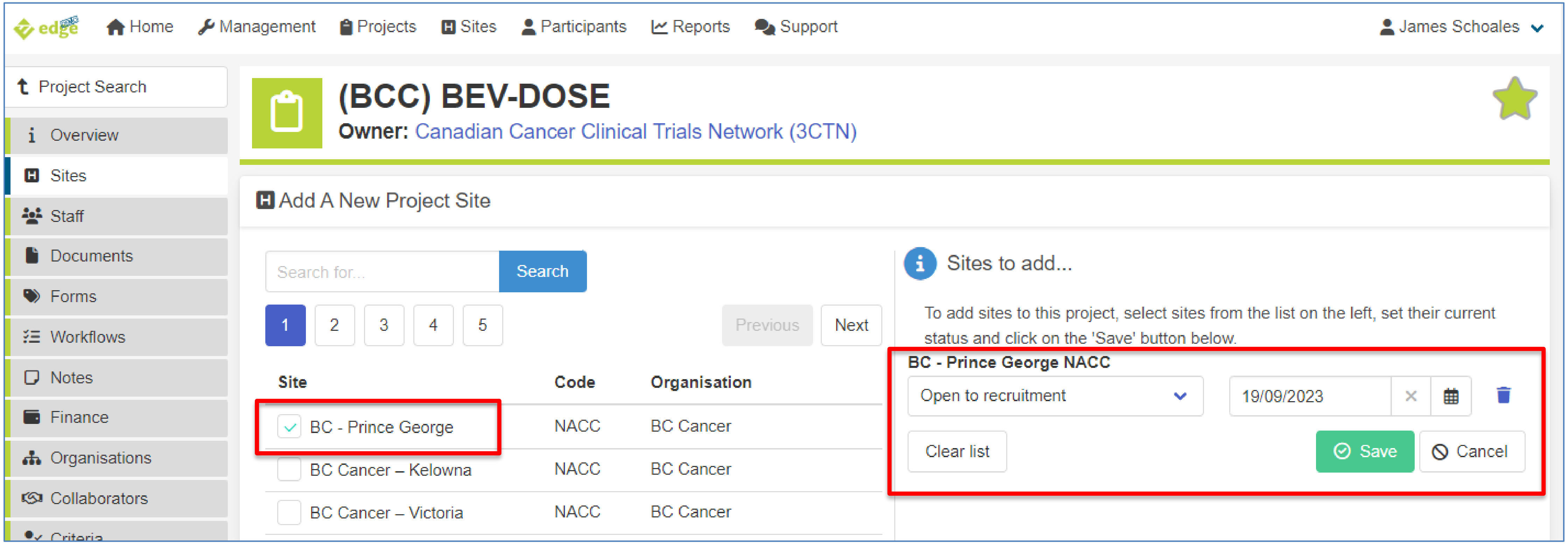
Adding a project site

4. Choose your site from the list or search
5. Fill in relevant data and click “**save**”



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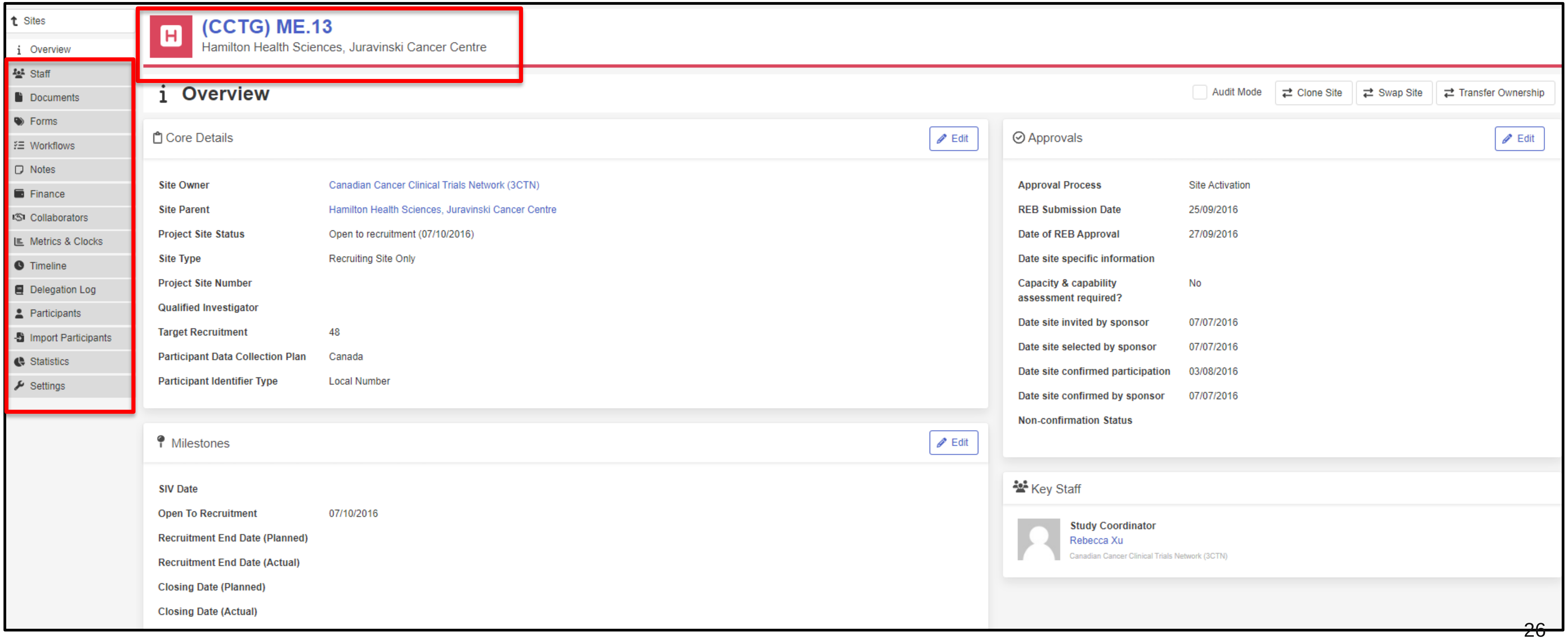
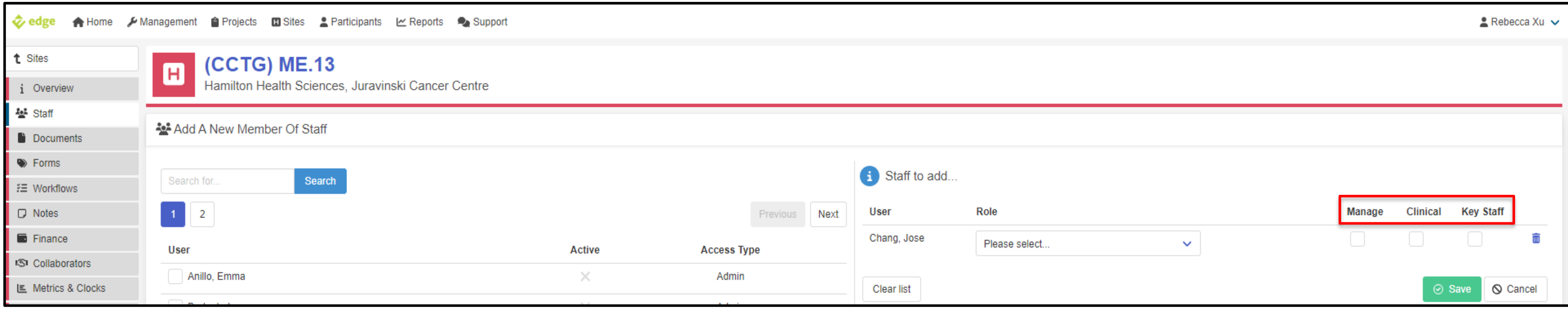
Overview of Project Site Level

- 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.



Add staff to site level

- 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.



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Trial Performance Data Entry

Updating / Adding trial statuses and activation dates

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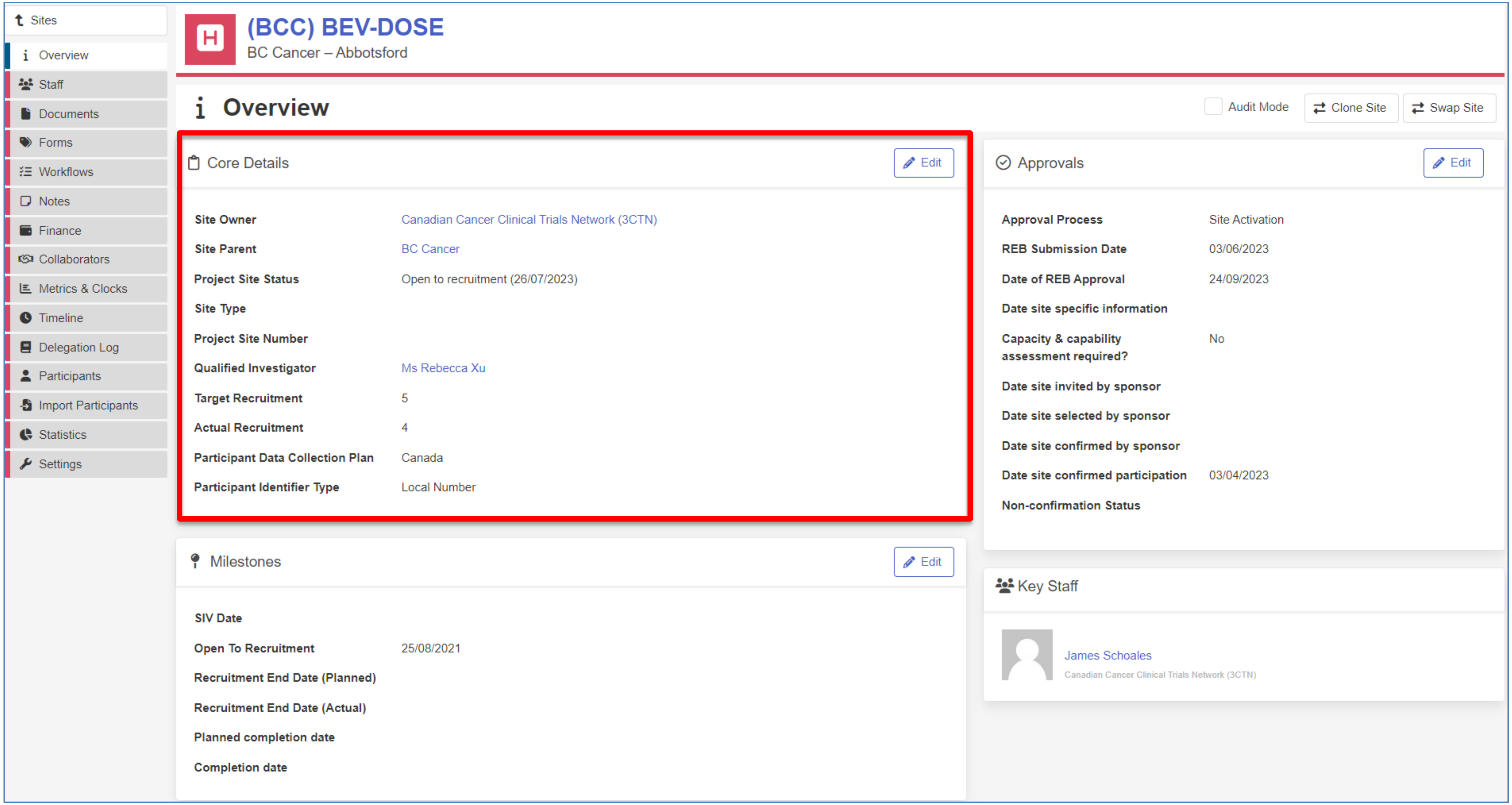
Project Site Detail Page



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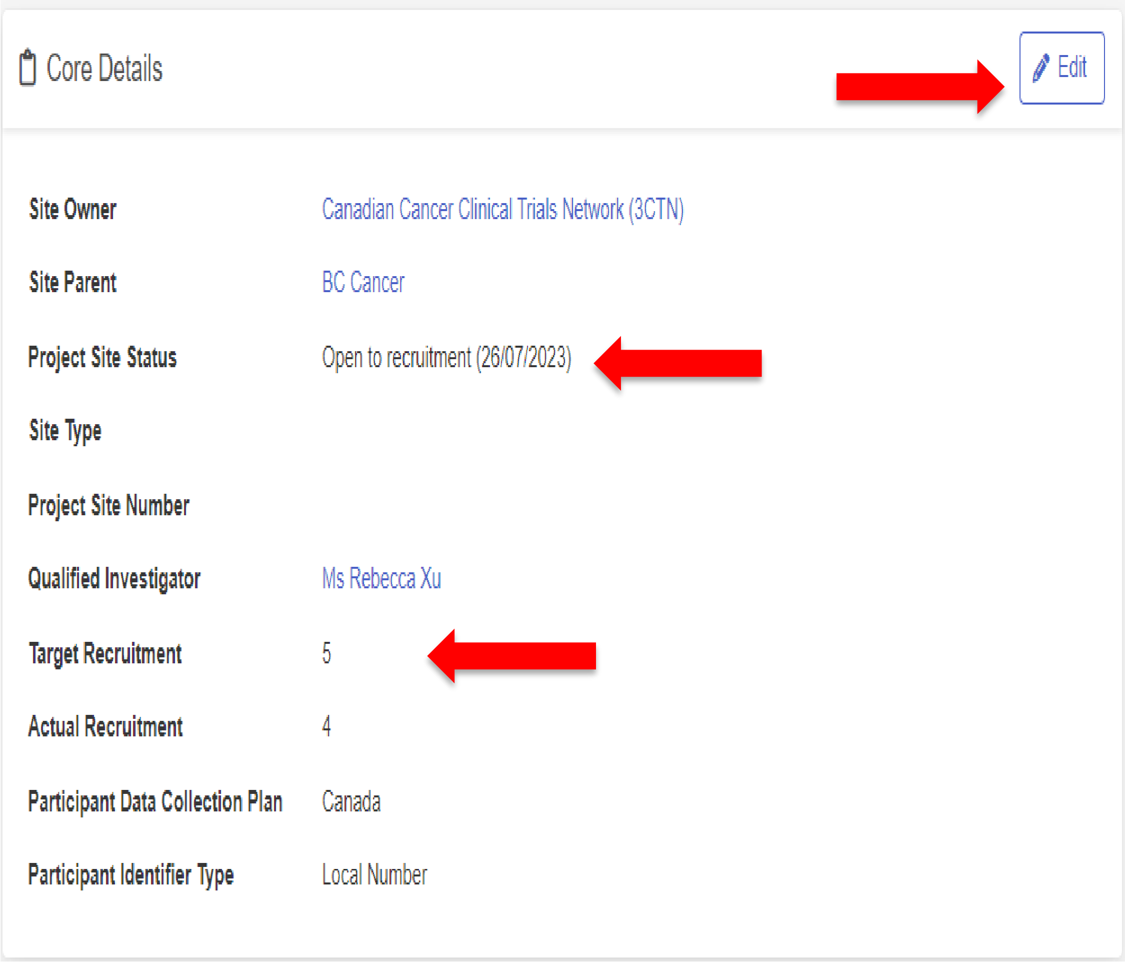
Project Site Detail Page – Details Section

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.

2. **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.



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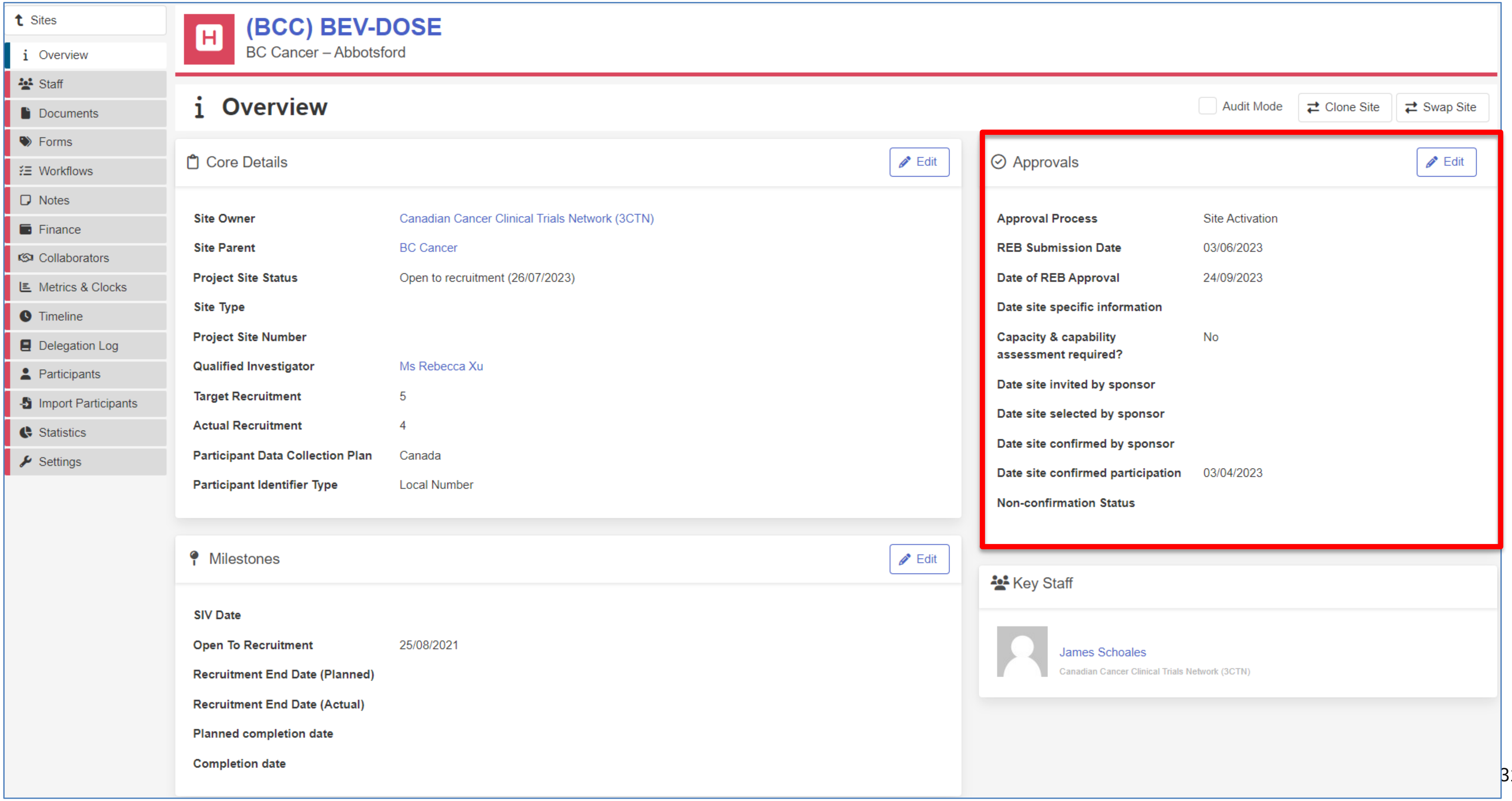
Project Site Detail Page



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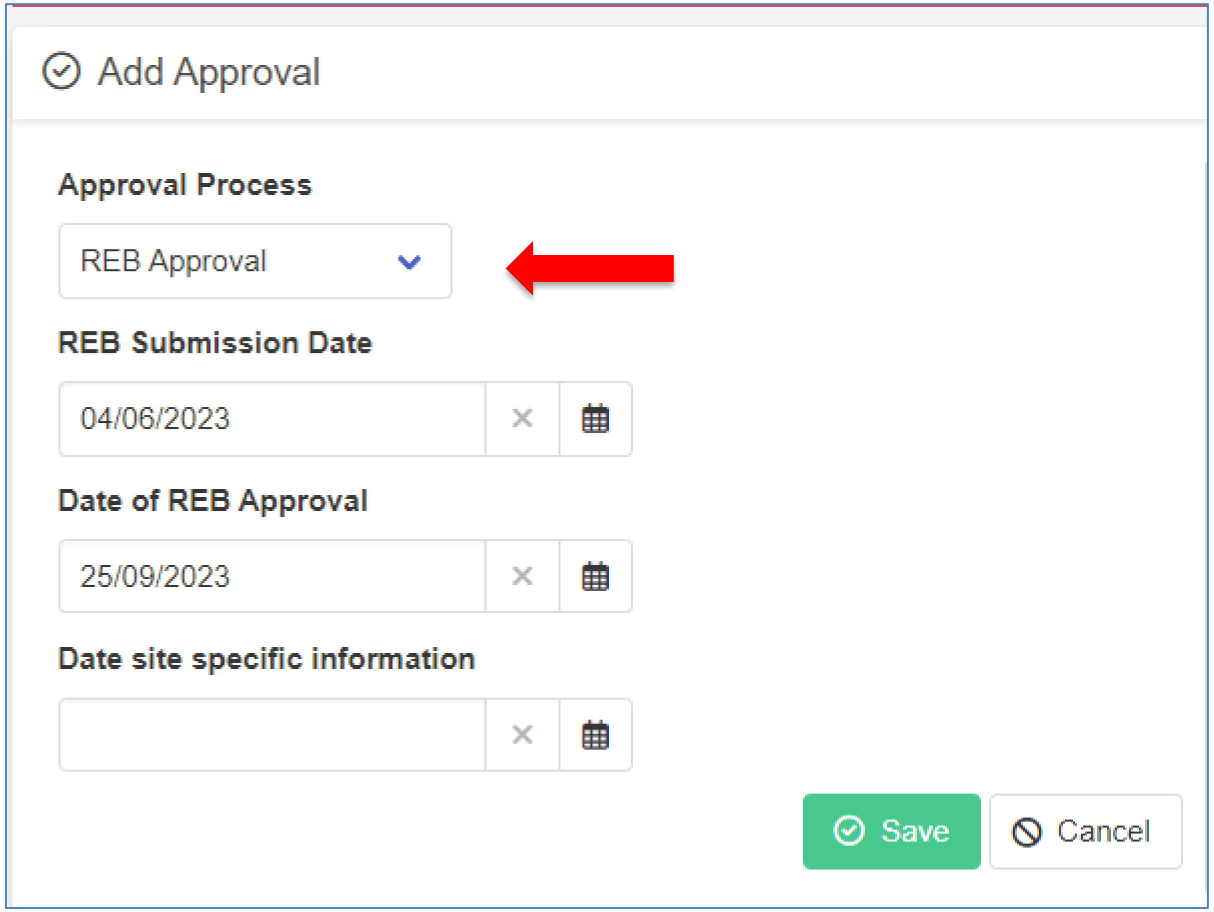
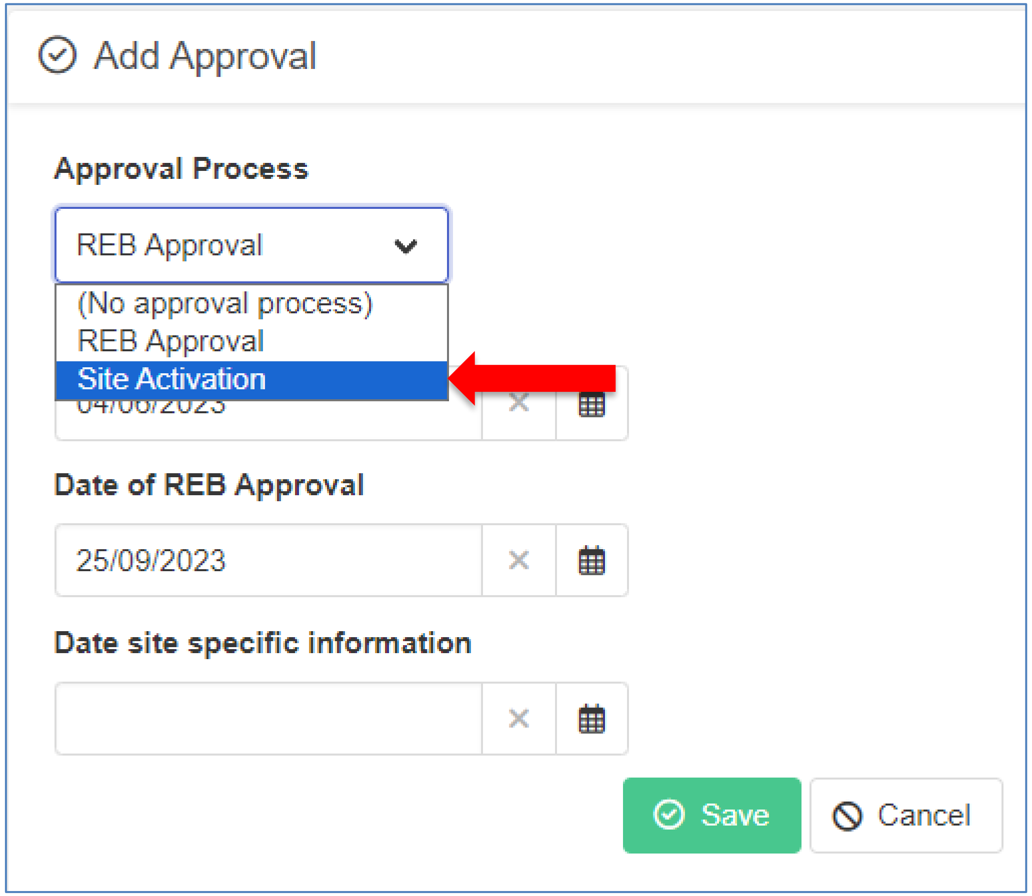
Project Site Detail Page – Approvals Section

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”.





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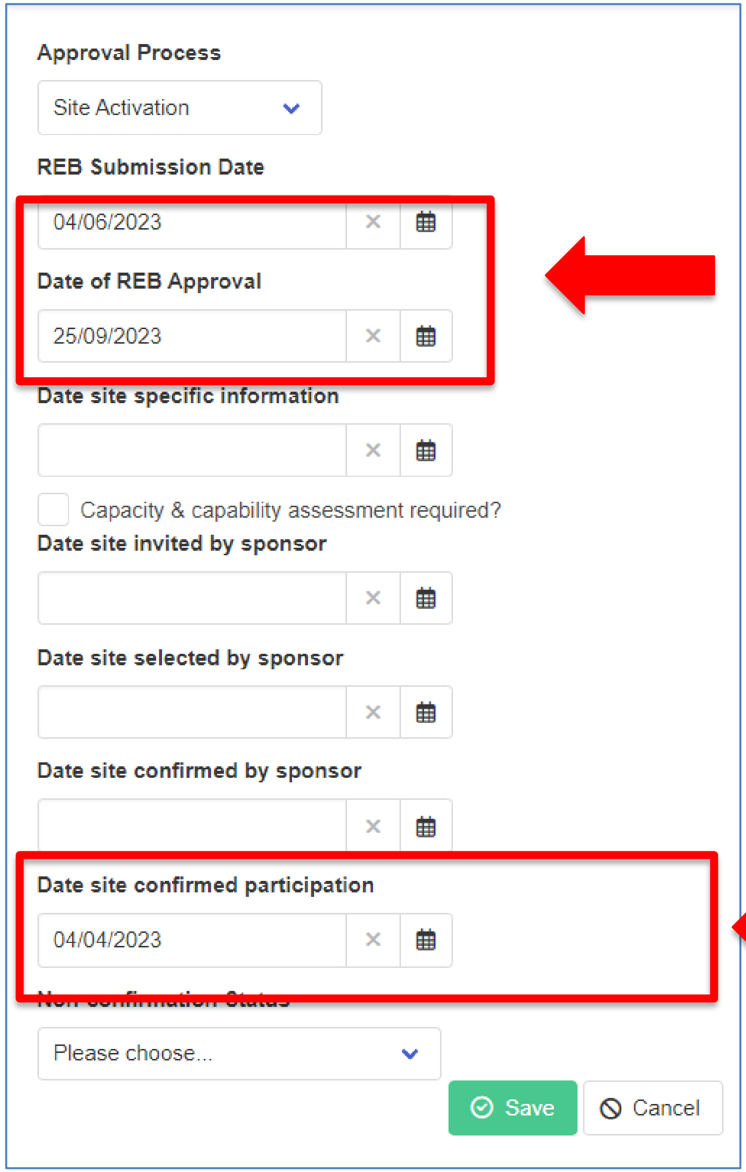
Project Site Detail Page – Approvals Section

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.



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Project Site Detail Page

Sites
- Overview
- Staff
- Documents
- Forms
- Workflows
- Notes
- Finance
- Collaborators
- Metrics & Clocks
- Timeline
- Delegation Log
- Participants
- Import Participants
- Statistics
- Settings

(BCC) BEV-DOSE

BC Cancer – Abbotsford

Overview

Audit Mode | Clone Site | Swap Site

Core Details

Edit

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

Approvals

Edit

Approval Process	Site Activation
REB Submission Date	03/06/2023
Date of REB Approval	24/09/2023
Date site specific information	
Capacity & capability assessment required?	No
Date site invited by sponsor	
Date site selected by sponsor	
Date site confirmed by sponsor	
Date site confirmed participation	03/04/2023
Non-confirmation Status	

Milestones

Edit

SIV Date	
Open To Recruitment	25/08/2021
Recruitment End Date (Planned)	
Recruitment End Date (Actual)	
Planned completion date	
Completion date	

Key Staff

James Schoales

Canadian Cancer Clinical Trials Network (3CTN)

Project Site Detail Page – Milestones Section

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)

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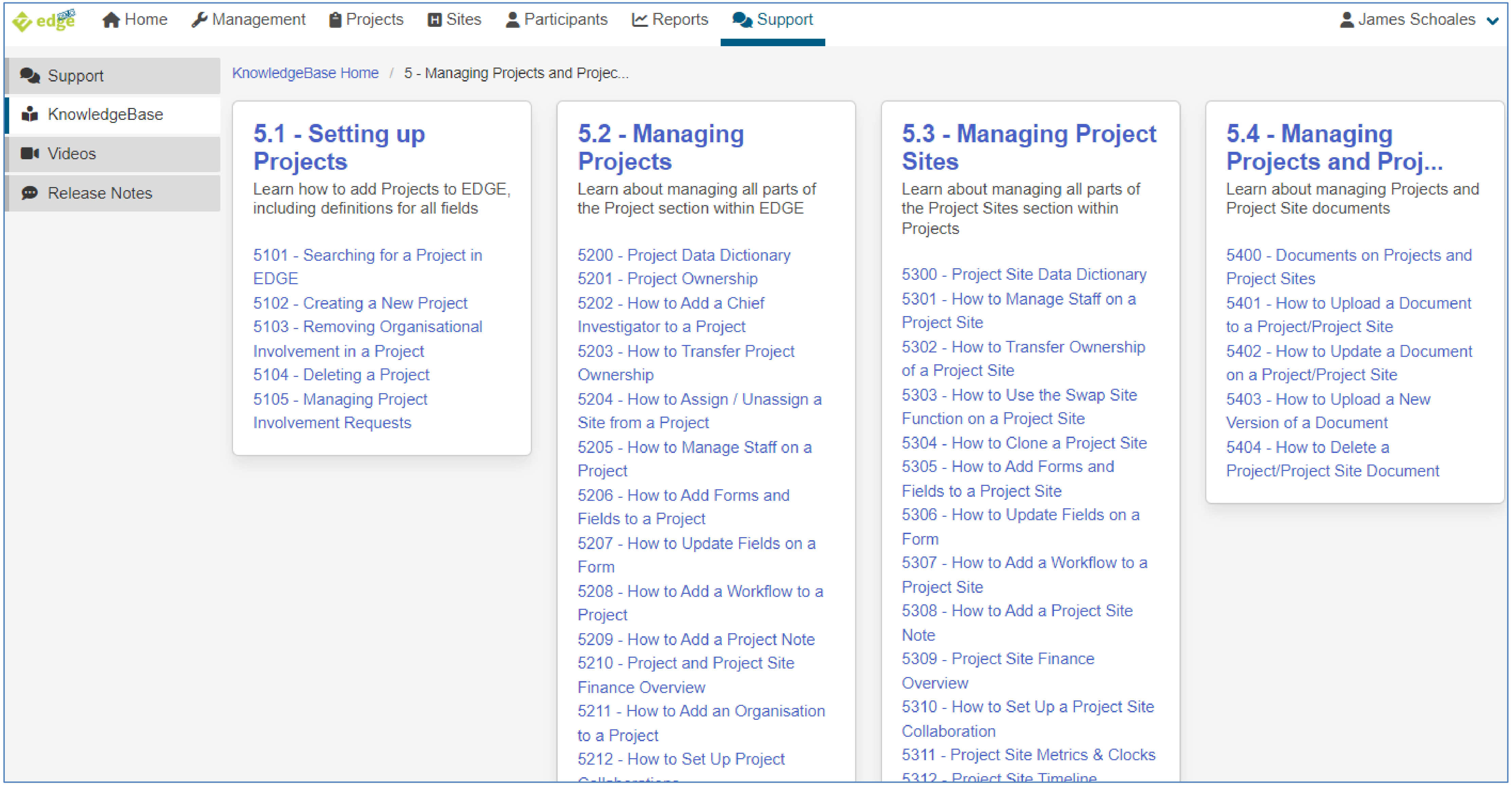
Knowledgebase - Tutorial Articles



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Reporting and Tracking Patients

Manually Adding Patients

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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

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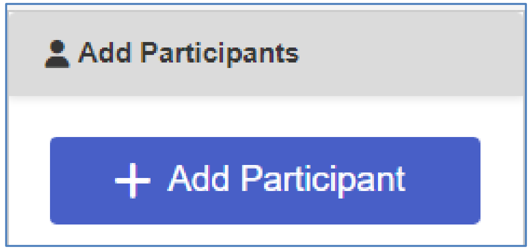
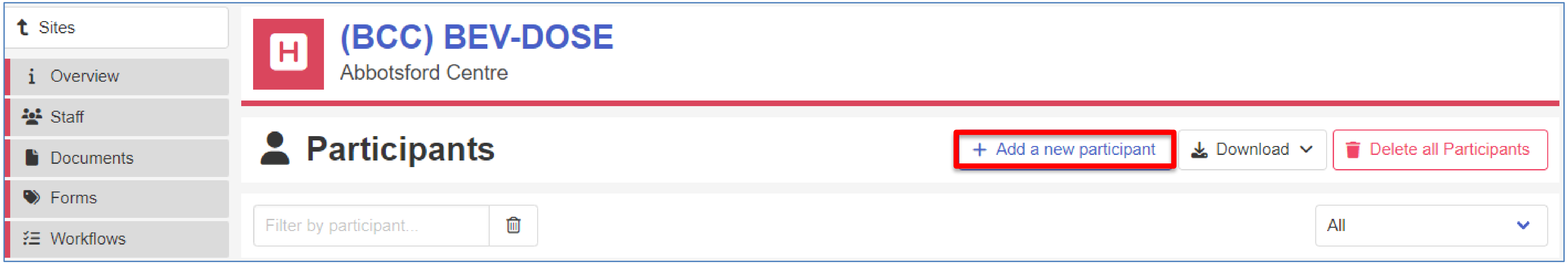
Manually Adding a Participant - Options

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



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.

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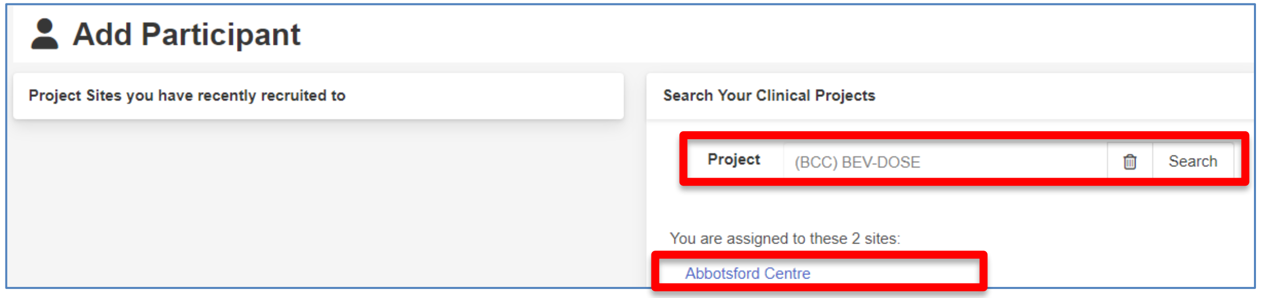
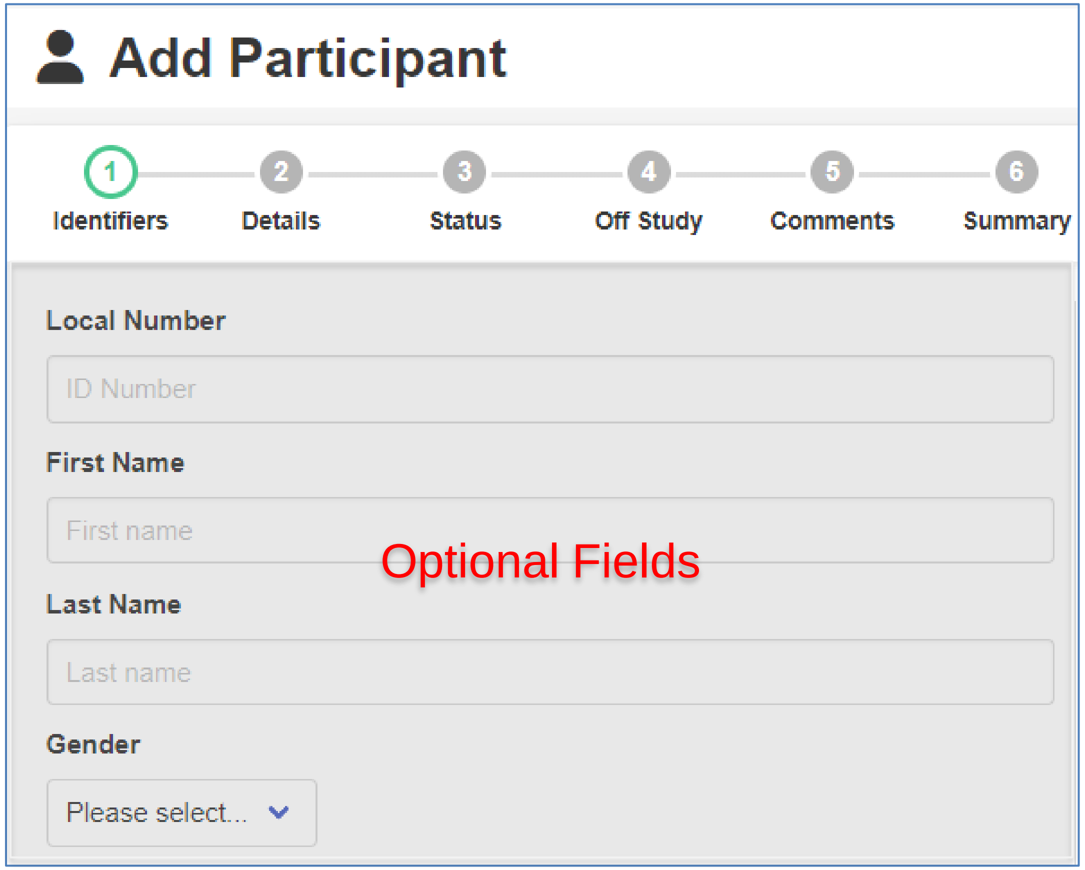
Adding a Participant – Participant Details





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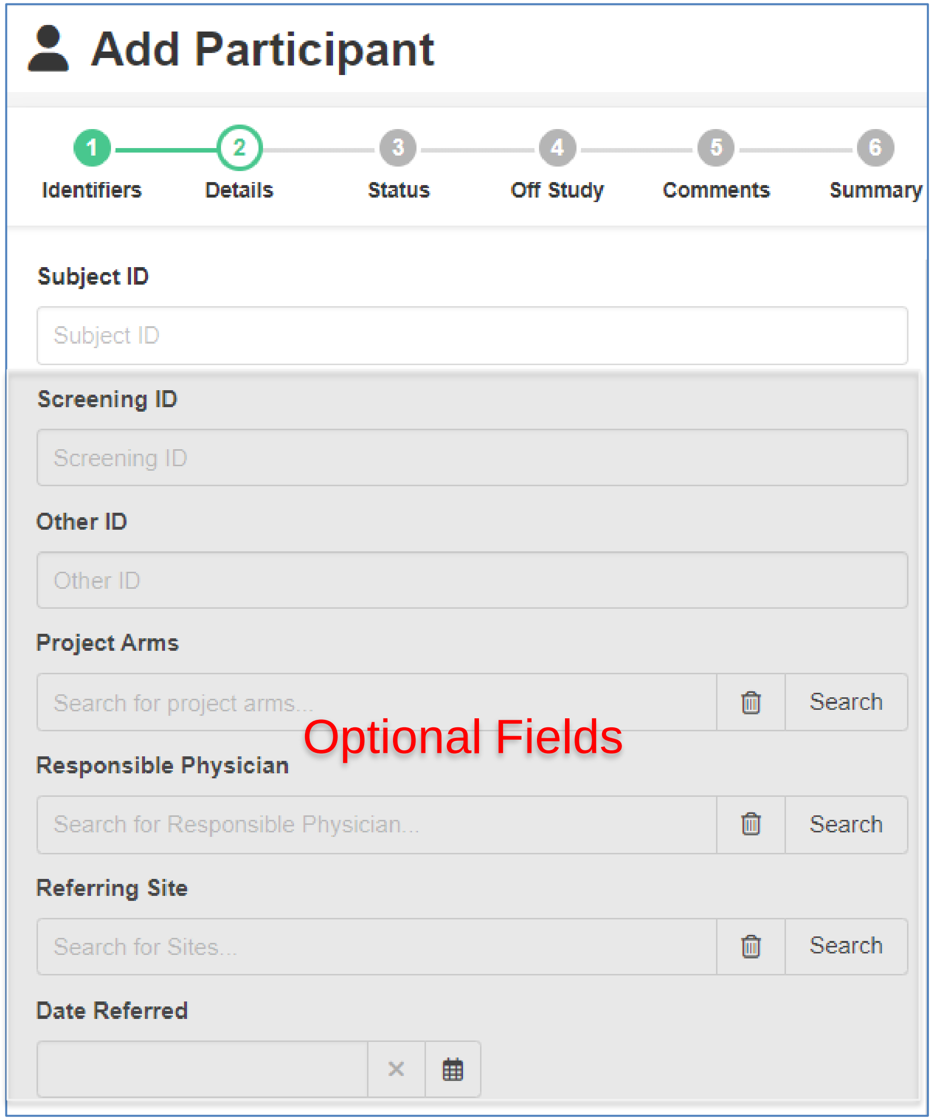
Adding a Participant – Participant Details



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Adding a Participant – Participant Status Dates

Add Participant

1 Identifiers — 2 Details — 3 Status — 4 Off Study — 5 Comments — 6 Summary

Exit Wizard | Previous | Next

Participant transfer is not enabled on this project

	Status Date	Actioned By
Pre-Screened	28/07/2023	James Schoales
Approached	28/07/2023	James Schoales
Consented	28/07/2023	James Schoales
Screened	28/07/2023	James Schoales
Recruited / Randomised	28/07/2023	James Schoales
On treatment		James Schoales
On follow-up		James Schoales
Completed		James Schoales

Note: All previous dates must also be filled in.

Exit Wizard | Previous | Next

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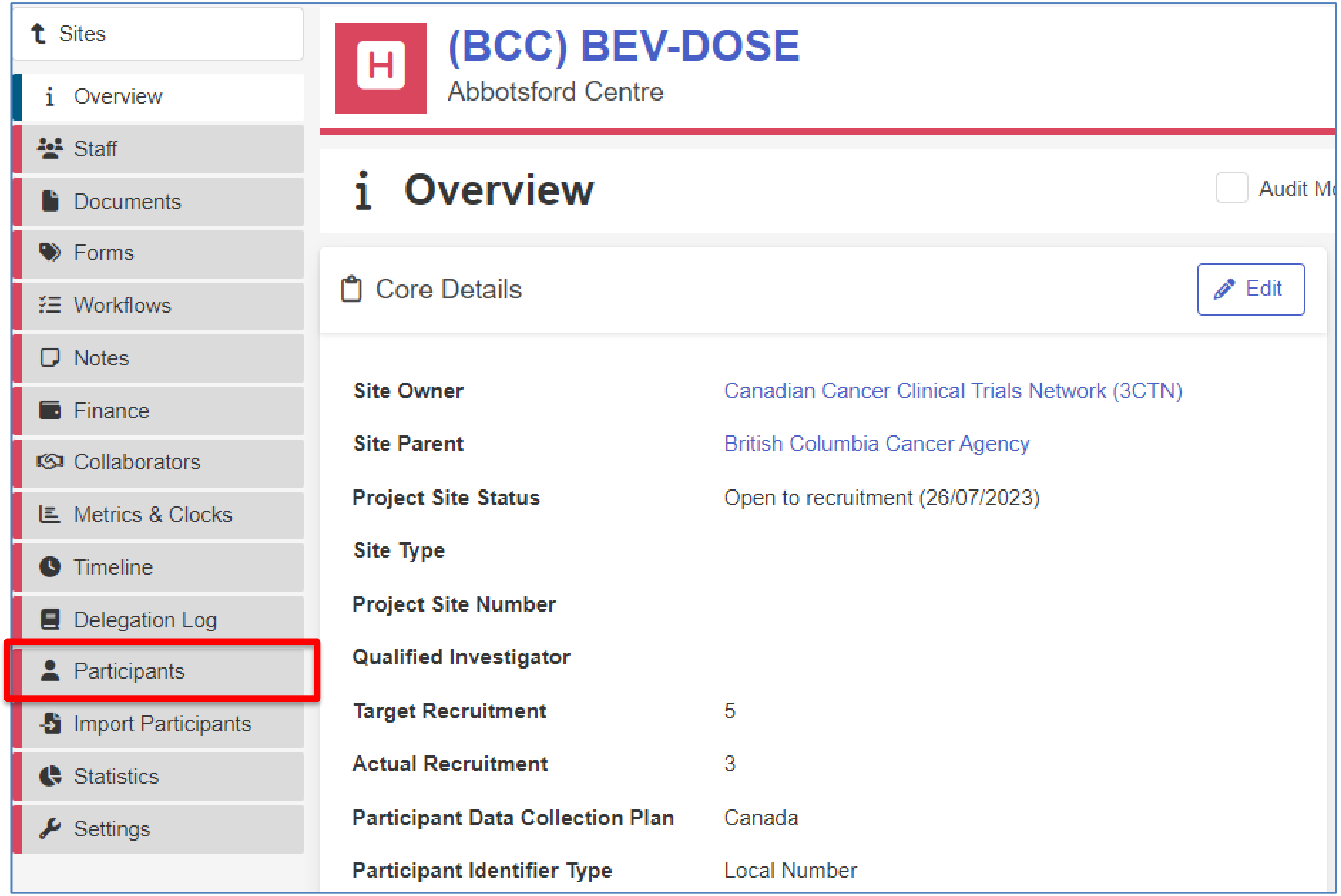
Adding a Participant – Within the Project Site level



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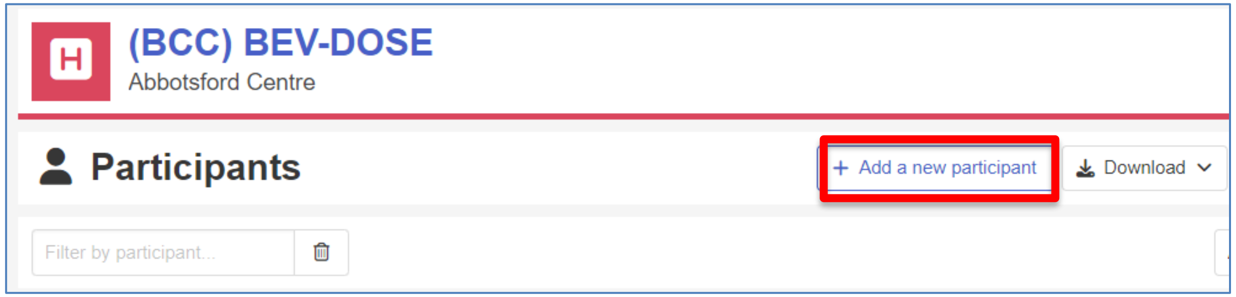
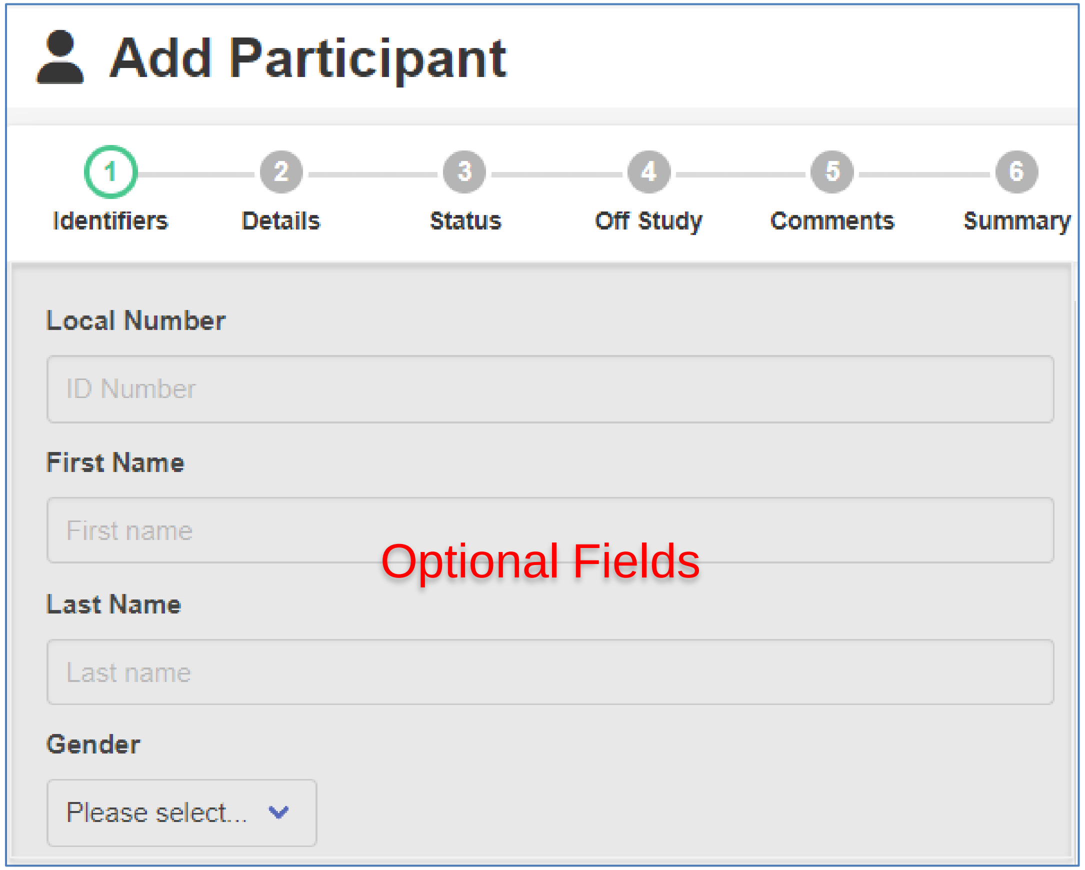
Adding a Participant – Participant Details





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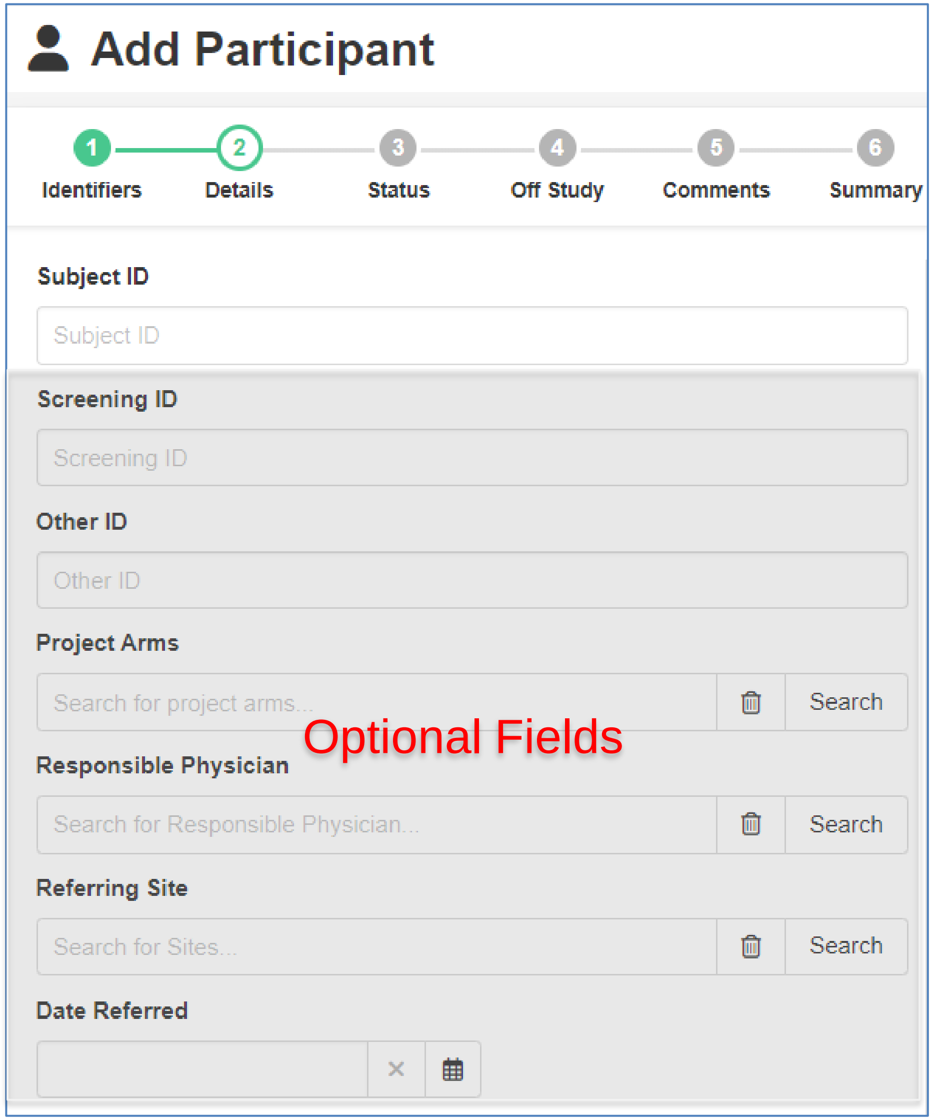
Adding a Participant – Participant Details



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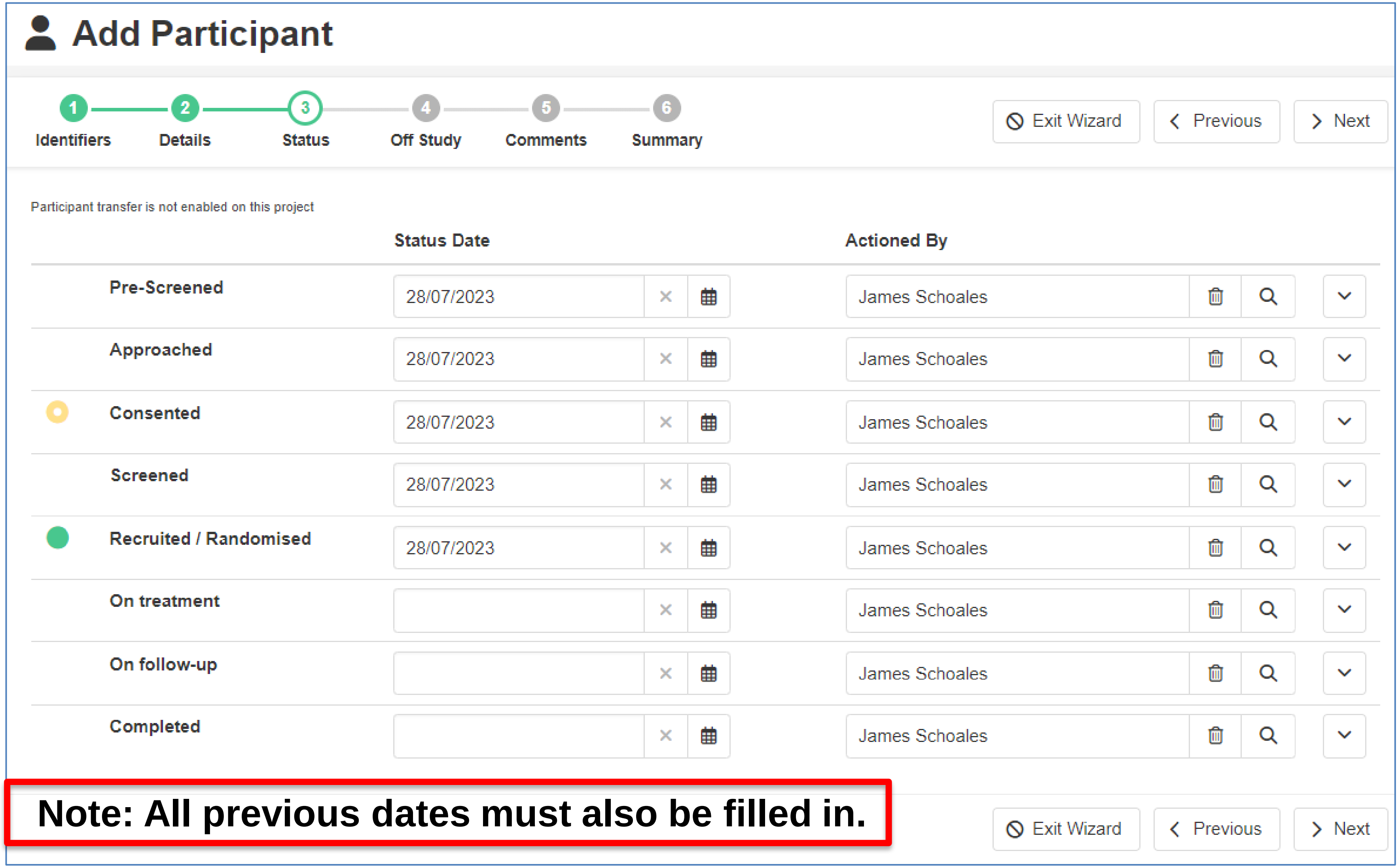
Adding a Participant – Participant Status Dates



Note: All previous dates must also be filled in.

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Reporting and Tracking Patients

Bulk Import Patients

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Importing Methods

- 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

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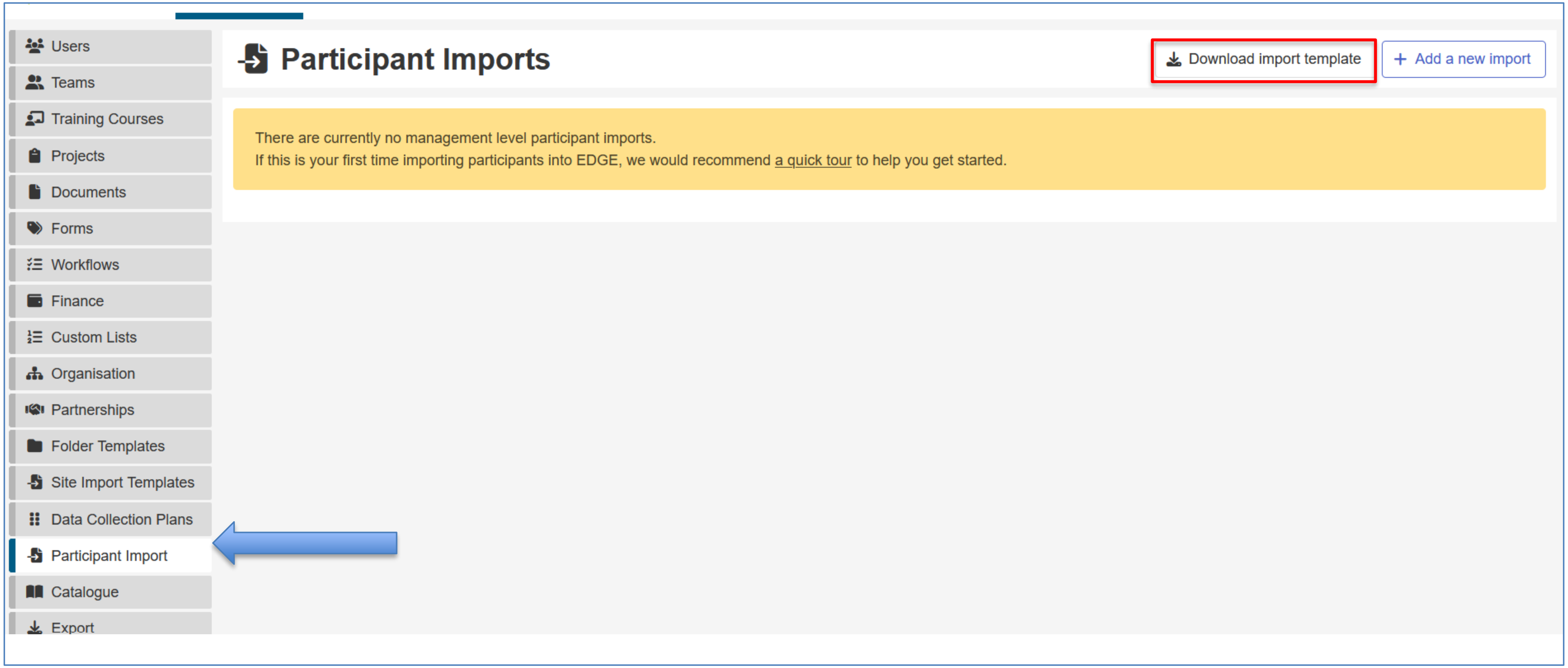
Bulk Importing

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



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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

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Bulk Importing

- 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

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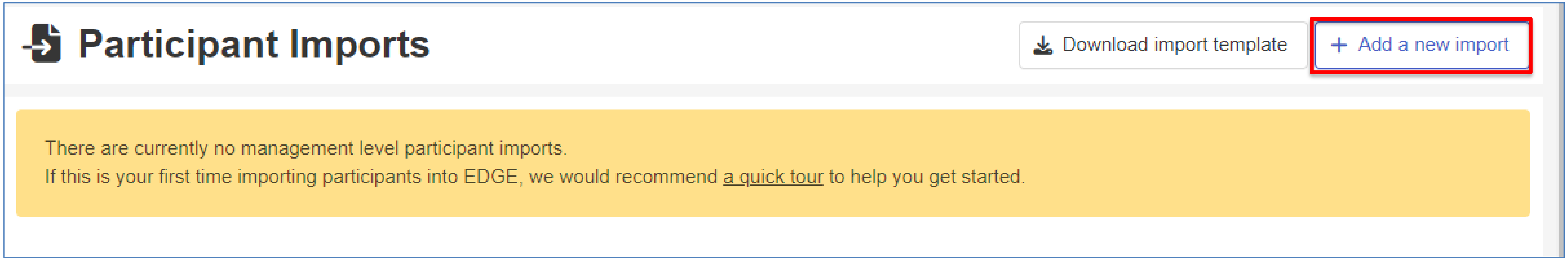
Bulk Importing

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

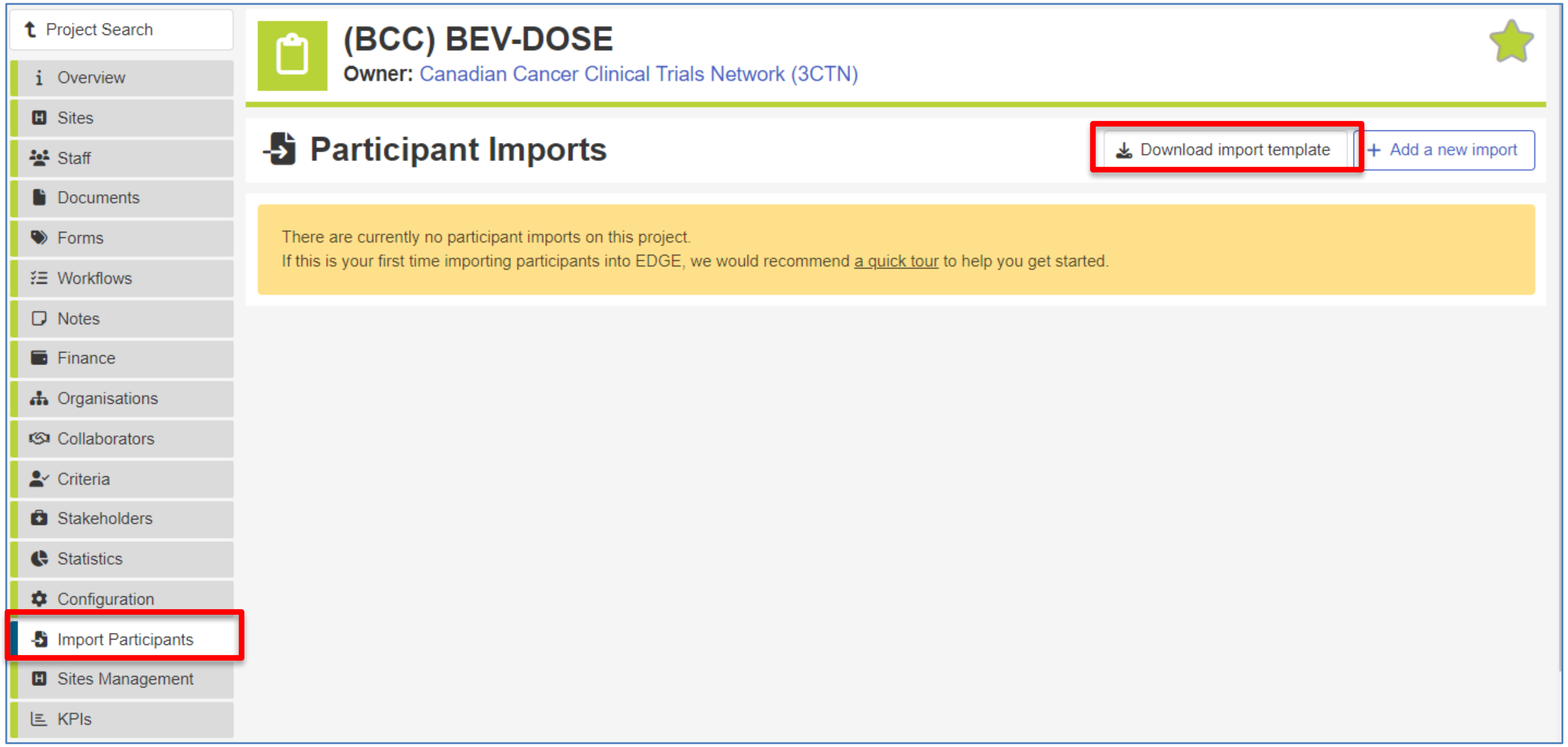


- Select your CSV file and click import.

- 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**

Detailed Import

- 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**



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Detailed Importing – Template Data Fields (Project Level)

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

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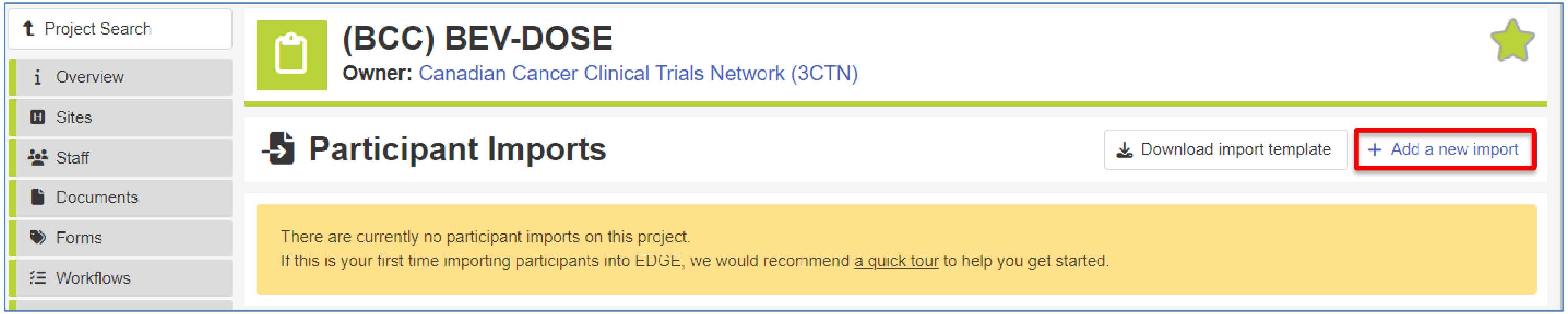
Detailed Import

- 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** .



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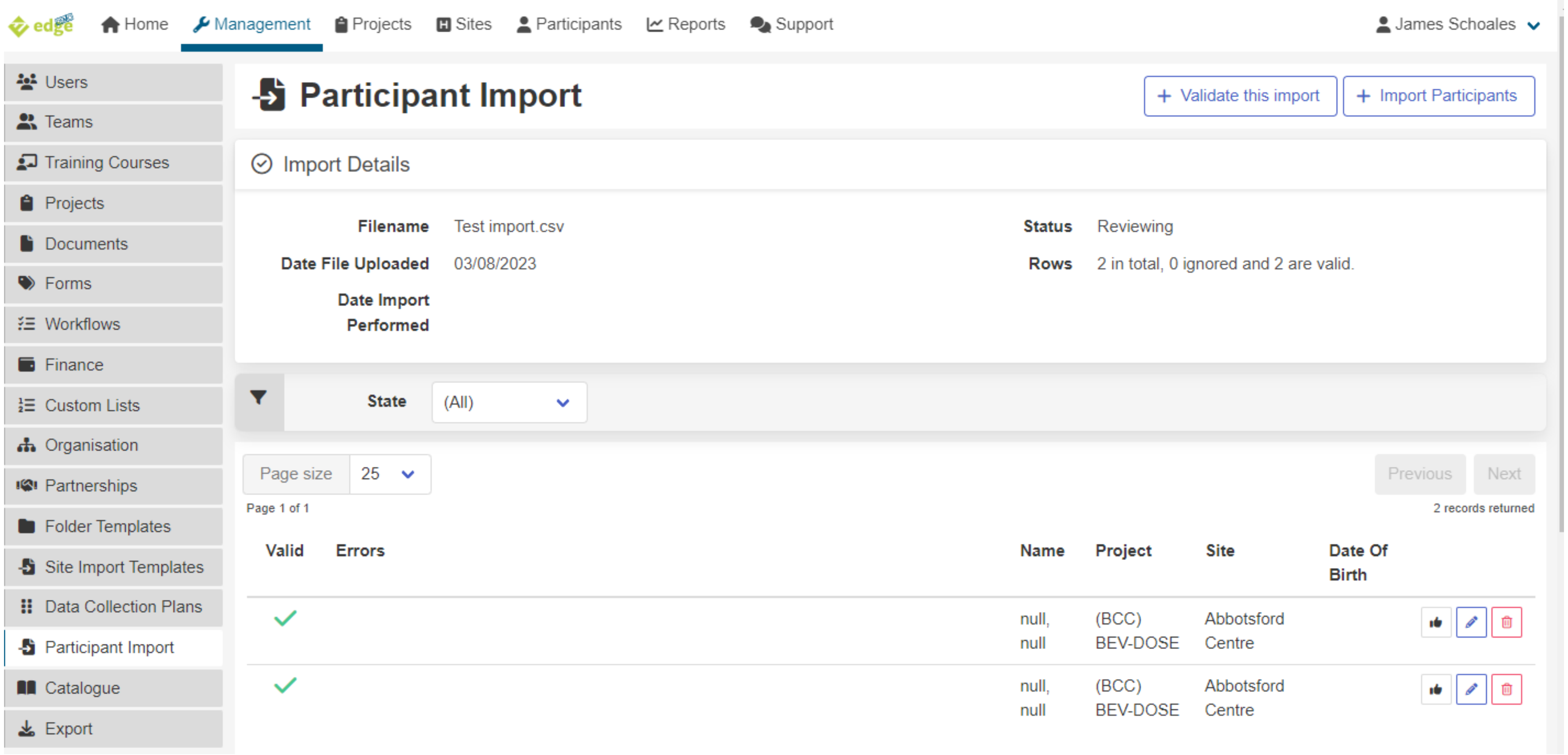
Bulk Importing – Import File Verification

- 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

Bulk Importing – Check the Data, Validate and Import

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



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Reporting and Tracking Patients

Priority Patient Reporting

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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: https://3ctn.ca/files/remote-access-ibf-definition

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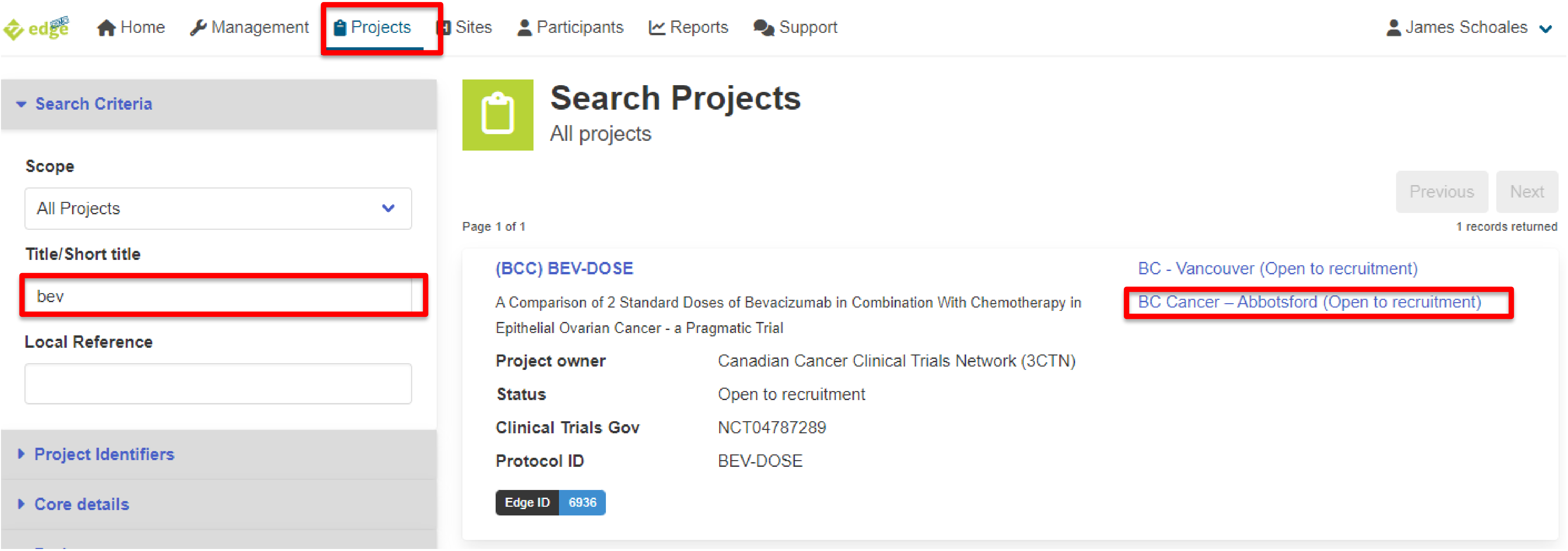
Priority Patient Tracking - Navigation

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



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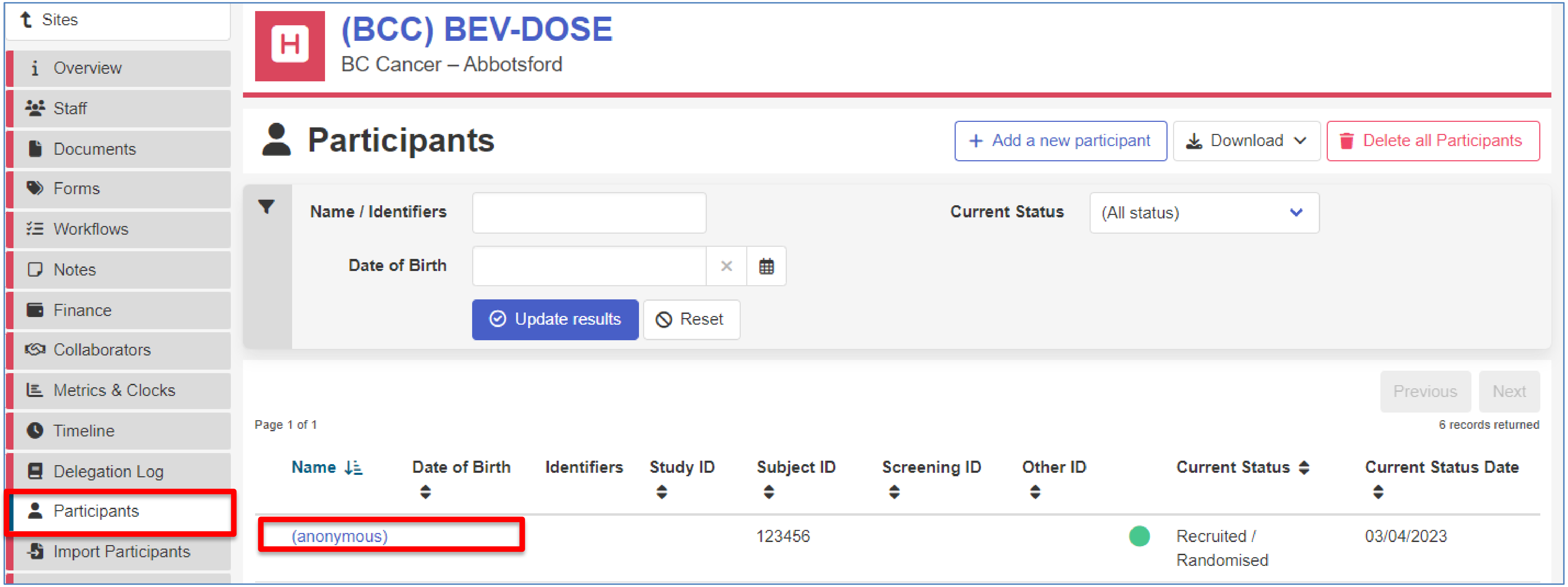
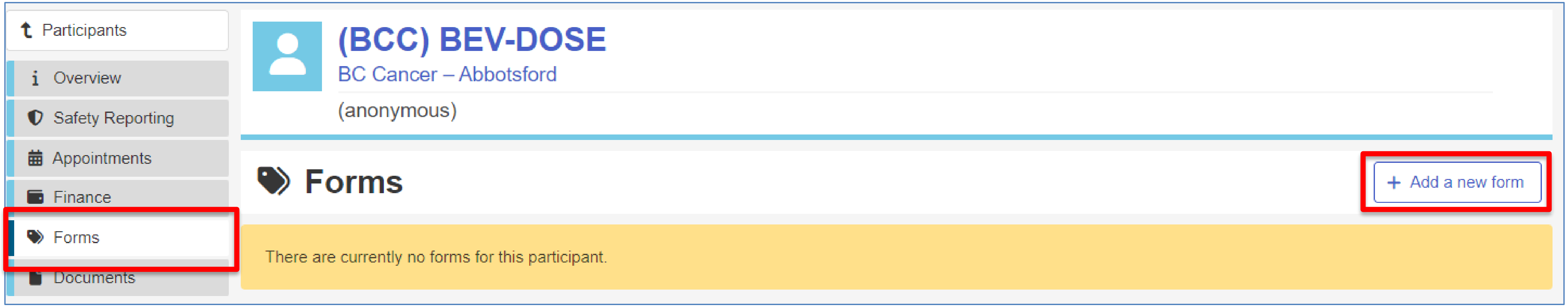
Priority Patient Tracking - Navigation

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



Priority Patient Tracking – Data Entry

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



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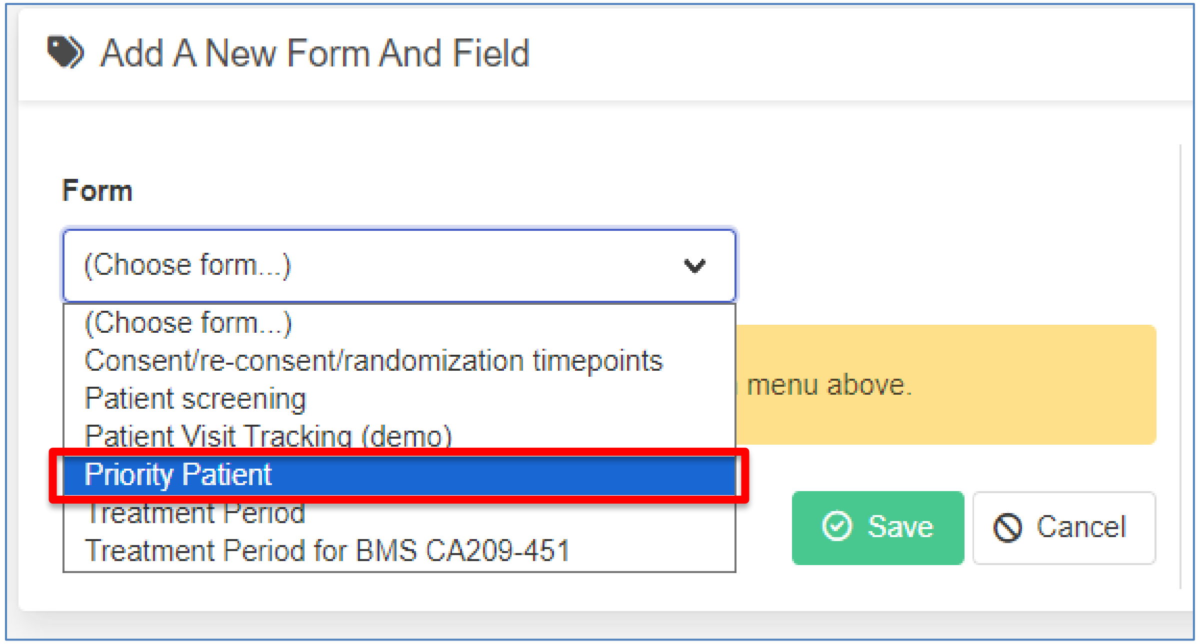
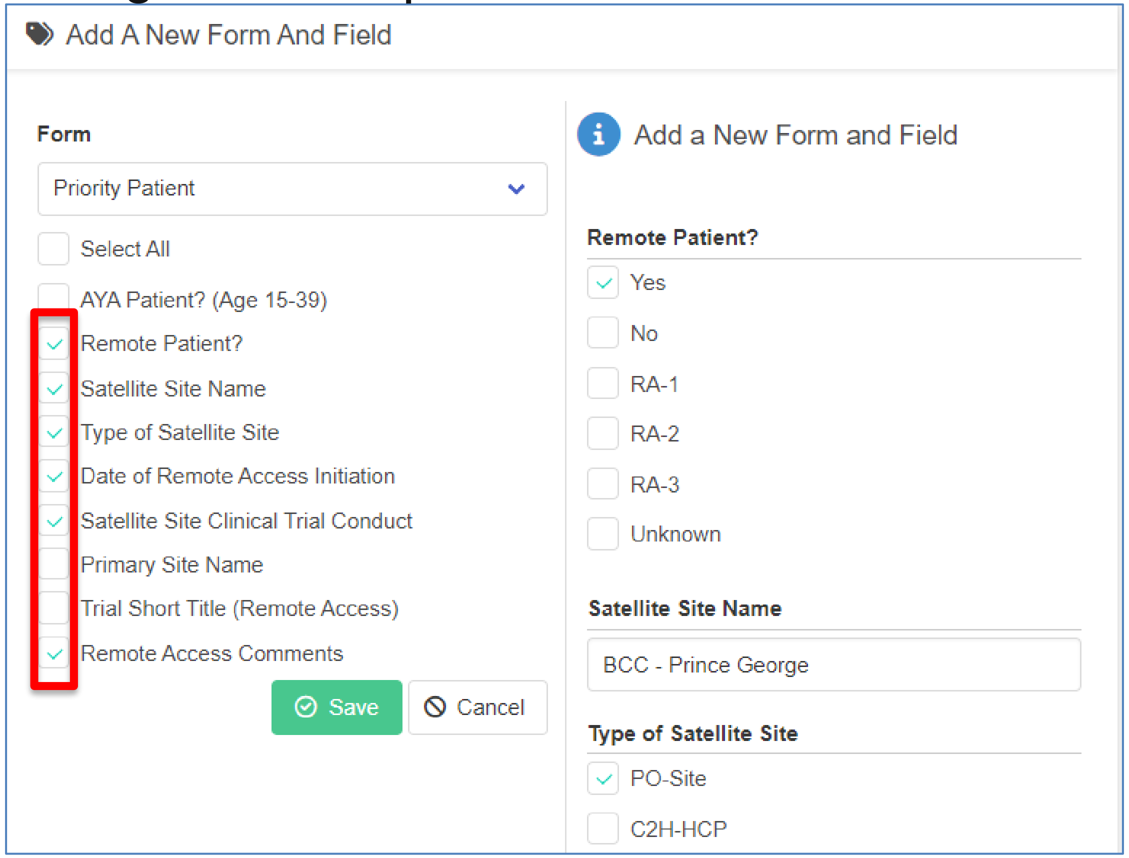
Priority Patient Tracking – Navigation / Data Entry

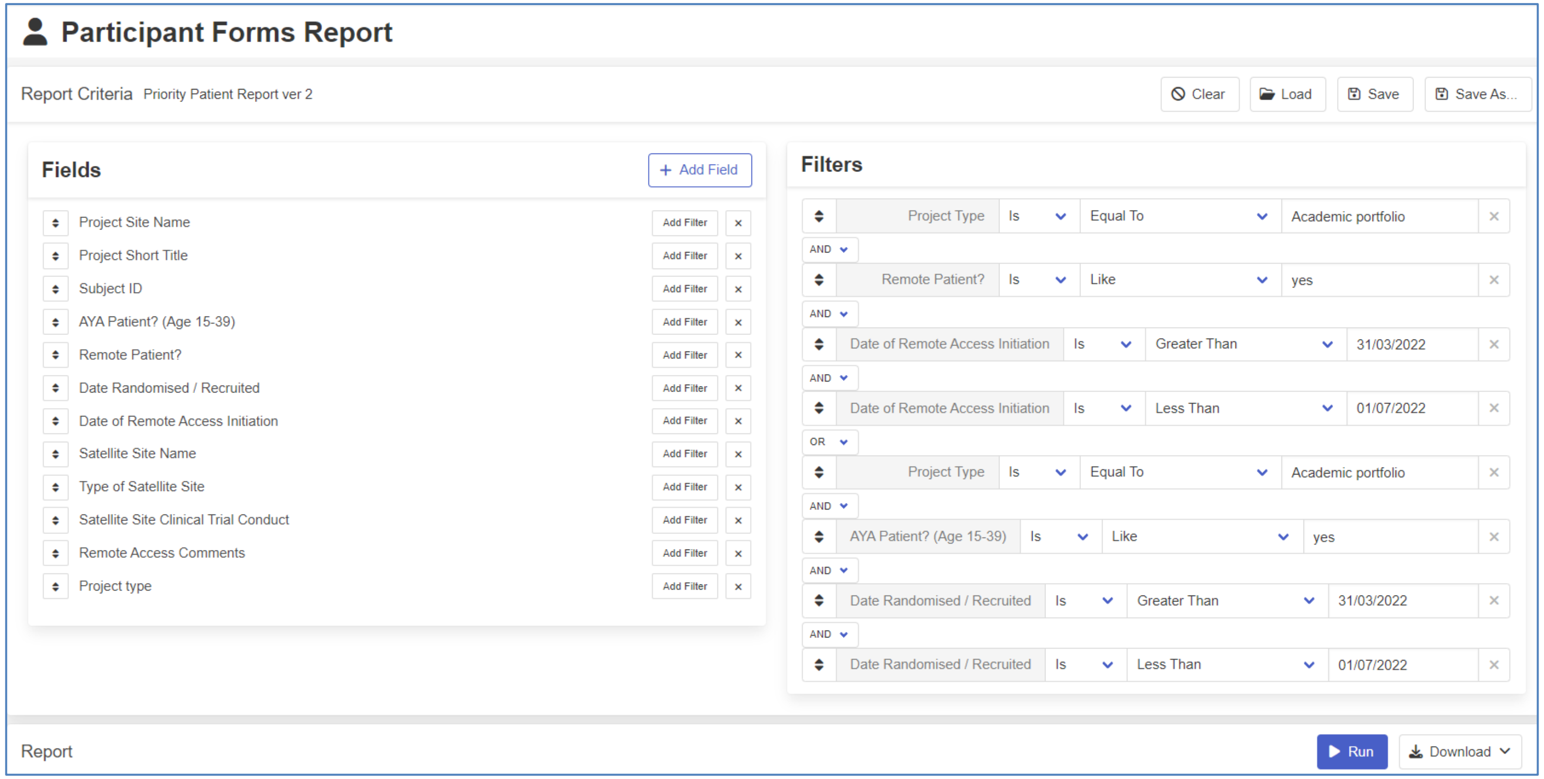
- Select the *Priority Patient* Form
- Check the box of relevant fields (below is an example of Remote Access Patient reporting by Primary Site) and fill in fields on the right, to complete relevant data





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



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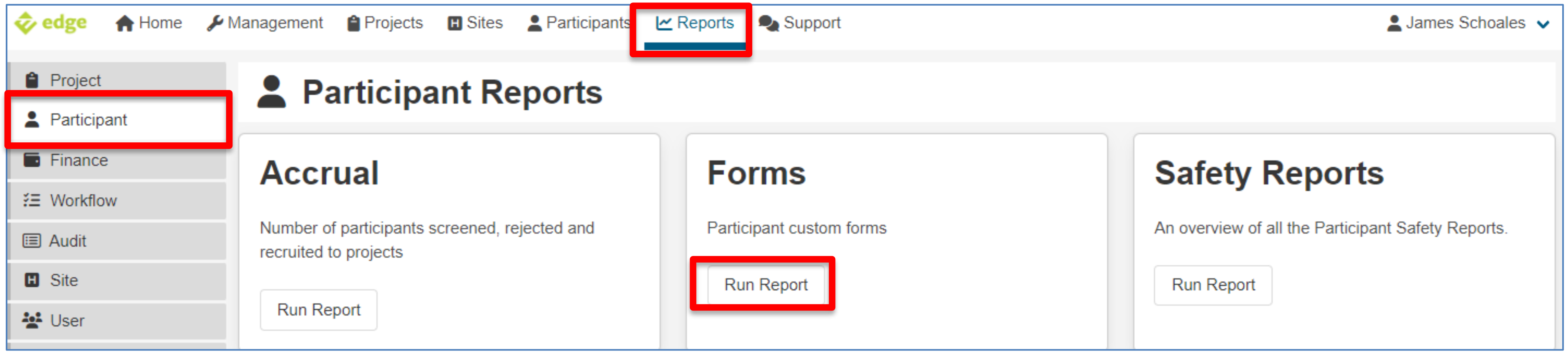
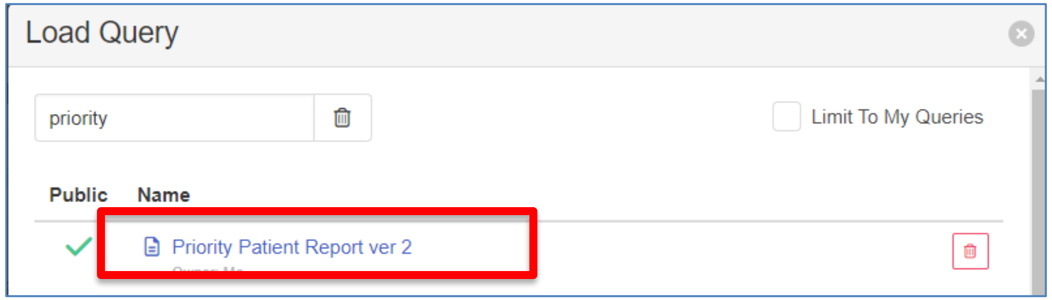
Priority Patient Report Navigation





Note: Report name may vary

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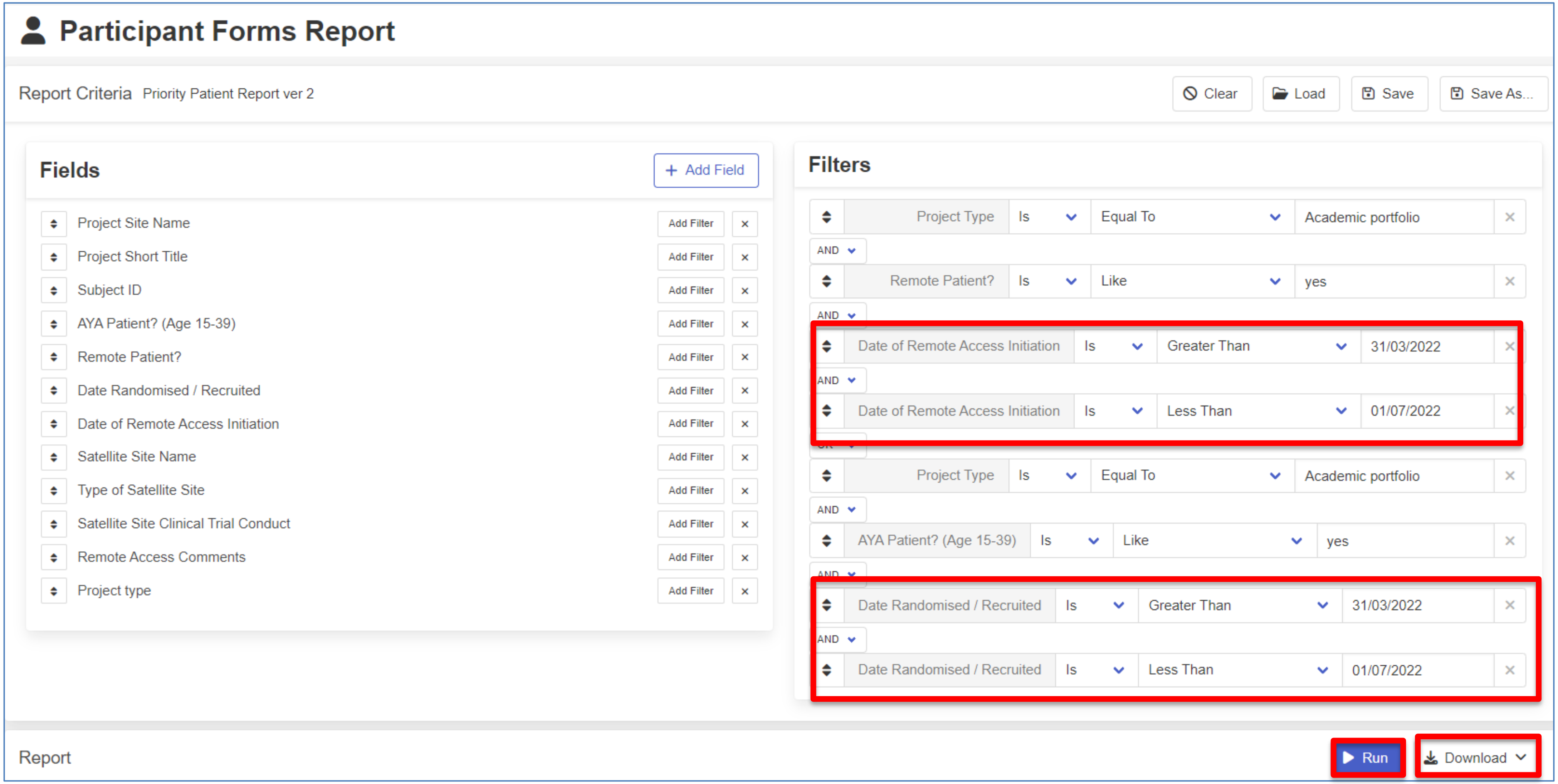
Priority Patient Report Generation



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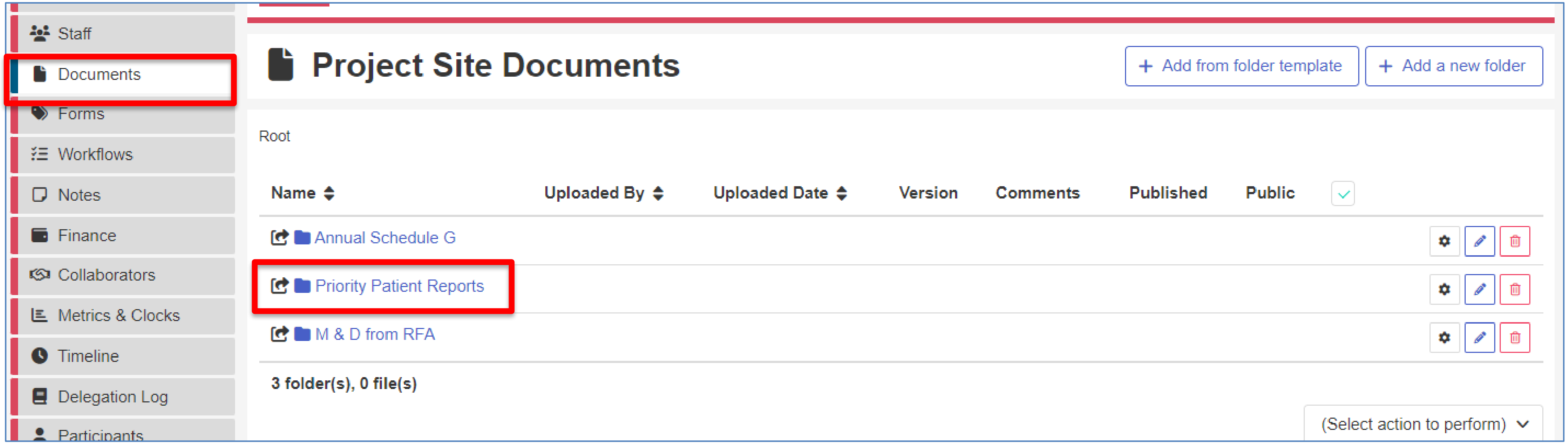
3CTN Priority Patient Reporting

- 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*



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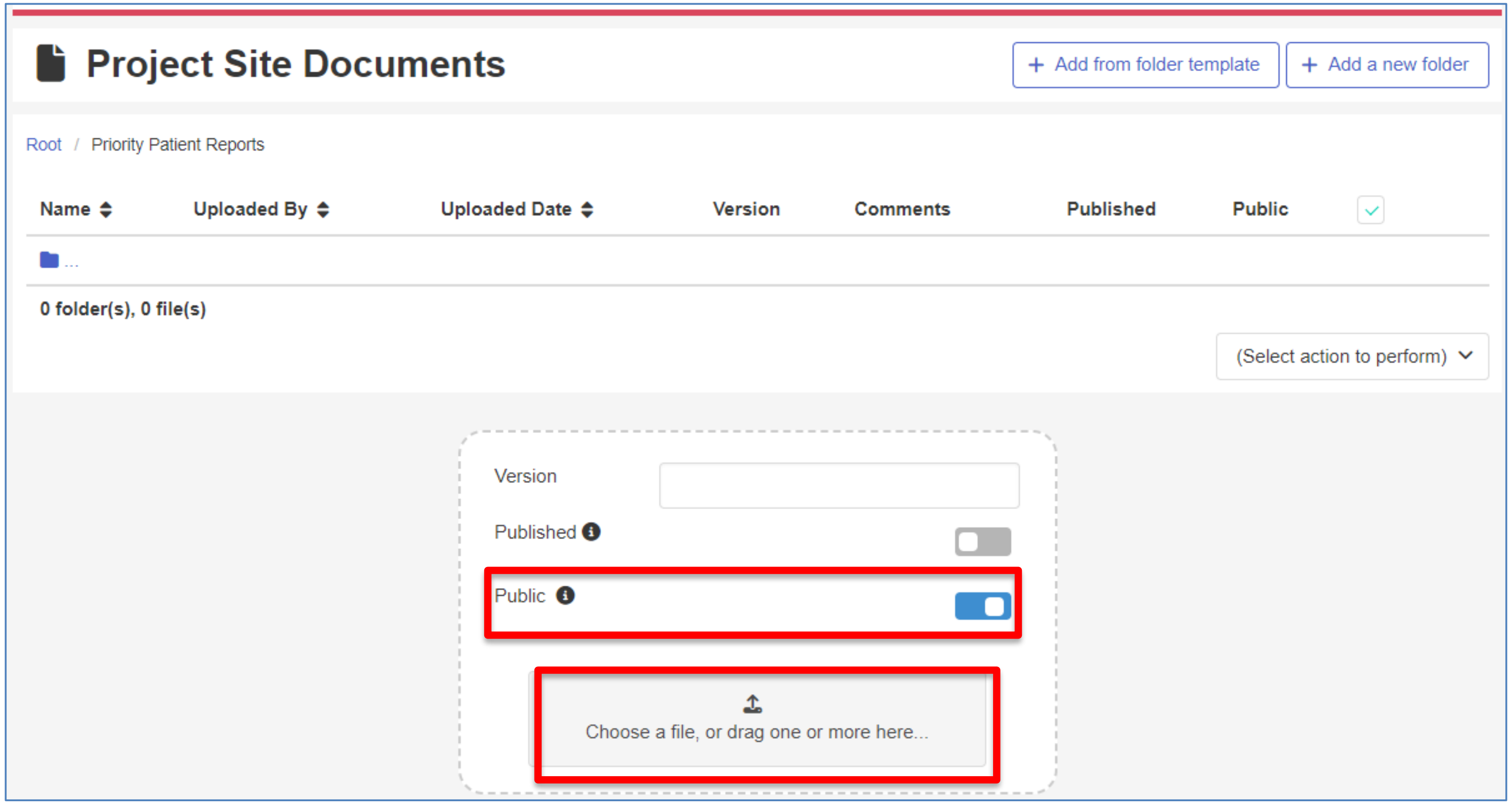
3CTN Priority Patient Reporting

- 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.



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M&D Reporting

Using EDGE site fields

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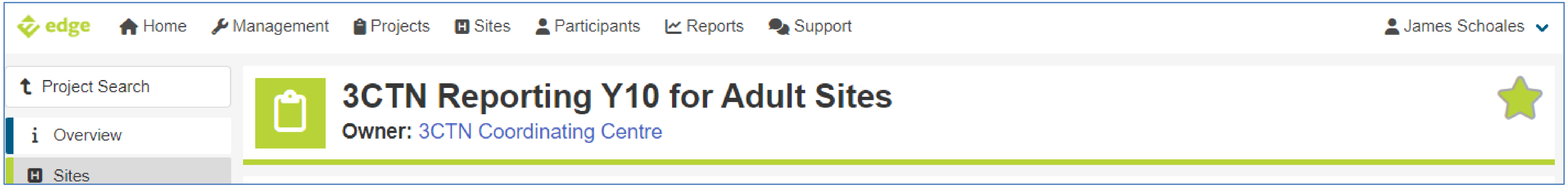
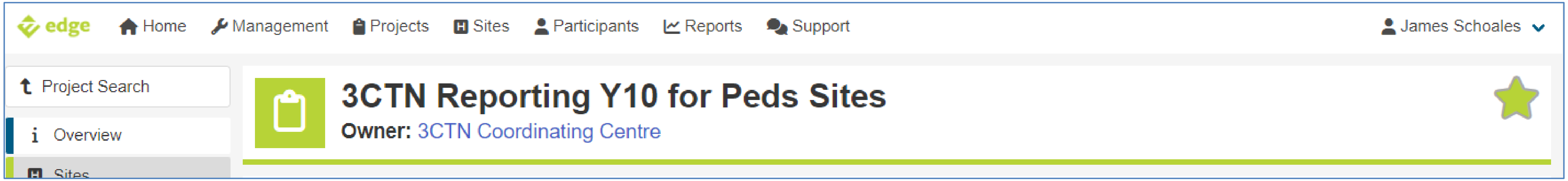
3CTN Reporting: Y9 (April 2022 – Mar 2022)

Reporting Obligations	Frequency	2014 -2022 Format	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:





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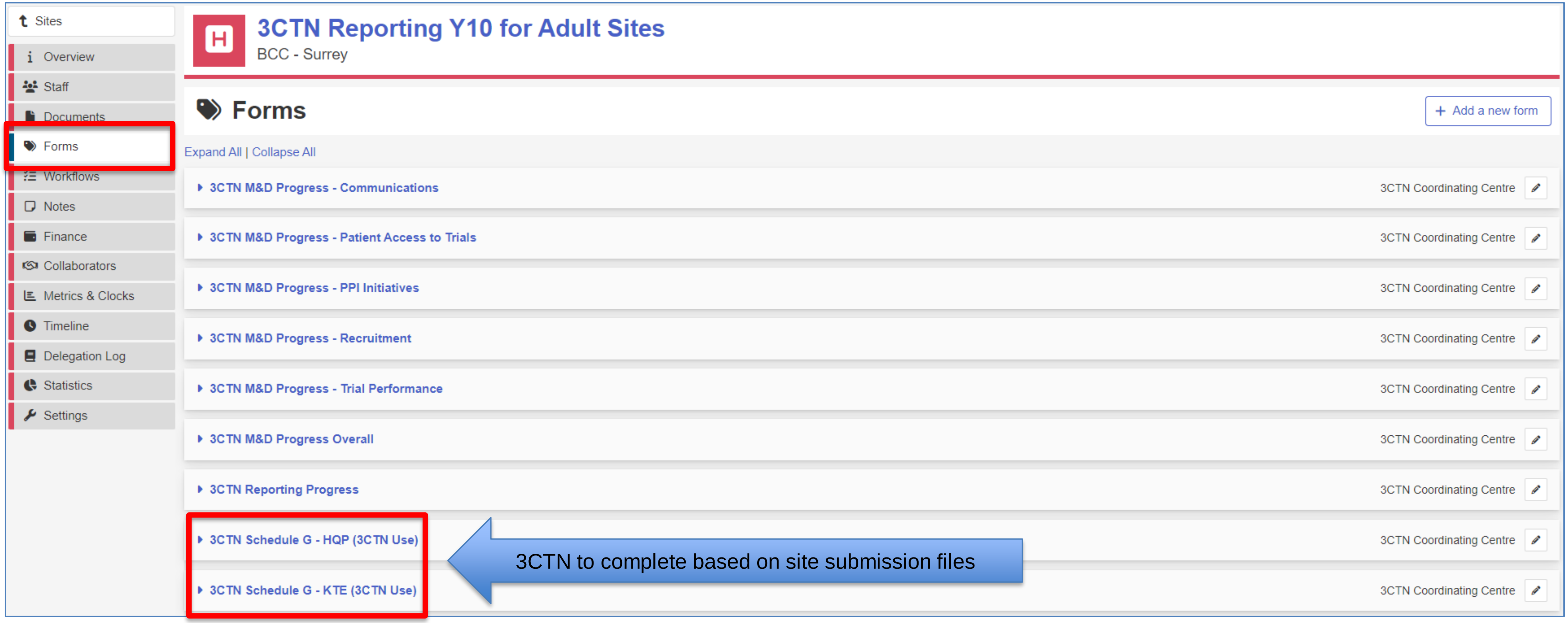
3CTN Reporting – Prefilled information from site M&D

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



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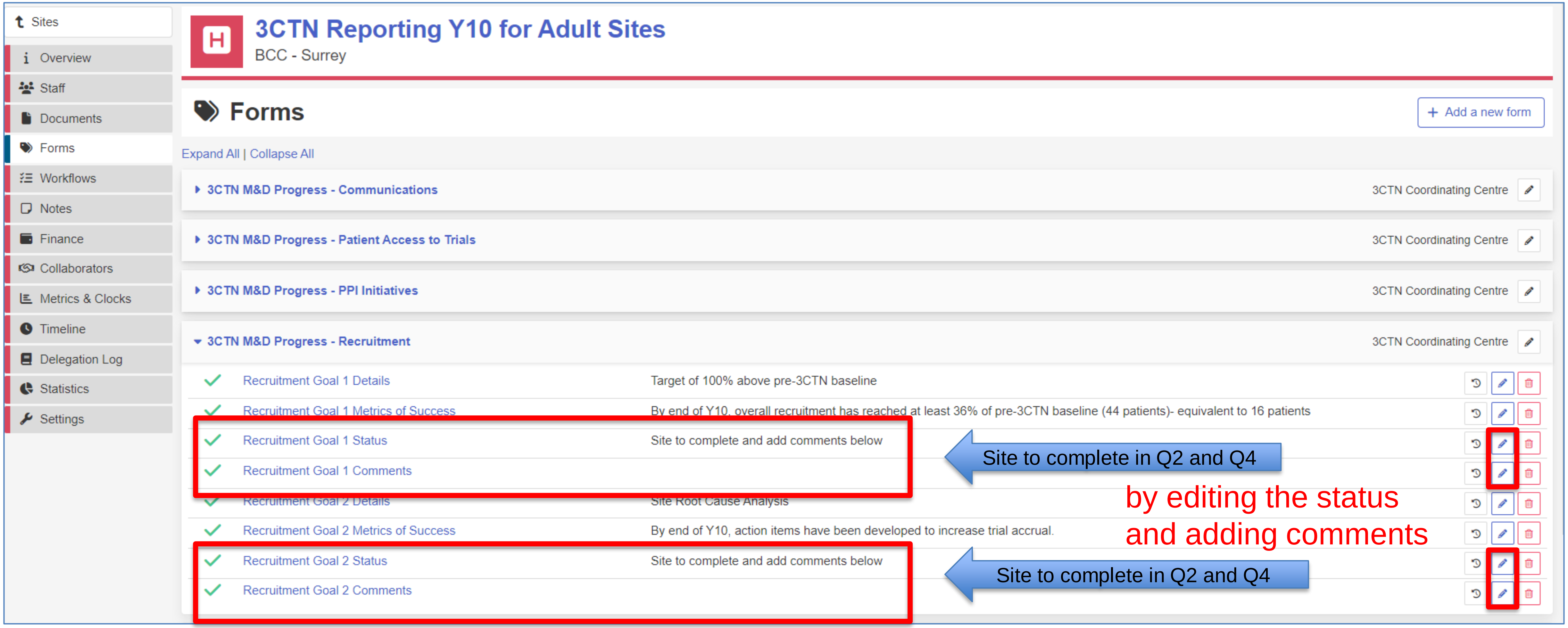
3CTN Reporting – Site to Complete in Q2 and Q4



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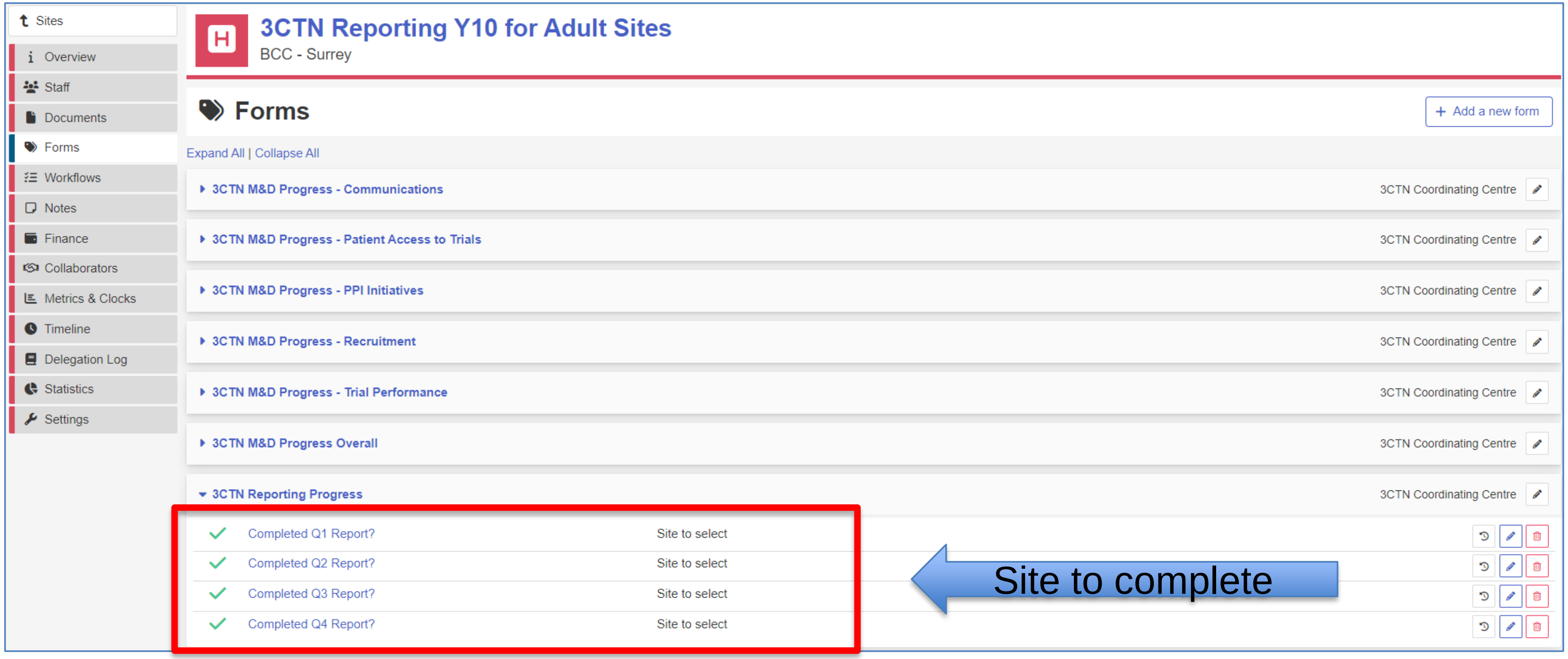
3CTN Reporting Progress – Site to complete

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.



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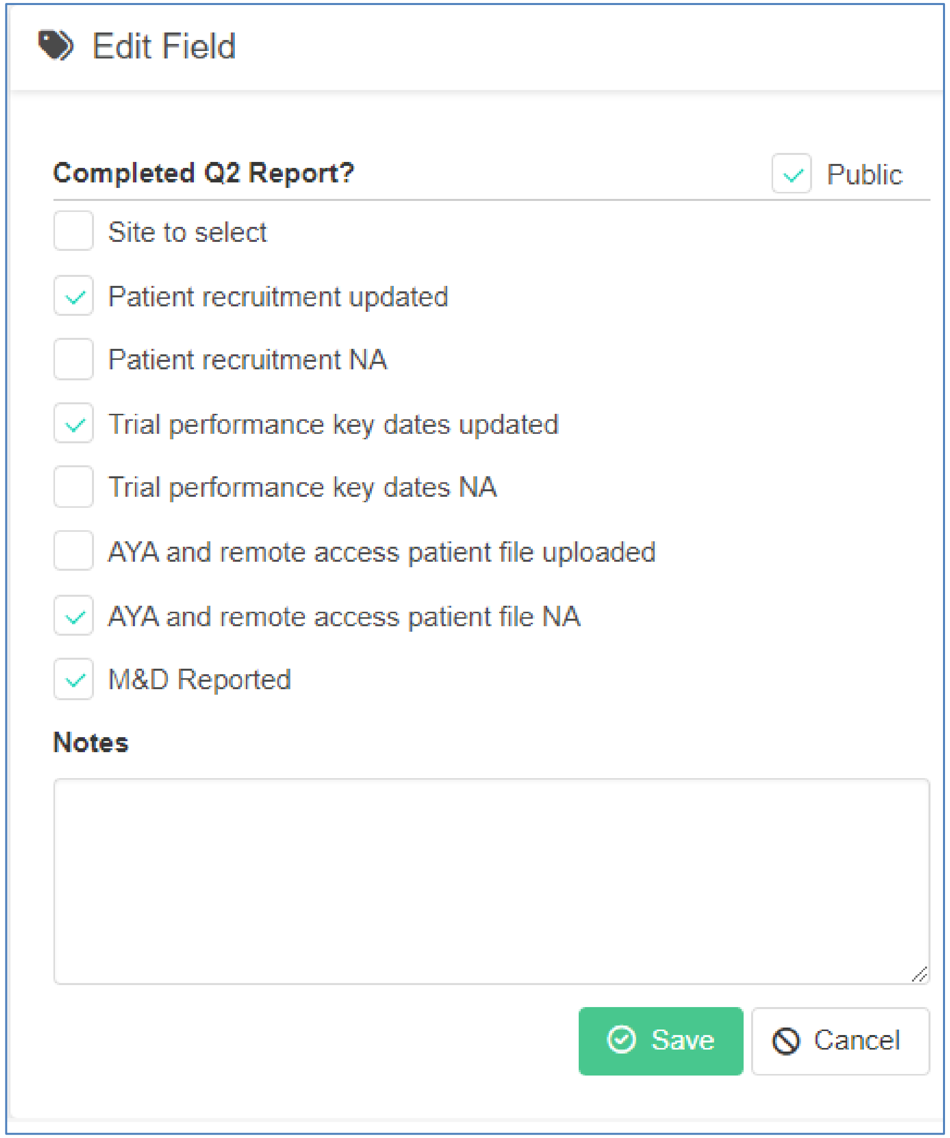
3CTN Reporting – Site to Complete

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



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Schedule G Reporting

Document Upload

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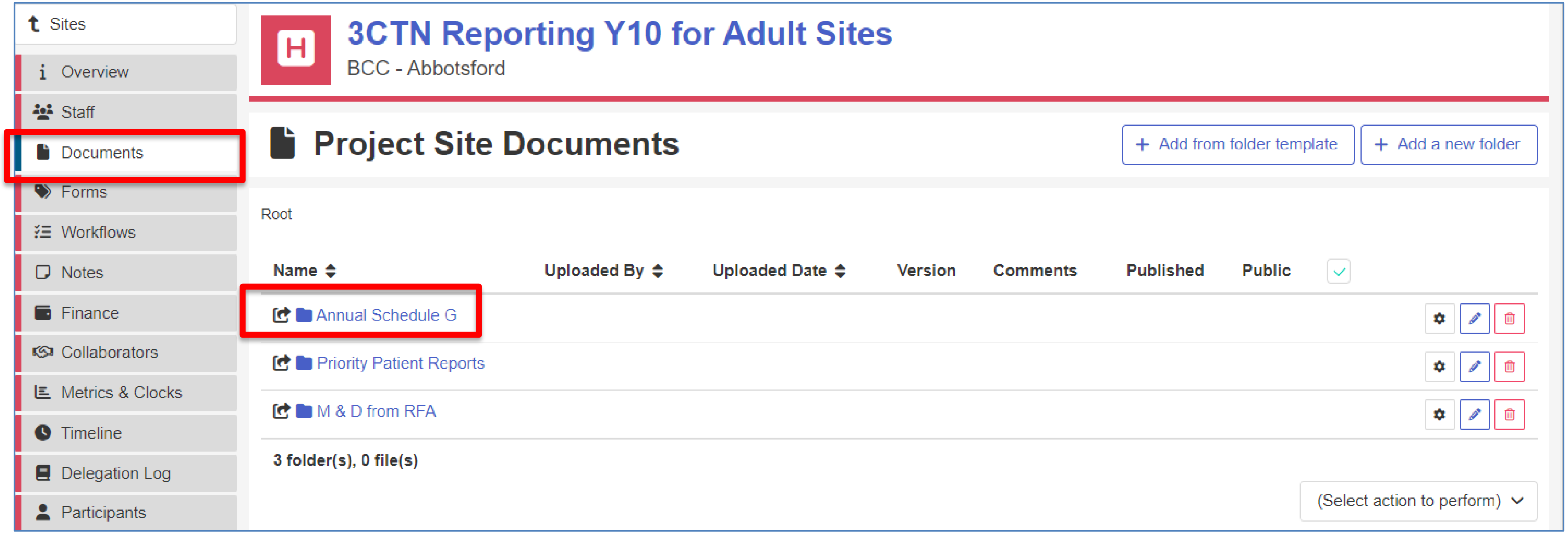
Schedule G Reporting

- 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



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Schedule G Reporting

- 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.