edge
INTELLIGENT RESEARCH MANAGEMENT™

Canadian
Cancer Clinical
Trials Network

3CTN Reporting Portal User Training

Portfolio and Patient Related

Account Activation

- Bookmark this link: https://edge-canada.ca/

- **Login** using the name and password provided to you

Forgot Password?

- Click on **FORGOTTEN YOUR PASSWORD?** Follow the on-screen prompts on the login screen and answer any security questions to reset your access.

- If you are still unable to access your account, please contact your Local Administrator.

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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

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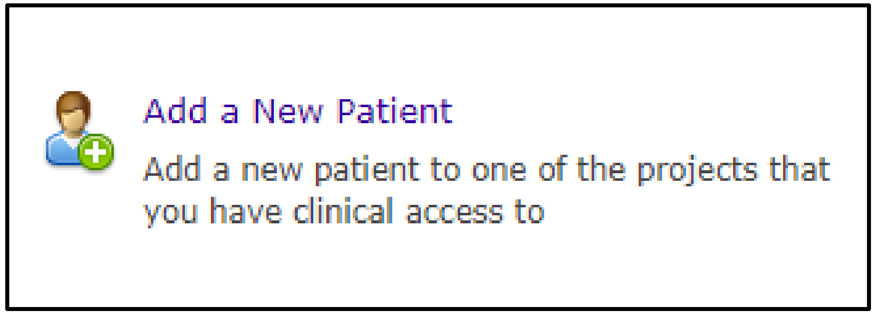
Manually Adding a Patient - Options

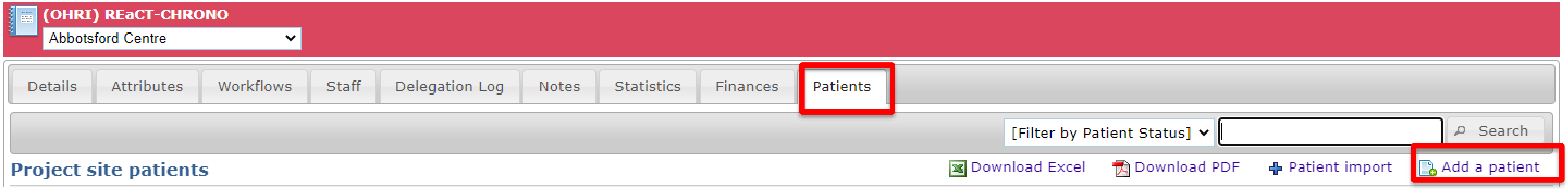
There are **2** ways to manually add patients to EDGE:

A. Using the “Add a New Patient” button on the home page

OR

B. 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 should be open to recruitment at your project site level.

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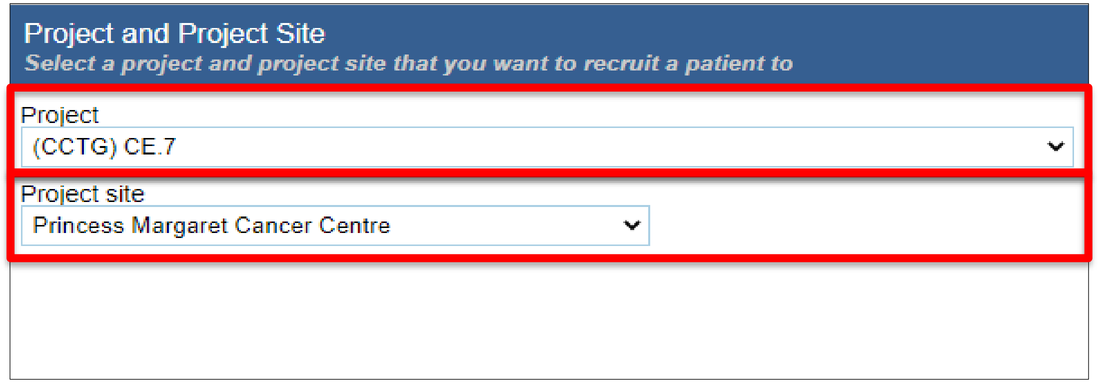
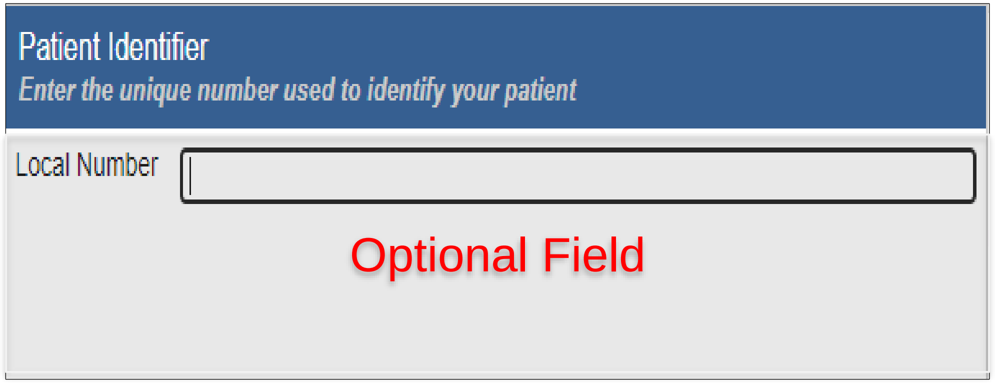
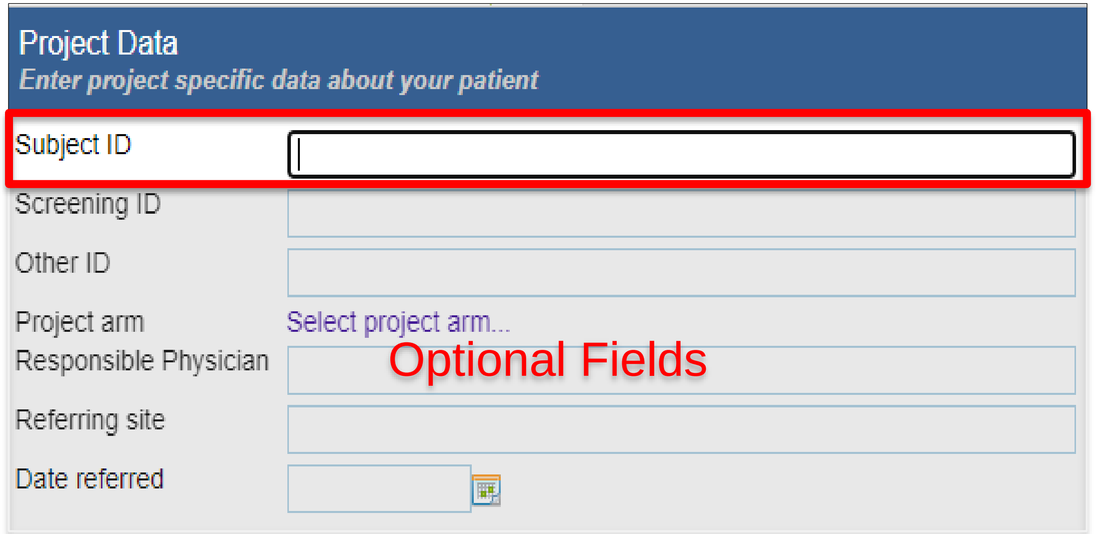
Option A: Adding a Patient – Patient Details







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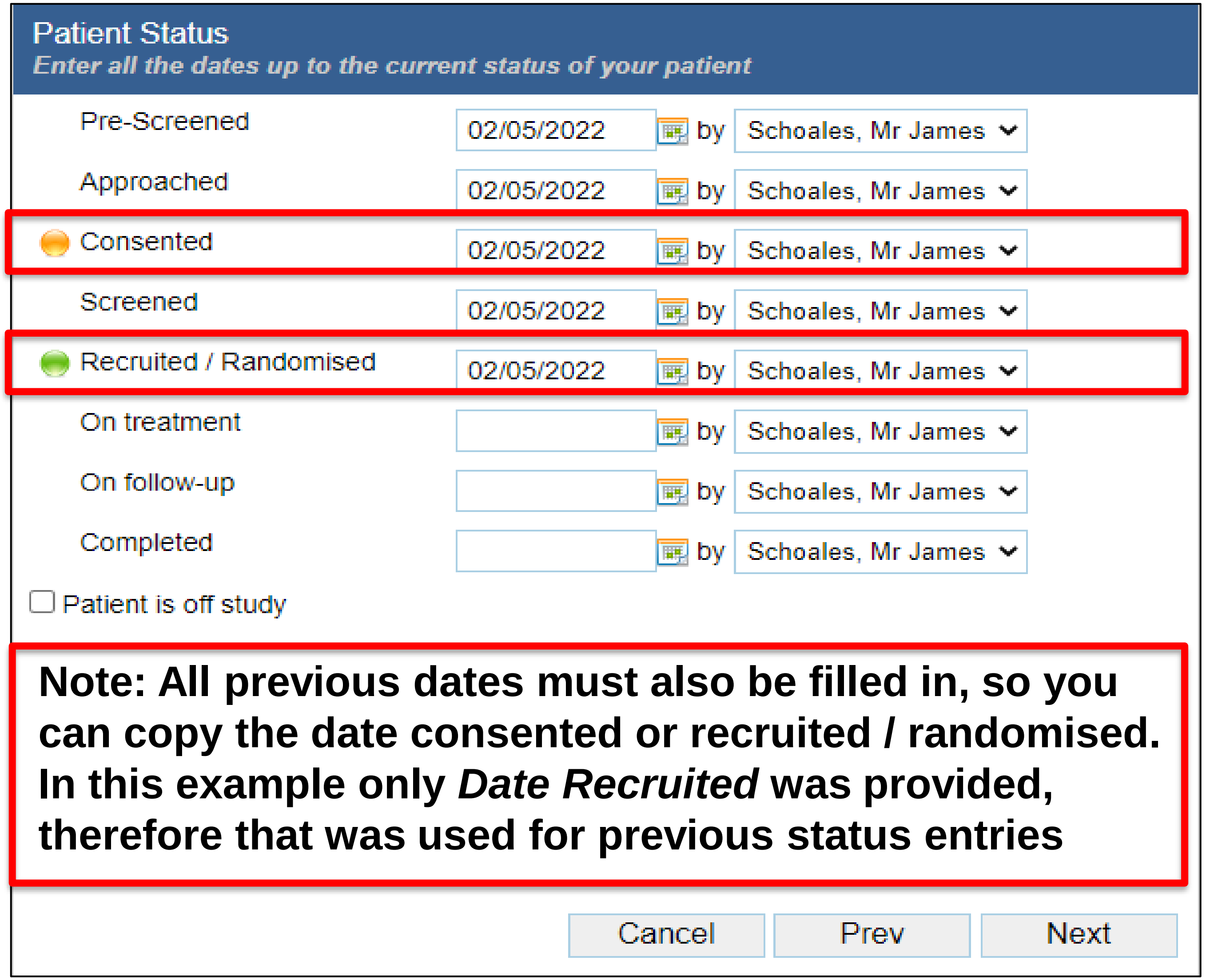
Option A: Adding a Patient – Patient Status Dates



Patient Status

Enter all the dates up to the current status of your patient

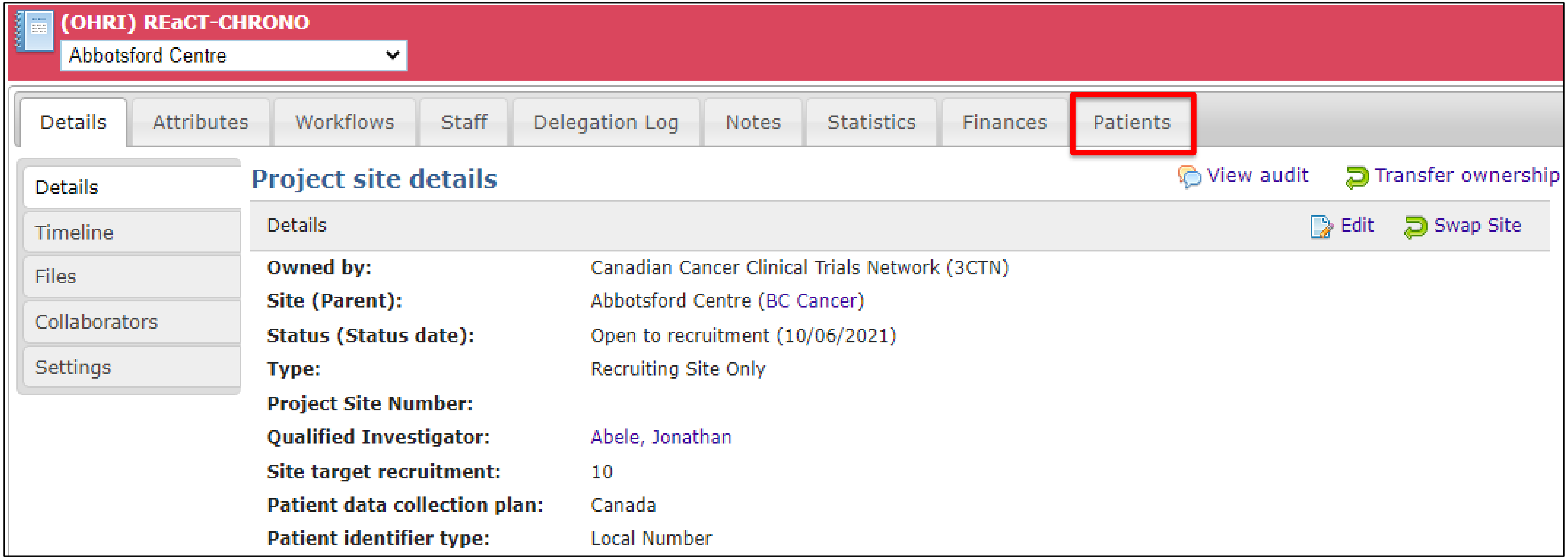
Pre-Screened	02/05/2022	by	Schoales, Mr James
Approached	02/05/2022	by	Schoales, Mr James
Consented	02/05/2022	by	Schoales, Mr James
Screened	02/05/2022	by	Schoales, Mr James
Recruited / Randomised	02/05/2022	by	Schoales, Mr James
On treatment		by	Schoales, Mr James
On follow-up		by	Schoales, Mr James
Completed		by	Schoales, Mr James

☐ Patient is off study

Note: All previous dates must also be filled in, so you can copy the date consented or recruited / randomised. In this example only *Date Recruited* was provided, therefore that was used for previous status entries

Cancel | Prev | Next

Option B: Adding a Patient – Within the Project Site level



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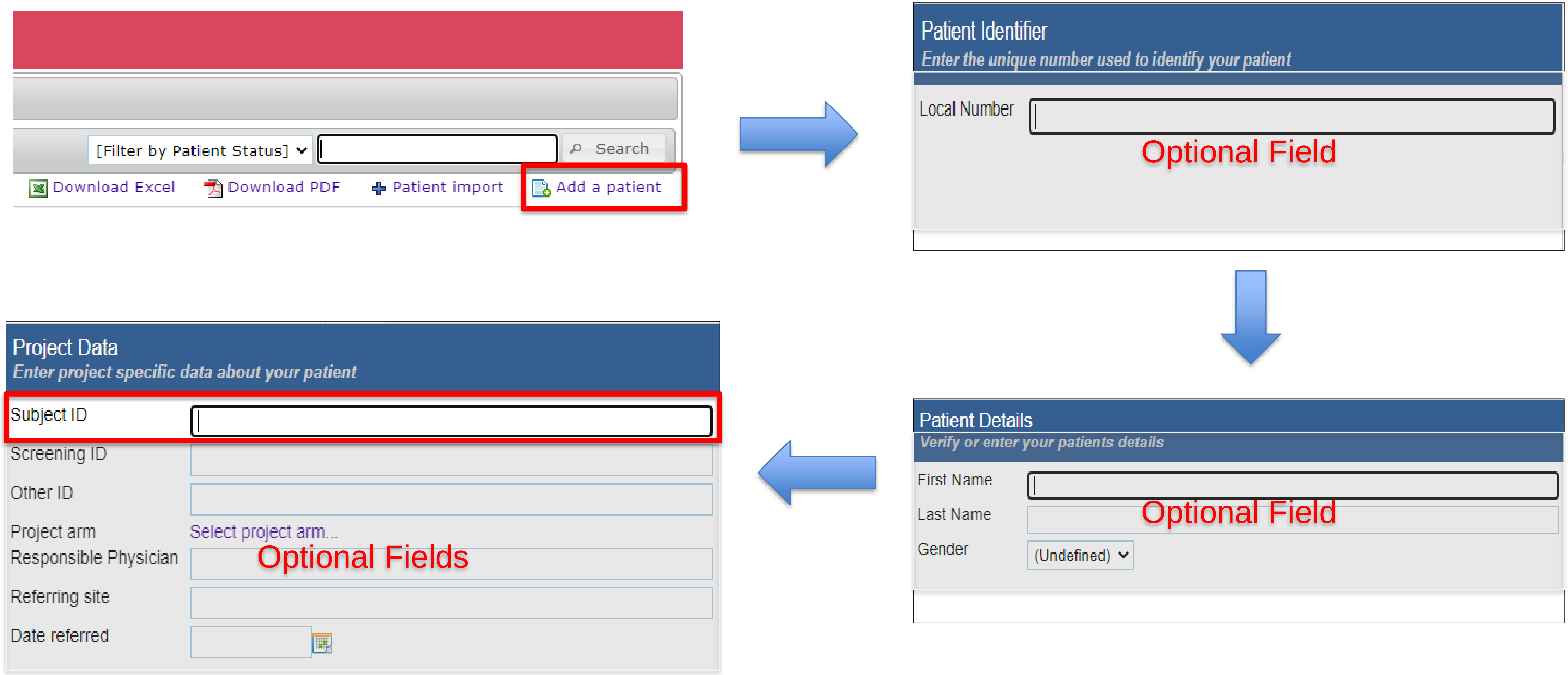
Option B: Adding a Patient – Patient Details



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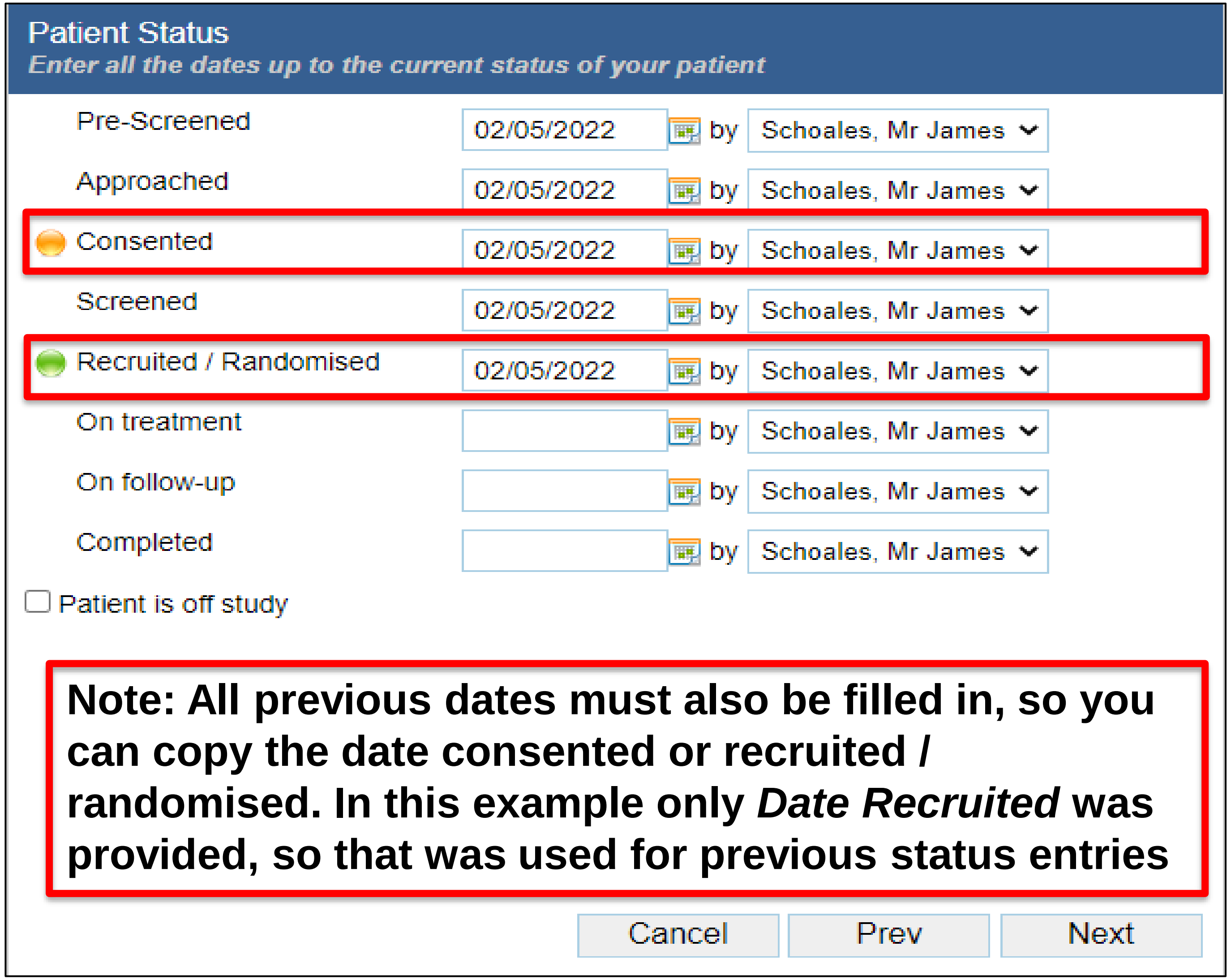
Option B: Adding a Patient – Patient Status Dates



Patient Status

Enter all the dates up to the current status of your patient

Pre-Screened	02/05/2022	by	Schoales, Mr James
Approached	02/05/2022	by	Schoales, Mr James
Consented	02/05/2022	by	Schoales, Mr James
Screened	02/05/2022	by	Schoales, Mr James
Recruited / Randomised	02/05/2022	by	Schoales, Mr James
On treatment		by	Schoales, Mr James
On follow-up		by	Schoales, Mr James
Completed		by	Schoales, Mr James

☐ Patient is off study

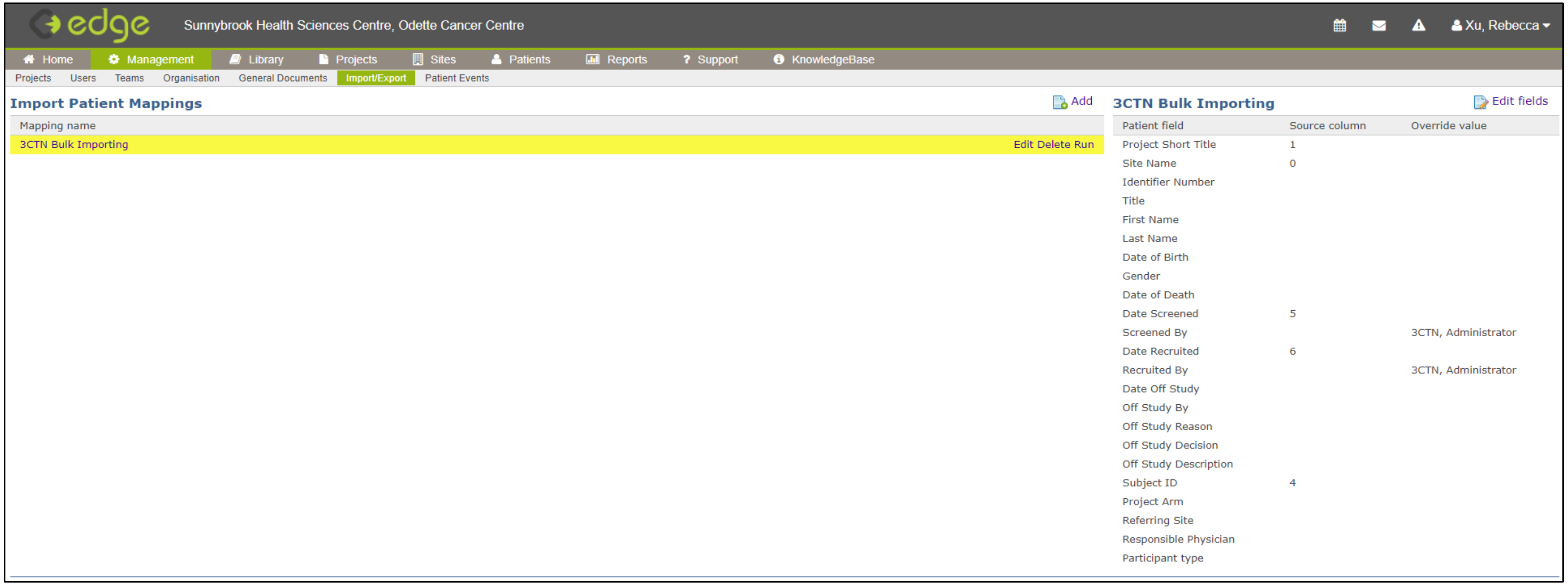
Note: All previous dates must also be filled in, so you can copy the date consented or recruited / randomised. In this example only *Date Recruited* was provided, so that was used for previous status entries

Cancel | Prev | Next

Bulk Import of Patients

Management tab import (Bulk Import)

- Allows admin level users to import patients to multiple projects/project sites at once regardless of project or project site status
- Can be mapped to an existing MS Excel file.



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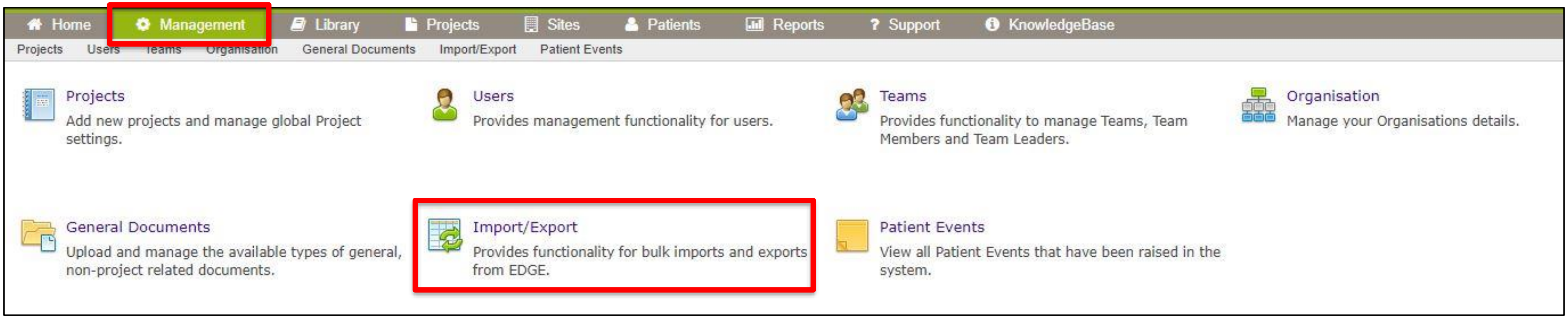
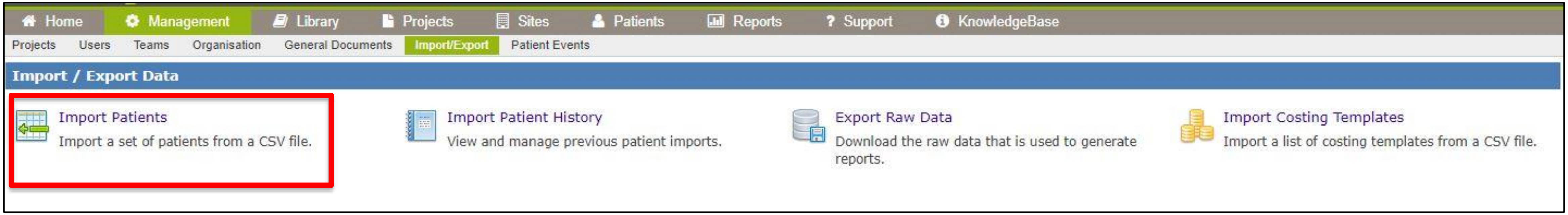
Bulk Import of Patients - Navigation





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Bulk Import Map and Reference Excel

0	1			4	5	6
Site name	**Short Title**	**Full Title**	**Clinical trials gov number**	**Patient Subject ID (Note: Please right click to insert more rows for more than one patient)**	**Patient Consented Date for Multi-Staged Trials (use this column to report the Patient consented dates for 1st recruited patients for multi-staged trials) Note: This column will be used to reassess IBF factors for Multi-Staged trials**	**Patient Recruited Date (dd/mm/yyyy) (Note: Please highlight if you include last or next period accrual)**
Sunnybrook Health Sciences Centre, Sunnybrook Research Institute	Refresher Training Import Demo			test001	15-Apr-22	16-Apr-22

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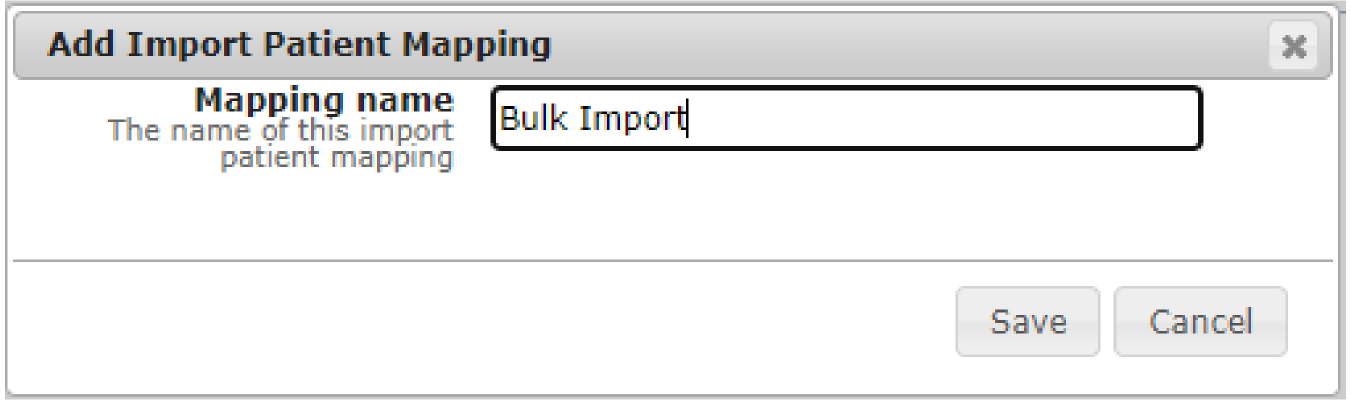
Bulk Importing – Custom Mapping

- In the management tab click on *Import/Export,* followed by *Import Patients*

- Click “*Add*” in the right-hand corner and enter a name for your Import Template



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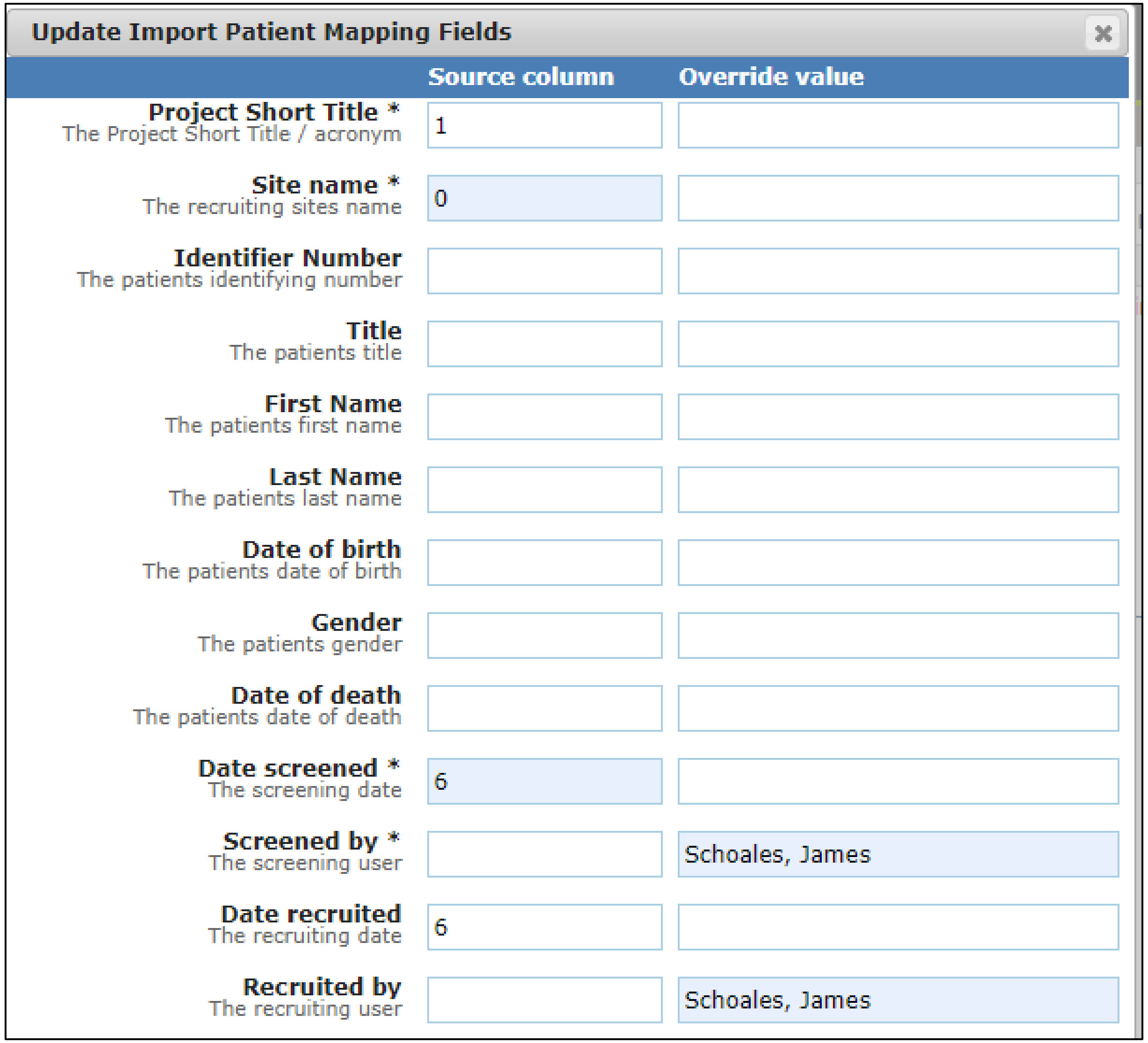
Bulk Importing – Custom Import Map Fields

- Click on the name of your Import Template then in the right-hand corner click *Edit Fields*
- Identify which columns in your csv file correlate to each data field (e.g. column A = 0 = *Site Name*)
- If you don't have a column for a non-mandatory field, designate an override value

  (e.g., Schoales, James for Screened By)



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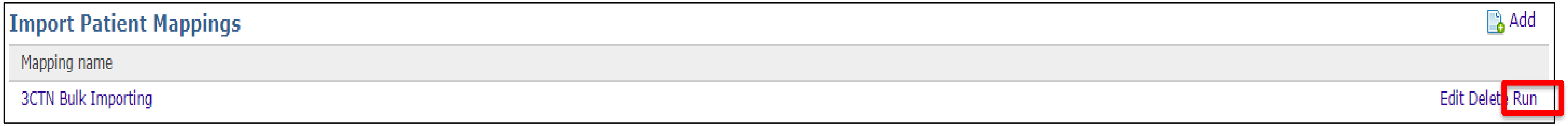
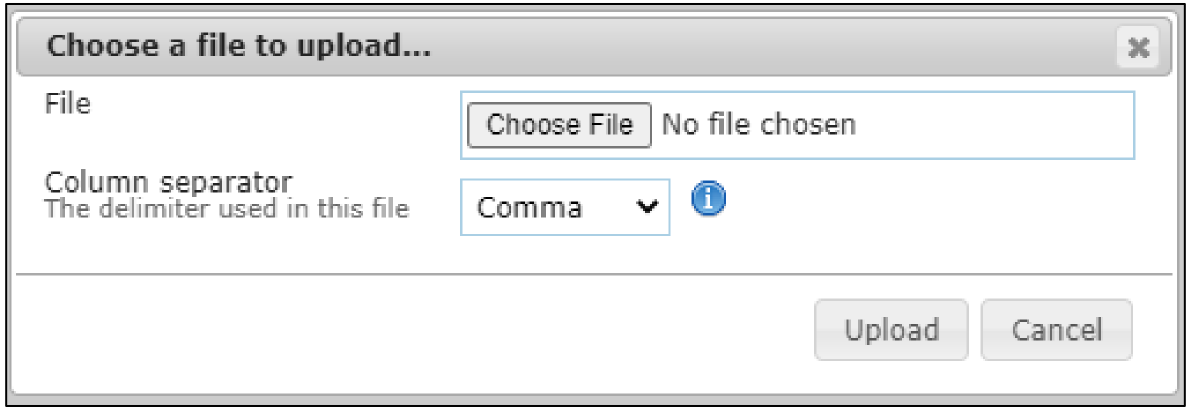
Bulk Importing – Running Import

- Click on run to the right of the Import map you want to use



- Choose your import file that has been saved as a .csv file



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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

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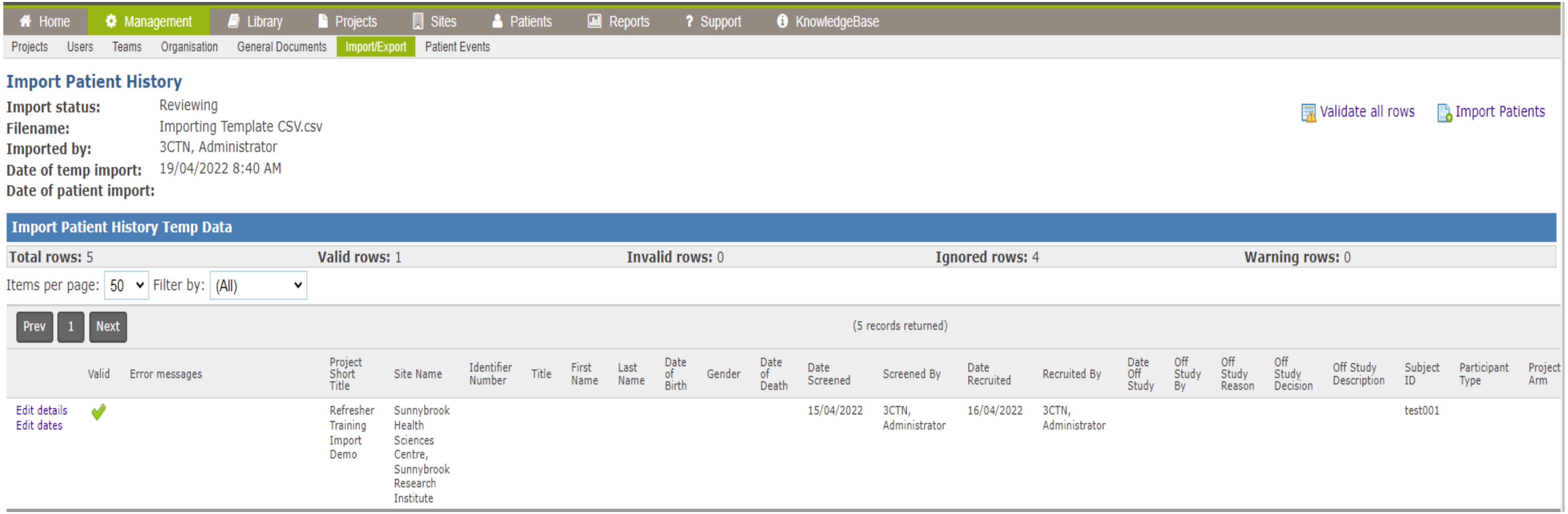
Bulk Importing – Check the Data, Validate and Import

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



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Priority Patient Tracking

Priority patient information will be tracked at the patient 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

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

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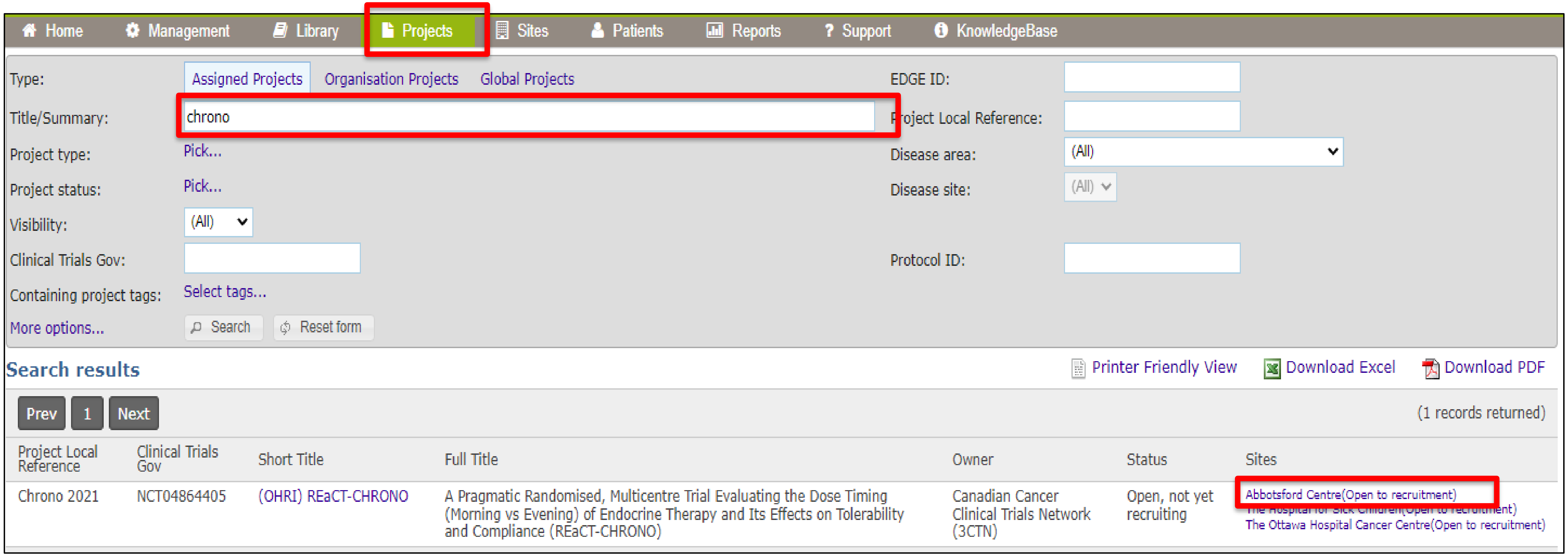
Priority Patient Tracking - Navigation

- 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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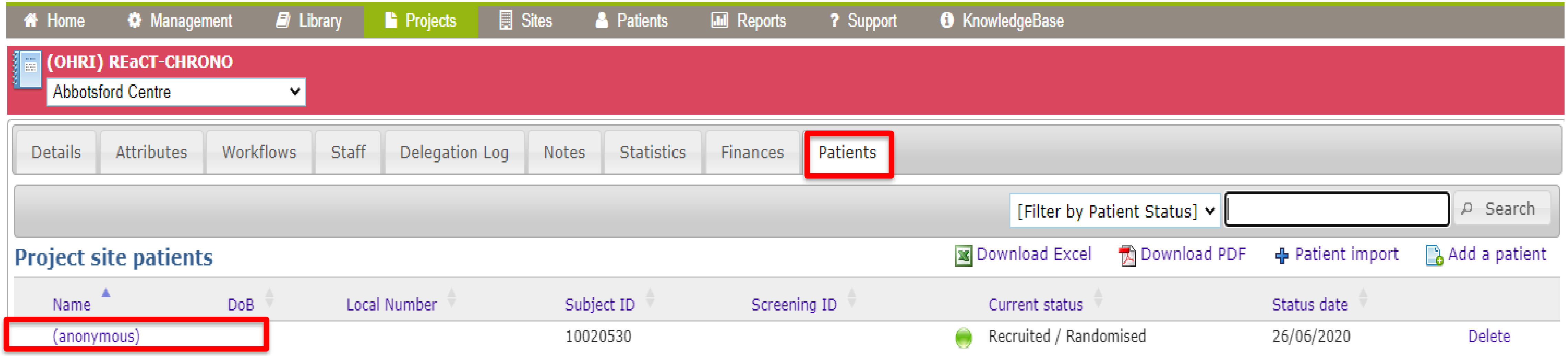
Priority Patient Tracking - Navigation

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



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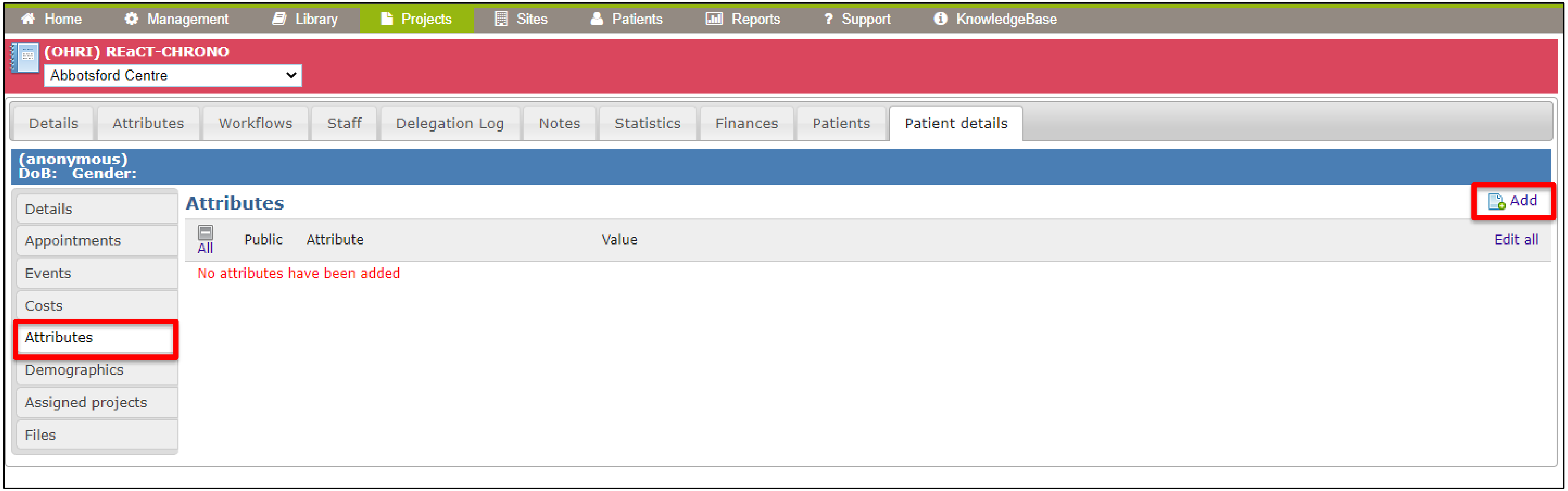
Priority Patient Tracking – Data Entry

- At the *Patient* level, go to *Attributes*
- Select *Add*



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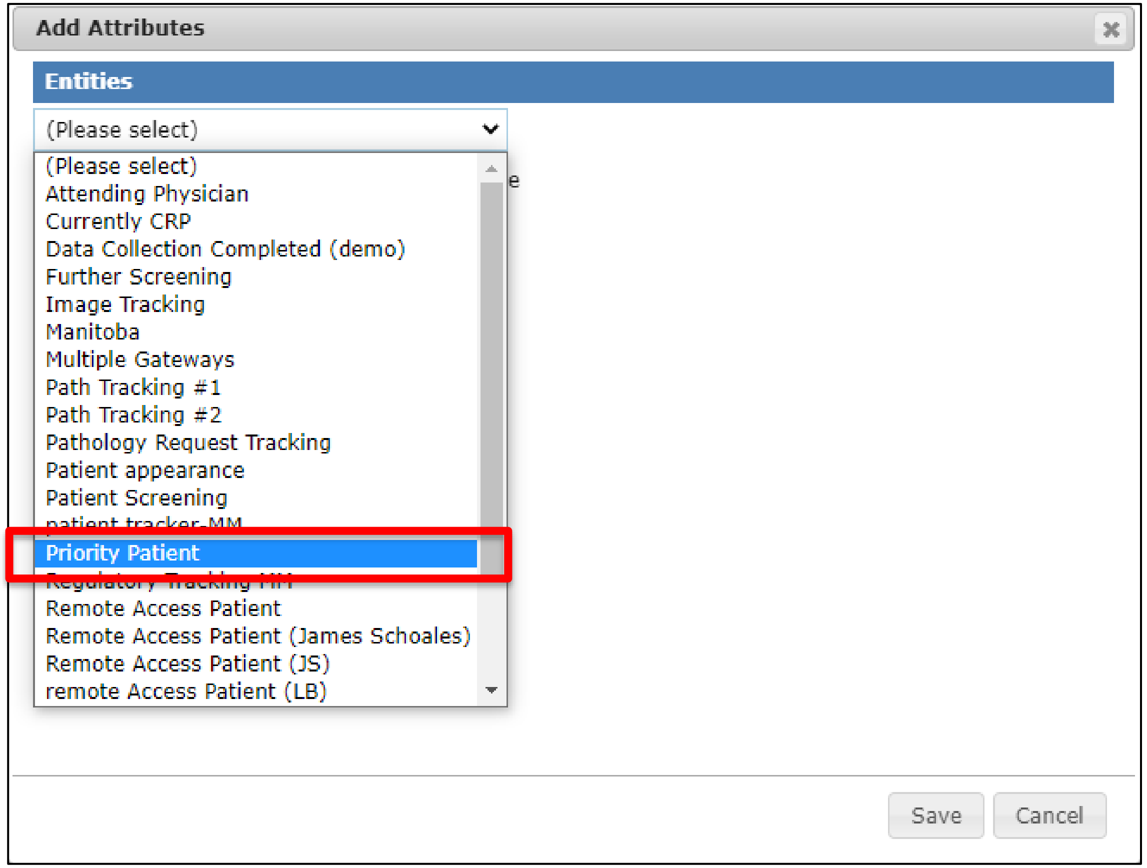
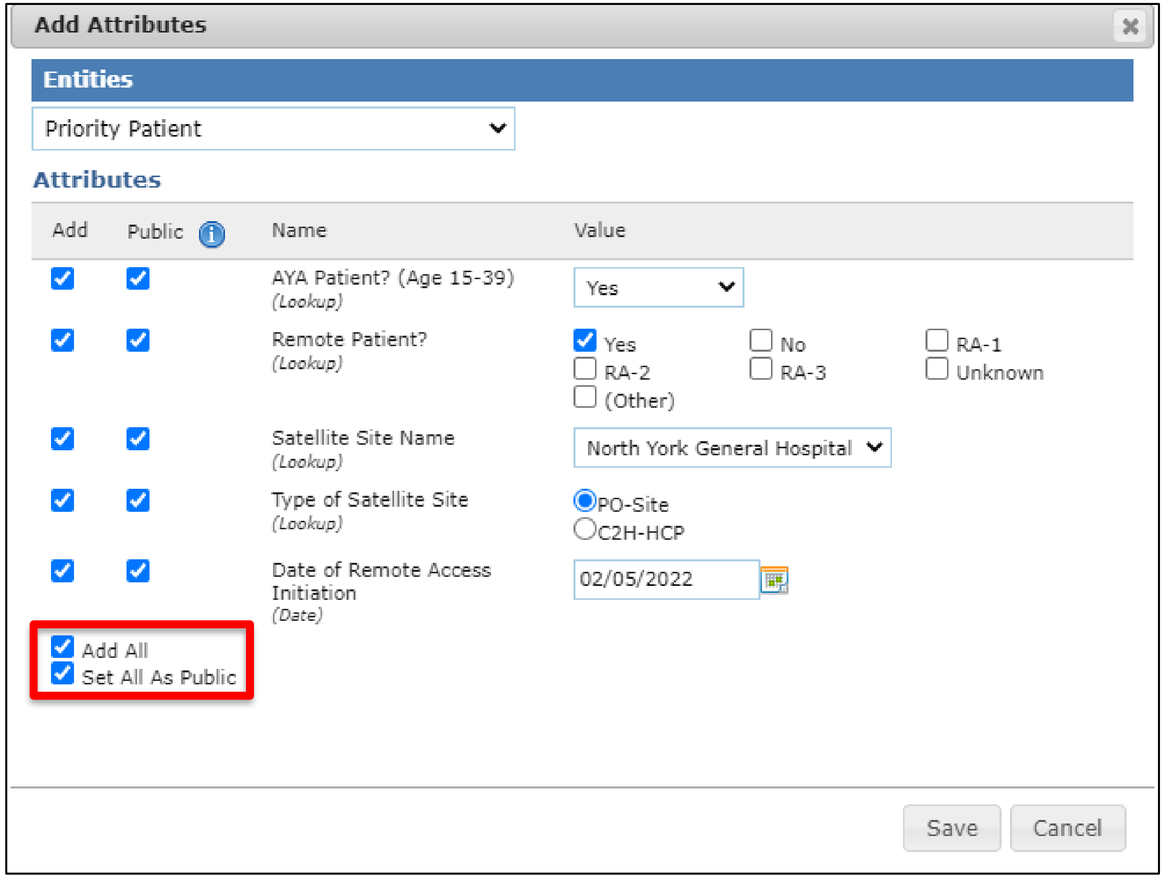
Priority Patient Tracking – Navigation / Data Entry

- Select the *Priority Patient* entity
- Click on *Add All* and *Set All As Public*, to complete relevant data





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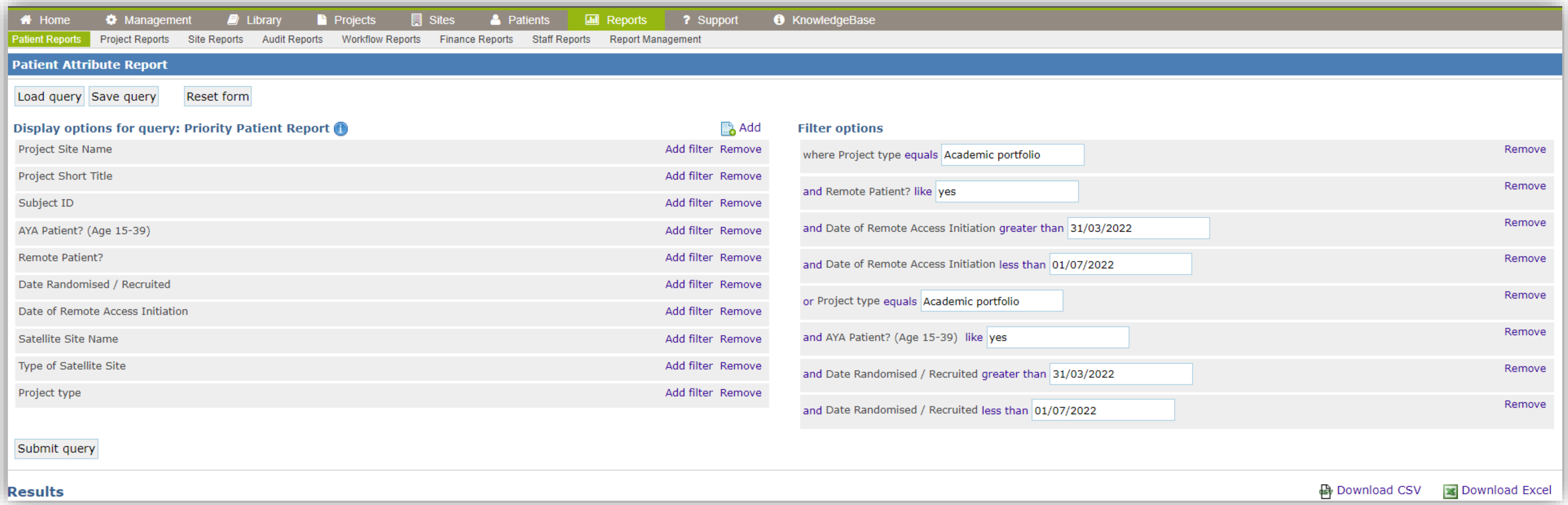
Priority Patient Reporting

- 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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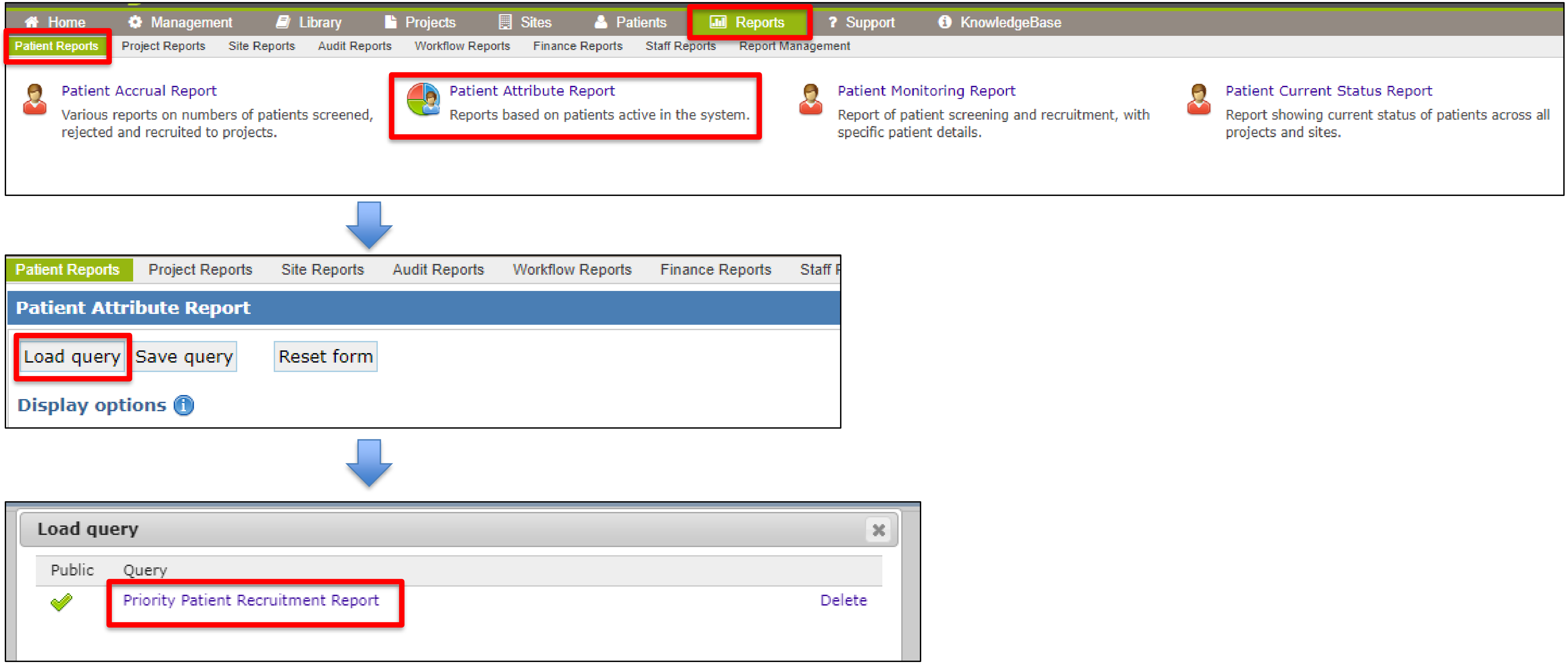
Priority Patient Report Navigation



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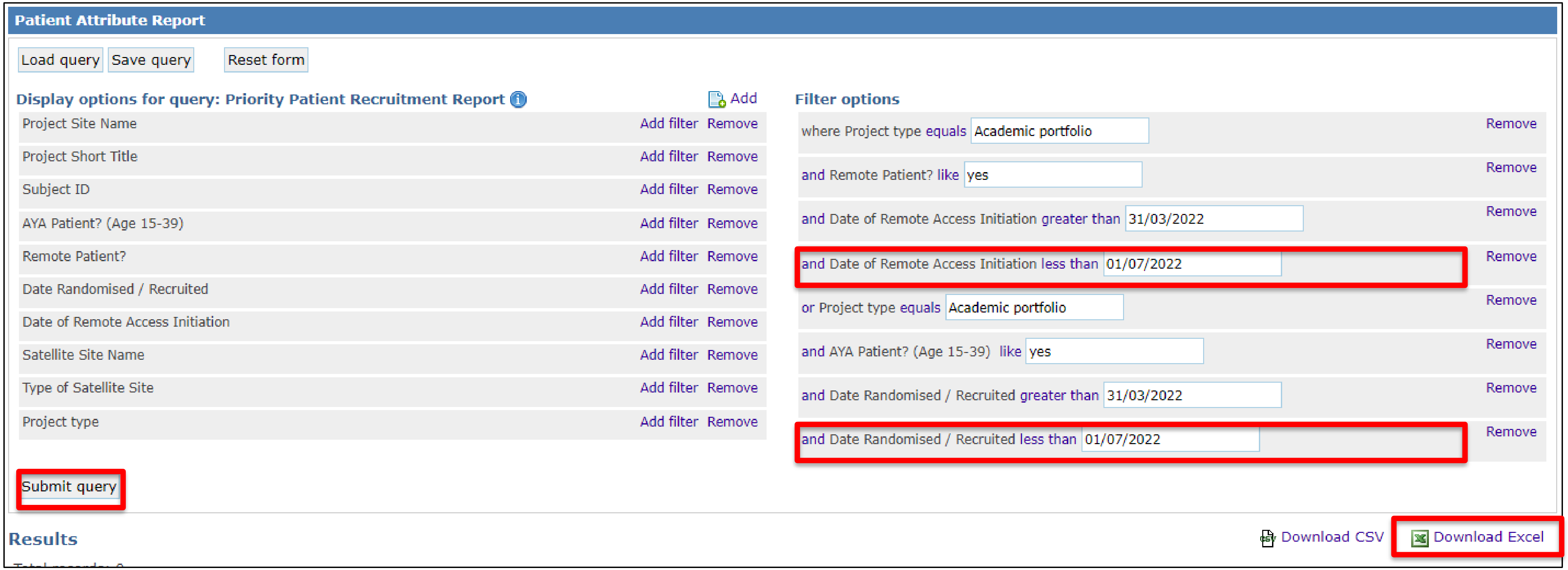
Priority Patient Report Generation



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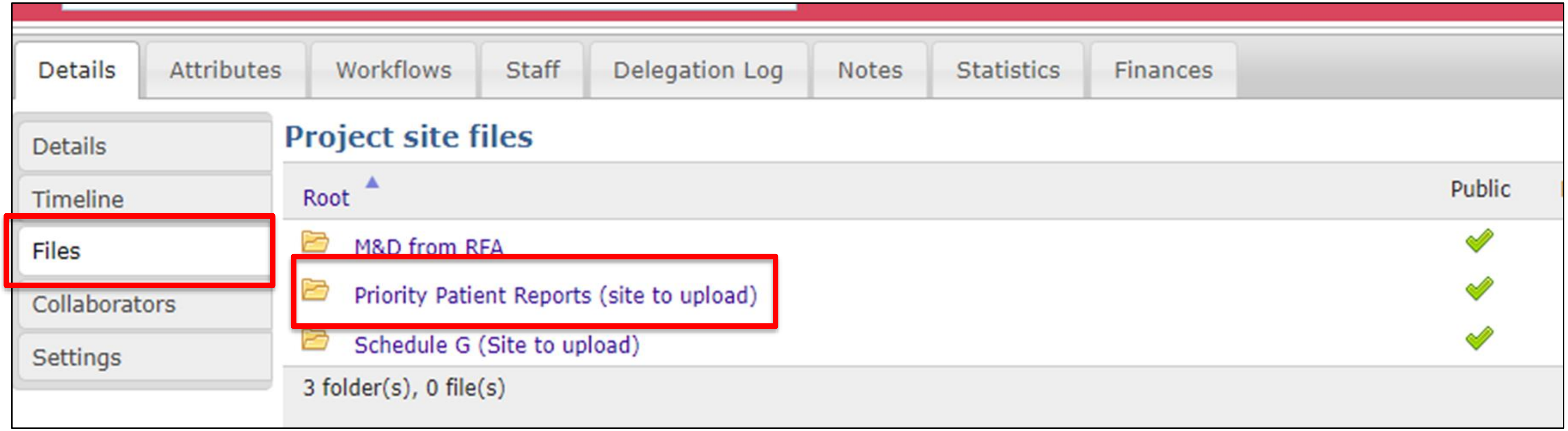
3CTN Priority Patient Reporting

- 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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Adding a Project to your Organization in EDGE

- Search global projects for your desired trial
- If found, click on **request involvement**
- 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 granted access to the project, you will then need to add your staff and project site to the project.

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Adding a Site to a Project

After receiving access to the trial and being added as a 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.

Canadian Cancer Clinical Trials Network

Project Site Detail Page

Project site details

View audit | Transfer ownership

Details

Edit | Swap Site

Owned by:	Canadian Cancer Clinical Trials Network (3CTN)
Site (Parent):	Abbotsford Centre (BC Cancer)
Status (Status date):	Open to recruitment (10/06/2021)
Type:	Recruiting Site Only
Project Site Number:	
Qualified Investigator:	Abele, Jonathan
Site target recruitment:	10
Patient data collection plan:	Canada
Patient identifier type:	Local Number

Approvals

Edit

Approval process:	REB Approval
REB Submission Date:	02/06/2021
Date of REB Approval:	08/06/2021
SSI date:	

Milestones

Edit

SIV date:	
Open to recruitment:	10/06/2021
Recruitment end date (Planned):	
Recruitment end date (Actual):	
Planned completion date:	
Completion date:	

Key staff

No key staff have been identified for this project site

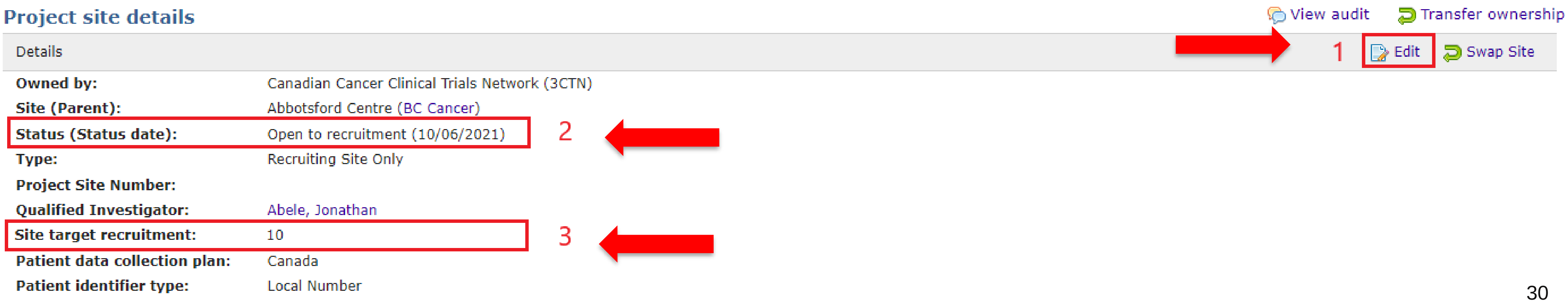
Canadian Cancer Clinical Trials Network

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** – This is your site’s expected recruitment over the lifespan of the project. This is set at the beginning of the trial initiation process. Note: this target shouldn’t change.



Canadian Cancer Clinical Trials Network

Project Site Detail Page

Project site details

View audit | Transfer ownership

Details | Edit | Swap Site

Owned by:	Canadian Cancer Clinical Trials Network (3CTN)
Site (Parent):	Abbotsford Centre (BC Cancer)
Status (Status date):	Open to recruitment (10/06/2021)
Type:	Recruiting Site Only
Project Site Number:	
Qualified Investigator:	Abele, Jonathan
Site target recruitment:	10
Patient data collection plan:	Canada
Patient identifier type:	Local Number

Approvals | Edit

Approval process:	REB Approval
REB Submission Date:	02/06/2021
Date of REB Approval:	08/06/2021
SSI date:	

Milestones | Edit

SIV date:	
Open to recruitment:	10/06/2021
Recruitment end date (Planned):	
Recruitment end date (Actual):	
Planned completion date:	
Completion date:	

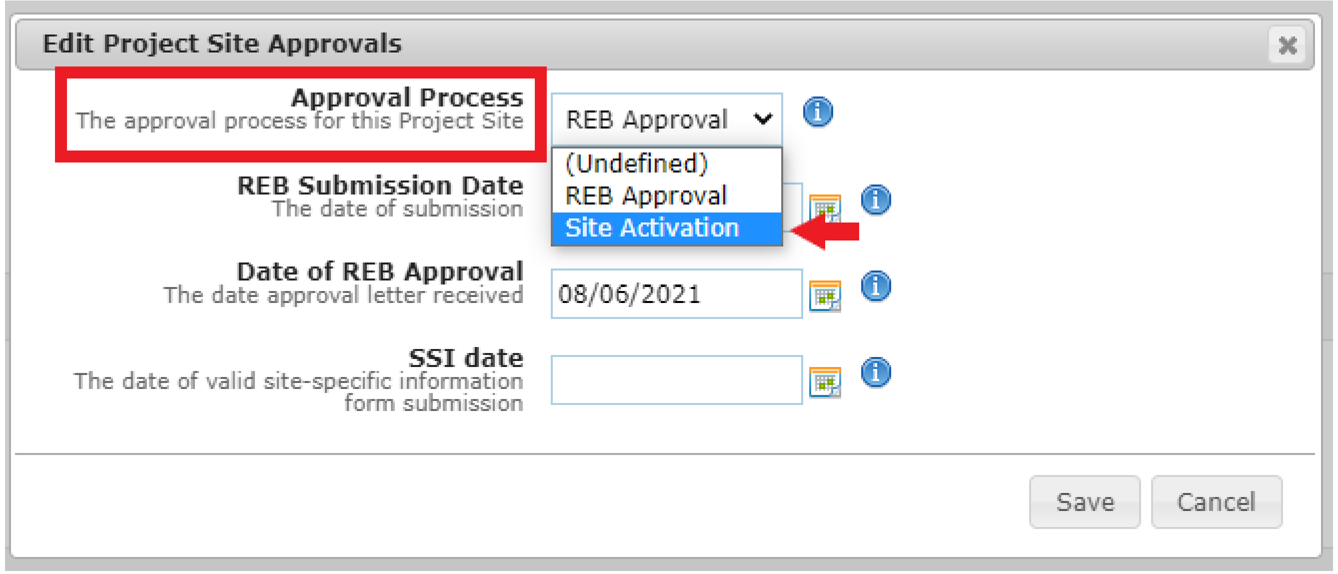
Key staff

No key staff have been identified for this project site

Canadian Cancer Clinical Trials Network

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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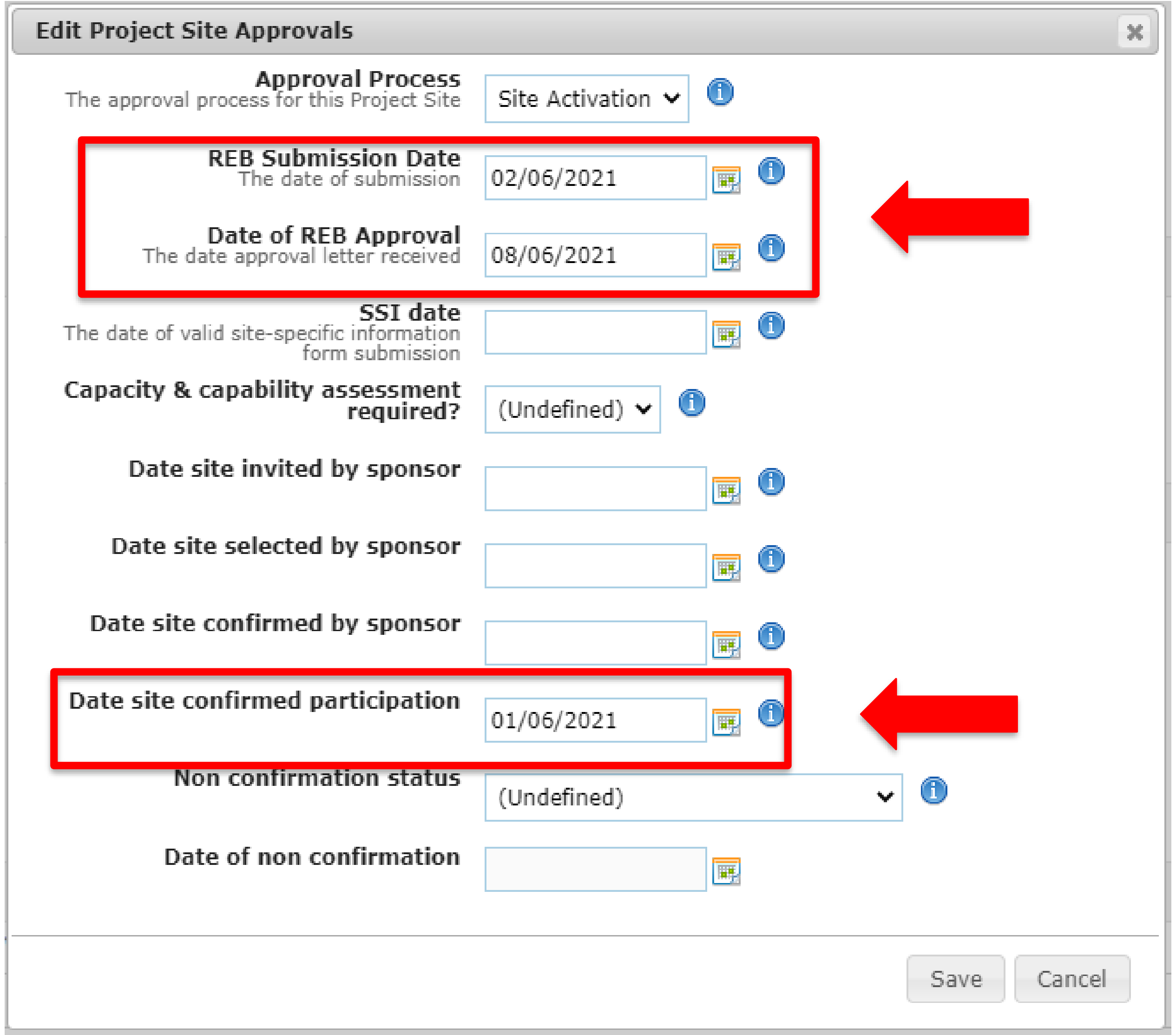
Project Site Detail Page – Approvals Section

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

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

Project site details

View audit   Transfer ownership

Details	Edit Swap Site
Owned by:	Canadian Cancer Clinical Trials Network (3CTN)
Site (Parent):	Abbotsford Centre (BC Cancer)
Status (Status date):	Open to recruitment (10/06/2021)
Type:	Recruiting Site Only
Project Site Number:	
Qualified Investigator:	Abele, Jonathan
Site target recruitment:	10
Patient data collection plan:	Canada
Patient identifier type:	Local Number

Approvals	Edit
Approval process:	Site Activation
REB Submission Date:	02/06/2021
Date of REB Approval:	08/06/2021
SSI date:	
Capacity & capability assessment required?:	
Date site invited by sponsor:	
Date site selected by sponsor:	
Date site confirmed by sponsor:	
Date site confirmed participation:	01/06/2021
Non confirmation status:	
Date of non confirmation:	

Milestones	Edit
SIV date:	
Open to recruitment:	10/06/2021
Recruitment end date (Planned):	
Recruitment end date (Actual):	
Planned completion date:	
Completion date:	

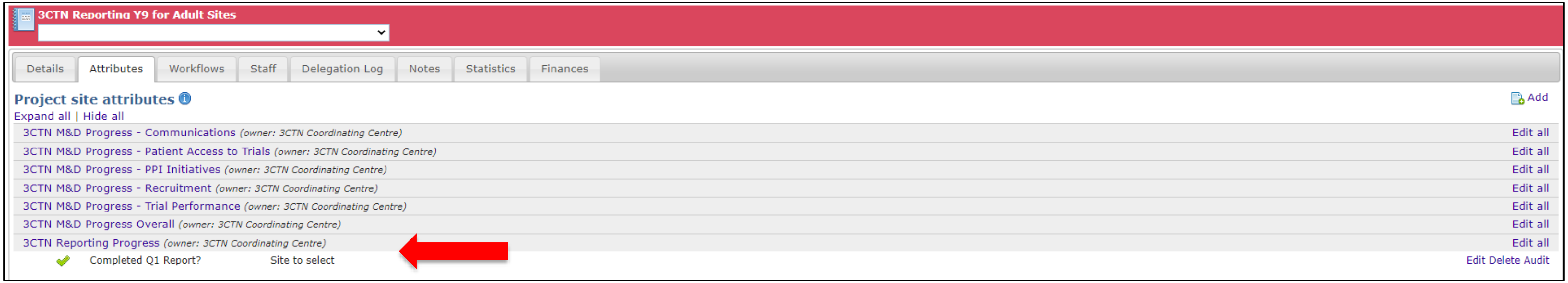
Project Site Detail Page – Milestones Section

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

Canadian Cancer Clinical Trials Network

3CTN Quarterly Report Confirmation

- Once you have completed adding/updating recruitment, priority patient and trial activation data you will need to let 3CTN know by completing a project site attribute.
- Note: This is also where you will be tracking completion of M&Ds and Schedule G reporting in Q2 and Q4



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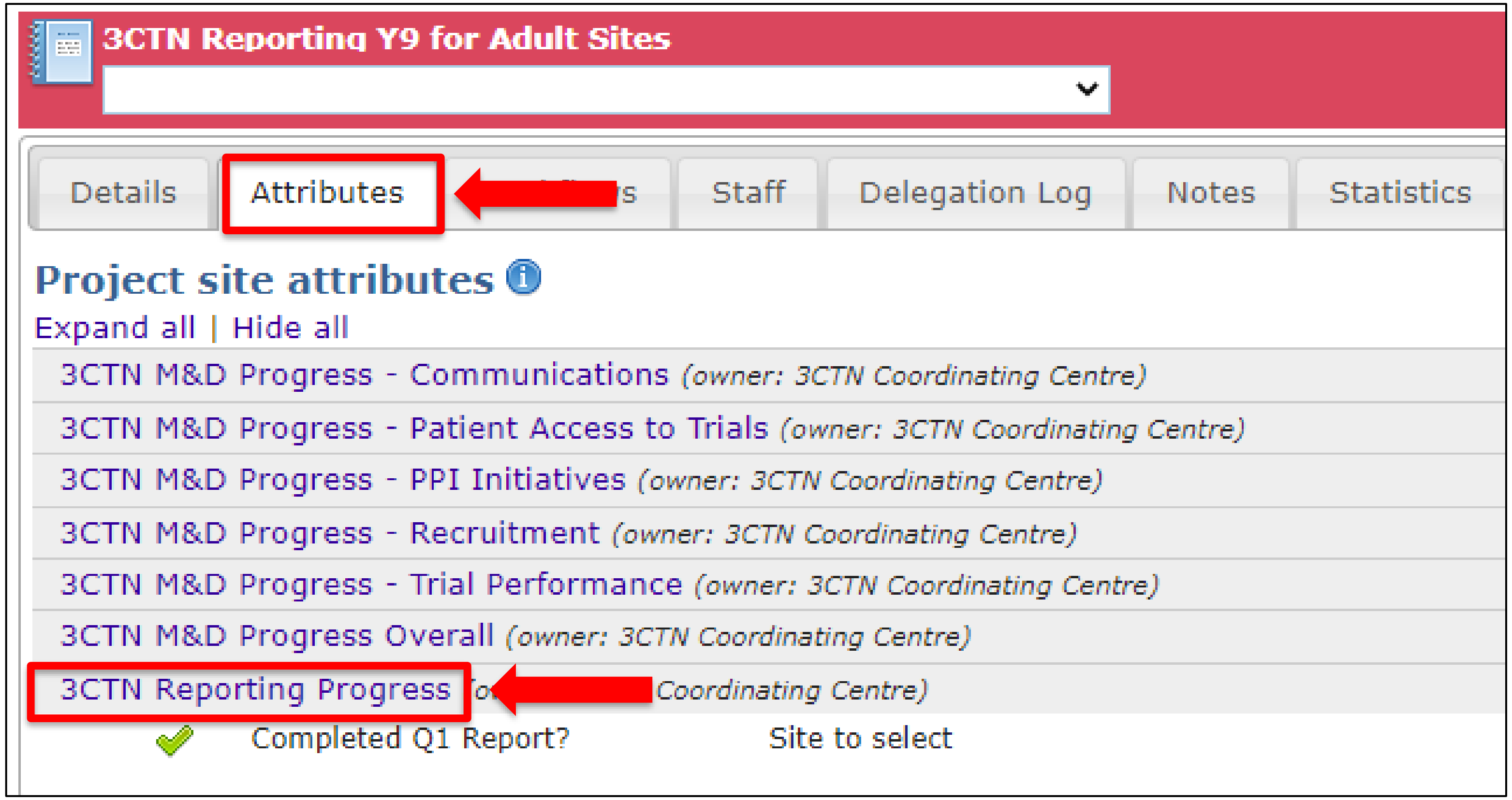
3CTN Quarterly Report Confirmation Navigation

- Go to your project site level (red banner) of either the *3CTN Reporting Y9 for Adult Sites* or *3CTN Reporting Y9 for Ped Sites*
- From there, click on the attributes tab, then click on “3CTN Reporting Progress” to show reporting attributes



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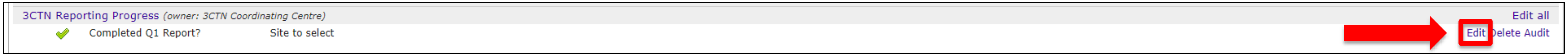
3CTN Quarterly Report Confirmation Navigation

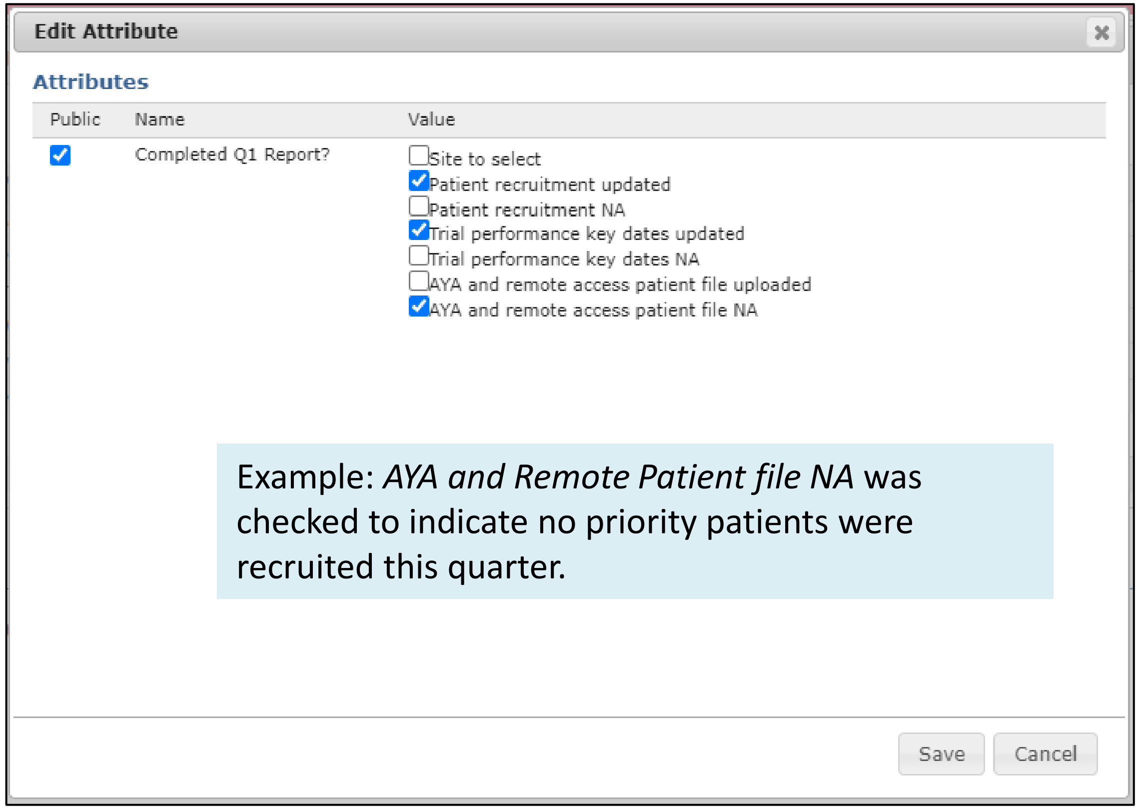
- Next click on the Edit button to the far right of the “Completed Q1 Report?”



- A dialogue box will pop up with a list of options that can be checked.

- Please select the relevant options to let us know if you have completed each part of the reporting process. If there are no updates, select the option with NA.

- Once done click save.



Example: *AYA and Remote Patient file NA* was checked to indicate no priority patients were recruited this quarter.