PAN AFRICAN CLINICAL TRIAL REGISTRY

User Manual

Author: Nagendra Keerthi Bollu

Version 0.1

Date: 22 Jan 2018

DATAWORLD

think • innovate • create

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Document Change Control

Revision No	Issue Date	Author	Description of Change
0.1	22/01/2018	Nagendra Keerthi Bollu	Document Creation

Primary Contact

The primary contact for questions regarding this document is:

Author	Nagendra Keerthi Bollu
Project Name	Pan African Clinical Trials Registry
Phone	(011) 024 4451
Email	keerthi@dataworld.co.za

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1. Introduction

The Pan African Clinical Trials Registry is designed to register researchers & submit trials online

This document details how to register and manage the trial applications & tracking them.

2. Summary

This document details the user guidance to use the modules of Pan African Clinical Trials Registry, and the modules are listed below:

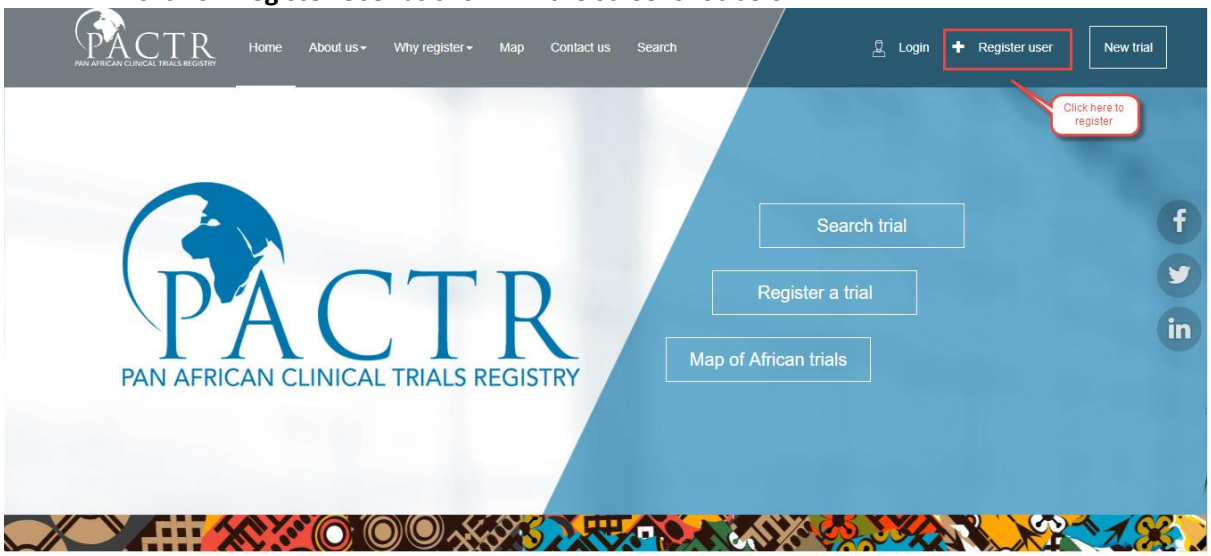
1. **Access Control** – this module is created for the Researcher to access the system.
2. **Researchers Registration-** this module is for the Researchers to register online to the Pan African Clinical Trials Registry.
3. **Researcher Profile**- this module is for the researcher to update profile details.
4. **Trial Registration & Updating Trial–** this module is for the researcher to register trials & updating trial information on the Pan African Clinical Trials Registry.
5. **Manage Trials-** This module is for listing and status tracking for the trials submitted by the researcher.
6. **Search Trials–** this module is for the researcher to search for various trails using basic and advanced search features
7. **Trial Sites–** this module is for the researcher to geo locate various trials.

3. Access Control

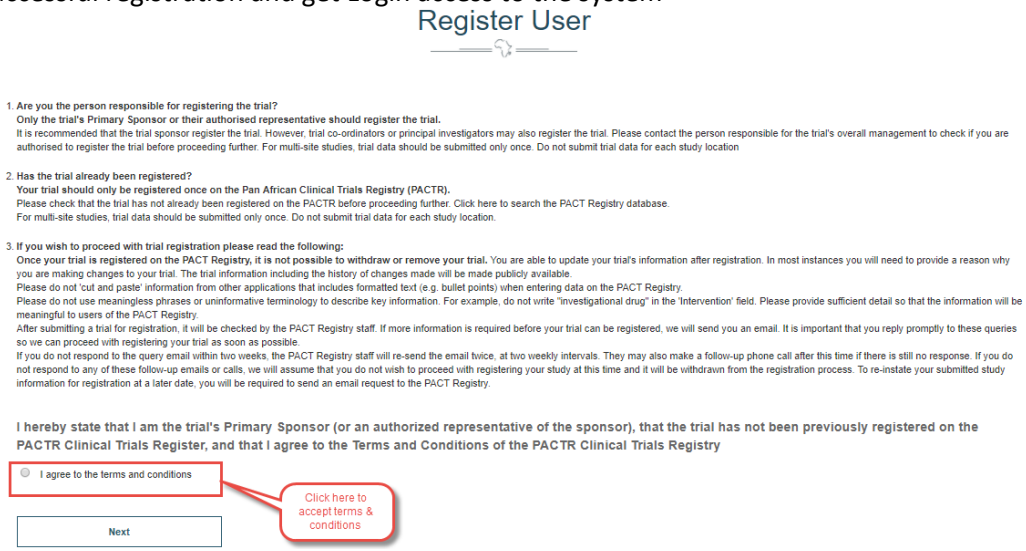
3.1 Registration

This system is web based and can be accessed by registering online first and there by getting user access to the application.

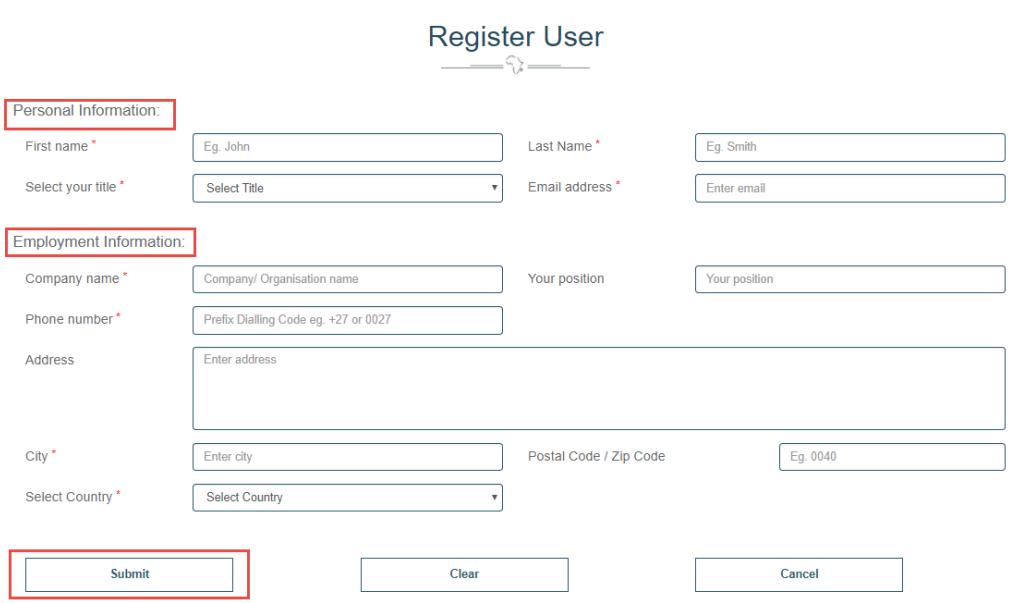
- Access the registration page using the URL www.pactr.org
- Click on **Register User** as shown in the screenshot below



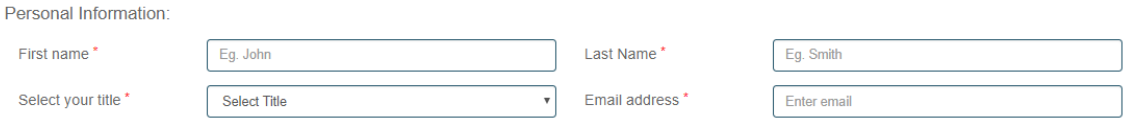
- The screen below shows the registration fields that are required to capture for the successful registration and get Login access to the system



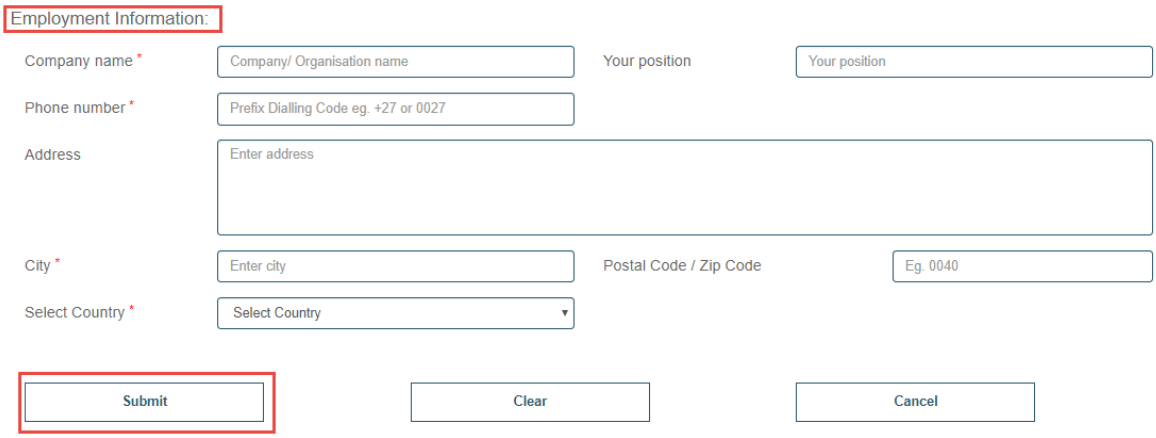
- User to start registering on the portal by reading the terms & conditions and click the accept button and proceed to next page by clicking “Next”.
- User to fill in all the mandatory information required to Register User as shown in the screenshot below:



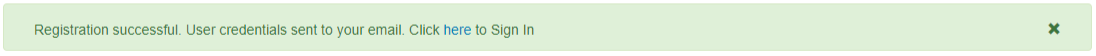
- **Personal Information** Section-Screenshot shown below-All Fields are mandatory to be captured.



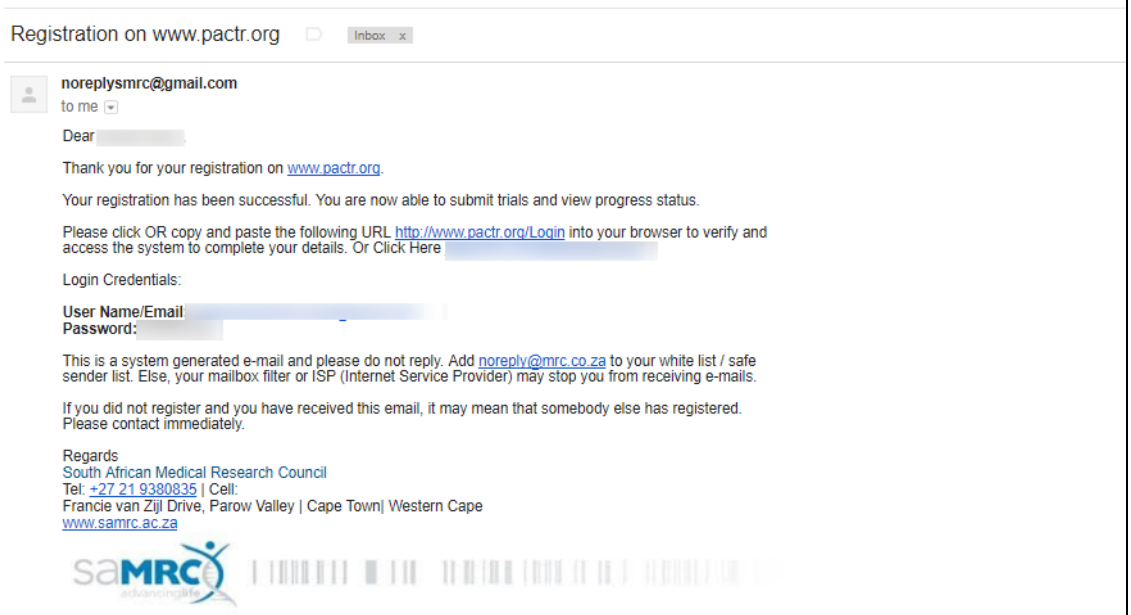
- **Employment Details** Section-Screenshot shown below-All mandatory Fields to be captured.



- Once all the mandatory fields are filled in user should click submit to complete registration.



- Below email will be sent to your registered email address along with the Login Access to the system.



Registration on www.pactr.org Inbox x

noreplysmrc@gmail.com
to me

Dear

Thank you for your registration on www.pactr.org.

Your registration has been successful. You are now able to submit trials and view progress status.

Please click OR copy and paste the following URL http://www.pactr.org/Login into your browser to verify and access the system to complete your details. Or Click Here

Login Credentials:

User Name/Email
Password:

This is a system generated e-mail and please do not reply. Add noreply@mrc.co.za to your white list / safe sender list. Else, your mailbox filter or ISP (Internet Service Provider) may stop you from receiving e-mails.

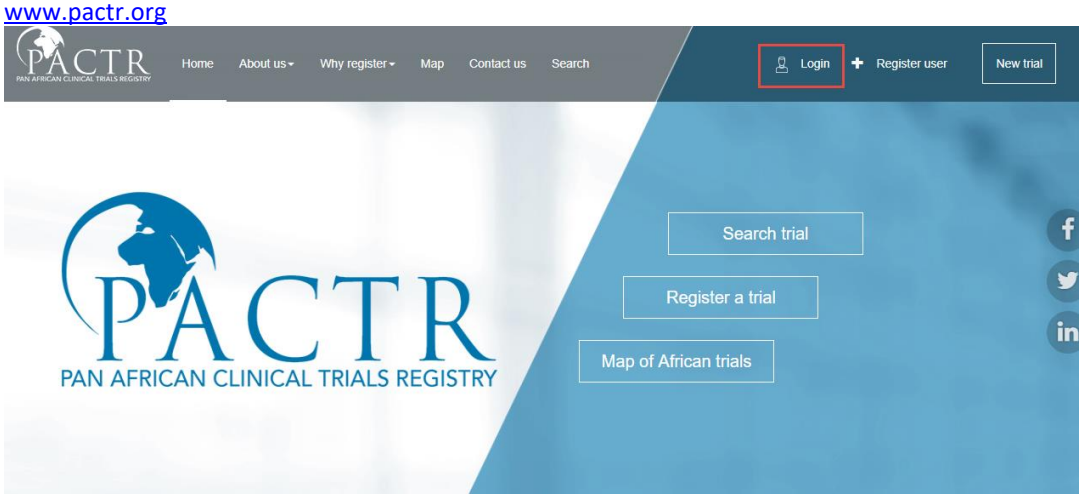
If you did not register and you have received this email, it may mean that somebody else has registered. Please contact immediately.

Regards
South African Medical Research Council
Tel: +27 21 9380835 | Cell:
Francie van Zijl Drive, Parow Valley | Cape Town| Western Cape
www.samrc.ac.za

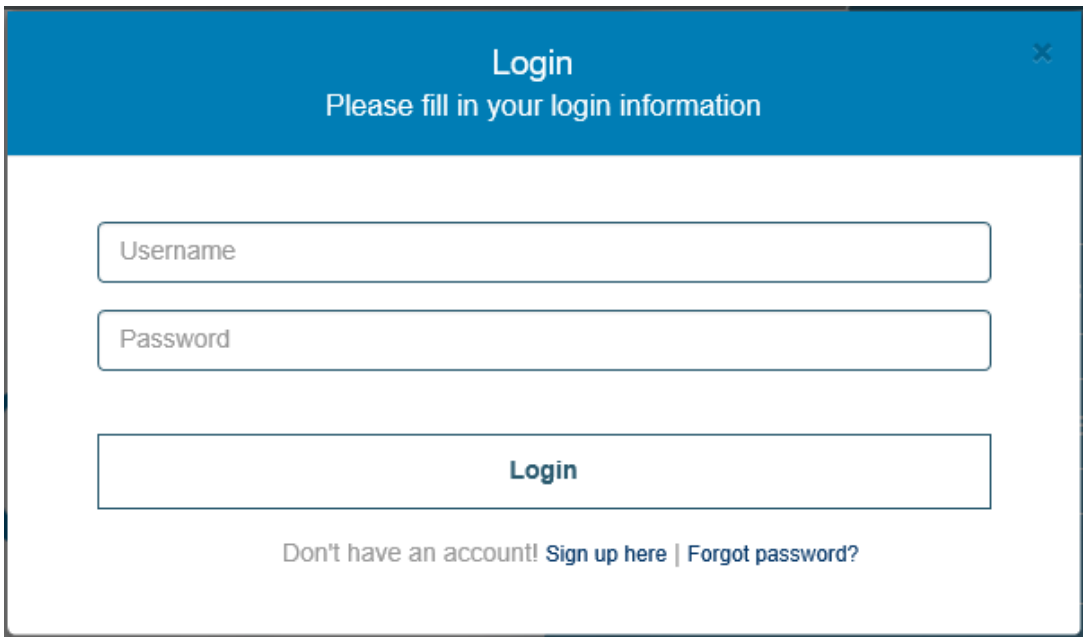
3.2 User Login

Users will get login access to the system by registering online & registration confirmation email (refer 3.1 Registration process).

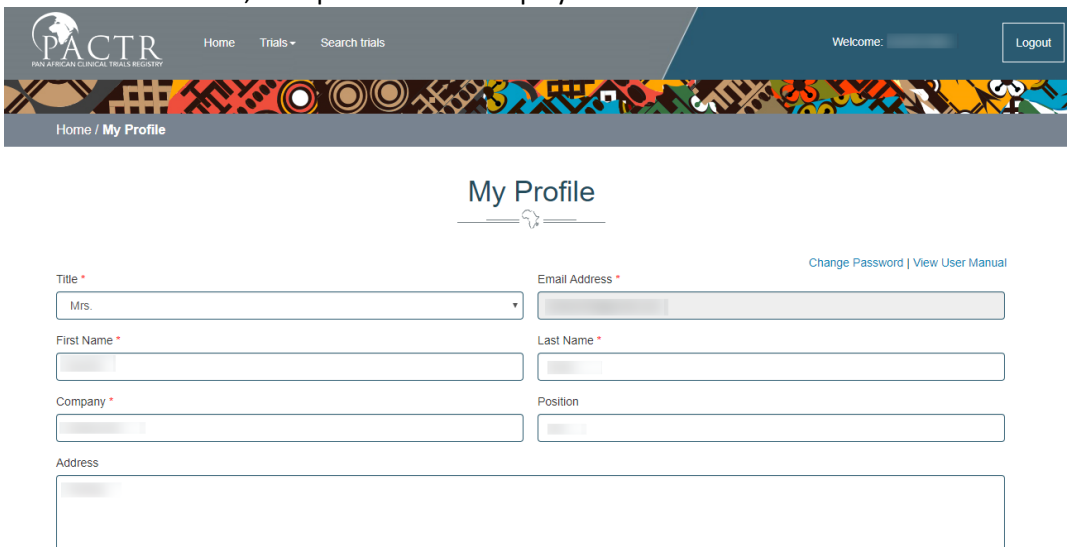
- Access the same URL as registration given below & click Login as highlighted below
  www.pactr.org



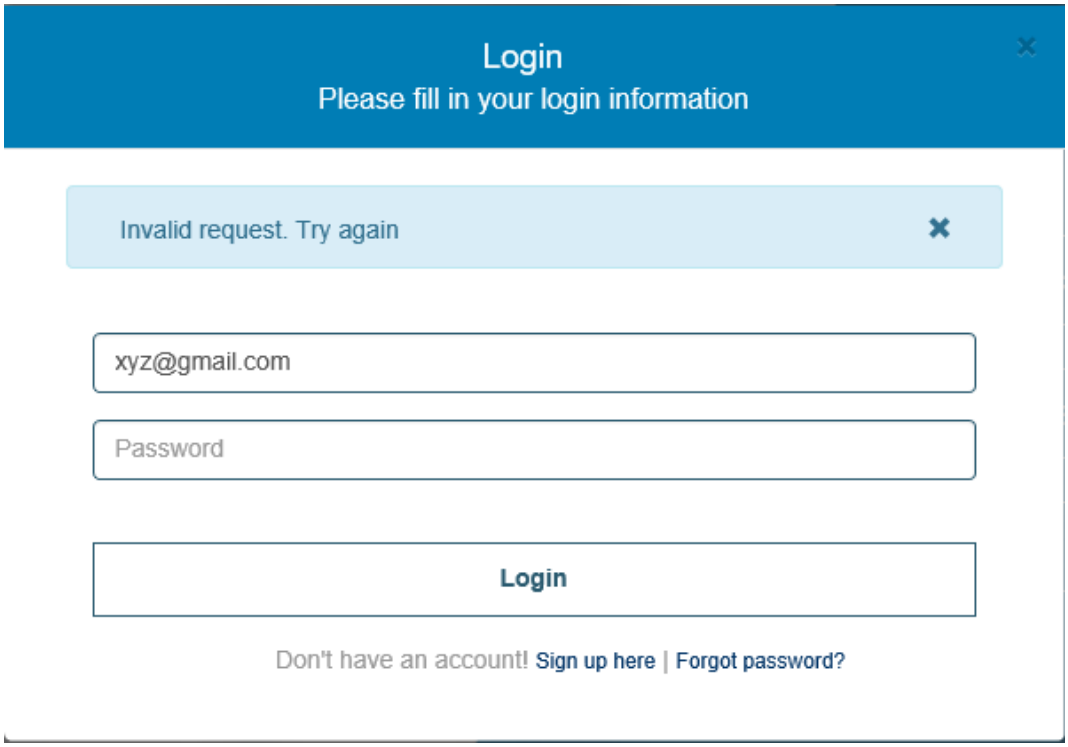
- The screenshot shown below will be displayed for the system user to enter “username” and “password” to access the system.



- Once the username and password are entered, user clicks login as highlighted in above screenshot to login into the system
- For valid credentials, user profile will be displayed as below:



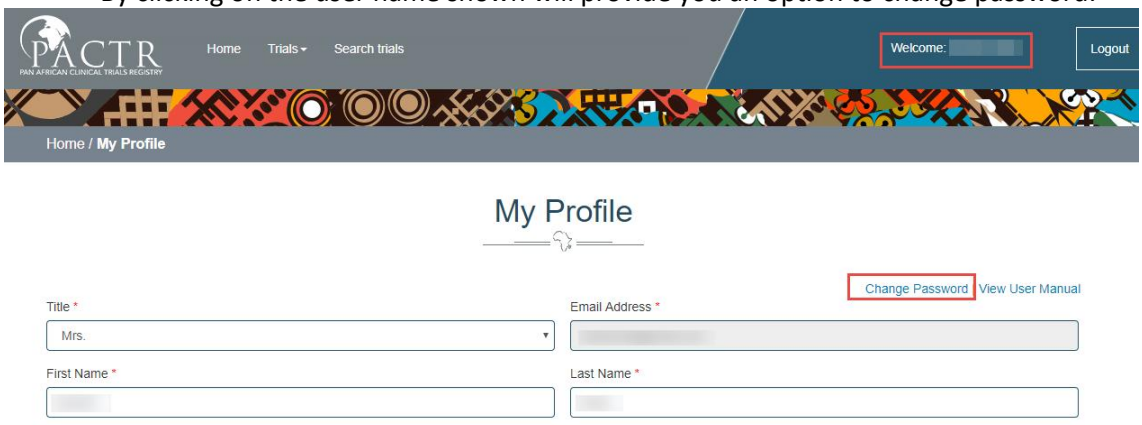
- For invalid username or password, the below screenshot with error message “Invalid request. Try again” will be displayed as below:



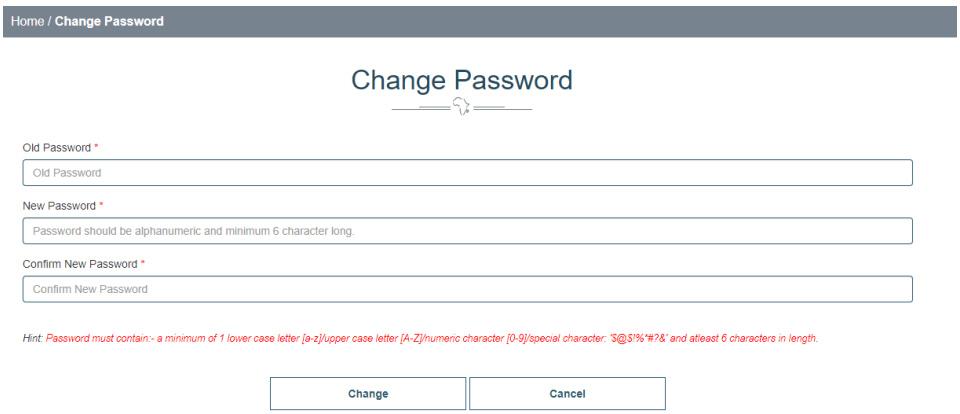
3.3 Change Password

Every System user is provided with a function to change their password.

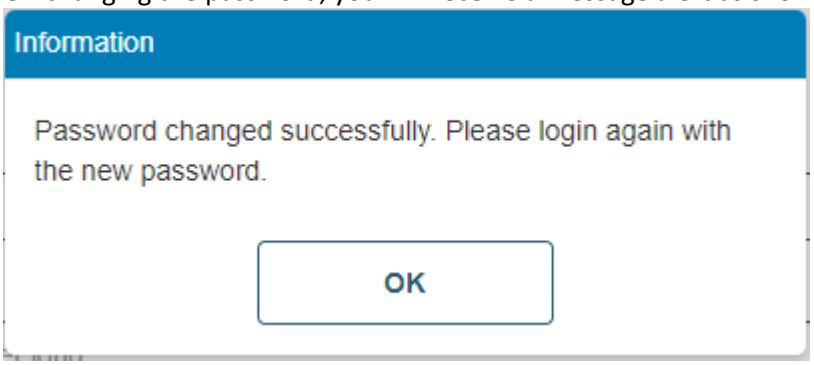
- By clicking on the user name shown will provide you an option to change password:



- On clicking the change password highlighted in the above screenshot, the below screen appears. User needs to enter the Old password, New password & Confirm new password and click change.



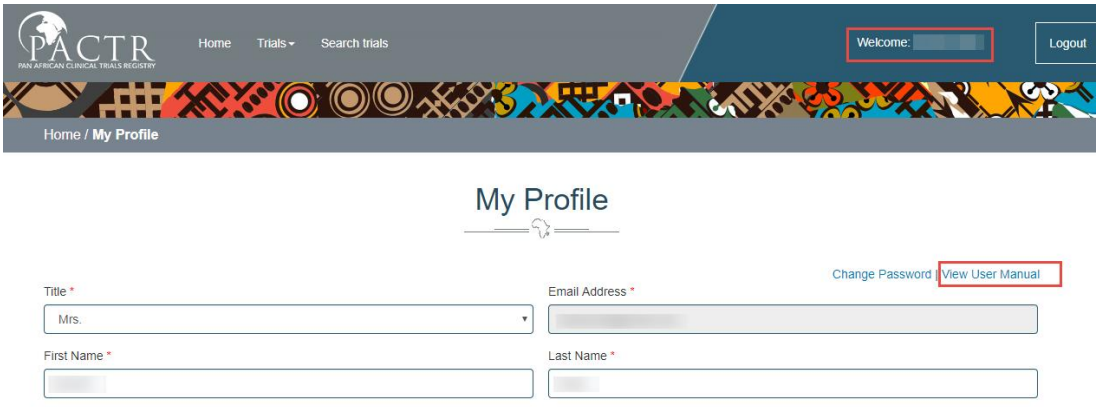
- On changing the password, you will receive a message alert as shown below:



- Click "Ok" to proceed with the login

3.4 User Manual

Every System user is provided with a user manual to see how the system can be used.

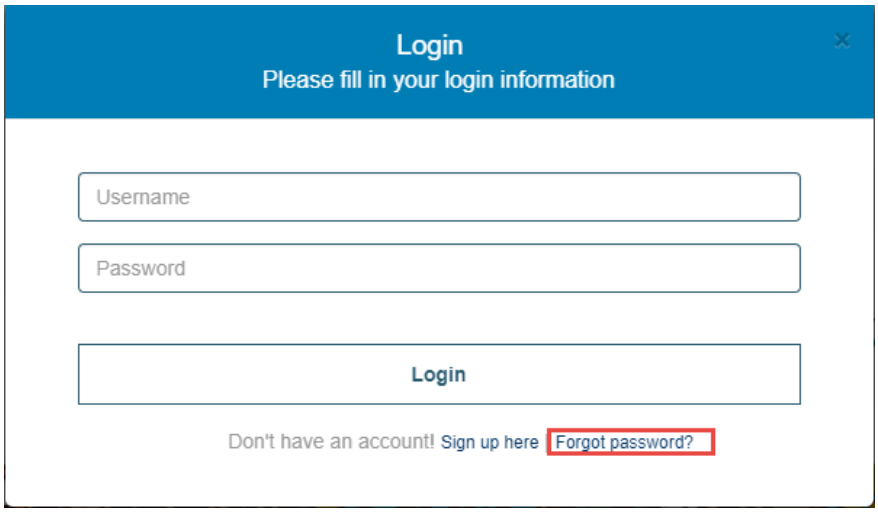


- The User manual is accessed by clicking the user name as shown above.

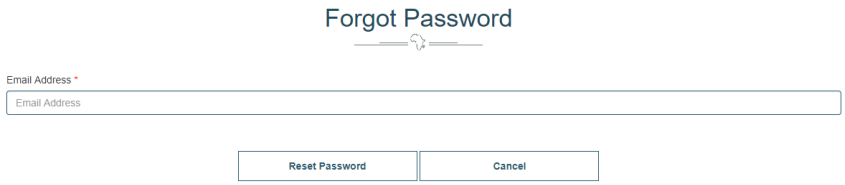
- The user can access the User manual by clicking the menu option as highlighted in the above screenshot.

3.5 Forgot Password

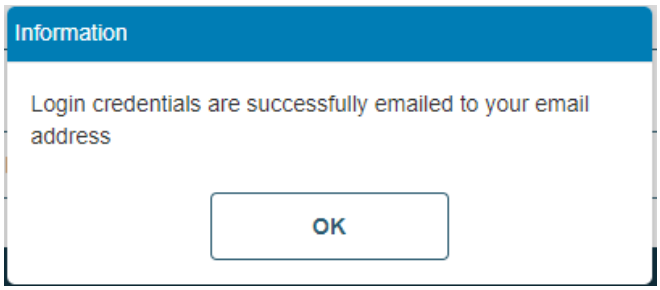
- If the user forgets their password, user should be able to retrieve password on the login screen as highlighted in the screenshot.



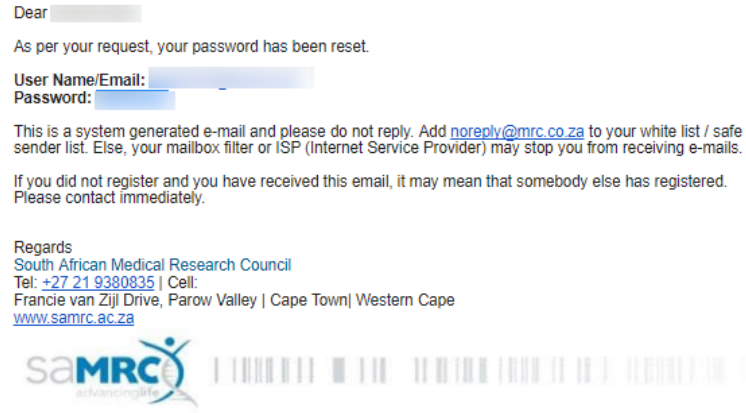
- Once user click on the “Forgot Password” link shown above, it requests for the registered email address.



- User enters the registered email address and click Reset Password, below message alert appears:



- User receives below shown email with a new password.



Dear

As per your request, your password has been reset.

User Name/Email:
Password:

This is a system generated e-mail and please do not reply. Add noreply@mrc.co.za to your white list / safe sender list. Else, your mailbox filter or ISP (Internet Service Provider) may stop you from receiving e-mails.

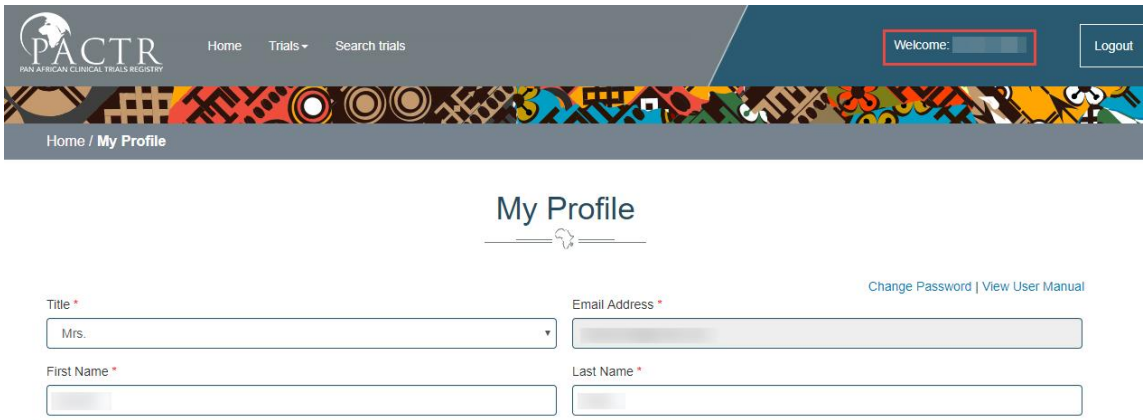
If you did not register and you have received this email, it may mean that somebody else has registered. Please contact immediately.

Regards
South African Medical Research Council
Tel: +27 21 9380835 | Cell:
Francie van Zijl Drive, Parow Valley | Cape Town| Western Cape
www.samrc.ac.za

- User logins using the new password and the system prompts for immediate change of the password. Refer 3.3 Change password for the complete process.

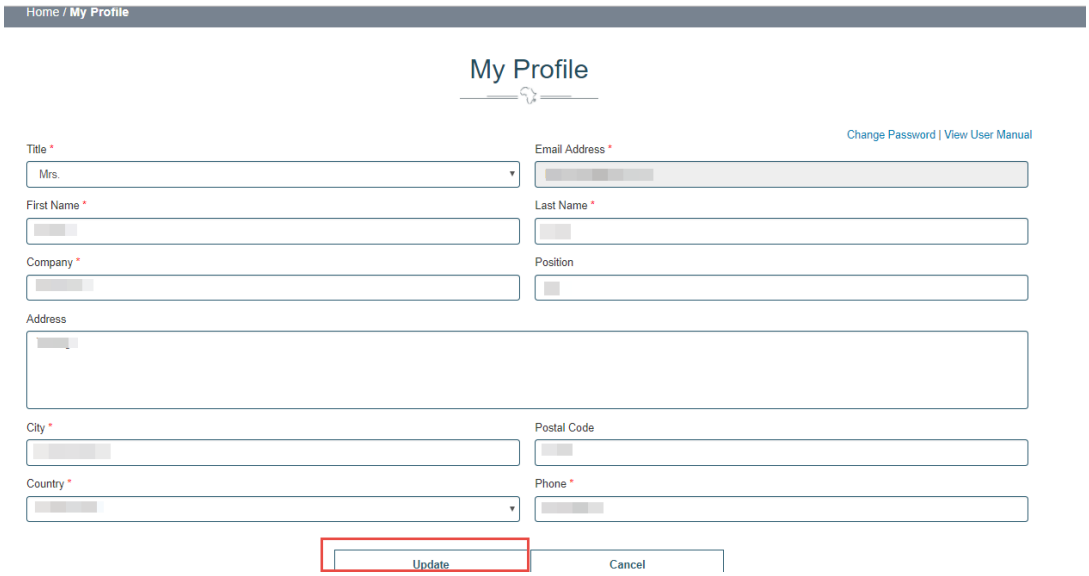
4. Researcher Profile

- The Researcher's profile can be updated by clicking "Username" as highlighted in the below screenshot:



4.1 My Profile

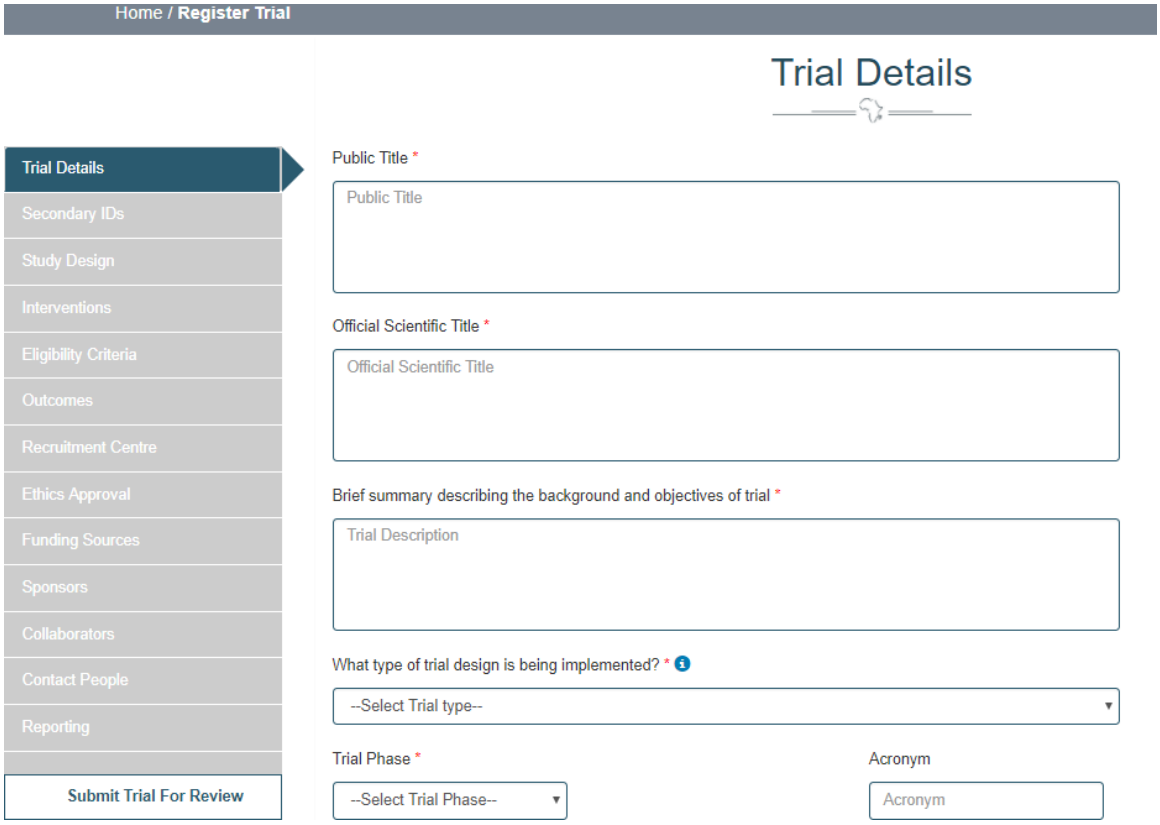
Once User clicks on the user name in the above screenshot, below shown below profile details will appear for user to update



- Except the email address, user should be able to update all other profile details.

5. Trial Registration

- Once user logins, go to Menu Trials>>Register Trial. User should be able to see all the trial section that needs to be captured as shown below.



5.1 Trial Details

- First section in the Trial registration process is to capture the Trial Details section. The following screenshots show the Trial details form to be captured.

Public Title *

Public Title

Official Scientific Title *

Official Scientific Title

Brief summary describing the background and objectives of trial *

Trial Description

What type of trial design is being implemented? *

--Select Trial type--

Trial Phase *

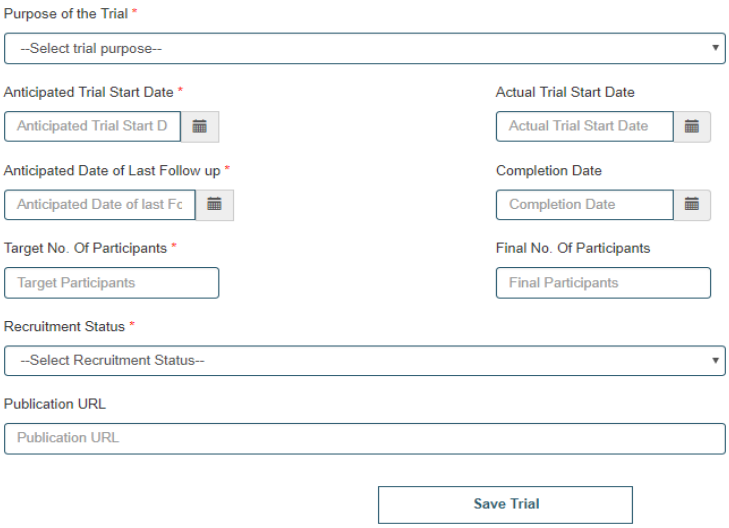
--Select Trial Phase--

Acronym

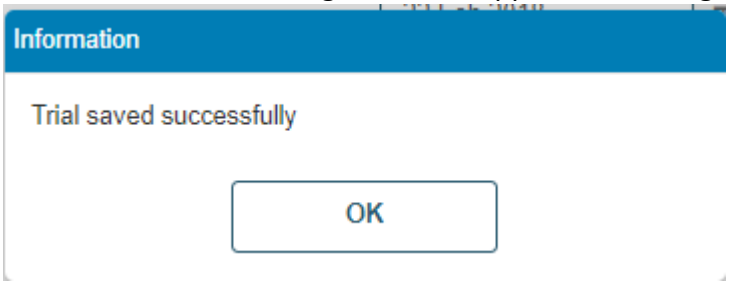
Acronym

Disease(s) or condition(s) being studied *

- Cancer
- Circulatory System
- Digestive System
- Ear, Nose and Throat
- Eye Diseases
- Genetic Diseases
- Haematological Disorders
- Infections and Infestations
  - HIV/AIDS
  - Tuberculosis
  - Malaria
  - Ebola
  - Other
- Injury, Occupational Diseases, Poisoning
- Mental and Behavioural Disorders
- Musculoskeletal Diseases
- Neonatal Diseases
- Nervous System Diseases
- Nutritional, Metabolic, Endocrine
- Oral Health
- Pregnancy and Childbirth
- Respiratory
- Signs and Symptoms
- Skin and Connective Tissue Diseases
- Surgery
- Urological and Genital Diseases
- Obstetrics and Gynecology
  - Fertility-male
  - Fertility-female
  - Other
- Paediatrics
- Other



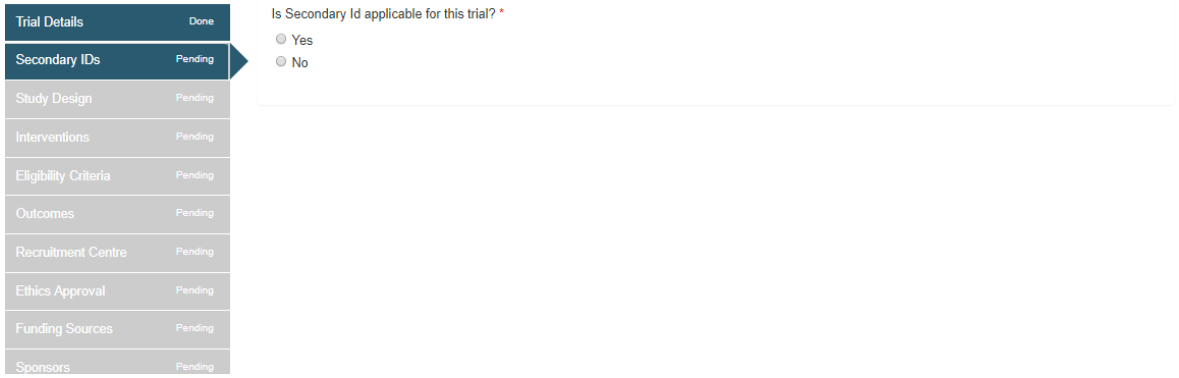
- User needs to capture all the mandatory fields and should click “Save Trial” as shown in the above screenshot
- The below shown message alert will appear on clicking “Save Trail”:



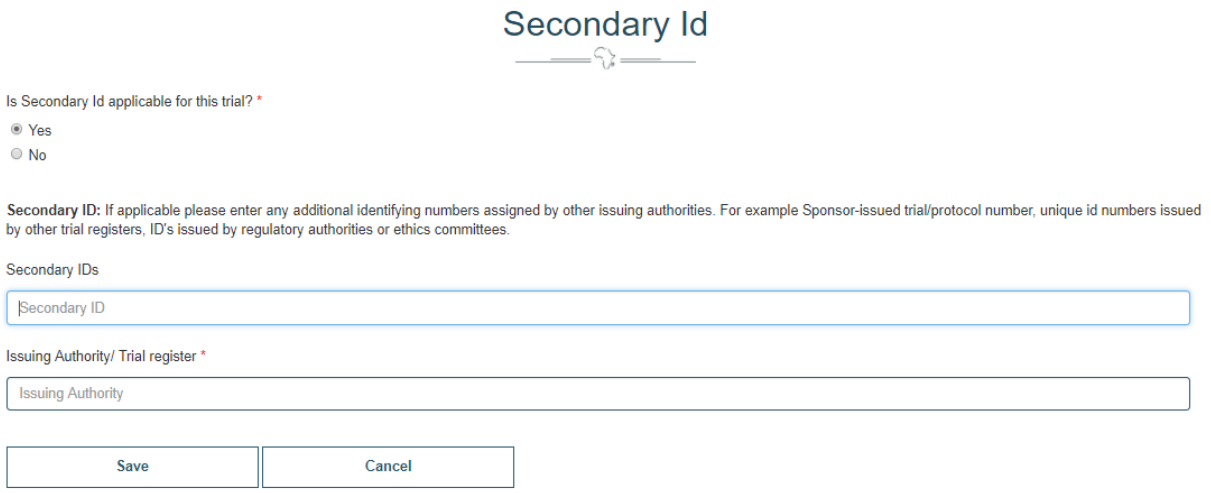
- One user clicking “ok” on the above screenshot, user will be directed to next section Secondary Id’s.

5.2 Secondary IDs

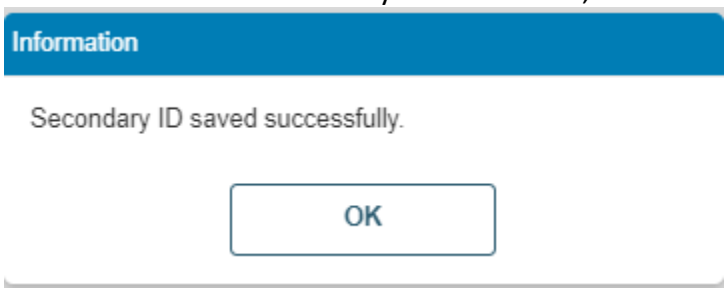
- User will be directed to the Secondary ID's section as shown below screenshot



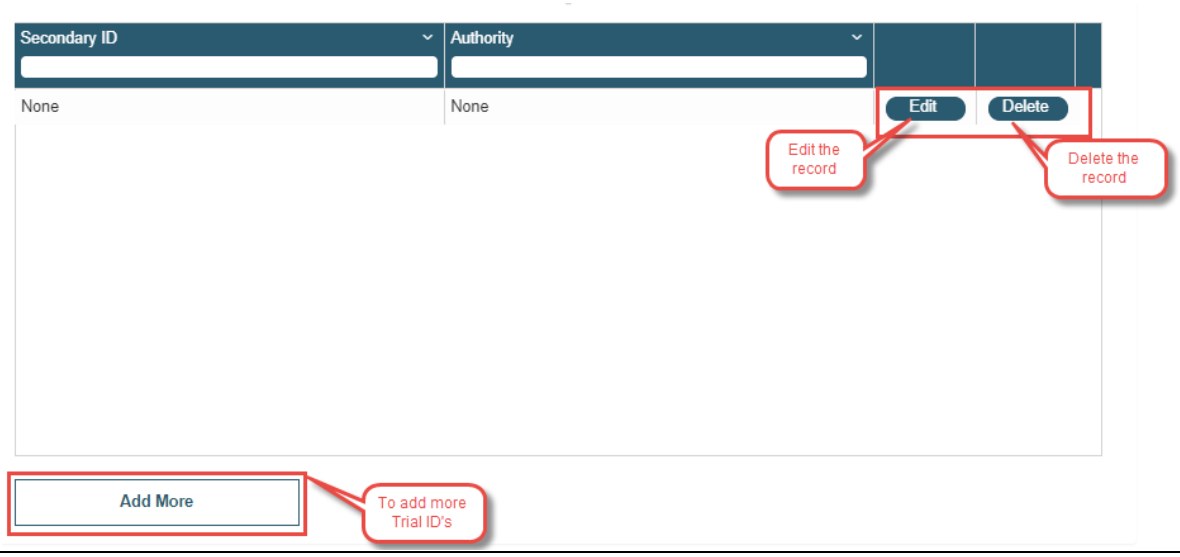
- If the Secondary Id's available for the trials, user should select "yes" and the below shown fields will appear:



- Once user added the secondary ID for the trial, below message alert will be displayed.

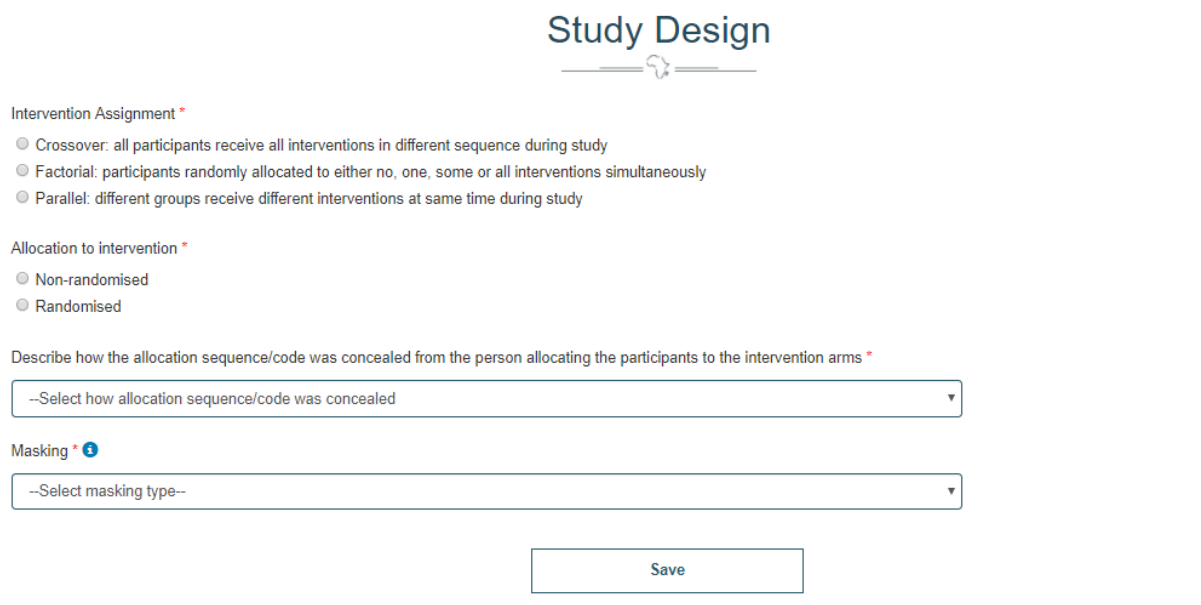


- Once record is added, it will be saved and displayed as shown. User should be able to Edit, Delete or Add more to the list.

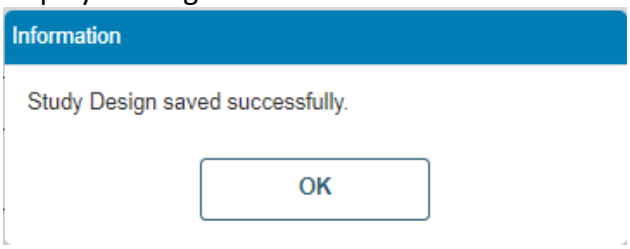


5.3 Study Design

- Once user captures the secondary ID's and then the next section to capture is "Study Design"
- The Study design section is as shown below:



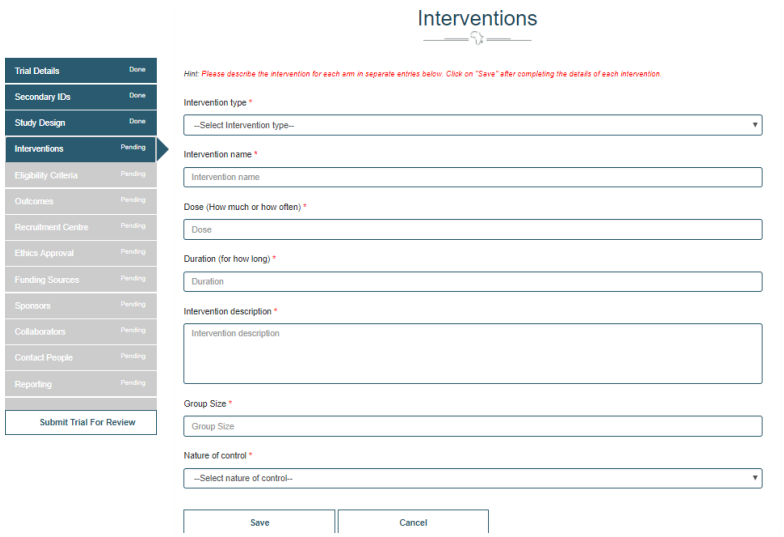
- User should capture all the mandatory fields and save the section and system will display message alert below:



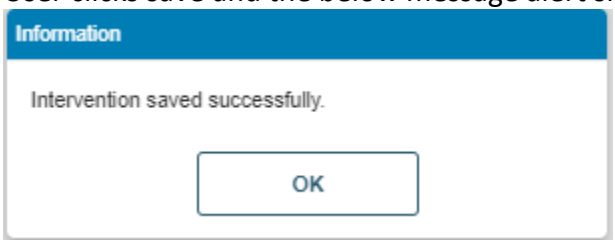
- Once user clicks “Ok” in the above screenshot, the system will direct the user to the next section “Interventions”.

5.4 Interventions

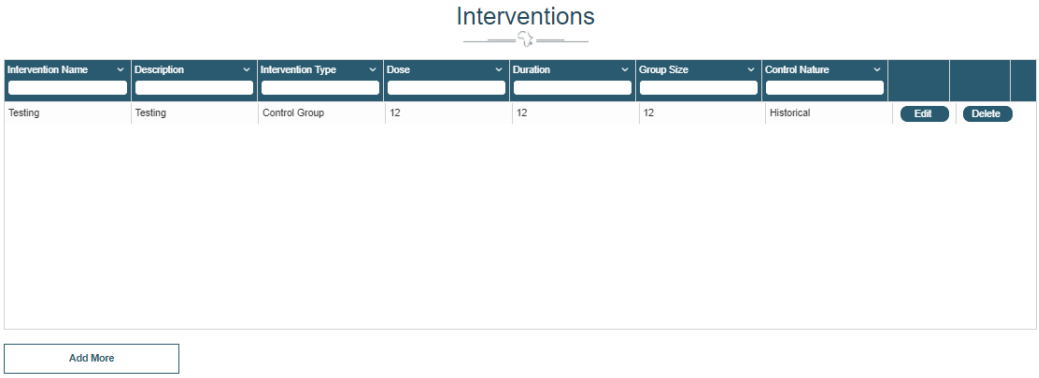
- User should be able to capture the required fields in this section and click save.
- The completion of this section will be done as per mentioned-*Hint:* *Please describe the intervention for each arm in separate entries below. Click on "Save" after completing the details of each intervention.*



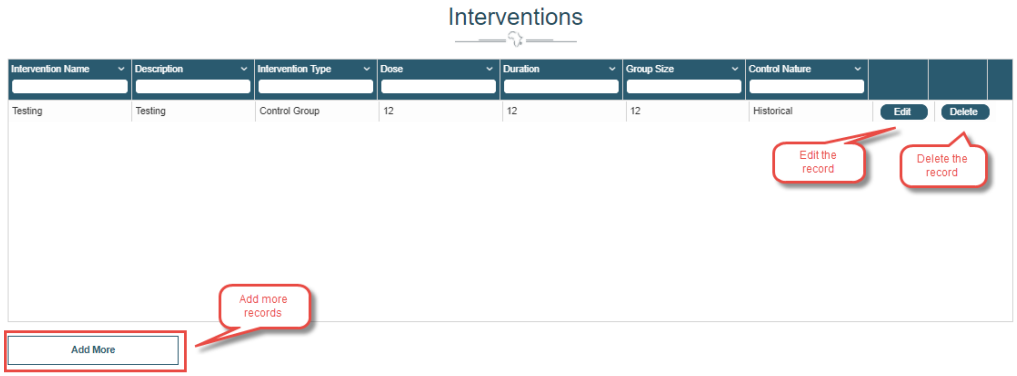
- User clicks save and the below message alert shows.



- Once user saves the record, it will show the records added in the below shown format:

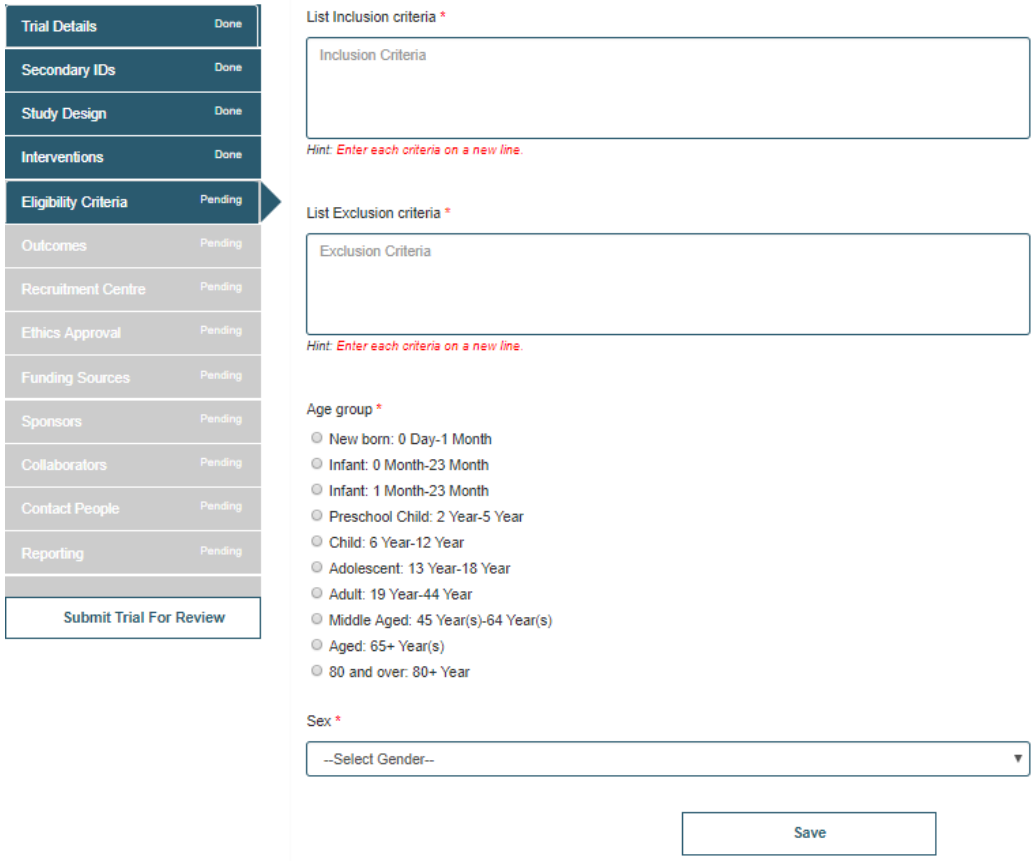


- User should be able to add more records by clicking “Add More” button as shown below

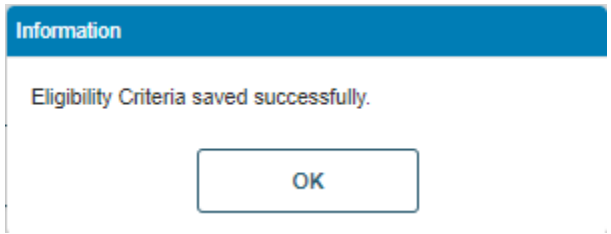


5.5 Eligibility Criteria

- User clicks on Eligibility Criteria section and the below fields will appear



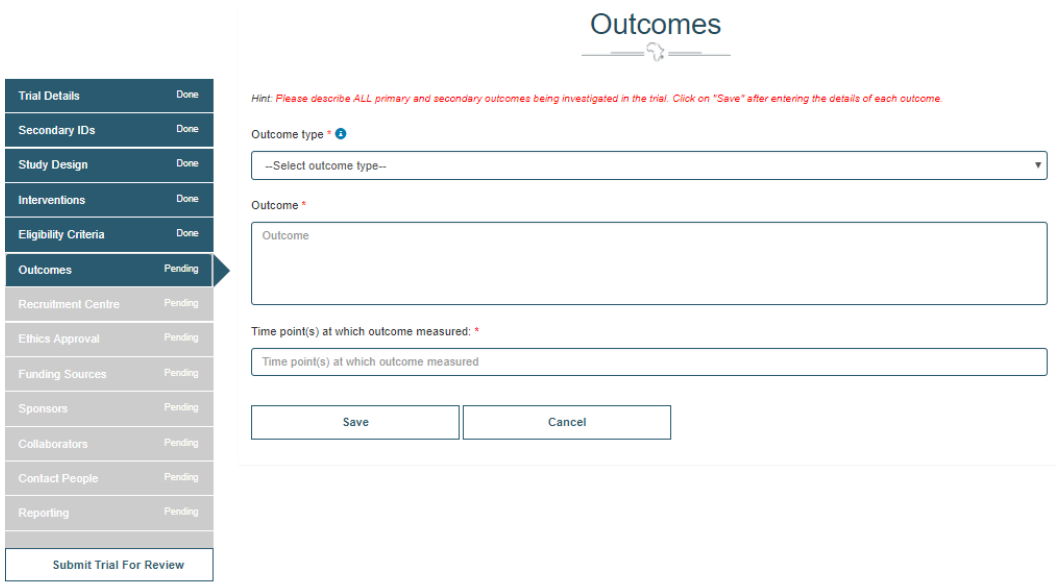
- User captures the above required fields and click “Save” the below shown message will appear.



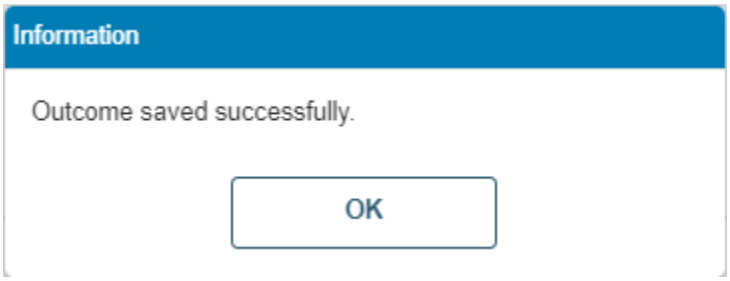
- User clicks on the “Ok” in the above message alert, system will redirect to the next section “Outcomes”

5.6 Outcomes

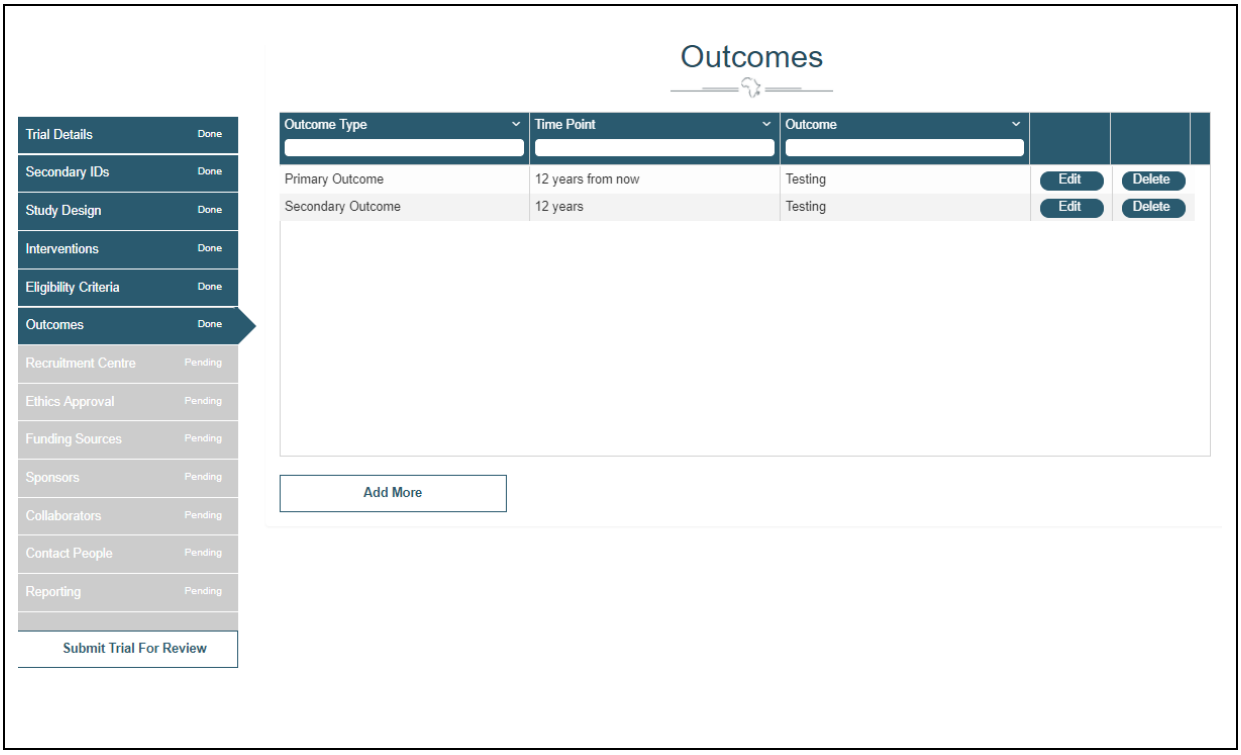
- User will be able to capture the fields required for the “Outcomes” Section.
- The completion of this section will be done as per mentioned-*Hint: Please describe ALL primary and secondary outcomes being investigated in the trial. Click on "Save" after entering the details of each outcome*



- User captures the above required fields and click “Save” the below shown message will appear.

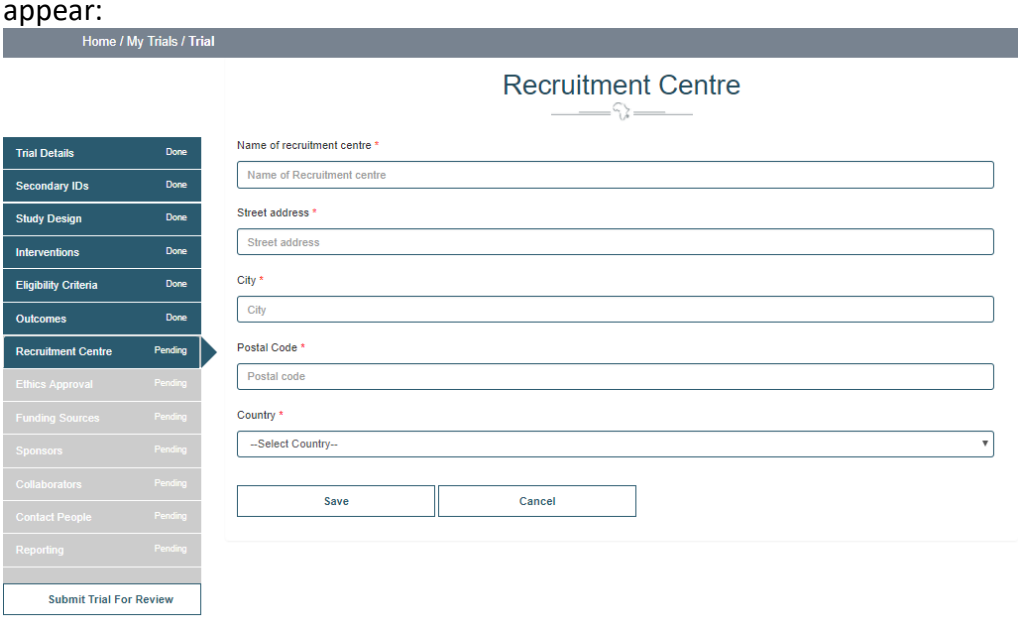


- Once user saves the record, it will show the records added in the below shown format:

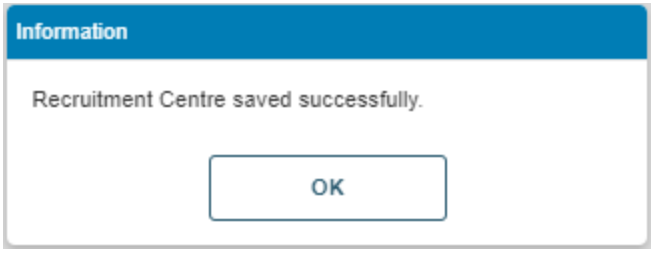


5.7 Recruitment Centre

- User clicks on the recruitment centre section and the below shown fields appear:



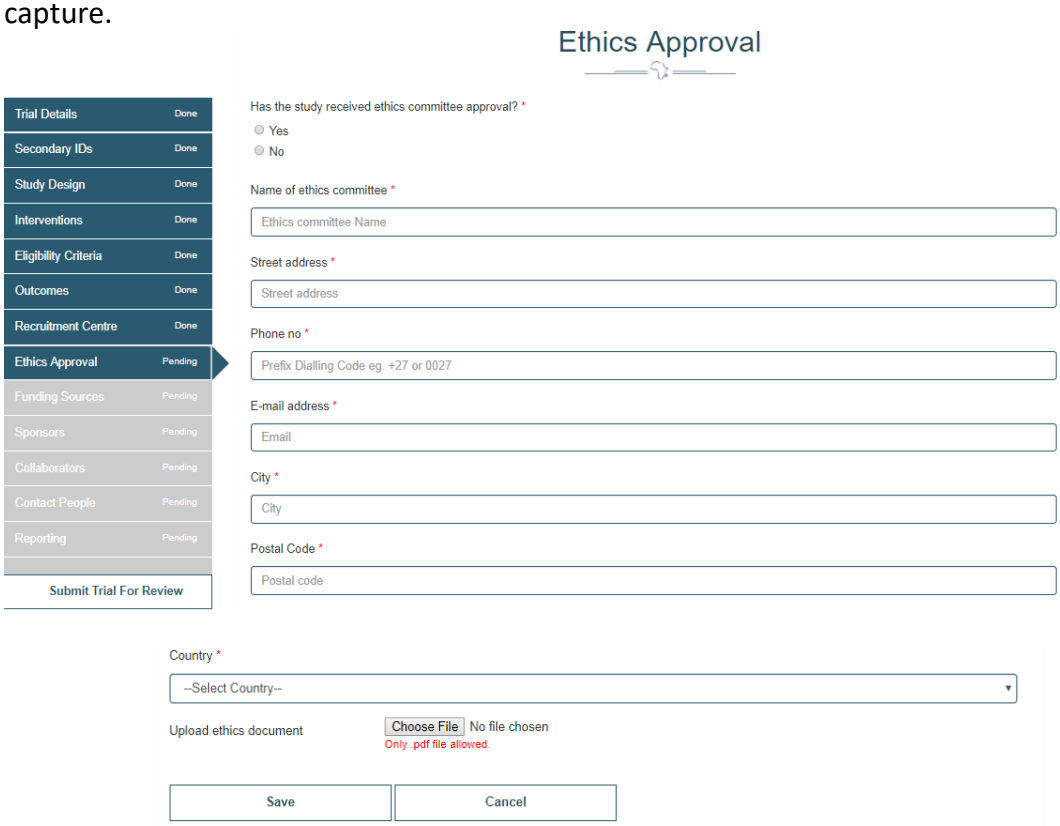
- Once the user captures the required fields and click save, the below message alert will appear.



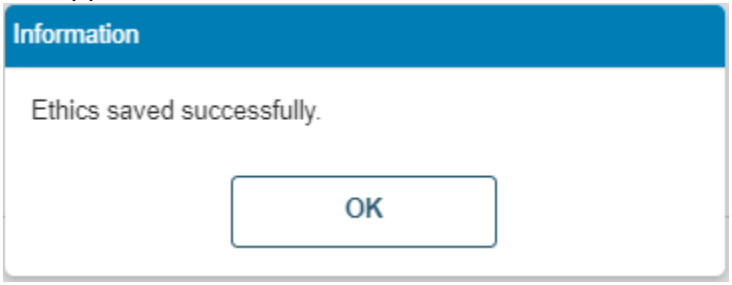
- On Clicking “Ok” the below shown table of recruitment centre records appear. User should be able to Edit, Delete and Add more records as highlighted in the below.

5.8 Ethics Approval

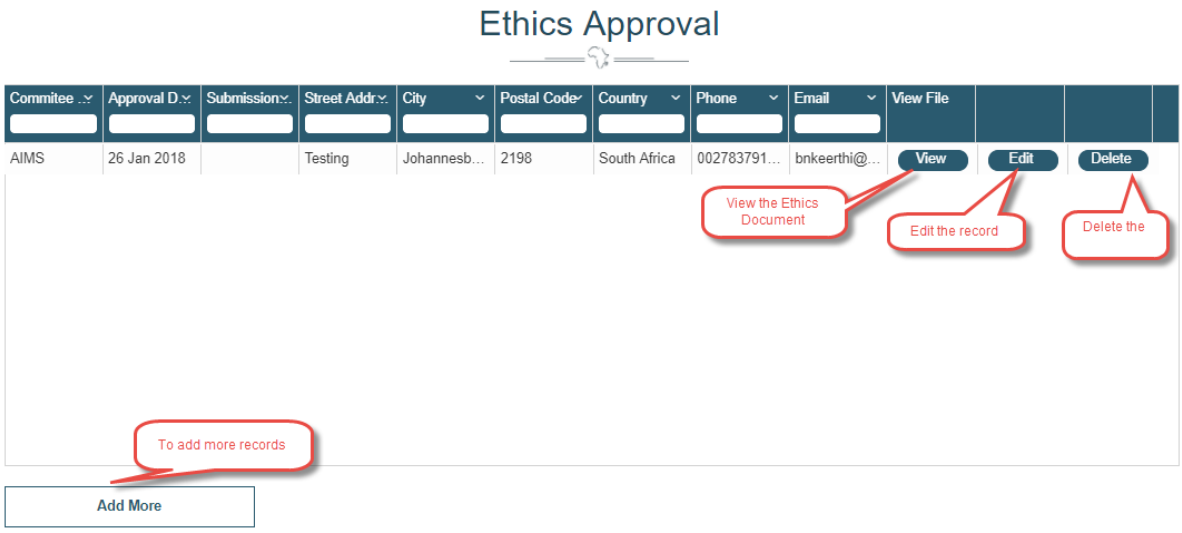
- User clicks on the Ethics Approval section and the below shown fields appear to capture.



- Once user capture all the required fields and click “Save” the following message alert will appear.



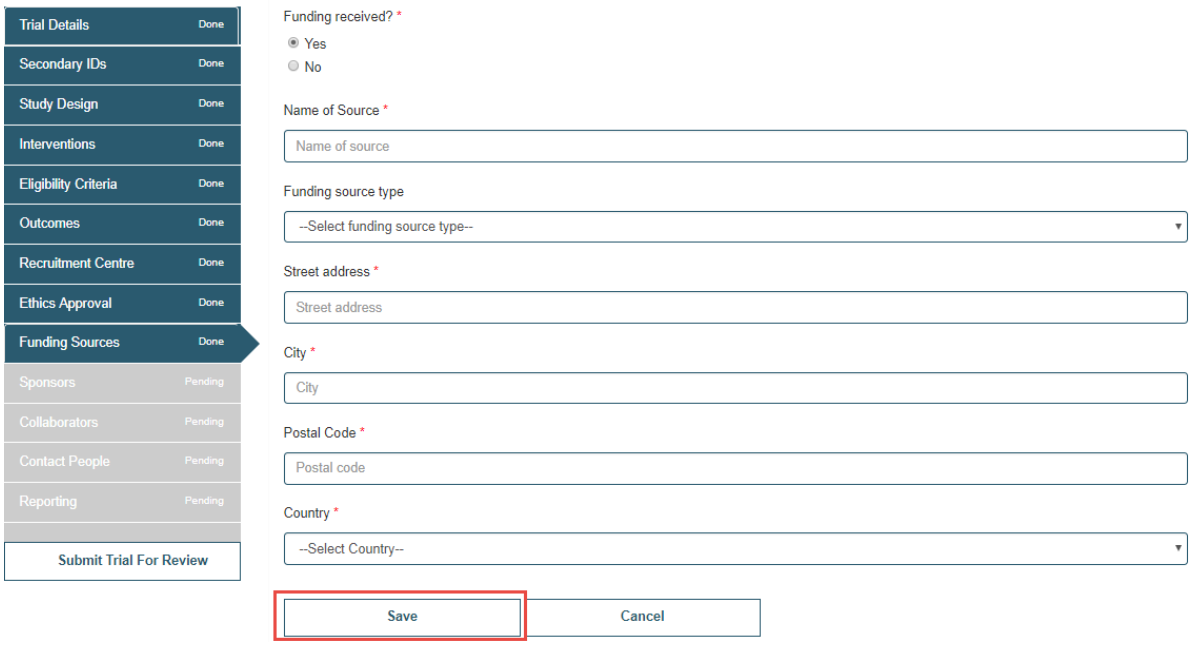
- On Clicking “Ok” the below shown table of Ethics Approval records appear. User should be able to Edit, Delete and Add more records as highlighted in the below:



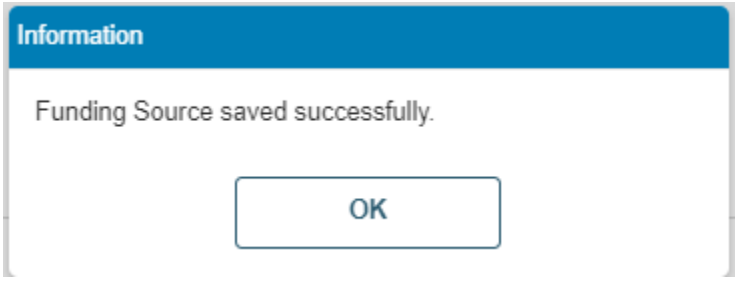
5.9 Funding Sources

- User clicks on the Funding sources section and the below shown query appears:

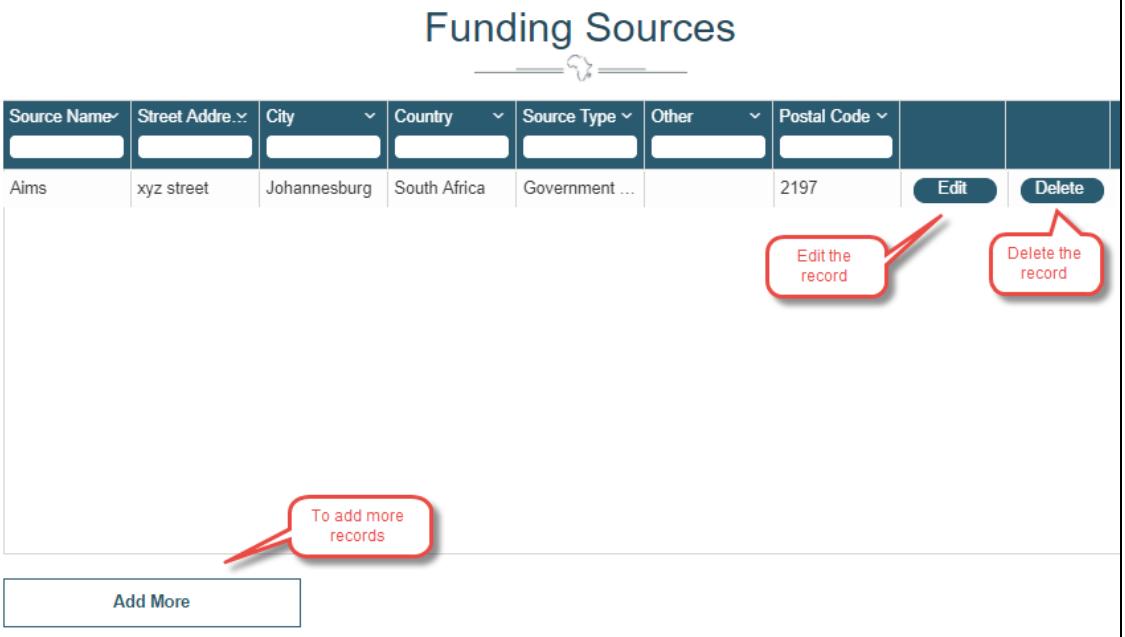
- User clicks on the Funding received? Query as “Yes” and the below shown fields appear to capture.



- Once user capture all the required fields and click “Save” the following message alert will appear.

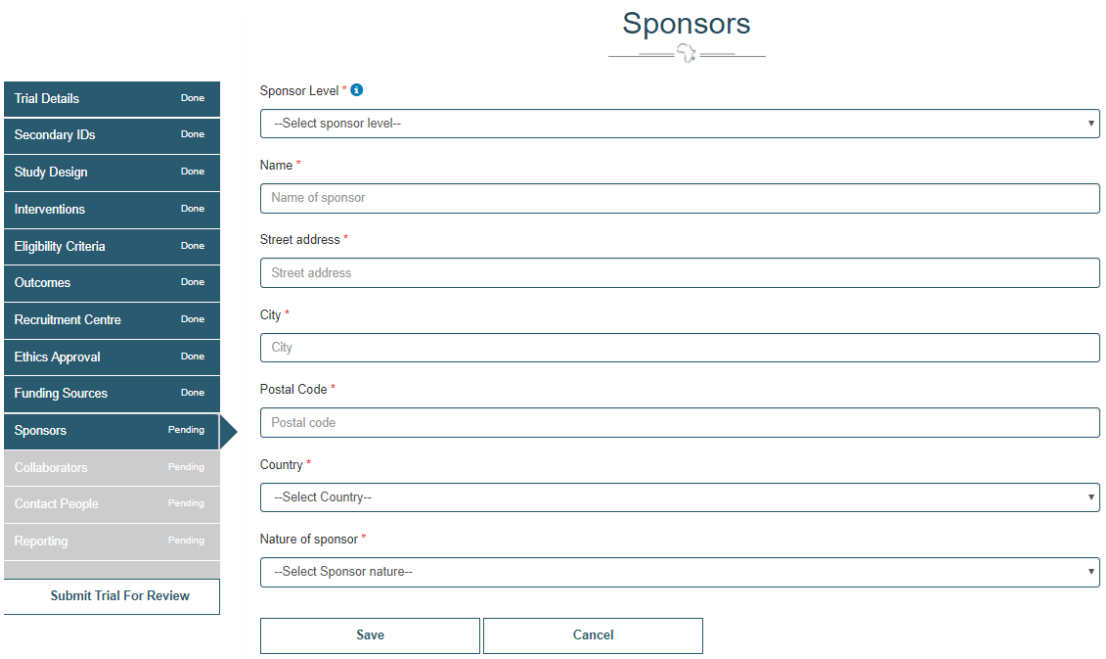


- On Clicking “Ok” the below shown table of Funding Source records appear. User should be able to Edit, Delete and Add more records as highlighted in the below:

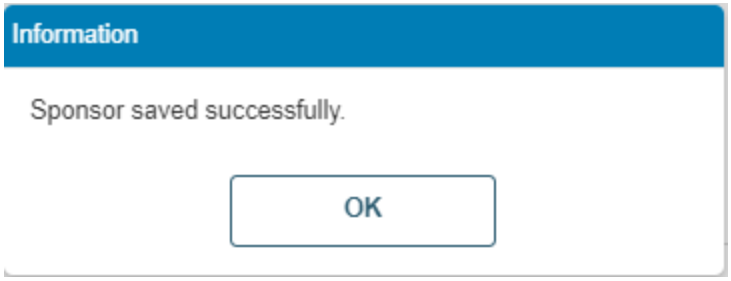


5.10 Sponsors

- User clicks on the Sponsors section and the below shown fields will appear:



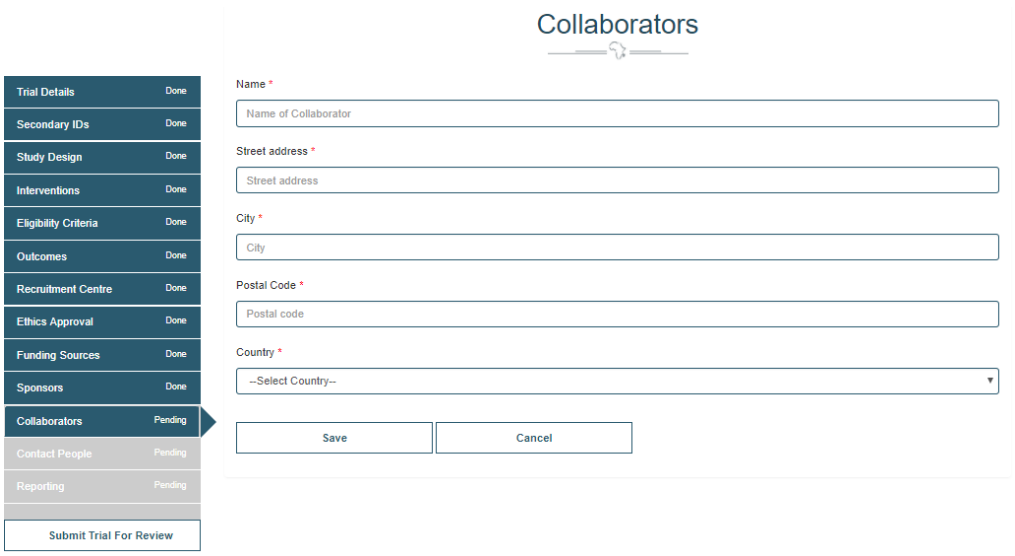
- Once user capture all the required fields and click “Save” the following message alert will appear.



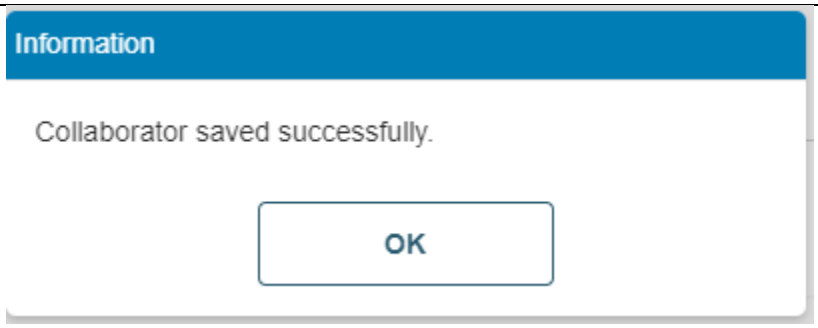
- On Clicking “Ok” the below shown table of sponsor records appear. User should be able to Edit, Delete and Add more records as highlighted in the below:

5.11 Collaborators

- User clicks on the Collaborators section and the below shown fields will appear:



- Once user captures all the required fields and click “Save” the following message alert will appear.



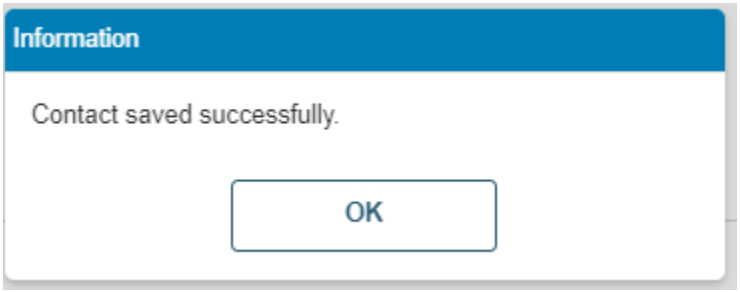
- On Clicking “Ok” the below shown table of Collaborator records appear. User should be able to Edit, Delete and Add more records as highlighted in the below:

5.12 Contact People

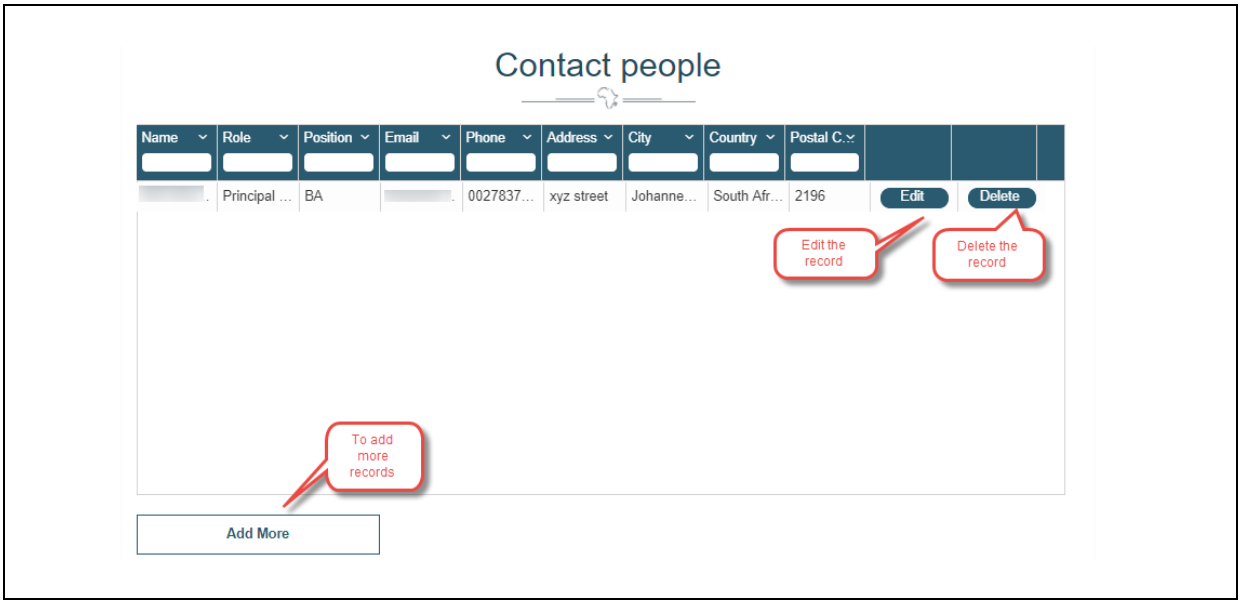
- User will be able to capture the fields required for the “Contact People” Section.
- The completion of this section will be done as per mentioned

Hint: Please enter the details for the following 3 contact people:
Principal investigator
Public enquiries: (Person responsible for general enquiries)
Scientific enquiries: (Person responsible for scientific enquires)

- Once user captures all the required fields and click “Save” the following message alert will appear.

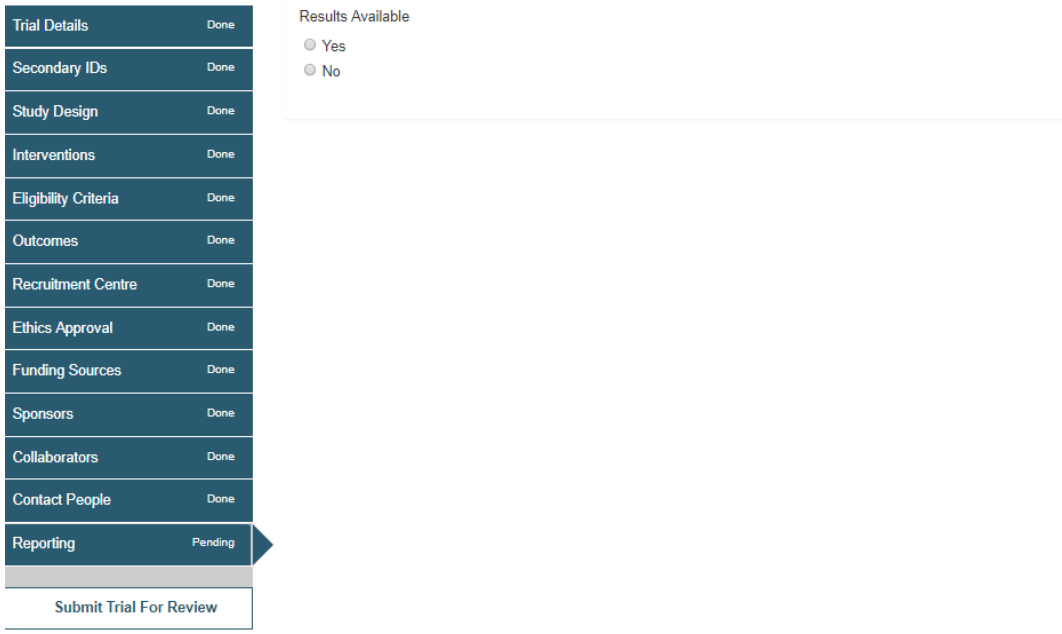


- On Clicking “Ok” the below shown table of Collaborator records appear. User should be able to Edit, Delete and Add more records as highlighted in the below:

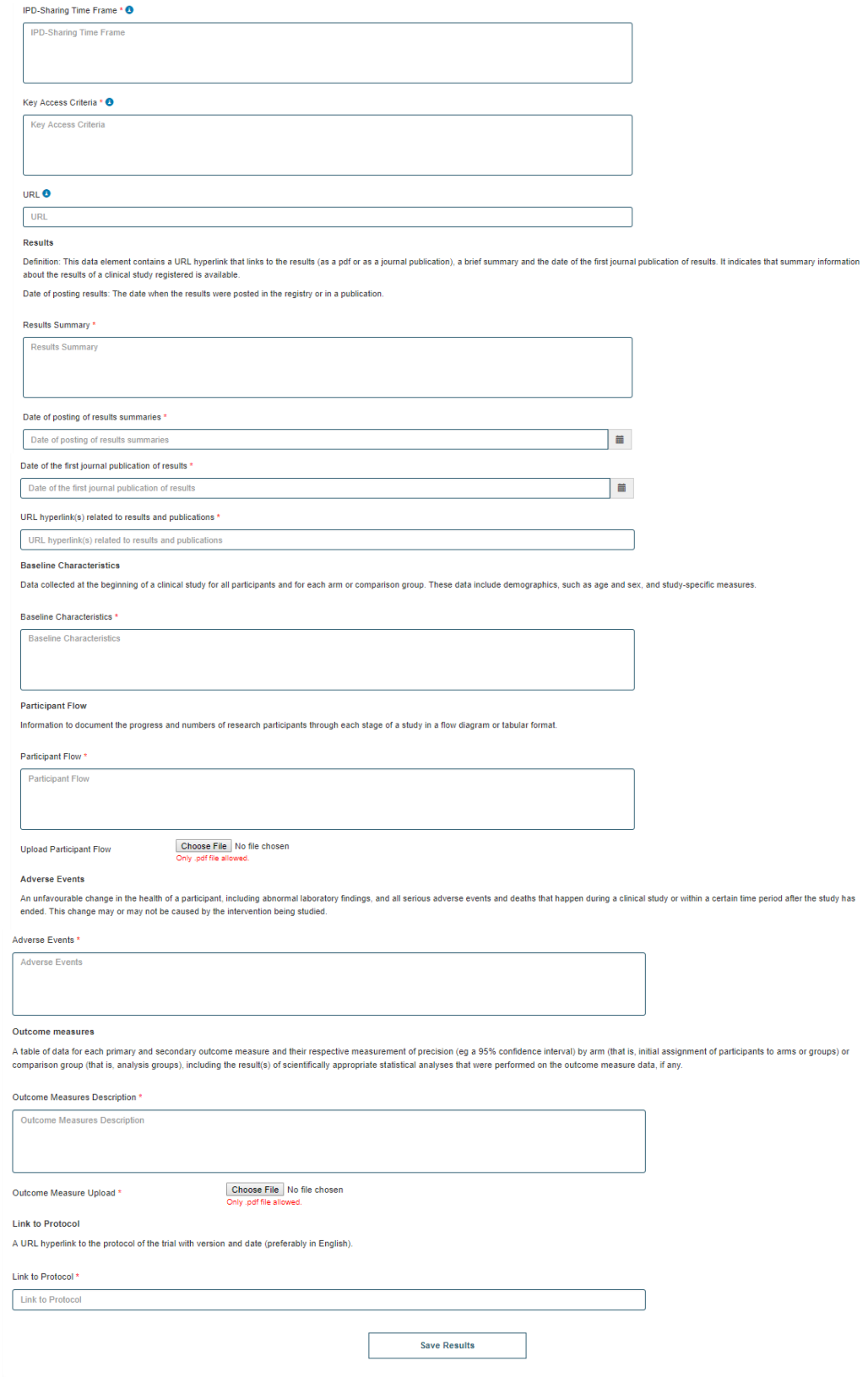

Contact people
Name
Role
Position
Email
Phone
Address
City
Country
Postal C...
Principal ...
BA
0027837...
xyz street
Johanne...
South Afr...
2196
Edit
Delete
Edit the record
Delete the record
To add more records
Add More

5.13 Reporting

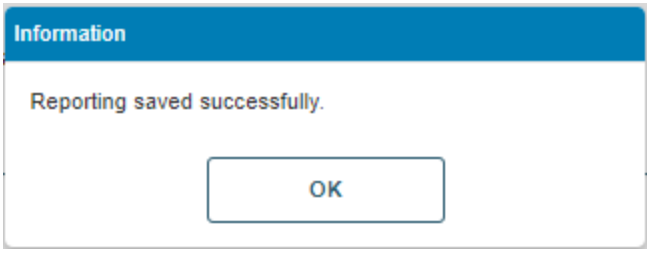
- User will be directed to the Reporting section as shown below screenshot



- If the Reporting information is available for the trials, user should select “yes” and the below shown fields will appear:

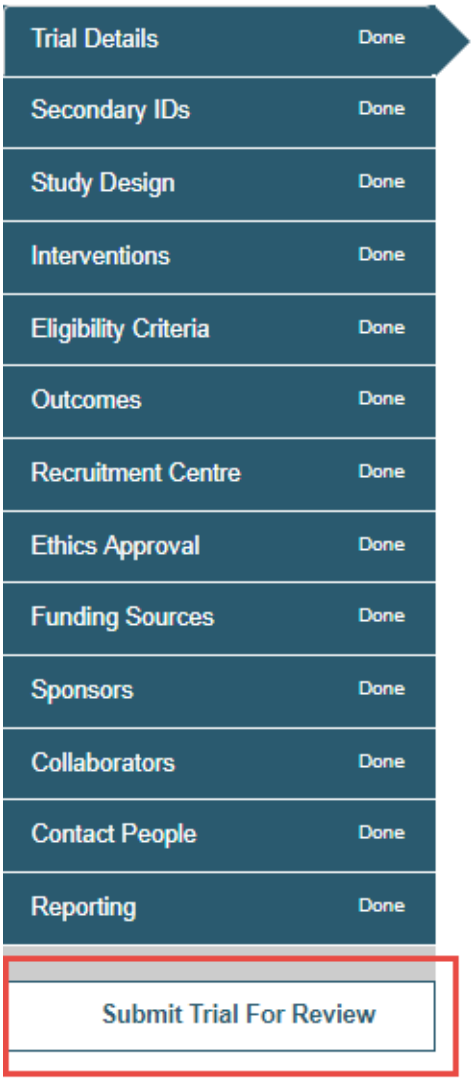


- Once user added the reporting section for the trial, below message alert will be displayed.

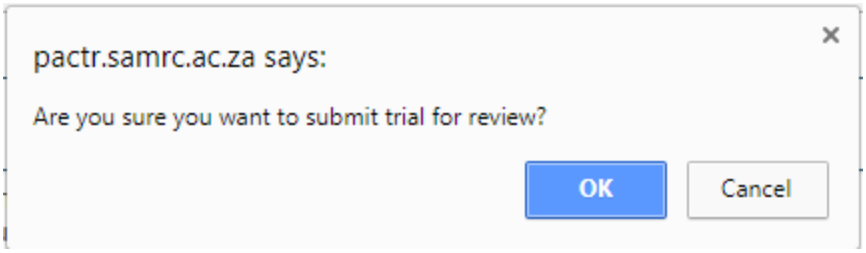


5.14 Submission

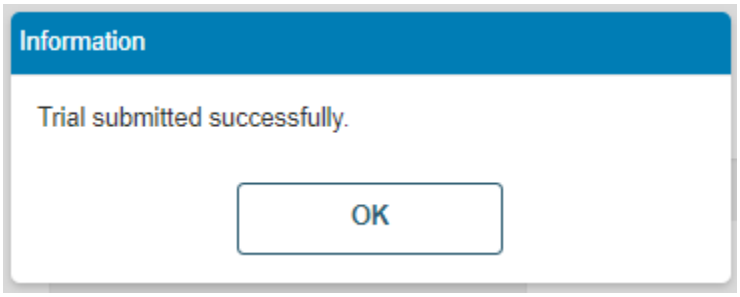
- Once user completes all the sections of Trial as shown below. User should be able to submit the trial by clicking the “Submit Trial for Review “as shown in the highlighted.



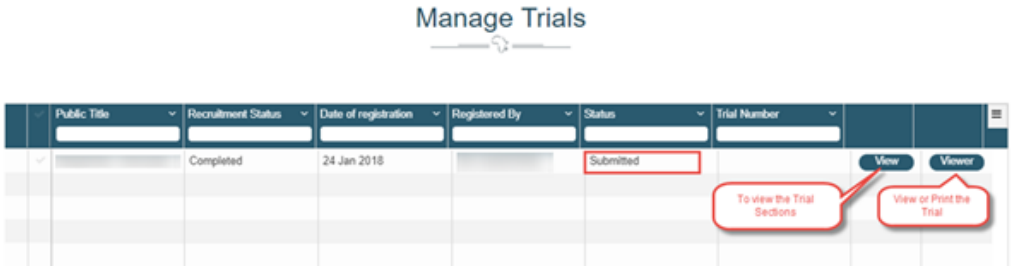
- Once user submits the Trial, below message alert will appear to confirm the submission of the Trail.



- Once the user clicks “Ok” below shown message alert will appear.

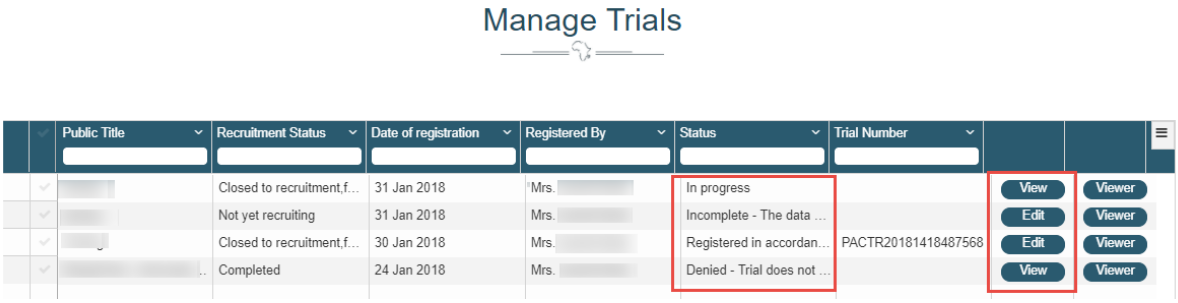


- Once user clicks on “ok”, user will be directed to the below shown and the status of the trial as “Submitted” and the “View” & “Viewer” options to view the submitted Trail sections and the print view of the Trail.

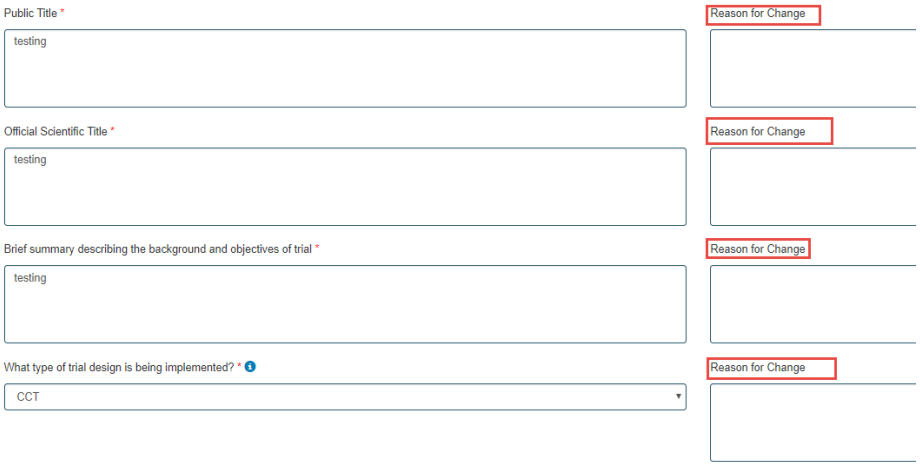


6. Manage Trials

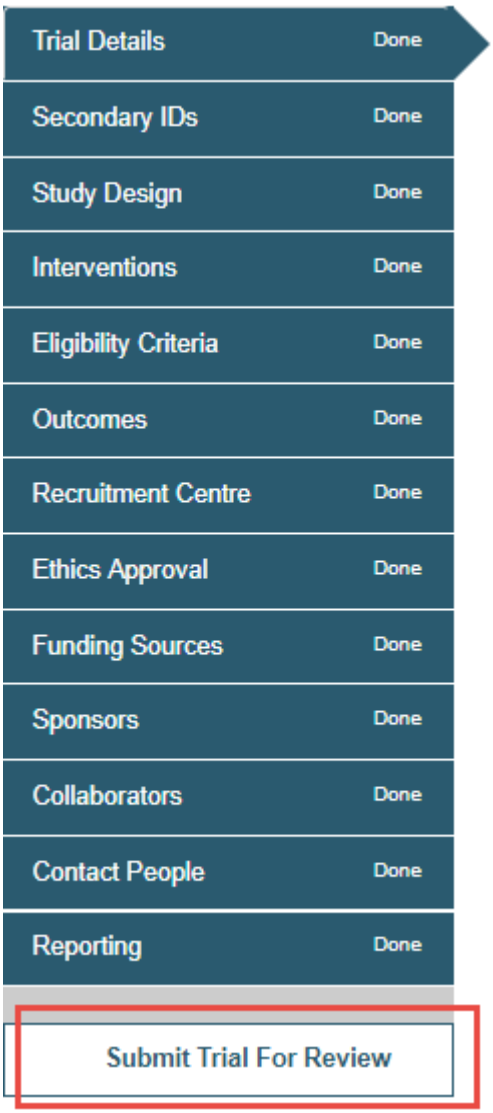
- User go to Trials>>My Trials, all the trials captured by the user will be listed as shown



- If the trial status is “Submitted/In progress/Denied-No Recruitment site on African continent/Denied-Trial does not meet requirements to be considered an RCT or CCT” user can only view the Trial information but cannot edit the trial.
- User should be able to edit if the Trial Status is “Incomplete-The data on this application is incomplete”/ “Registered in accordance with WHO and ICMJE Standards” / “Retrospective registration – This trial was registered after enrolment of the first participant.
- On Edit, user should be able to edit the sections of the Trial by capturing the “Reason for change” for each field as shown below



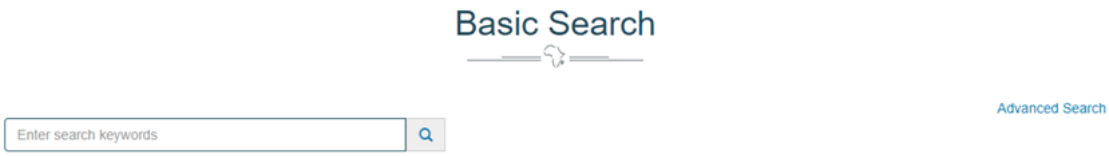
- If the Trial status is “Incomplete-The data on this application is incomplete” user should be able to edit and resubmit the trial for the review as shown below:


Trial Details Done
Secondary IDs Done
Study Design Done
Interventions Done
Eligibility Criteria Done
Outcomes Done
Recruitment Centre Done
Ethics Approval Done
Funding Sources Done
Sponsors Done
Collaborators Done
Contact People Done
Reporting Done
Submit Trial For Review

7. Search Trials

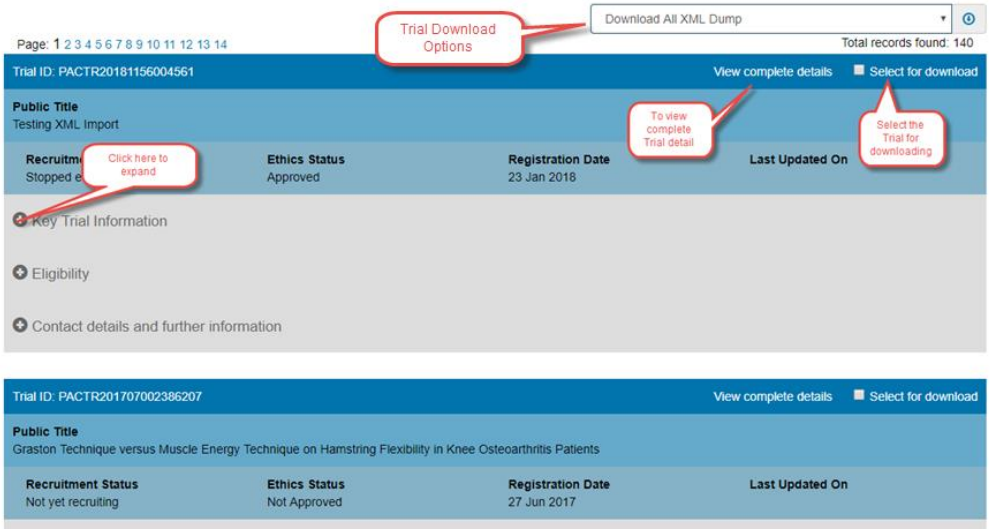
7.1 Basic Search

- User goes to Search trials menu, lands on the Basic Search page as shown below:



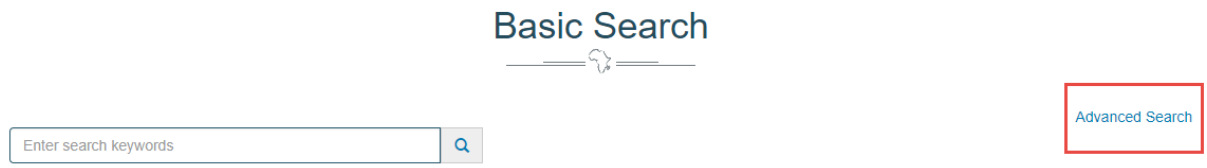
- User should be able to search the trials by providing a search keyword and click search.

- The below screenshot will show the search results and various option highlighted.

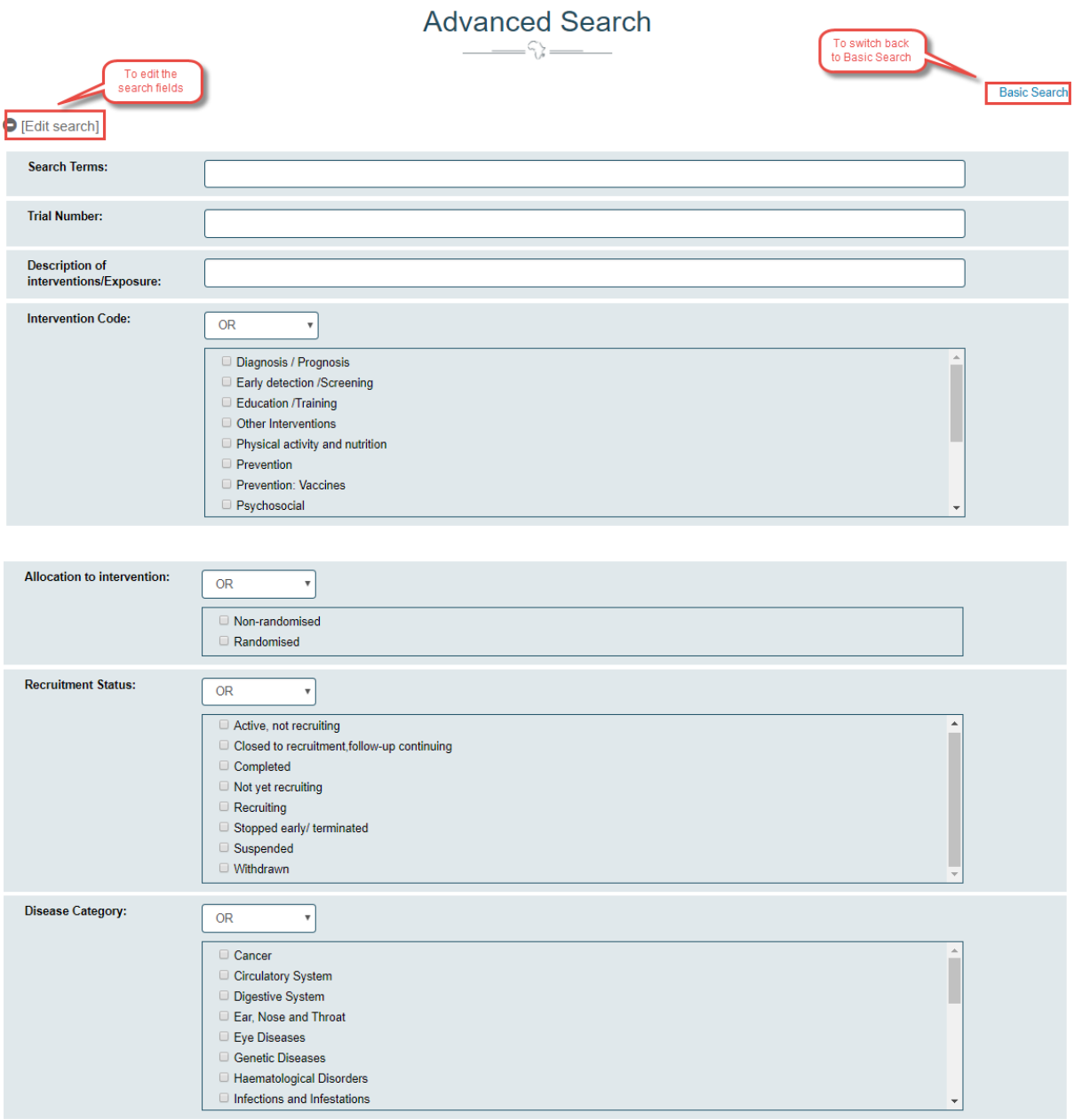


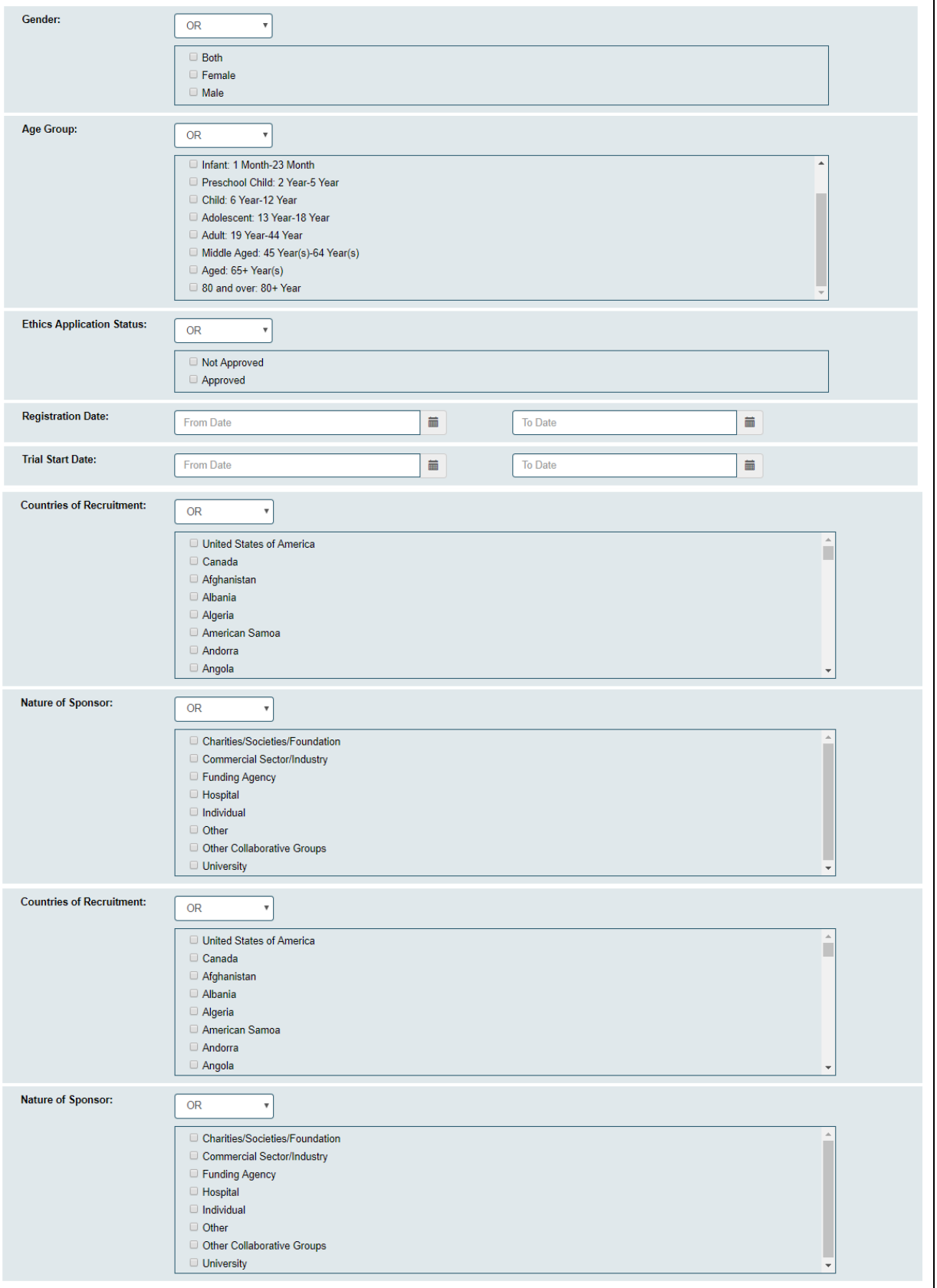
7.2 Advanced Search

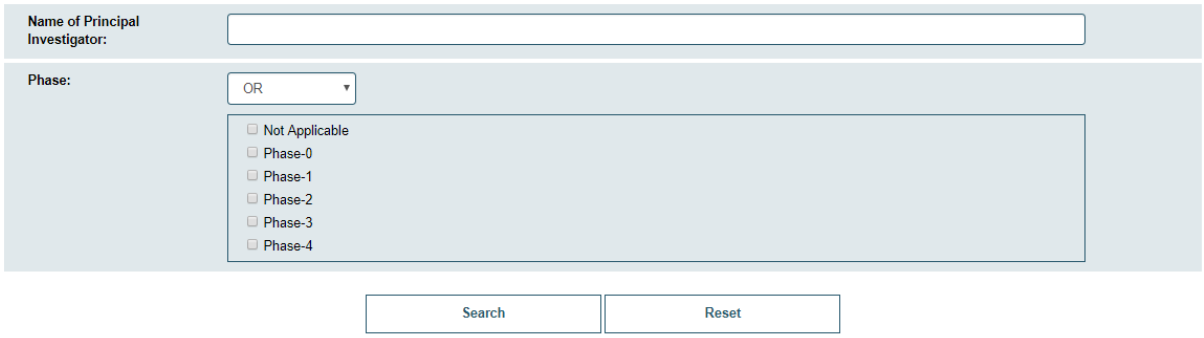
- User goes to Search trials menu, lands on the Basic Search page and there is an option for “Advanced Search” as highlighted below:



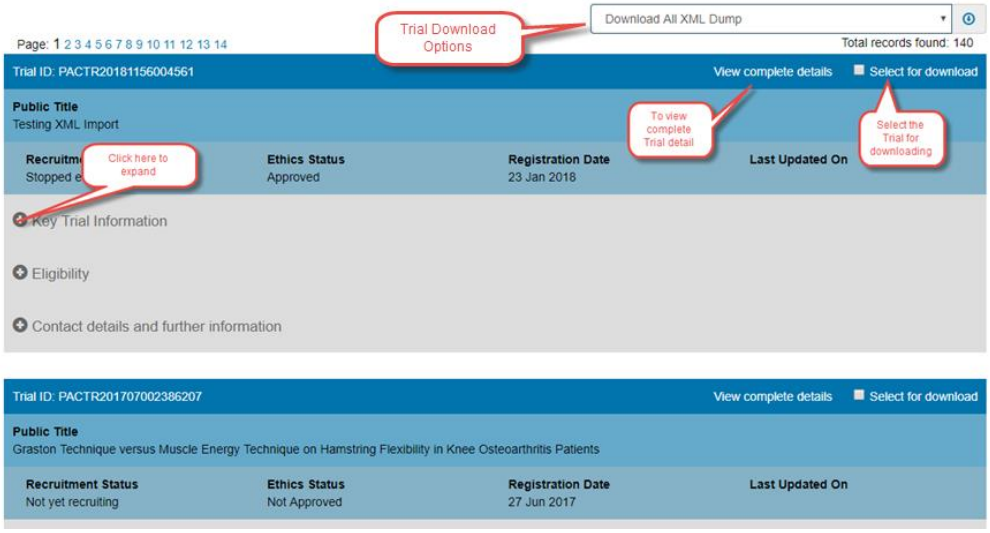
- Once user clicks on the Advanced Search link in the above shown it opens the Advanced Search Screen as shown:




Gender:
OR
Both
Female
Male
Age Group:
OR
Infant: 1 Month-23 Month
Preschool Child: 2 Year-5 Year
Child: 6 Year-12 Year
Adolescent: 13 Year-18 Year
Adult: 19 Year-44 Year
Middle Aged: 45 Year(s)-64 Year(s)
Aged: 65+ Year(s)
80 and over: 80+ Year
Ethics Application Status:
OR
Not Approved
Approved
Registration Date:
From Date
To Date
Trial Start Date:
From Date
To Date
Countries of Recruitment:
OR
United States of America
Canada
Afghanistan
Albania
Algeria
American Samoa
Andorra
Angola
Nature of Sponsor:
OR
Charities/Societies/Foundation
Commercial Sector/Industry
Funding Agency
Hospital
Individual
Other
Other Collaborative Groups
University
Countries of Recruitment:
OR
United States of America
Canada
Afghanistan
Albania
Algeria
American Samoa
Andorra
Angola
Nature of Sponsor:
OR
Charities/Societies/Foundation
Commercial Sector/Industry
Funding Agency
Hospital
Individual
Other
Other Collaborative Groups
University

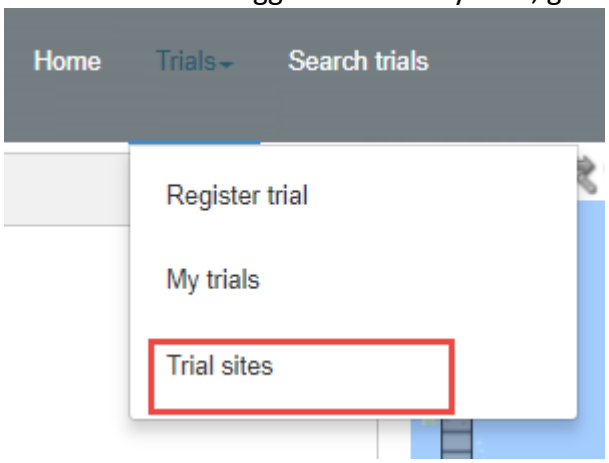


- Advanced search gives an option to search by using various options for different Trial parameters as shown above.
- User should also be able to search using “AND” / “OR” conjunction between the trial parameters.
- The below screenshot will show the search results and various option highlighted.

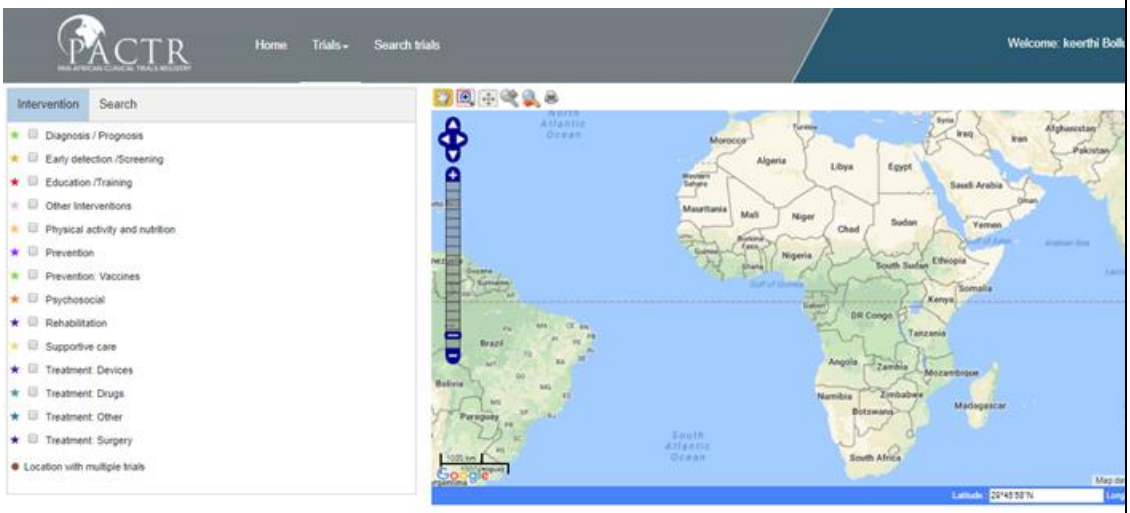


8. Trial Sites

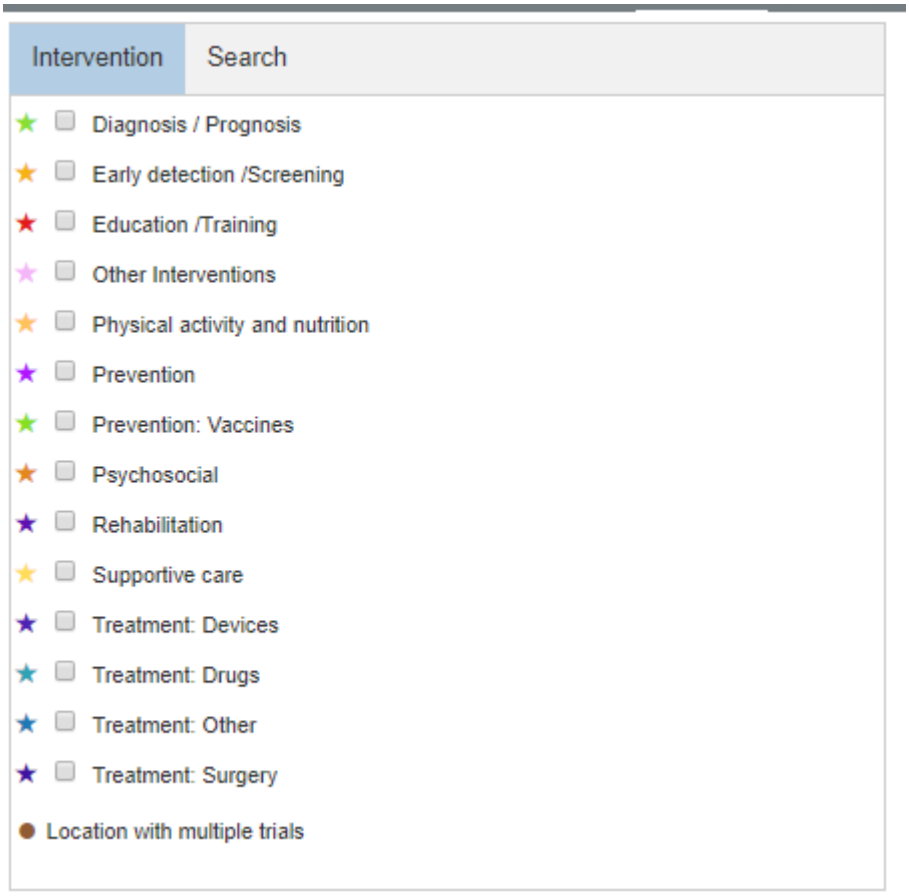
- Once user is logged in to the system, go to Trials>>Trial Sites menu as shown below:



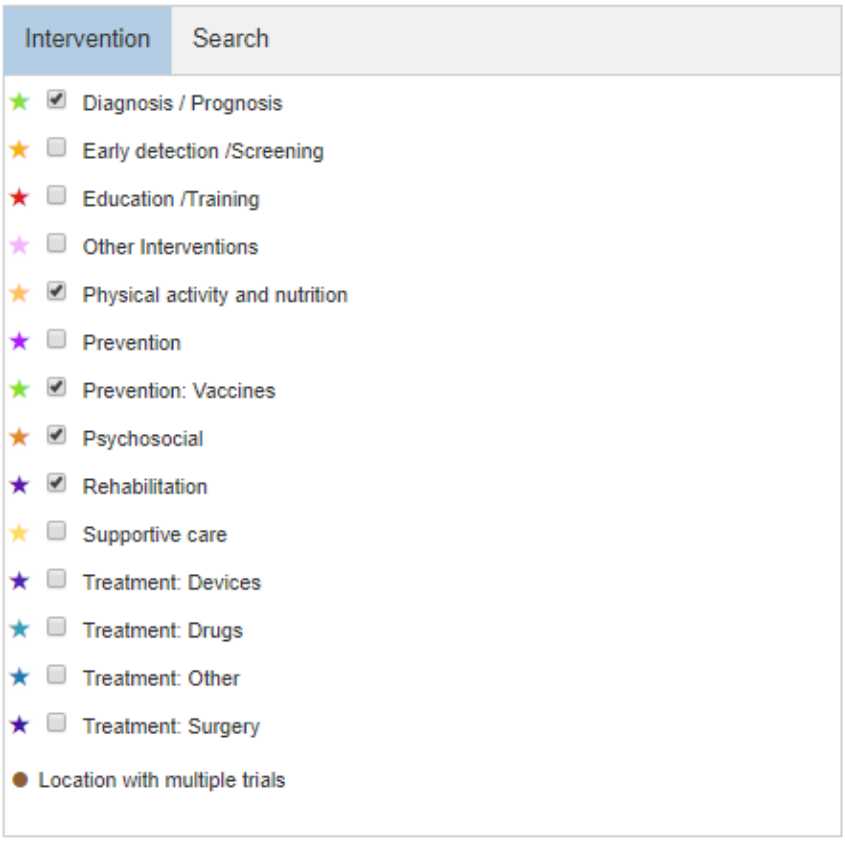
- User should be able to view the GIS viewer as shown below:



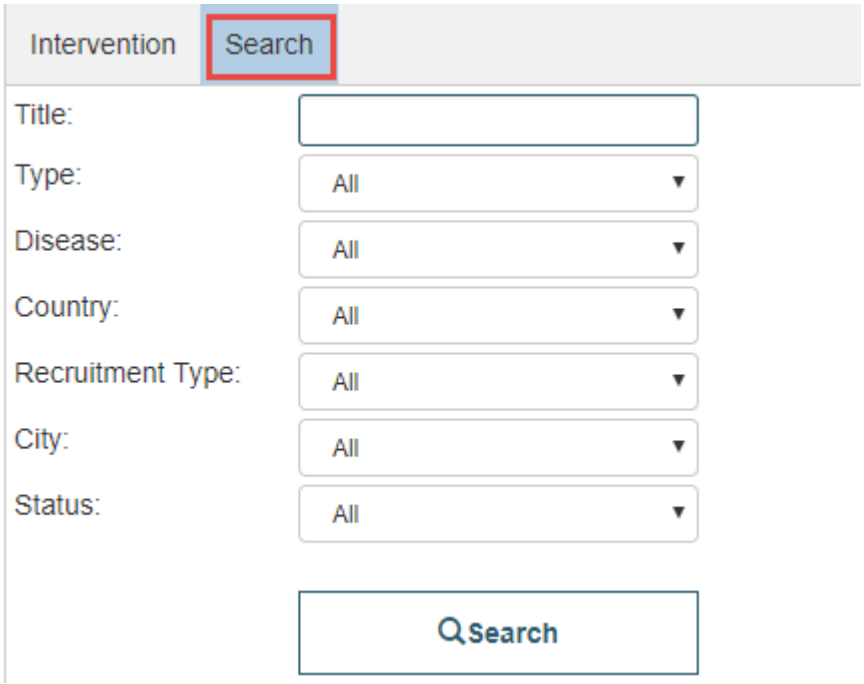
- User should be able to use the intervention filter shown below to locate the trial sites on the GIS Viewer.



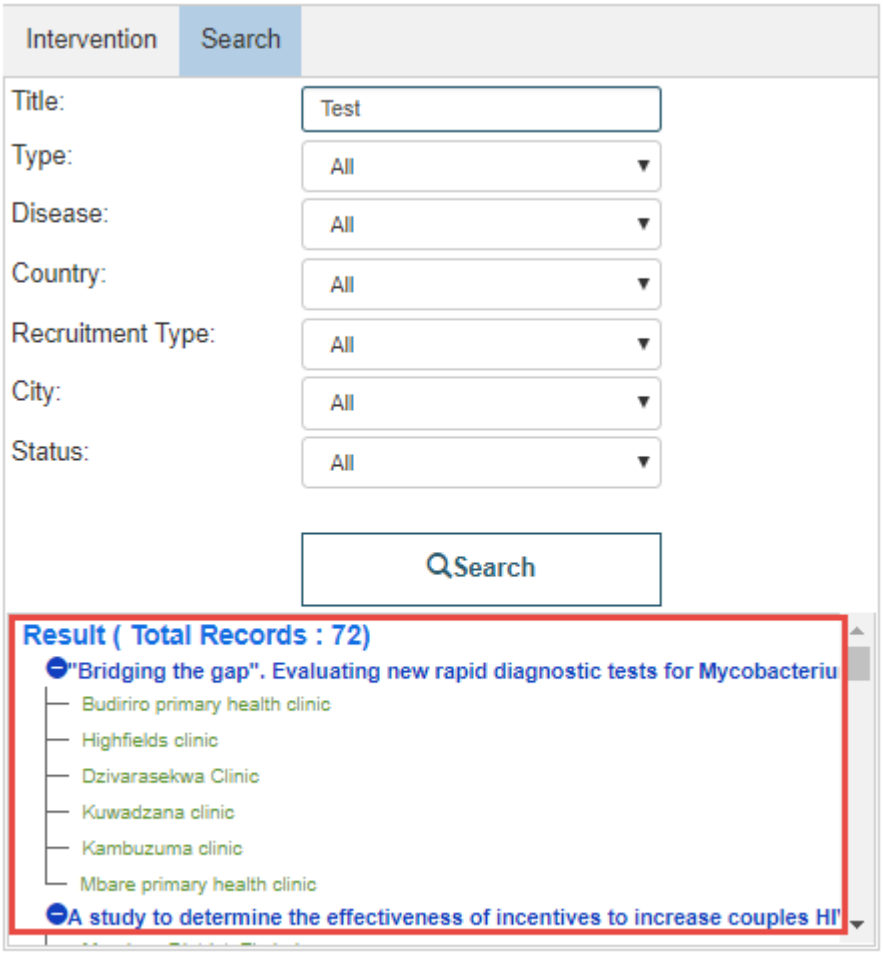
- Once user checks the checkboxes of the required Intervention type as shown below, the GIS viewer will show the location of the trial sites.



- Apart from the Intervention type filtering, user should also be able to search the trial sites using filters shown below:

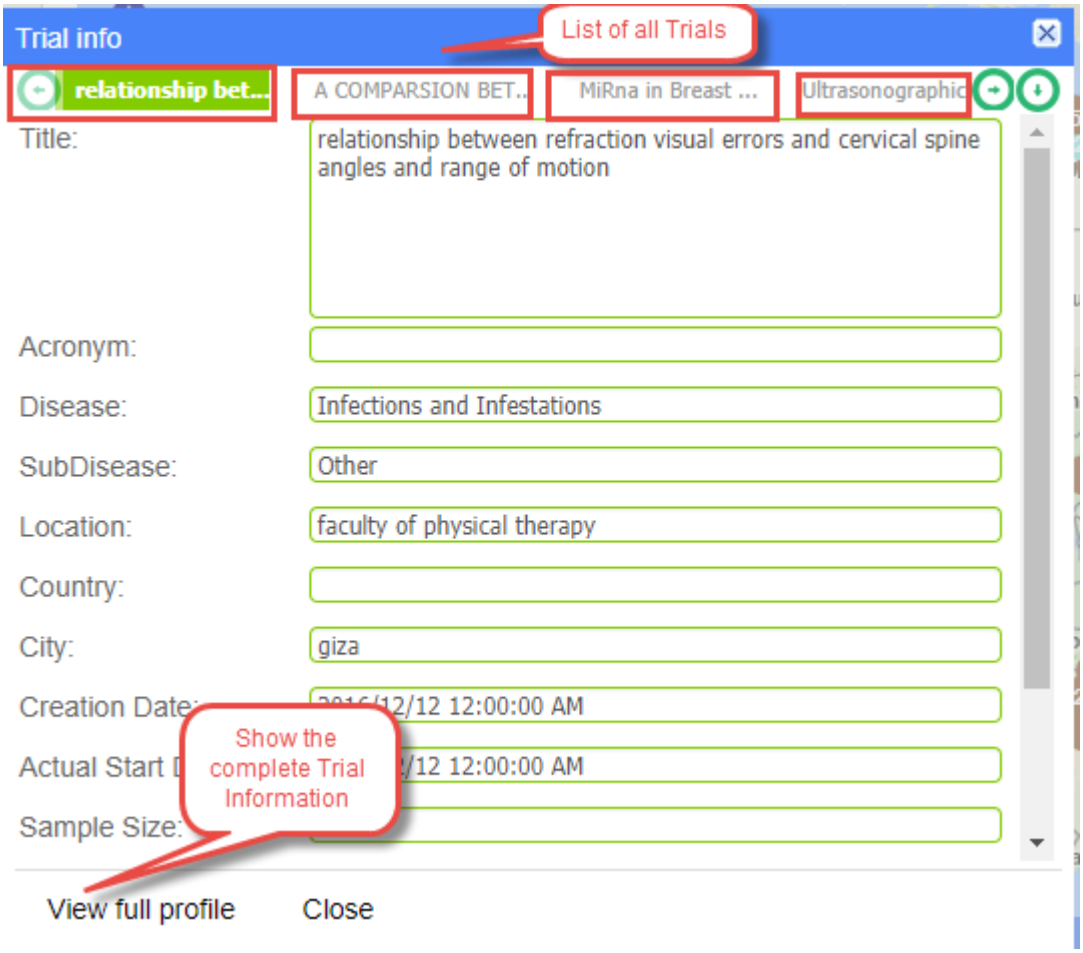


- User choosing the required search parameters and clicking the search will show the results as shown below:


Intervention
Search
Title:
Test
Type:
All
Disease:
All
Country:
All
Recruitment Type:
All
City:
All
Status:
All
Search
Result (Total Records : 72)
"Bridging the gap". Evaluating new rapid diagnostic tests for Mycobacteriu
Budiriro primary health clinic
Highfields clinic
Dzivarasekwa Clinic
Kuwadzana clinic
Kambuzuma clinic
Mbare primary health clinic
A study to determine the effectiveness of incentives to increase couples HI

- User can click on the Trial site links to track trial site location on the GIS viewer.
- User when clicks on the Trial site location with single/multiple trial location on GIS viewer as shown below:

- User should be able to view the trial information as shown below from the GIS viewer:


Trial info
List of all Trials
relationship bet...
A COMPARSION BET..
MiRna in Breast ...
Ultrasonographic
Title:
relationship between refraction visual errors and cervical spine angles and range of motion
Acronym:
Disease:
Infections and Infestations
SubDisease:
Other
Location:
faculty of physical therapy
Country:
City:
giza
Creation Date:
Actual Start D
/12 12:00:00 AM
Sample Size:
Show the complete Trial Information
View full profile
Close