



PAN AFRICAN CLINICAL TRIAL REGISTRY

User Manual

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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:

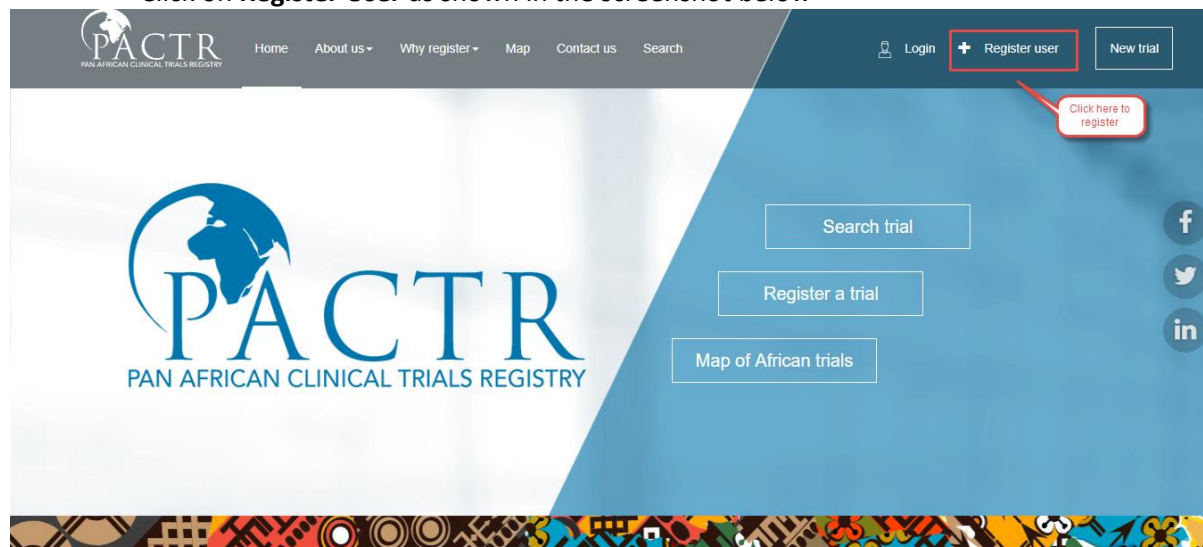
1. **Access Control** – this module is created for the Researcher to access the system.
2. **Researchers Registration**- this module is for the Researchers to register online to the Pan African Clinical Trials Registry.
3. **Researcher Profile**- this module is for the researcher to update profile details.
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

Register User

1. Are you the person responsible for registering the trial?
Only the trial's Primary Sponsor or their authorised representative should register the trial.
It is recommended that the trial sponsor register the trial. However, trial co-ordinators or principal investigators may also register the trial. Please contact the person responsible for the trial's overall management to check if you are authorised to register the trial before proceeding further. For multi-site studies, trial data should be submitted only once. Do not submit trial data for each study location.

2. Has the trial already been registered?
Your trial should only be registered once on the Pan African Clinical Trials Registry (PACTR).
Please check that the trial has not already been registered on the PACTR before proceeding further. Click here to search the PACTR Registry database.
For multi-site studies, trial data should be submitted only once. Do not submit trial data for each study location.

3. If you wish to proceed with trial registration please read the following:
Once your trial is registered on the PACT Registry, it is not possible to withdraw or remove your trial. You are able to update your trial's information after registration. In most instances you will need to provide a reason why you are making changes to your trial. The trial information including the history of changes made will be made publicly available.
Please do not 'cut and paste' information from other applications that includes formatted text (e.g. bullet points) when entering data on the PACT Registry.
Please do not use meaningless phrases or uninformative terminology to describe key information. For example, do not write 'investigational drug' in the 'Intervention' field. Please provide sufficient detail so that the information will be meaningful to users of the PACT Registry.
After submitting a trial for registration, it will be checked by the PACT Registry staff. If more information is required before your trial can be registered, we will send you an email. It is important that you reply promptly to these queries so we can proceed with registering your trial as soon as possible.
If you do not respond to the query email within two weeks, the PACT Registry staff will re-send the email twice, at two weekly intervals. They may also make a follow-up phone call after this time if there is still no response. If you do not respond to any of these follow-up emails or calls, we will assume that you do not wish to proceed with registering your study at this time and it will be withdrawn from the registration process. To re-instate your submitted study information for registration at a later date, you will be required to send an email request to the PACT Registry.

I hereby state that I am the trial's Primary Sponsor (or an authorized representative of the sponsor), that the trial has not been previously registered on the PACTR Clinical Trials Register, and that I agree to the Terms and Conditions of the PACTR Clinical Trials Registry

I agree to the terms and conditions

Next

Click here to accept terms & conditions

- 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:

Register User

Personal Information:

| | | | |
|---------------------|---|-----------------|--|
| First name * | <input type="text" value="Eg. John"/> | Last Name * | <input type="text" value="Eg. Smith"/> |
| Select your title * | <input type="text" value="Select Title"/> | Email address * | <input type="text" value="Enter email"/> |

Employment Information:

| | | | |
|------------------|---|------------------------|--|
| Company name * | <input type="text" value="Company/ Organisation name"/> | Your position | <input type="text" value="Your position"/> |
| Phone number * | <input type="text" value="Prefix Dialling Code eg. +27 or 0027"/> | | |
| Address | <input type="text" value="Enter address"/> | | |
| City * | <input type="text" value="Enter city"/> | Postal Code / Zip Code | <input type="text" value="Eg. 0040"/> |
| Select Country * | <input type="text" value="Select Country"/> | | |

Submit

Clear

Cancel

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

Personal Information:

| | | | |
|---------------------|---|-----------------|--|
| First name * | <input type="text" value="Eg. John"/> | Last Name * | <input type="text" value="Eg. Smith"/> |
| Select your title * | <input type="text" value="Select Title"/> | Email address * | <input type="text" value="Enter email"/> |

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

Employment Information:

| | | | |
|------------------|---|------------------------|--|
| Company name * | <input type="text" value="Company/ Organisation name"/> | Your position | <input type="text" value="Your position"/> |
| Phone number * | <input type="text" value="Prefix Dialling Code eg. +27 or 0027"/> | | |
| Address | <input type="text" value="Enter address"/> | | |
| City * | <input type="text" value="Enter city"/> | Postal Code / Zip Code | <input type="text" value="Eg. 0040"/> |
| Select Country * | <input type="text" value="Select Country"/> | | |

Submit

Clear

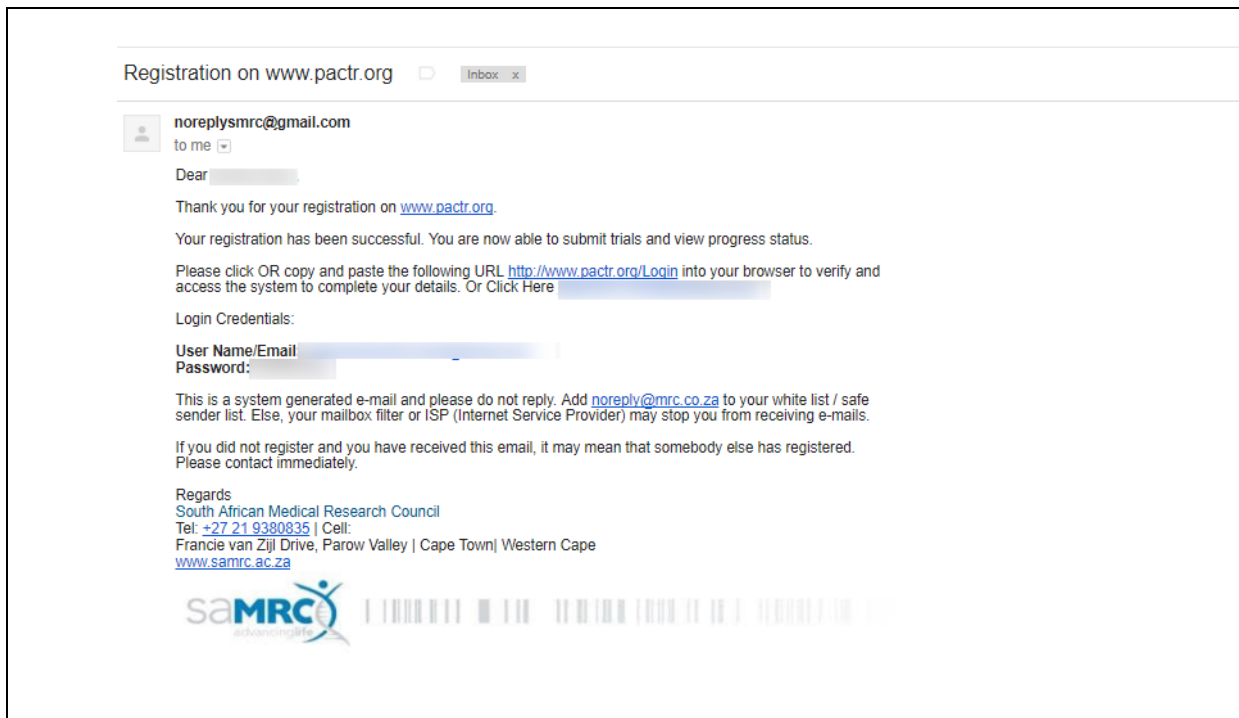
Cancel

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

Registration successful. User credentials sent to your email. [Click here](#) to Sign In



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

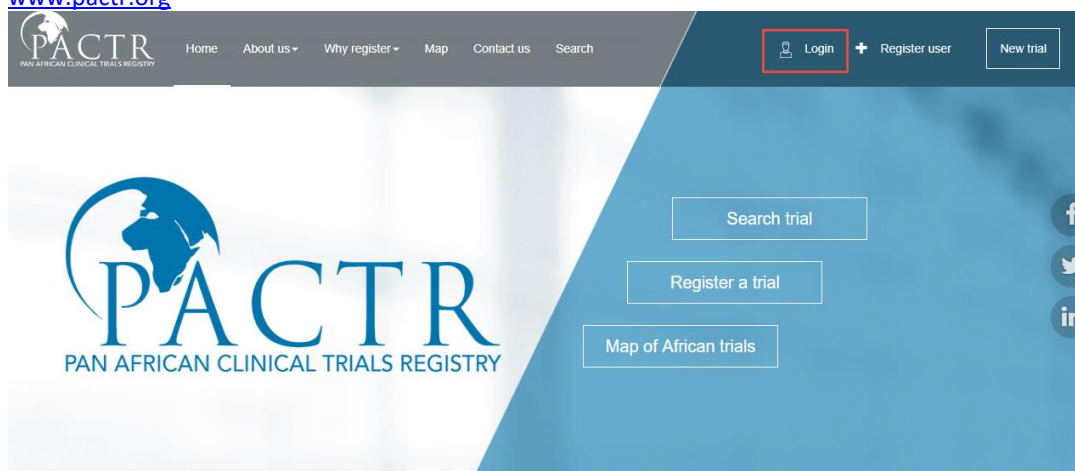


3.2 User Login

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:

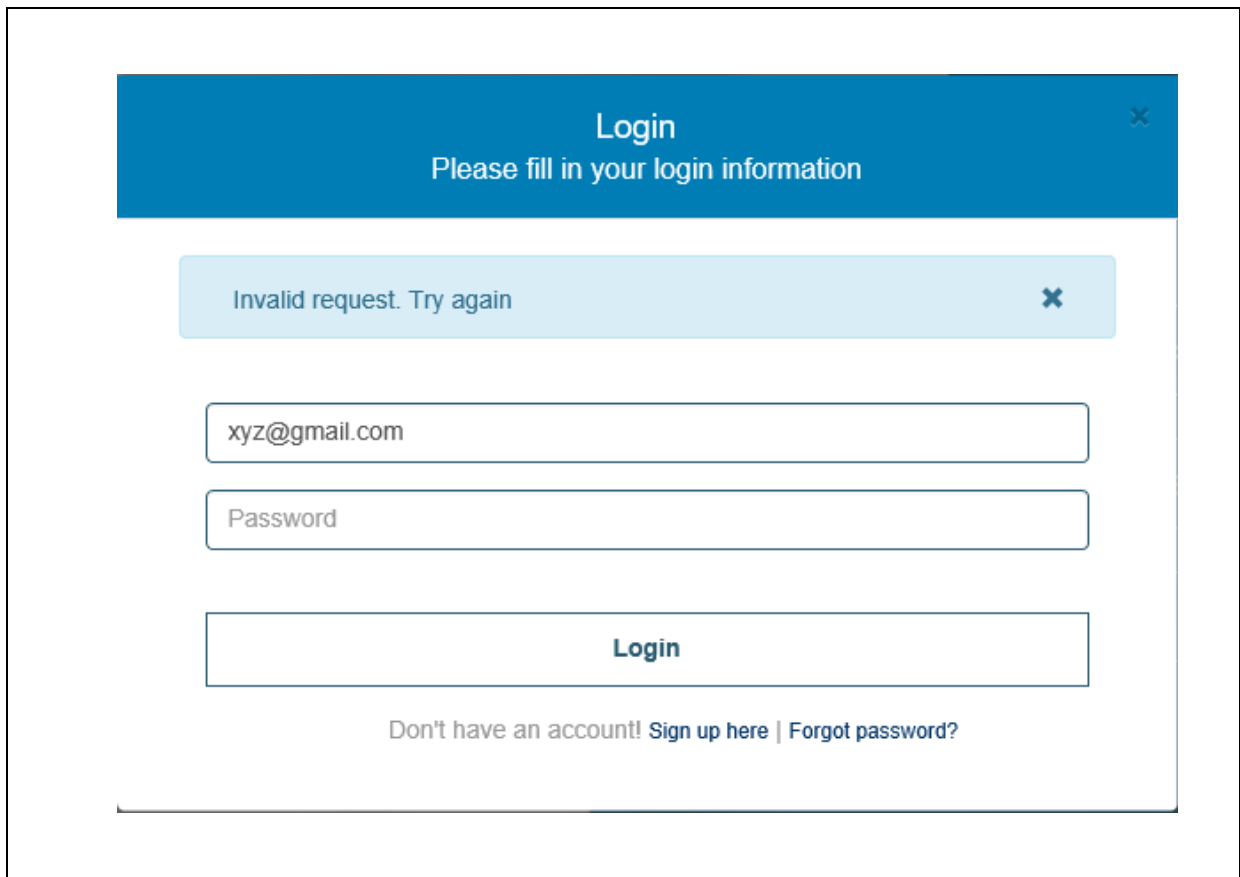


My Profile

[Change Password](#) | [View User Manual](#)

| | |
|---|--|
| <p>Title * <input type="text" value="Mrs."/></p> | <p>Email Address * <input type="text"/></p> |
| <p>First Name * <input type="text"/></p> | <p>Last Name * <input type="text"/></p> |
| <p>Company * <input type="text"/></p> | <p>Position <input type="text"/></p> |
| <p>Address <input type="text"/></p> | |

- 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.

Home / Change Password

Change Password

Old Password *

New Password *

Confirm New Password *

Hint: Password must contain:- a minimum of 1 lower case letter [a-z]/upper case letter [A-Z]/numeric character [0-9]/special character: '\$@!%*?&' and atleast 6 characters in length.

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

Information

Password changed successfully. Please login again with the new password.

- 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.

Home / My Profile

My Profile

Change Password [View User Manual](#)

Title * Mrs. Email Address * [Redacted]

First Name * [Redacted] Last Name * [Redacted]

- 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.

The screenshot shows a login form with a blue header. The header contains the text 'Login' and a close icon. Below the header, it says 'Please fill in your login information'. There are three input fields: 'Username', 'Password', and a 'Login' button. At the bottom, there is a link 'Forgot password?' highlighted with a red box.

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

The screenshot shows a 'Forgot Password' screen. The title is 'Forgot Password'. Below the title is a text input field labeled 'Email Address'. Below the input field are two buttons: 'Reset Password' and 'Cancel'.

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

The screenshot shows an information message alert. The title is 'Information'. The message text is 'Login credentials are successfully emailed to your email address'. Below the message is an 'OK' button.

- User receives below shown email with a new password.

Dear [REDACTED]

As per your request, your password has been reset.

User Name/Email: [REDACTED]

Password: [REDACTED]

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](tel:+27219380835) | Cell:

Francie van Zijl Drive, Parow Valley | Cape Town| Western Cape

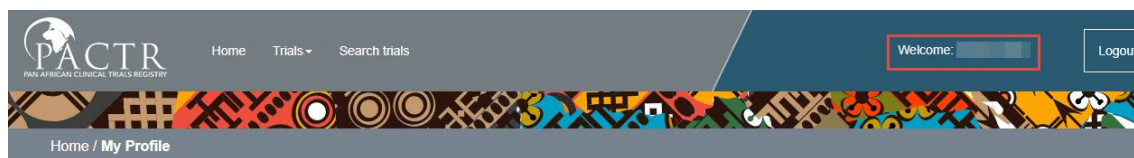
www.samrc.ac.za



-
- User logs in 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:



My Profile

[Change Password](#) | [View User Manual](#)

| | |
|-----------------------------------|----------------------|
| Title * | Email Address * |
| <input type="text" value="Mrs."/> | <input type="text"/> |
| First Name * | Last Name * |
| <input type="text"/> | <input type="text"/> |

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

Home / My Profile

My Profile

[Change Password](#) | [View User Manual](#)

| | |
|-----------------------------------|----------------------|
| Title * | Email Address * |
| <input type="text" value="Mrs."/> | <input type="text"/> |
| First Name * | Last Name * |
| <input type="text"/> | <input type="text"/> |
| Company * | Position |
| <input type="text"/> | <input type="text"/> |
| Address | |
| <input type="text"/> | |
| City * | Postal Code |
| <input type="text"/> | <input type="text"/> |
| Country * | Phone * |
| <input type="text"/> | <input type="text"/> |

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

5. Trial Registration

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

Home / Register Trial

Trial Details

Trial Details

- Secondary IDs
- Study Design
- Interventions
- Eligibility Criteria
- Outcomes
- Recruitment Centre
- Ethics Approval
- Funding Sources
- Sponsors
- Collaborators
- Contact People
- Reporting

Submit Trial For Review

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

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

Purpose of the Trial *

--Select trial purpose--

Anticipated Trial Start Date *

Anticipated Trial Start D

Actual Trial Start Date

Actual Trial Start Date

Anticipated Date of Last Follow up *

Anticipated Date of last Fc

Completion Date

Completion Date

Target No. Of Participants *

Target Participants

Final No. Of Participants

Final Participants

Recruitment Status *

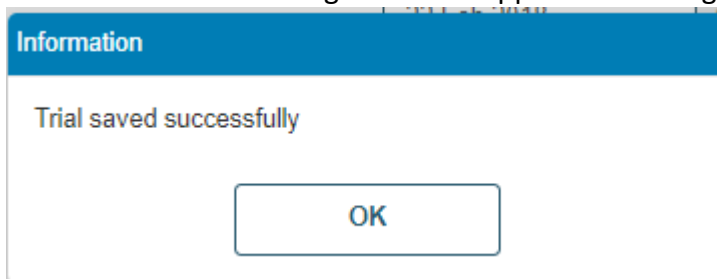
--Select Recruitment Status--

Publication URL

Publication URL

Save Trial

- 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

| | |
|----------------------|---------|
| Trial Details | Done |
| Secondary IDs | Pending |
| Study Design | Pending |
| Interventions | Pending |
| Eligibility Criteria | Pending |
| Outcomes | Pending |
| Recruitment Centre | Pending |
| Ethics Approval | Pending |
| Funding Sources | Pending |
| Sponsors | Pending |

Is Secondary Id applicable for this trial? *

Yes

No

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

Secondary Id

Is Secondary Id applicable for this trial? *

Yes

No

Secondary ID: If applicable please enter any additional identifying numbers assigned by other issuing authorities. For example Sponsor-issued trial/protocol number, unique id numbers issued by other trial registers, ID's issued by regulatory authorities or ethics committees.

Secondary IDs

Secondary ID

Issuing Authority/ Trial register *

Issuing Authority

Save Cancel

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

Information

Secondary ID saved successfully.

OK

- 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.

| Secondary ID | Authority | | |
|--------------|-----------|----------------------|------------------------|
| None | None | Edit | Delete |

[Add More](#) To add more Trial ID's

Edit the record Delete the record

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:

Study Design

Intervention Assignment *

- Crossover: all participants receive all interventions in different sequence during study
- Factorial: participants randomly allocated to either no, one, some or all interventions simultaneously
- Parallel: different groups receive different interventions at same time during study

Allocation to intervention *

- Non-randomised
- Randomised

Describe how the allocation sequence/code was concealed from the person allocating the participants to the intervention arms *

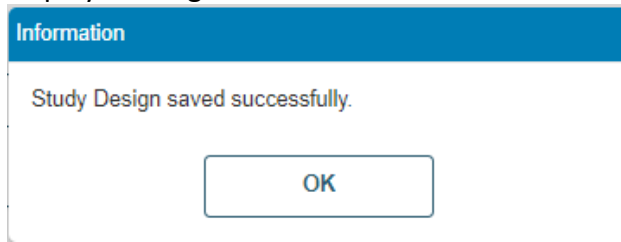
--Select how allocation sequence/code was concealed

Masking *

--Select masking type--

[Save](#)

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



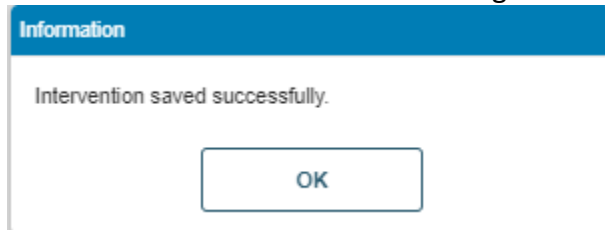
- Once user clicks “Ok” in the above screenshot, the system will direct the user to the next section “Interventions”.

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.*

The screenshot shows a web application interface for 'Interventions'. On the left is a sidebar with a list of menu items: Trial Details (Done), Secondary IDs (Done), Study Design (Done), Interventions (Pending), Eligibility Criteria (Pending), Outcomes (Pending), Recruitment Centre (Pending), Ethics Approval (Pending), Funding Sources (Pending), Sponsors (Pending), Collaborators (Pending), Contact People (Pending), Reporting (Pending), and a 'Submit Trial For Review' button. The main content area is titled 'Interventions' and contains a red hint: 'Hint! Please describe the intervention for each arm in separate entries below. Click on "Save" after completing the details of each intervention.' Below the hint are several form fields: 'Intervention type *' (a dropdown menu), 'Intervention name *' (a text input), 'Dose (How much or how often) *' (a text input), 'Duration (for how long) *' (a text input), 'Intervention description *' (a large text area), 'Group Size *' (a text input), and 'Nature of control *' (a dropdown menu). At the bottom of the form are two buttons: 'Save' and 'Cancel'.

- 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:

Interventions

| Intervention Name | Description | Intervention Type | Dose | Duration | Group Size | Control Nature | | |
|-------------------|-------------|-------------------|------|----------|------------|----------------|------|--------|
| Testing | Testing | Control Group | 12 | 12 | 12 | Historical | Edit | Delete |

Add More

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

Interventions

| Intervention Name | Description | Intervention Type | Dose | Duration | Group Size | Control Nature | | |
|-------------------|-------------|-------------------|------|----------|------------|----------------|------|--------|
| Testing | Testing | Control Group | 12 | 12 | 12 | Historical | Edit | Delete |

Add More

Edit the record

Delete the record

Add more records

5.5 Eligibility Criteria

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

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

List Inclusion criteria *

Hint: Enter each criteria on a new line.

List Exclusion criteria *

Hint: Enter each criteria on a new line.

Age group *

- New born: 0 Day-1 Month
- Infant: 0 Month-23 Month
- 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

Sex *

--Select Gender--

Save

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

Information

Eligibility Criteria saved successfully.

OK

- 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*

Outcomes

Hint: Please describe ALL primary and secondary outcomes being investigated in the trial. Click on "Save" after entering the details of each outcome.

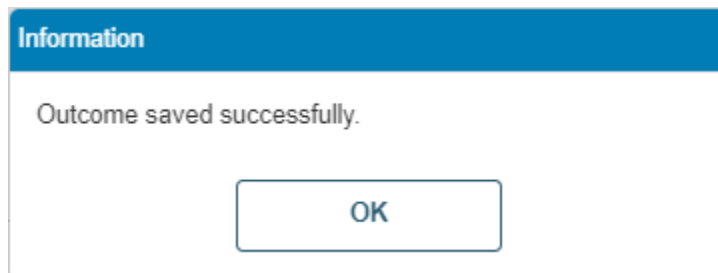
Outcome type *
--Select outcome type--

Outcome *
Outcome

Time point(s) at which outcome measured: *
Time point(s) at which outcome measured

Save Cancel

- 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:

Outcomes

| Outcome Type | Time Point | Outcome | | |
|-------------------|-------------------|---------|----------------------|------------------------|
| Primary Outcome | 12 years from now | Testing | Edit | Delete |
| Secondary Outcome | 12 years | Testing | Edit | Delete |

[Add More](#)

5.7 Recruitment Centre

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

Home / My Trials / Trial

Recruitment Centre

| | | | |
|---|---------|------------------------------|---|
| Trial Details | Done | Name of recruitment centre * | <input type="text" value="Name of Recruitment centre"/> |
| Secondary IDs | Done | Street address * | <input type="text" value="Street address"/> |
| Study Design | Done | City * | <input type="text" value="City"/> |
| Interventions | Done | Postal Code * | <input type="text" value="Postal code"/> |
| Eligibility Criteria | Done | Country * | <input type="text" value="--Select Country--"/> |
| Outcomes | Done | | |
| Recruitment Centre | Pending | | |
| Ethics Approval | Pending | | |
| Funding Sources | Pending | | |
| Sponsors | Pending | | |
| Collaborators | Pending | | |
| Contact People | Pending | | |
| Reporting | Pending | | |
| Submit Trial For Review | | | |

[Save](#) [Cancel](#)

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

Information

Recruitment Centre saved successfully.

OK

- 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.

Recruitment Centre

| Centre Name | Street Address | City | Country | Postal Code | | |
|-------------|----------------|--------------|--------------|-------------|------|--------|
| Testing | xyz street | Johannesburg | South Africa | 2198 | Edit | Delete |

Edit the record

Delete the record

Add More

Add More

5.8 Ethics Approval

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

Ethics Approval

| | |
|------------------------|----------------|
| Trial Details | Done |
| Secondary IDs | Done |
| Study Design | Done |
| Interventions | Done |
| Eligibility Criteria | Done |
| Outcomes | Done |
| Recruitment Centre | Done |
| Ethics Approval | Pending |
| Funding Sources | Pending |
| Sponsors | Pending |
| Collaborators | Pending |
| Contact People | Pending |
| Reporting | Pending |

[Submit Trial For Review](#)

Has the study received ethics committee approval? *

Yes
 No

Name of ethics committee *

Street address *

Phone no *

E-mail address *

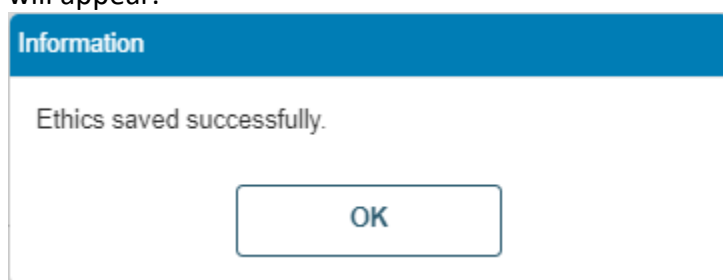
City *

Postal Code *

Country *

Upload ethics document No file chosen
Only .pdf file allowed.

- 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:

Ethics Approval

| Committee | Approval D. | Submission | Street Addr. | City | Postal Code | Country | Phone | Email | View File | | |
|-----------|-------------|------------|--------------|--------------|-------------|--------------|--------------|---------------|-----------|------|--------|
| AIMS | 26 Jan 2018 | | Testing | Johannesb... | 2198 | South Africa | 002783791... | bnkeerthi@... | View | Edit | Delete |

View the Ethics Document
Edit the record
Delete the

To add more records

[Add More](#)

5.9 Funding Sources

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

Funding Sources

| | |
|----------------------|---------|
| Trial Details | Done |
| Secondary IDs | Done |
| Study Design | Done |
| Interventions | Done |
| Eligibility Criteria | Done |
| Outcomes | Done |
| Recruitment Centre | Done |
| Ethics Approval | Done |
| Funding Sources | Pending |

Funding received? *

Yes
 No

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

| | |
|-------------------------|---------|
| 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 | Pending |
| Collaborators | Pending |
| Contact People | Pending |
| Reporting | Pending |
| Submit Trial For Review | |

Funding received? *

Yes
 No

Name of Source *

Funding source type

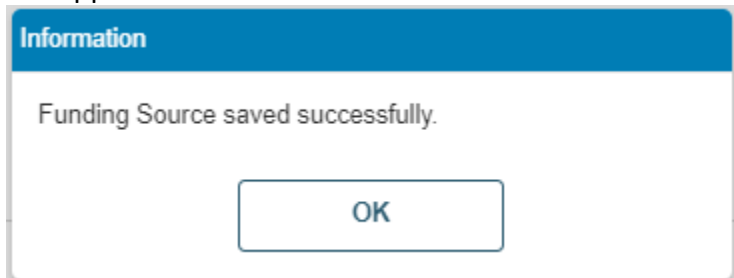
Street address *

City *

Postal Code *

Country *

- 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:

Funding Sources

| Source Name | Street Address | City | Country | Source Type | Other | Postal Code | | |
|---|----------------|--------------|--------------|----------------|-------|-------------|-------------------------------------|---------------------------------------|
| Aims | xyz street | Johannesburg | South Africa | Government ... | | 2197 | <input type="button" value="Edit"/> | <input type="button" value="Delete"/> |
| <input type="button" value="Add More"/> | | | | | | | | |

Edit the record

Delete the record

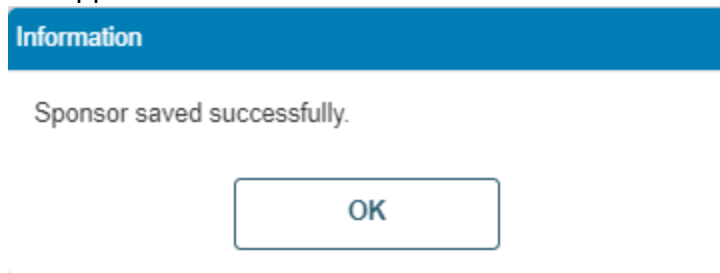
To add more records

5.10 Sponsors

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

The screenshot shows a web application interface for adding a sponsor. On the left is a sidebar menu with the following items: 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 (Pending), Collaborators (Pending), Contact People (Pending), Reporting (Pending), and a 'Submit Trial For Review' button. The main content area is titled 'Sponsors' and contains the following form fields: Sponsor Level (dropdown menu with '--Select sponsor level--'), Name (text input with 'Name of sponsor'), Street address (text input with 'Street address'), City (text input with 'City'), Postal Code (text input with 'Postal code'), Country (dropdown menu with '--Select Country--'), and Nature of sponsor (dropdown menu with '--Select Sponsor nature--'). At the bottom of the form are 'Save' and 'Cancel' buttons.

- 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:

Sponsors

| Name | Street Address | City | Country | Sponsor Type | Other | Sponsor Level | Postal Code | | |
|------|----------------|--------------|--------------|--------------|-------|-----------------|-------------|----------------------|------------------------|
| AIMS | xyz street | Johannesburg | South Africa | Individual | | Primary Sponsor | 2198 | Edit | Delete |

Edit the record
Delete the record

To add more records

[Add More](#)

5.11 Collaborators

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

| | |
|----------------------|----------------|
| 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 | Pending |
| Contact People | Pending |
| Reporting | Pending |

[Submit Trial For Review](#)

Collaborators

Name *

Street address *

City *

Postal Code *

Country *

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

Information

Collaborator saved successfully.

OK

- 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:

Collaborators

| Name | Street Address | City | Country | Postal Code | | |
|---------|----------------|-----------|--------------|-------------|------|--------|
| Testing | xyz street | hyderabad | South Africa | 2198 | Edit | Delete |

Click here to add more

Edit the record

Delete the record

Add More

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)

Contact people

| | |
|--------------------------------|---------|
| 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 | Pending |
| Reporting | Pending |
| Submit Trial For Review | |

*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 enquiries)*

Role *

First Name *

Last Name *

Title *

Email *

Additional email

Phone *

Street address *

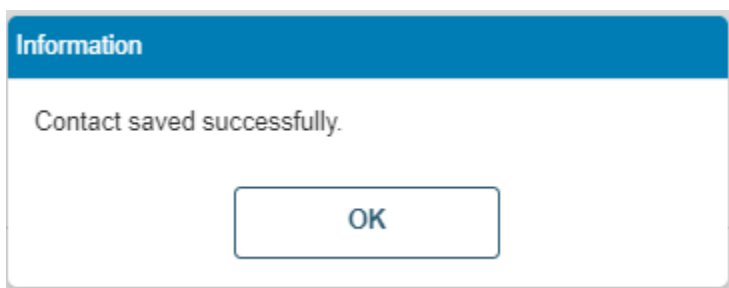
City *

Postal Code

Country *

Position/Affiliation *

- 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 |

To add more records

[Add More](#)

Edit the record

Delete the record

5.13 Reporting

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

| | |
|----------------------|---------|
| 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 | Pending |

Results Available

Yes

No

Submit Trial For Review

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

Reporting

| | |
|----------------------|---------|
| 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 | Pending |

Results Available

Yes

No

Date of Study Completion *

Date of Study Completion

Individual Participant Data (IPD) Sharing Statement

Plan to Share IPD(including data dictionaries) *

Yes

No

Undecided

IPD Description *

IPD Description

Additional Document Types *

Study Protocol

Statistical Analysis Plan

Informed Consent Form

Clinical Study Report

Analytic Code

Submit Trial For Review

IPD-Sharing Time Frame *

Key Access Criteria *

URL *

Results

Definition: This data element contains a URL hyperlink that links to the results (as a pdf or as a journal publication), a brief summary and the date of the first journal publication of results. It indicates that summary information about the results of a clinical study registered is available.

Date of posting results: The date when the results were posted in the registry or in a publication.

Results Summary *

Date of posting of results summaries *

Date of the first journal publication of results *

URL hyperlink(s) related to results and publications *

Baseline Characteristics

Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age and sex, and study-specific measures.

Baseline Characteristics *

Participant Flow

Information to document the progress and numbers of research participants through each stage of a study in a flow diagram or tabular format.

Participant Flow *

Upload Participant Flow

No file chosen
Only .pdf file allowed.

Adverse Events

An unfavourable change in the health of a participant, including abnormal laboratory findings, and all serious adverse events and deaths that happen during a clinical study or within a certain time period after the study has ended. This change may or may not be caused by the intervention being studied.

Adverse Events *

Outcome measures

A table of data for each primary and secondary outcome measure and their respective measurement of precision (eg a 95% confidence interval) by arm (that is, initial assignment of participants to arms or groups) or comparison group (that is, analysis groups), including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any.

Outcome Measures Description *

Outcome Measure Upload *

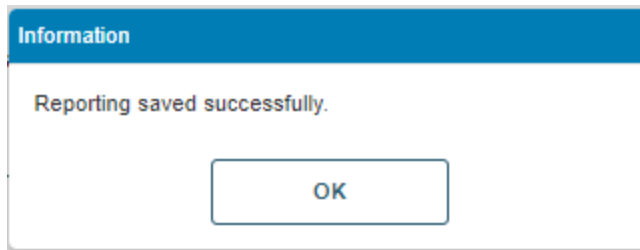
No file chosen
Only .pdf file allowed.

Link to Protocol

A URL hyperlink to the protocol of the trial with version and date (preferably in English).

Link to Protocol *

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

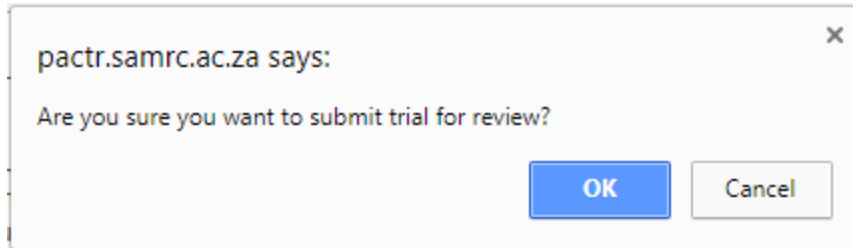


5.14 Submission

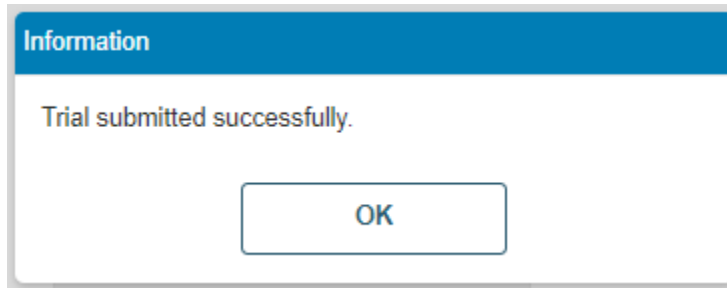
- Once user completes all the sections of Trial as shown below. User should be able to submit the trial by clicking the “Submit Trial for Review “as shown in the highlighted.



- 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.

Manage Trials

| Public Title | Recruitment Status | Date of registration | Registered By | Status | Trial Number | | |
|--------------|--------------------|----------------------|---------------|-----------|--------------|------|--------|
| | Completed | 24 Jan 2018 | | Submitted | | View | Viewer |
| | | | | | | | |
| | | | | | | | |

Annotations: A red box highlights the "Submitted" status. A red callout bubble points to the "View" button with the text "To view the Trial Sections". Another red callout bubble points to the "Viewer" button with the text "View or Print the Trial".

6. Manage Trials

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

Manage Trials

| | Public Title | Recruitment Status | Date of registration | Registered By | Status | Trial Number | | |
|---|--------------|----------------------------|----------------------|---------------|-----------------------------|---------------------|------|--------|
| ✓ | | Closed to recruitment,f... | 31 Jan 2018 | "Mrs. ... | In progress | | View | Viewer |
| ✓ | | Not yet recruiting | 31 Jan 2018 | Mrs. ... | Incomplete - The data ... | | Edit | Viewer |
| ✓ | | Closed to recruitment,f... | 30 Jan 2018 | Mrs. ... | Registered in accordan... | PACTR20181418487568 | Edit | Viewer |
| ✓ | | Completed | 24 Jan 2018 | Mrs. ... | Denied - Trial does not ... | | View | Viewer |

- 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

| | |
|---|----------------------|
| Public Title * | Reason for Change |
| <input type="text" value="testing"/> | <input type="text"/> |
| Official Scientific Title * | Reason for Change |
| <input type="text" value="testing"/> | <input type="text"/> |
| Brief summary describing the background and objectives of trial * | Reason for Change |
| <input type="text" value="testing"/> | <input type="text"/> |
| What type of trial design is being implemented? * | Reason for Change |
| <input type="text" value="CCT"/> | <input type="text"/> |

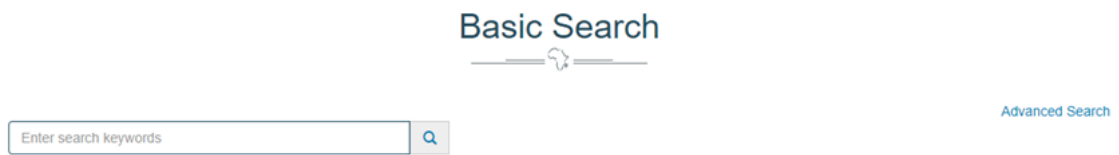
- If the Trial status is “Incomplete-The data on this application is incomplete” user should be able to edit and resubmit the trial for the review as shown below:

| | |
|--------------------------------|------|
| 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

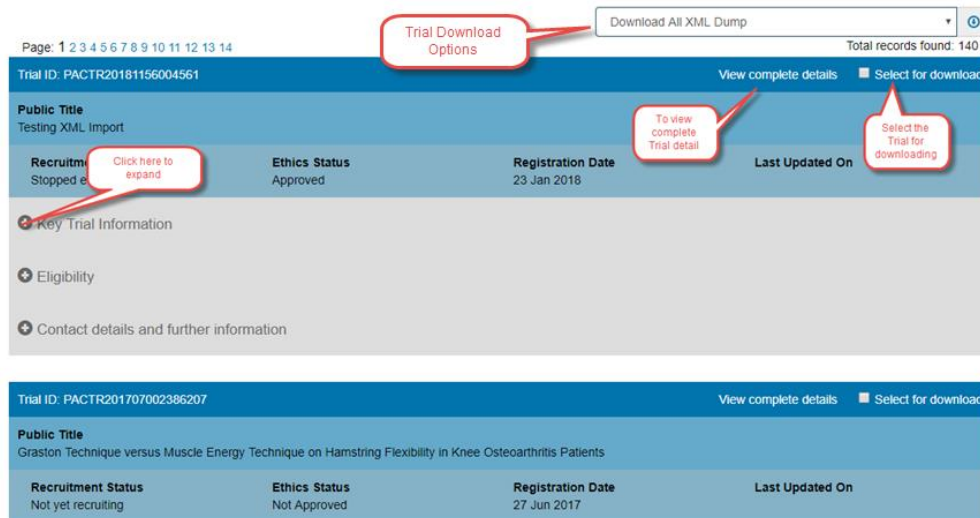
- User goes to Search trials menu, lands on the Basic Search page as shown below:



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

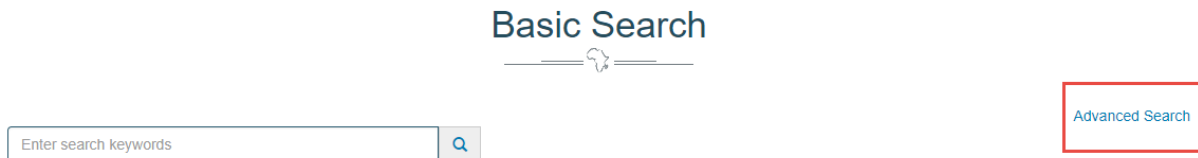


- The below screenshot will show the search results and various option highlighted.

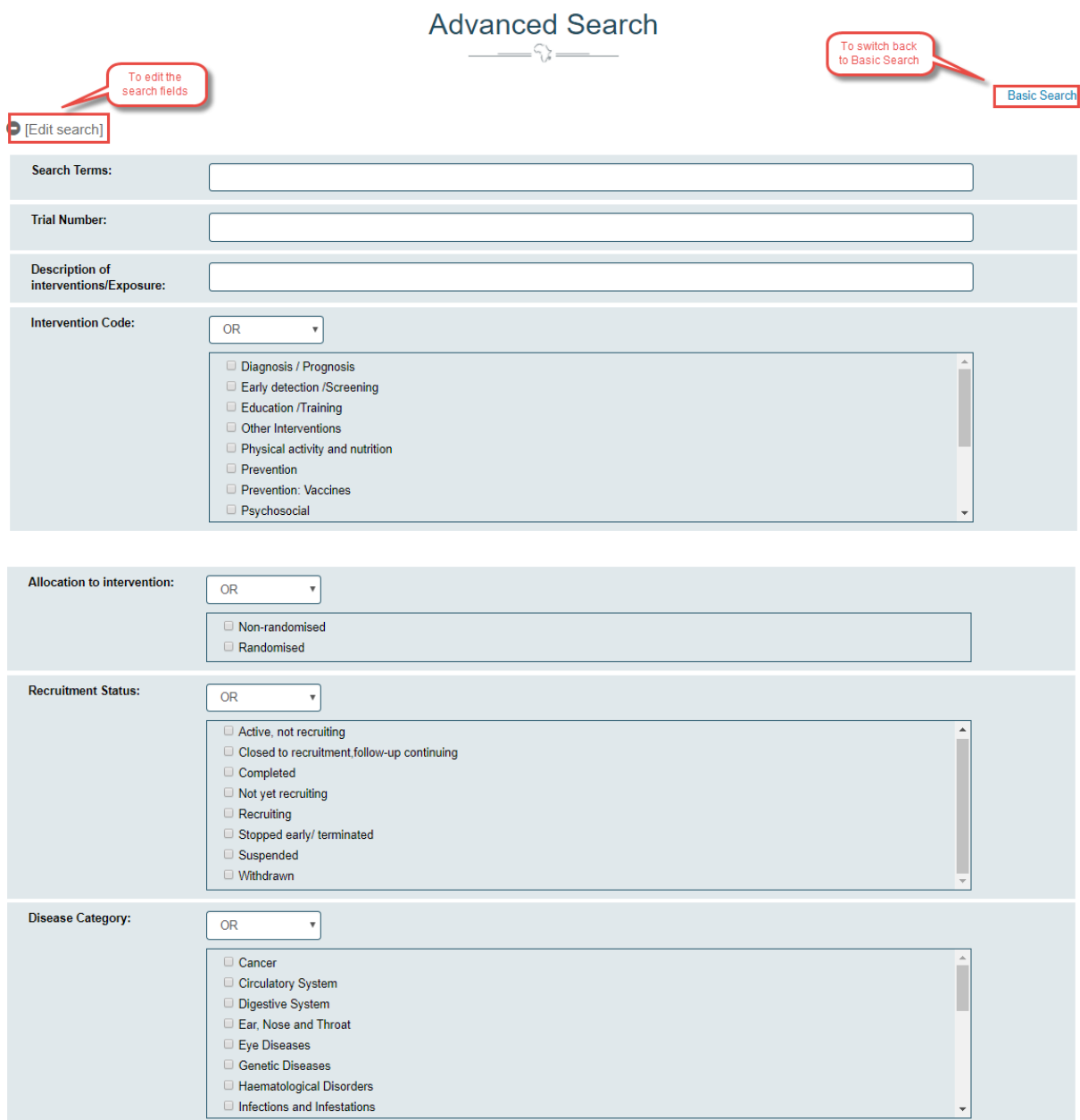


7.2 Advanced Search

- 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:
 Both
 Female
 Male

Age Group:
 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:
 Not Approved
 Approved

Registration Date:

Trial Start Date:

Countries of Recruitment:
 United States of America
 Canada
 Afghanistan
 Albania
 Algeria
 American Samoa
 Andorra
 Angola

Nature of Sponsor:
 Charities/Societies/Foundation
 Commercial Sector/Industry
 Funding Agency
 Hospital
 Individual
 Other
 Other Collaborative Groups
 University

Countries of Recruitment:
 United States of America
 Canada
 Afghanistan
 Albania
 Algeria
 American Samoa
 Andorra
 Angola

Nature of Sponsor:
 Charities/Societies/Foundation
 Commercial Sector/Industry
 Funding Agency
 Hospital
 Individual
 Other
 Other Collaborative Groups
 University

Name of Principal Investigator:

Phase:

Not Applicable
 Phase-0
 Phase-1
 Phase-2
 Phase-3
 Phase-4

- 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.

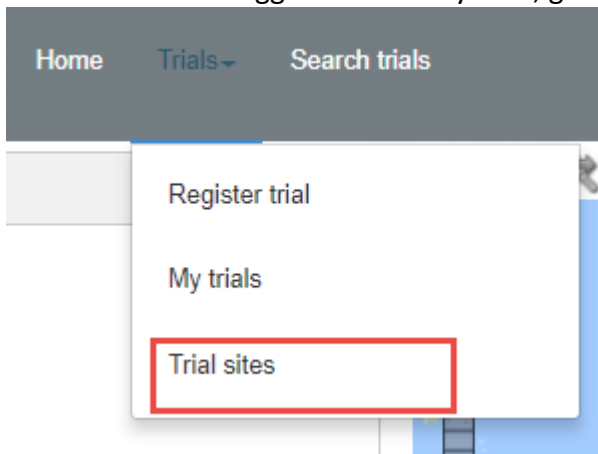
Page: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 Download All XML Dump Total records found: 140

| Trial ID: PACTR20181156004561 | View complete details | | | Select for download |
|---|----------------------------------|---|------------------------|---------------------|
| Public Title Testing XML Import | | | | |
| Recruitment Status Stopped | Ethics Status Approved | Registration Date 23 Jan 2018 | Last Updated On | |
| <div style="display: flex; justify-content: space-between;"> Click here to expand To view complete Trial detail Select the Trial for downloading </div> <p> <input checked="" type="checkbox"/> Key Trial Information <input type="checkbox"/> Eligibility <input type="checkbox"/> Contact details and further information </p> | | | | |

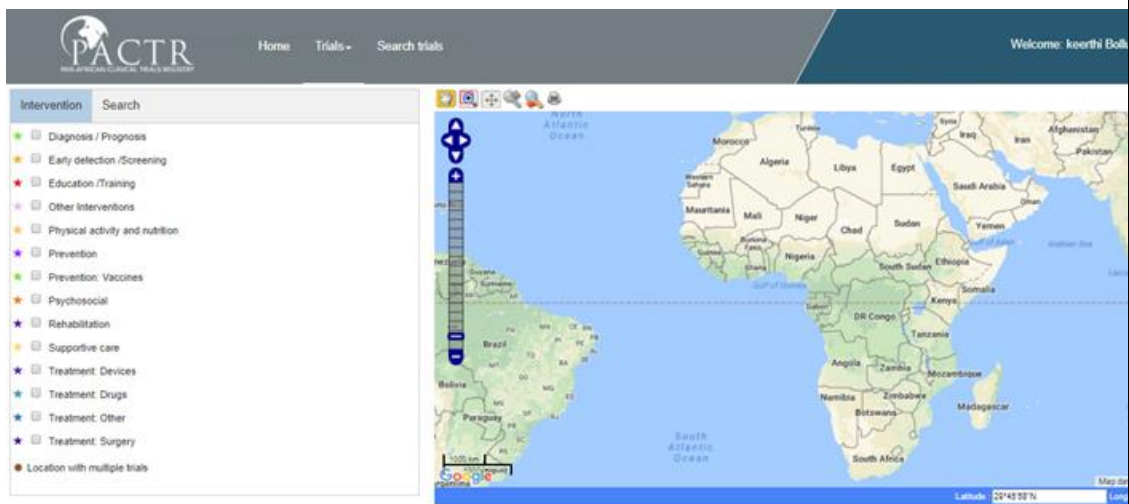
| Trial ID: PACTR201707002386207 | View complete details | | | Select for download |
|--|--------------------------------------|---|------------------------|---------------------|
| Public Title Graston Technique versus Muscle Energy Technique on Hamstring Flexibility in Knee Osteoarthritis Patients | | | | |
| Recruitment Status Not yet recruiting | Ethics Status Not Approved | Registration Date 27 Jun 2017 | Last Updated On | |

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.

| Intervention | Search |
|--|---------------------------------|
|  <input type="checkbox"/> | Diagnosis / Prognosis |
|  <input type="checkbox"/> | Early detection /Screening |
|  <input type="checkbox"/> | Education /Training |
|  <input type="checkbox"/> | Other Interventions |
|  <input type="checkbox"/> | Physical activity and nutrition |
|  <input type="checkbox"/> | Prevention |
|  <input type="checkbox"/> | Prevention: Vaccines |
|  <input type="checkbox"/> | Psychosocial |
|  <input type="checkbox"/> | Rehabilitation |
|  <input type="checkbox"/> | Supportive care |
|  <input type="checkbox"/> | Treatment: Devices |
|  <input type="checkbox"/> | Treatment: Drugs |
|  <input type="checkbox"/> | Treatment: Other |
|  <input type="checkbox"/> | Treatment: Surgery |
|  | Location with multiple trials |

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

| Intervention | Search |
|---------------------------------------|---------------------------------|
| ★ <input checked="" type="checkbox"/> | Diagnosis / Prognosis |
| ★ <input type="checkbox"/> | Early detection /Screening |
| ★ <input type="checkbox"/> | Education /Training |
| ★ <input type="checkbox"/> | Other Interventions |
| ★ <input checked="" type="checkbox"/> | Physical activity and nutrition |
| ★ <input type="checkbox"/> | Prevention |
| ★ <input checked="" type="checkbox"/> | Prevention: Vaccines |
| ★ <input checked="" type="checkbox"/> | Psychosocial |
| ★ <input checked="" type="checkbox"/> | Rehabilitation |
| ★ <input type="checkbox"/> | Supportive care |
| ★ <input type="checkbox"/> | Treatment: Devices |
| ★ <input type="checkbox"/> | Treatment: Drugs |
| ★ <input type="checkbox"/> | Treatment: Other |
| ★ <input type="checkbox"/> | Treatment: Surgery |
| ● | Location with multiple trials |



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

| Intervention | Search |
|---|----------------------|
| Title: | <input type="text"/> |
| Type: | All ▼ |
| Disease: | All ▼ |
| Country: | All ▼ |
| Recruitment Type: | All ▼ |
| City: | All ▼ |
| Status: | All ▼ |
| <input type="button" value="Q Search"/> | |

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

| Intervention | Search |
|--|------------------------------------|
| Title: | <input type="text" value="Test"/> |
| Type: | <input type="text" value="All"/> ▼ |
| Disease: | <input type="text" value="All"/> ▼ |
| Country: | <input type="text" value="All"/> ▼ |
| Recruitment Type: | <input type="text" value="All"/> ▼ |
| City: | <input type="text" value="All"/> ▼ |
| Status: | <input type="text" value="All"/> ▼ |
| <input type="button" value="Search"/> | |
| <p>Result (Total Records : 72)</p> <ul style="list-style-type: none"> ● "Bridging the gap". Evaluating new rapid diagnostic tests for Mycobacteriu <ul style="list-style-type: none"> — 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: 2016/12/12 12:00:00 AM

Actual Start Date: 2016/12/12 12:00:00 AM

Sample Size:

Show the complete Trial Information

View full profile Close