



PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

**MCAZ Electronic online Clinical Trial Application (e-CTR)
Registry System for use by applicants and researchers –
EXTERNAL USER MANUAL**



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MCAZ Electronic online Clinical Trial Application (e-CTR) Registry System for use by applicants and researchers – EXTERNAL USER MANUAL

This Manual has been approved for use by the Director- General.

Signature: _____

G.N. Mahlangu (Ms)

Date: _____

9/10/2020

1.0 APPLICATION:

This is revision 0_June 2020 of the MCAZ e-CTR (Clinical Trial Application & Registry) Online System-External User Manual for use by applicants & researchers when they submit a clinical trial application for authorisation including subsequent protocol amendments, progress reports etc. For the safety reporting of clinical trials please use the on-line e-PV system External User Manual Revision 0_June 2020 guide.

2.0 PURPOSE:

The guide will assist applicants and researchers to submit an online clinical trial application in accordance with the Medicines and Allied Substances Control Act Chapter 15:03 and regulations, and applicable current Good Clinical Practice Guidelines, Revision_1.0 June 2020, and Clinical Trial Application Guide Revision_1.0 June 2020, and Pharmacy Guideline for Investigational Medical Products Revision 1.0 June 2020. The clinical trials registry platform is simply a tracking tool of the approved clinical trial applications in terms of MASCA chapter 15:03 in line with the WHO and Declaration of Helsinki guidelines for Good Clinical Practice (GCP) monitoring and clinical trial registry platform.

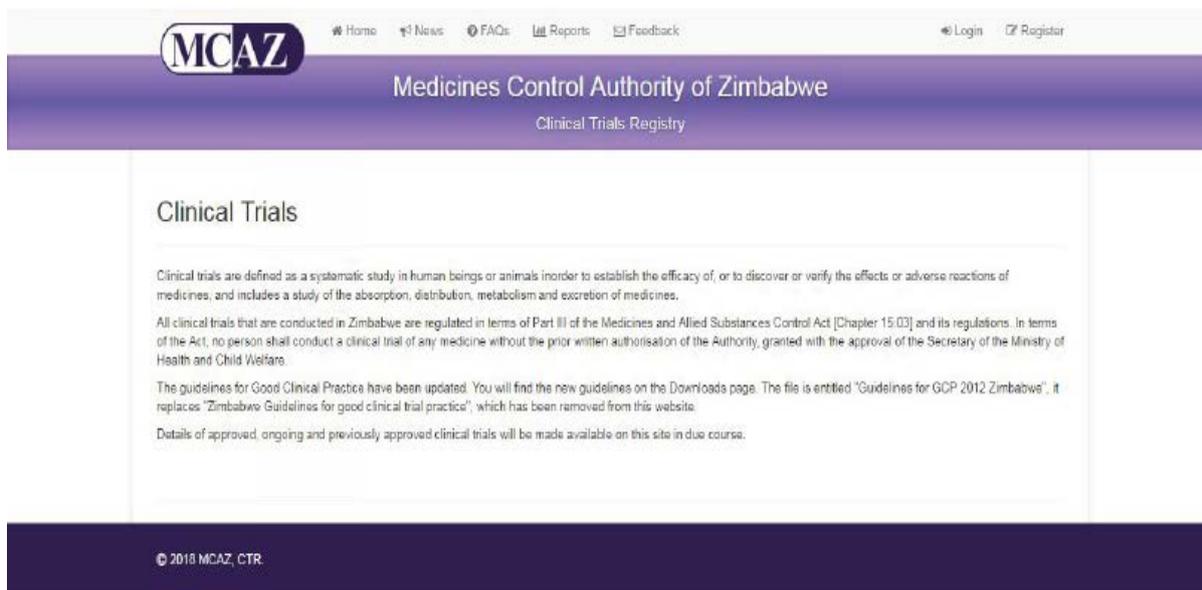
3.0 BACKGROUND AND INTRODUCTION:

Applicants are required to submit their applications via the online portal found at <https://e-ctr.mcaz.co.zw/>. After approval of the clinical trial application, the principal investigator is required to submit to MCAZ all AEs, AEFIs and SAEs safety reporting via the online portal found at <https://e-pv.mcaz.co.zw/>

For further information refer to the MASCA [Chapter 15:03], MASCA Statutory Instrument SI 150, MASCA Fee schedule, Good Clinical Trial Practice (GCP) Guidelines for Zimbabwe, and Research Pharmacy Guidelines available on MCAZ website www.mcaz.co.zw.

4.0 GETTING STARTED:

When accessing the Clinical Trial Registry (CTR) the first page the user lands on is the home page. This gives a brief description of the CTR, the registration and login buttons can be found at the top left of the page.



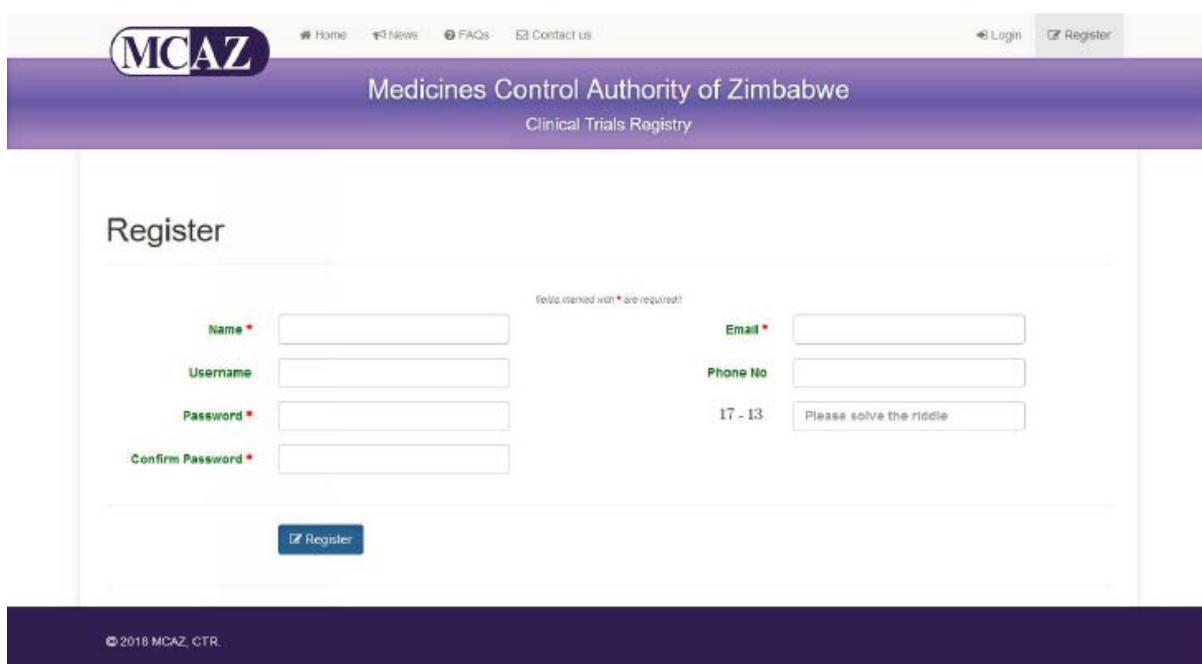
Home Page CTR

4.1 Registration & Login

4.1.1 Registration

4.1.1.1 When a user first accesses the system they need to create a new account. This can be done in the following way:

- i. Click on the register button on the top left to access the registration page
- ii. Fill in the mandatory fields marked with the asterisks (*), these fields include
 - Name
 - Password
 - Confirm Password
 - Email
- iii. Click on Register to complete the registration process.



- iv. An email with a link to activate your account will be sent to your email.

4.1.2 Login

Once the registration is done the account is now active and you can proceed to the login page. You can either use your username or email and the password you entered. If the credentials are correct the system will log the user into the system.

Login Page

4.1.3 Forgot Password

1.1.3.1 In the event a user is not able to remember their password they can reset it by using the forgot password link on the login page.

- i. Click the forgot password link on the login page
- ii. This will redirect you to another page where you will be requested to enter your email

1.1.3.2 The email will be checked against the existing emails before a password reset is sent.

5.0 USER ACCOUNT

5.1 On logging into a user account the first screen is the user dashboard. This gives the user the following options:

- 5.1.1 Dashboard - Here a user can create a new application, recent protocols and notifications.
- 5.1.2 My Applications
- 5.1.3 My Messages
- 5.1.4 Fees Schedule
- 5.1.5 Committee Dates
- 5.1.6 My Profile -Edit user information and change password

Medicines Control Authority of Zimbabwe

Clinical Trials Registry

Applicant Menu: [Dashboard](#) [My Applications](#) [My Notifications](#) [Fees Schedule](#) [Committee Dates](#) [My Profile](#)

New Application

Email Address

Create

NOTE! Fields marked with * are mandatory and your application will not be submitted to MCAZ without first completing them.

Notifications will be sent to the email address entered above

Recent Protocols

1. CT47/2018 - Director/General
2. CT46/2018 DirectorAuthorize-DirectorAuthorize
3. CT41/2018 DirectorAuthorize-DirectorAuthorize
4. CT40/2018 DirectorAuthorize-DirectorAuthorizes
5. CT18/2018 Authorize-FinalStage

Page 1 of 2, showing 5 record(s) out of 10 total

< >

Recent Amendments

1. CT18/2018 - FN3/2018 Submitted
2. CT18/2018 - FN2/2018 Submitted
3. CT18/2018 - AMD1/2018 Evaluated

Page 1 of 1, showing 3 record(s) out of 3 total

< >

Notifications

Actions that require your attention

Thank you for submitting the amendment CT18/2018 - FN... more

open X

Thank you for submitting the amendment CT18/2018 - FN... more

open X

Section 75 Request: .applicant_name has sent a sec... more

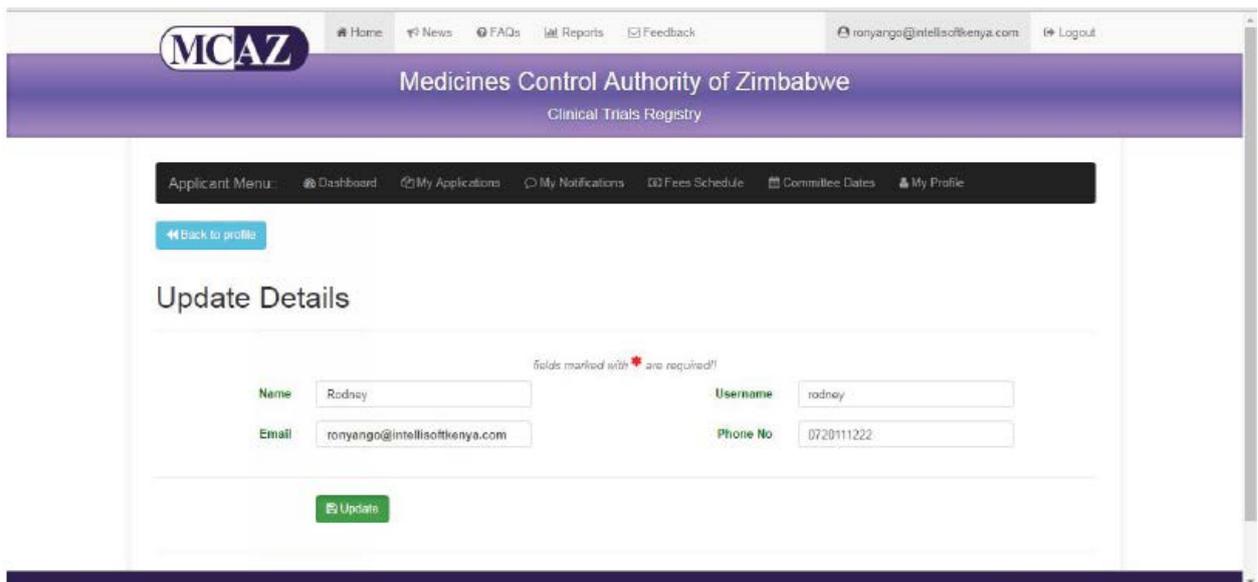
open X

5.2 My Profile

- 5.2.1 Click on my profile on the navigation bar which will redirect to a page that displays the user profile and allows for a password change.
- 5.2.2 To change the password enter the old password, new password and confirm the new password.



5.2.3 To edit the user details, click on edit which will allow you to edit the details, click **update** to save the changes.



5.3 My Applications

A user is able to either create a new application or view previously created applications

5.3.1 Create Application

5.3.1.1 To create a new application click on the create button on the dashboard under new application. This will redirect the user to a page with the application data split into 14 different tabs as listed below.

- i. Abstract
- ii. Investigator
- iii. Sponsor
- iv. Participants
- v. Sites
- vi. Interventions
- vii. Criteria
- viii. Scope
- ix. Design
- x. Ethical Considerations
- xi. Other details
- xii. Checklist
- xiii. MC10 Form
- xiv. Financials

5.3.1.2 The different tabs are guided by the MC10 Form and the 24 minimum requirements of the International Clinical Trials Registry Platform (ICTRP). When all the mandatory details have been entered, and the user clicks on submit to MCAZ, the form will be checked for validation and if there are any errors they will be displayed at the top.

The screenshot shows the MCAZ Clinical Trials Registry application form interface. The header includes the MCAZ logo and navigation links: Home, News, FAQs, Reports, Feedback, and a user profile section with the email ronyango@intellisofkenya.com and a Logout button. The main navigation bar contains: Applicant Menu, Dashboard, My Applications (active), My Notifications, Fees Schedule, Committee Dates, and My Profile. A red error message states: "Report could not be saved. Kindly correct the errors and try again." Below this, a list of errors is shown: "1. Abstract: Scientific Title is required", "1. Abstract: Contact name for scientific queries required", and "1. Abstract: Designation for scientific queries required". The form is divided into 14 tabs: 1. Abstract, 2. Investigator, 3. Sponsor, 4. Participants, 5. Sites, 6. Interventions, 7. Criteria, 8. Scope, 9. Design, 10. Ethical Considerations, 11. Other details, 12. Checklist, 13. MC10 Form, and 14. Financials. The 'Financials' tab is currently selected. A 'Fees Schedule' section prompts the user to upload scanned receipts for required fees, with an 'Add +' button. A table with columns for '#', 'RECEIPT', and 'DESCRIPTION OF CONTENTS' is visible, with one row containing '1' and 'The Alchemest.pdf'. On the right side, there are four buttons: 'Save changes', 'Submit to MCAZ', 'Cancel', and 'Delete'.

5.3.2 Submitted Protocol

5.3.2.1 Once the form is submitted, the options are no longer editable and therefore a user will have to submit an amendment to be able to make changes to the document. When an amendment is made the amendment will appear next to the original content on the form showing which amendment it is. Either 1st, 2nd or any other subsequent amendment. Other than adding an amendment other options will also appear once a form has been submitted to MCAZ, these include:

- i. Finance (for submission of proof of payment of application fee).
- ii. Section 75 (of MASCA Chapter 15:03 for application of importation of investigational medical products).
- iii. Feedback. (Communications, Committee Feedback, Approvals)
- iv. Committee.
- v. Indemnity Forms
- vi. Notifications
- vii. GCP Inspections
- viii. Stages
- ix. Approvals
- x. Final Reports
- xi. Annual Reports

[Home](#)
[News](#)
[FAQs](#)
[Reports](#)
[Feedback](#)
romyango@intellisoftkenya.com
[Logout](#)

MCAZ Medicines Control Authority of Zimbabwe
 Clinical Trials Registry

Applicant Menu: [Dashboard](#) **[My Applications](#)** [My Notifications](#) [Fees Schedule](#) [Committee Dates](#) [My Profile](#)

[New Amendment](#) [Download PDF](#)

CT18/2018

Finance
 Section 75
 Feedback
 Committee
 Notifications
 GCP Inspections
 STAGES
 Final Reports
 Annual Approvals

1. Abstract	2. Investigator	3. Sponsor	4. Participants	5. Sites	6. Interventions	7. Criteria	8. Scope
9. Design	10. Ethical Considerations	11. Other details	12. Checklist	13. MC10 Form	14. Financials		
PUBLIC TITLE/ACRONYM: qwerty Scientific Title: qwerty Contact for Public Queries: Name: qwerty Designation: qwerty Email: qwerty@qwerty.com Phone number: 123-4567896 Postal Address: 125-47 Affiliation: Empty Contact for Scientific Queries: Name: qwerty Designation: qwerty Email: qwerty@qwerty.com Phone number: 123-4567893 Postal Address: qwerty Affiliation: Empty Countries of Recruitment: qwerty Purpose and Reason for Trial: qwerty Trial Identifying Number: qwerty Date Of Protocol: 04-03-2018 Study Product: qwerty <input checked="" type="checkbox"/> Chemical <input type="checkbox"/> Biological <input type="checkbox"/> Medical Device Protocol Version No.: qwerty							

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5.4 My Notifications

On the user account, click on my notifications to see the notification updates for the PI. These inform you on the status of the protocol or amendment similar to the emails.

5.5 Fees schedule

On the user account, click on fees schedule to see the applicable fees for the PI. Locally funded and Non-resident

6.0 KEY RELEVANT DOCUMENTS

- 6.1 Medicines and Allied Substances Control Act (MASCA) [Chapter 15:03] and its Regulations
- 6.2 Guidelines for Good Clinical Trial Practice in Zimbabwe Revision 1.0 June 2020
- 6.3 Application Guidelines for Clinical Trial Authorization in Zimbabwe Revision 0 June 2020 and the following forms required as part of the e-CT application:
 - 6.3.1 MC10 New Clinical Trial Application Form online <https://e-ctr.mcaz.co.zw/>
 - 6.3.2 Checklist For Completeness Of An Application To Conduct A Clinical Trial
 - 6.3.3 Declaration by Applicant
 - 6.3.4 Recommended Format For CV's Of Individuals Participating In Clinical Trial
 - 6.3.5 Joint Declaration By Sponsor And Principal Investigator Concerning Sufficient Funds To Complete Study
 - 6.3.6 Declaration By Principal Investigator For GCP Compliance
 - 6.3.7 Declaration By Co- And Sub-Investigators For GCP Compliance
- 6.4 Statutory Instrument 150 of 1991 and MCAZ current gazetted fee schedule
- 6.5 ICH E6R (2) GCP, ICHE8, ICHE9, ICHE2A to E2F guidelines & other applicable ICH guidelines for pharmaceutical development of a medical product.
- 6.6 Mak, T. K. *et al.* (2020) 'Global regulatory agility during Covid-19 and other health emergencies', *BMJ*. British Medical Journal Publishing Group, 369, p. m1575. doi: 10.1136/bmj.m1575.
- 6.7 WHO Media release: African regulatory agencies, ethics committees to expedite COVID-19 clinical trial reviews accessible on <https://www.afro.who.int/health-topics/immunization/avaref>
- 6.8 AVAREF Guideline for Joint and Assisted Reviews of Clinical Trial Applications for National Regulatory Authorities (NRAs) and Ethics Committees (EC)

7.0 Review of the manual

The manual will be the guiding document for all external users of the MCAZ eCTR system and will be reviewed as and when required due to the changes in regulations, standards and best practices as appropriate.