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

Signature: _____ **Date:** _____

G.N. Mahlangu (Ms)

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.

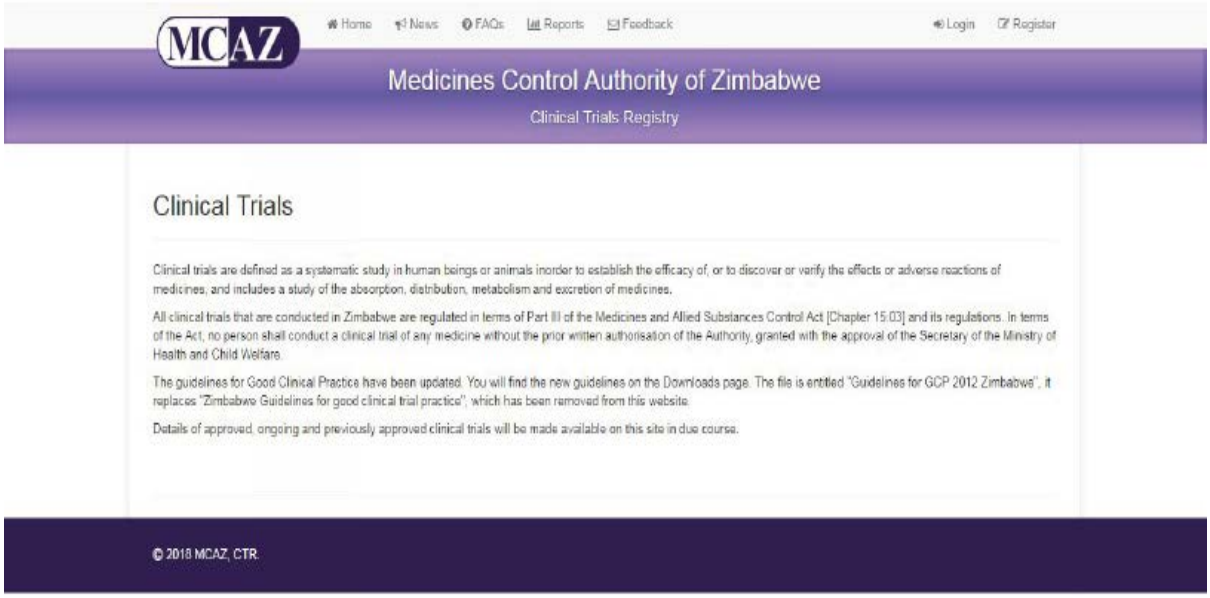
3.0 BACKGROUND AND INTRODUCTION:

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.



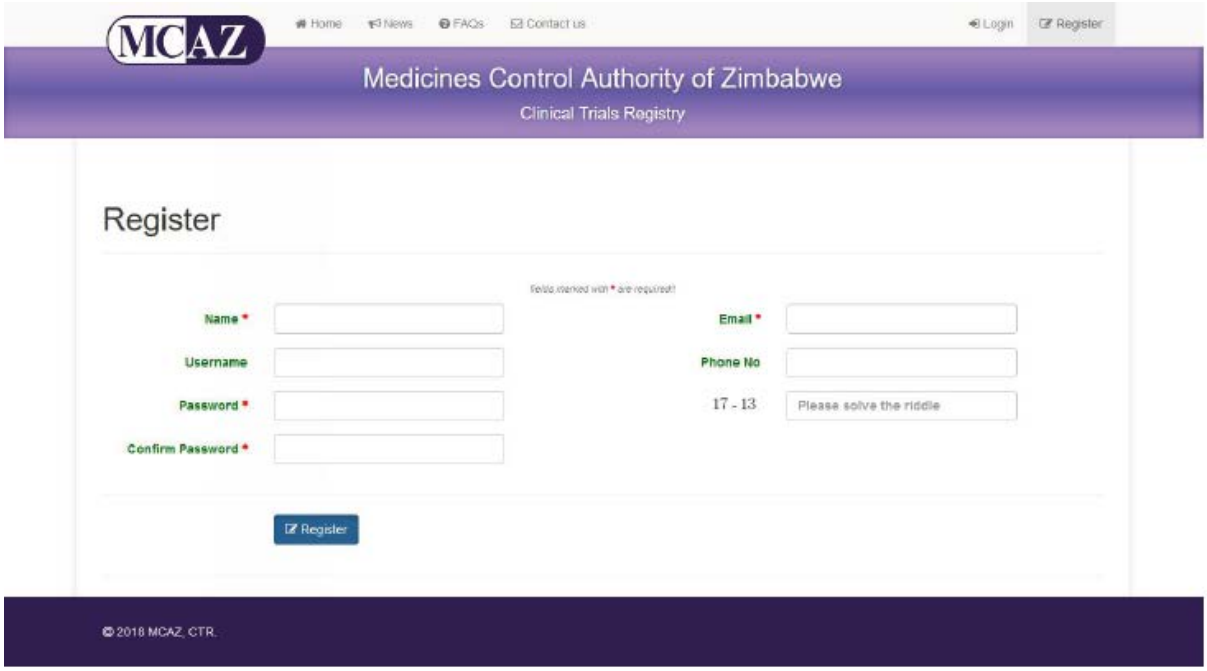
Home Page CTR

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.

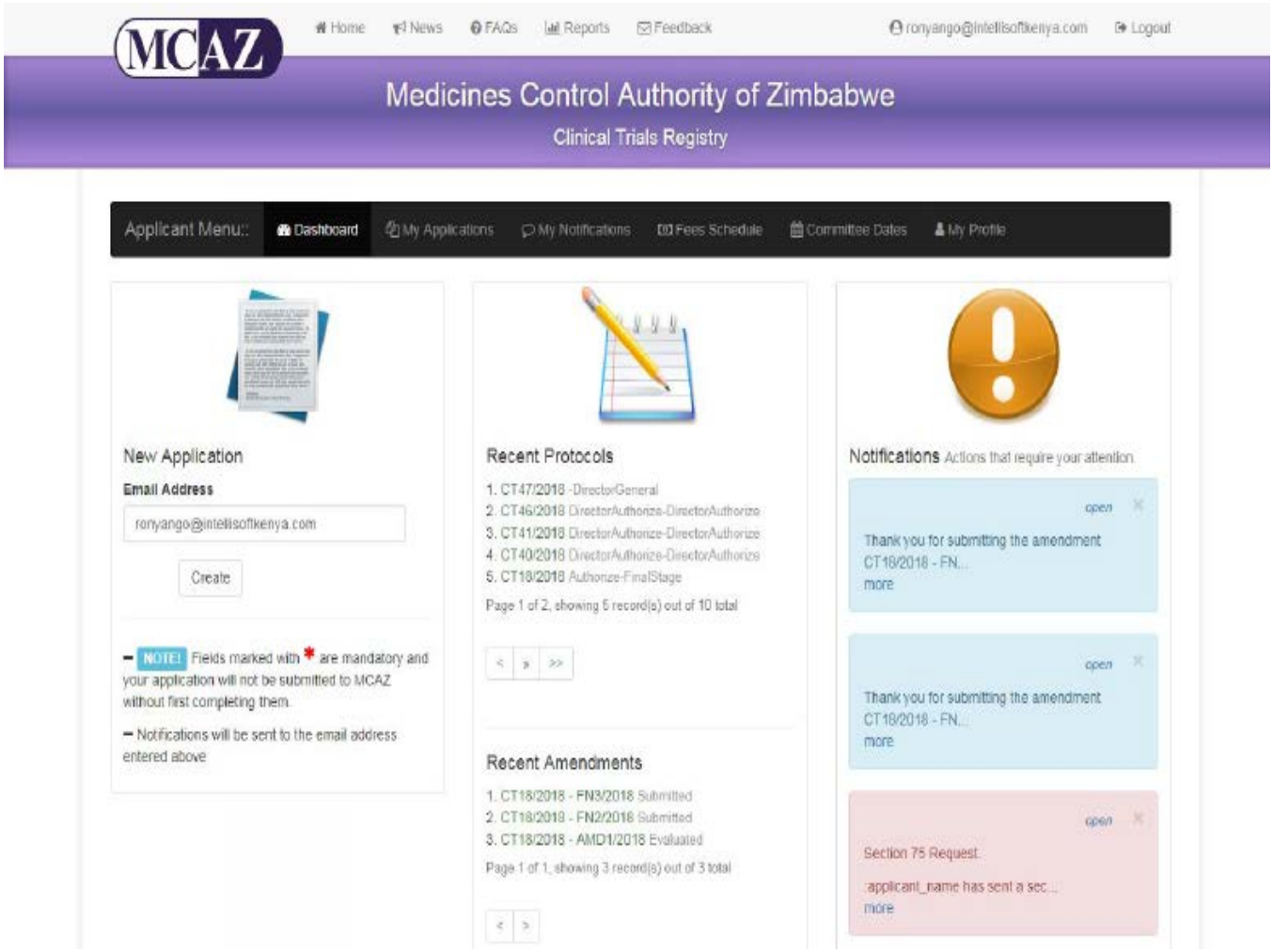
i. Click the forgot password link on the login page
ii. This will redirect you to another page where you will be requested to enter your email

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:

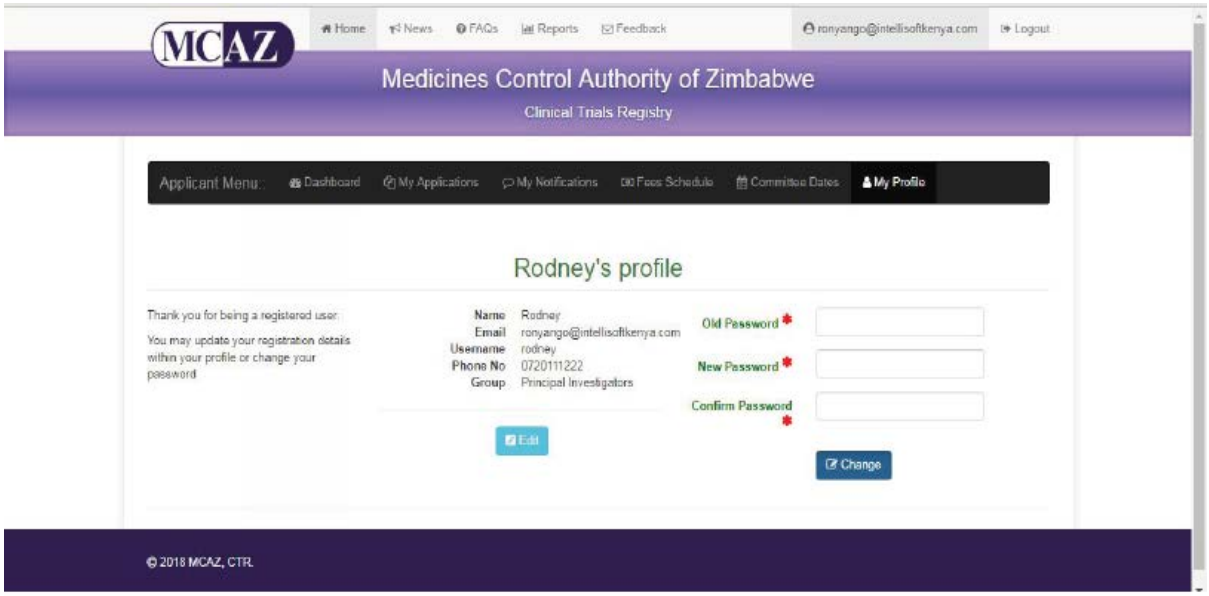
5.1.1 Dashboard - Here a user can create a new application, recent protocols and notifications.
5.1.2 My Applications
5.1.3 My Messages
5.1.4 Fees Schedule
5.1.5 Committee Dates
5.1.6 My Profile -Edit user information and change password



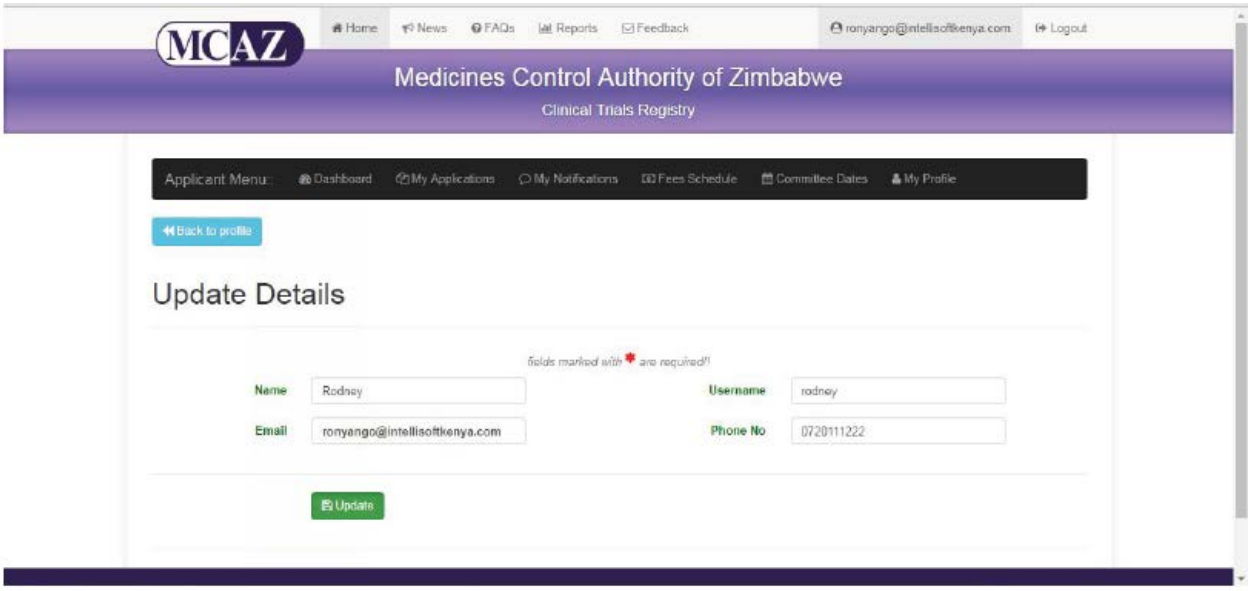
5.2 My Profile

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.

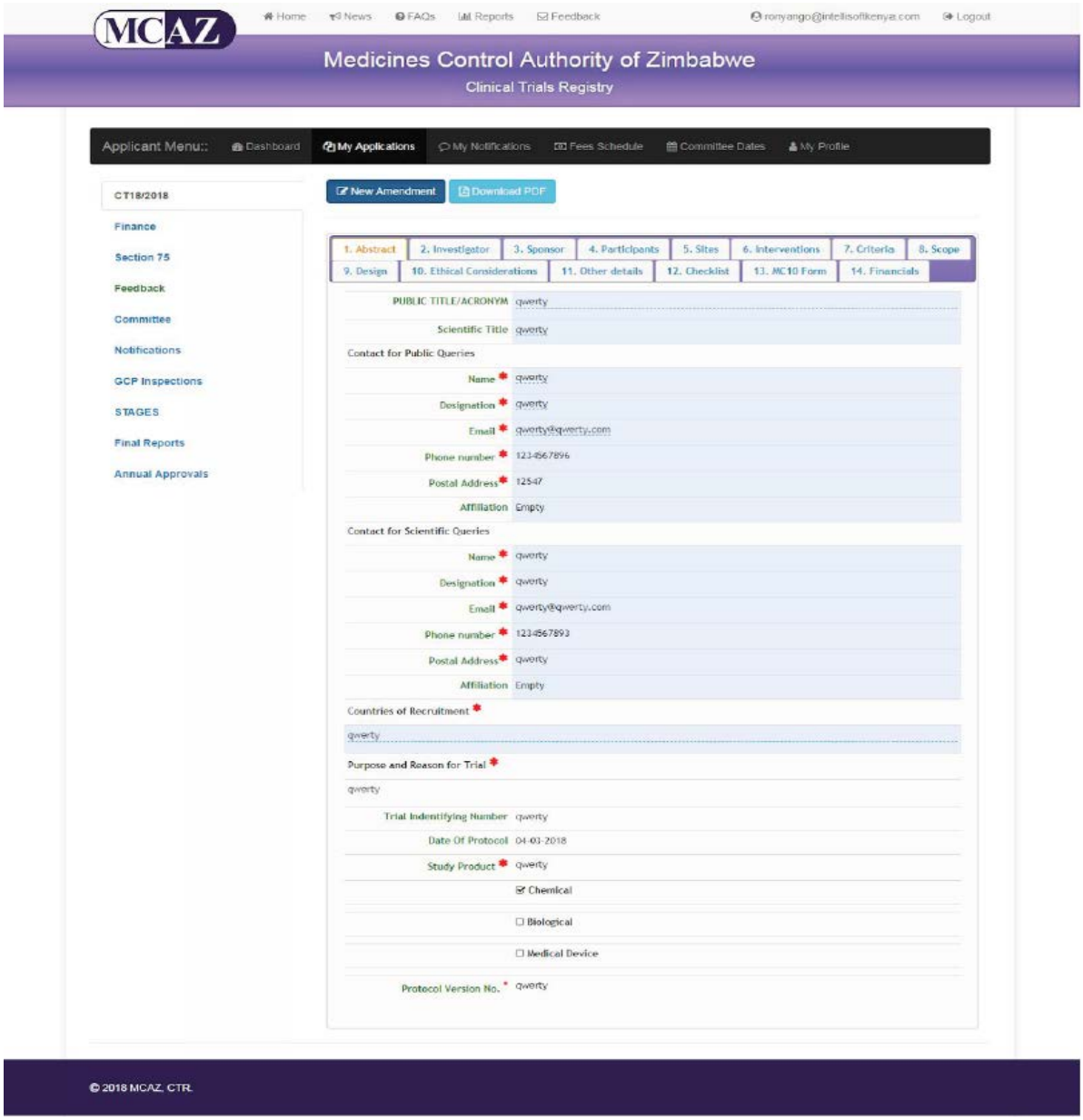
i. Abstract
ii. Investigator
iii. Sponsor
iv. Participants
v. Sites
vi. Interventions
vii. Criteria
viii. Scope
ix. Design
x. Ethical Considerations
xi. Other details
xii. Checklist
xiii. MC10 Form
xiv. Financials

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.

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



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.