

## GCP TRAINING AND EXPEDITED REVIEW OF CLINICAL TRIAL APPLICATIONS DURING COVID-19 PANDEMIC

TO ALL APPLICANTS

The South African Regulatory Authority (SAHPRA) plays a significant role in protecting trial participants from public health threats including the Coronavirus Disease 2019 (COVID-19) pandemic in ensuring that the healthcare professionals conducting clinical trials are qualified and trained to comply with Good Clinical Practice (GCP). Furthermore, SAHPRA is committed to facilitate timely access to health products particularly those required for use in COVID-19 infections.

SAHPRA recognise that the COVID-19 pandemic impacts on social distancing and approach to the conduct of clinical trials. The Authority took note of the high transmission of COVID-19 and some of the affected being the healthcare professionals. In line with the recommendations for social distancing and in order to combat the spread of COVID-19, SAHPRA has amended the requirements for face to face GCP training to allow comprehensive on-line Good Clinical Practice (GCP) training during the COVID-19 pandemic.

With the above recommendations SAHPRA believes this will capacitate the healthcare personnel and enable safety of trial participants, maintain compliance with good clinical practice, and minimising risks to trial integrity during the COVID-19 pandemic.

SAHPRA has recently received queries regarding the procedure for submission of COVID-19 Clinical Trials Applications. The Authority is committed to expedite review of COVID-19 related clinical trial applications with the review timeline between 7-10 working days. The applications should be emailed to [ctcreponses@sahpra.org.za](mailto:ctcreponses@sahpra.org.za) and copy the following email addresses [kedibone.malatji@sahpra.org.za](mailto:kedibone.malatji@sahpra.org.za) and [dominicah.thosago@sahpra.org.za](mailto:dominicah.thosago@sahpra.org.za). The Applicants are advised to also refer to the application to conduct the clinical trial in case of a public health emergency; the guide is available on the SAHPRA website.

Yours faithfully

**Dr B Semete-Makokotlela**  
**CHIEF EXECUTIVE OFFICER**

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