

APPLICATION TO CONDUCT A CLINICAL TRIAL

TO ALL APPLICANTS

The purpose of this document is to notify applicants of the latest submission requirements process in the Clinical Trials Unit (CTU), South African Health Products Regulatory Authority (SAHPRA), in order to improve the internal processes in order to improve turnaround times of applications.

The following are the requirements applicable when submitting clinical trials, amendments, Bioequivalence, additional investigator(s) or change of investigator(s) and additional site applications at SAHPRA reception:

1. Cover letter (letter of application), two hard copies
2. Proof of Payments, two hard copies
3. Two Compact Discs (CDs) containing complete application with all the required documents
4. One USB flash drive containing complete application with all the required documents

The following are the requirements applicable when submitting documents for responses, notifications and any other documents at SAHPRA reception:

1. Cover letter (letter of application), two hard copies
2. Two Compact Discs (CDs) containing all the required documents
3. One USB flash drive containing all the required documents. (applicable if big documents and multiple attachments are included)

Yours faithfully

Dr Boitumelo Semete-Makokotlela

CHIEF EXECUTIVE OFFICER