



22 April 2024

SOUTH AFRICAN GOOD CLINICAL PRACTICE (GCP) TRAINING POST COVID-19 PANDEMIC

To all Applicants:

This communication intends to clarify the expectation for Good Clinical Practice (GCP) training post COVID-19 pandemic and supersedes the communication dated 13 April 2020 regarding online SA GCP training.

According to Section 4.3.3.10 of the SA GCP 2020 V3 guidelines: “Basic GCP training must be done by means of attendance at a face-to-face course and must include specific SA GCP 2020 training. Thereafter, three-yearly refresher GCP training must occur. Refresher GCP training may be done online; however, the course must be relevant to the South African research environment and must include SA GCP 2020 training”.

South African Health Products Regulatory Authority (SAHPRA) and National Health Research Ethics Council (NHREC) acknowledge that due to the advent of virtual meetings via Zoom, Teams, etc., the methods of GCP training should also be adapted to align with local and global practices and trends relating to the conduct of virtual trainings.

In view of the above, virtual methods will be acceptable (via Zoom, Teams, etc.) provided that the training is done properly; it is interactive; active engagement of participants is monitored; with a full-time facilitator (qualified to conduct training) available the entire duration for questions and answers. Both SAHPRA and NHREC support the virtual training for the purpose of increasing capacity building; accessibility; empowerment and inclusivity of the researchers, healthcare



personnel and Research Ethics Committees (RECs); and a reduction of travel and logistic costs for researchers and RECs. To ensure inclusivity and fairness, consideration should be given to the candidates who are unable to attend virtual training, especially those placed in remote areas where internet accessibility remains a challenge. A hybrid model could be considered in this case.

The duration of the training for basic GCP training should be in alignment with the prescribed outcomes or unit standards (approximately 2 days). The training content should be accredited by HPCSA.

The above changes are effective from 01 June 2024, or as soon thereafter as implementation of virtual training is possible, and whilst the SA GCP guidelines are in the process of being updated.

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