SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

INVESTIGATOR WORKLOAD IN CLINICAL TRIALS

This document has been prepared to guide the industry on the expectation of SAHPRA and inform reviewers on the capacity of investigators to safely conduct clinical studies. This guideline represents the SAHPRA current thinking on measures to protect the participants and ensure safe conduct of clinical trials. SAHPRA reserves the right to make amendments in keeping with current knowledge. Guidelines and application forms are available from the office of the SAHPRA CEO and the SAHPRA website.

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1 INTRODUCTION

Clinical research has undergone a beneficial expansion in the past 25 years, but with this growth has come an increase in both the clinical as well as the administrative workload for investigators. This "investigator overload" is, however, potentially counterproductive to the protection of human participants in clinical trials. The value of the Clinical Trial Industry to the South African economy is, however, unquestionable. It is both a source of foreign revenue and employment for the country. Moreover, undertaking clinical trials in South Africa helps to retain and increase valuable clinical research expertise, as well as playing an important role in the teaching of healthcare professionals.

A factor in the current set-up has been ascendance of multicentre, multinational clinical trials run by individual pharmaceutical companies, by clinical research organisations (CROs) and grant funded groups. Furthermore, the practice of allocating a large number of such clinical trials to the same South African sites and Principal investigators (PIs) tends to monopolize resources to these same sites and investigators without promoting diversity, capacity building, and knowledge transfer, and potentially could jeopardize patients' safety due to "investigator overload".

Participation in clinical trials is mainly determined by the initial motivation of the practitioners motivated by affiliation to an academic research group, interest in the research topic, research experience, and other factors such as financial incentives, new knowledge assimilation, teaching and growth opportunities.

The current South African Good Clinical Practice (GCP) Guidelines have been developed to promote good practice in the conduct of clinical trials in South Africa. These guidelines provide a basis both for the scientific and ethical integrity of research involving human participants and for generating valid observations and sound documentation of the findings. These guidelines not only serve the interests of the parties actively involved in the research process, but also protect the rights and safety of participants, and ensure that the investigators are sensitised toward the advancement of public health objectives.

2 RESOURCES

According to the South African GCP Guidelines, the conduct of clinical trials with human participants stipulates the competencies and responsibilities of the Principal Investigator (PI).

2.1 Principal Investigator should:

2.1.1 have sufficient time to properly conduct and complete the trial within the agreed trial period.

2.1.2 have available an adequate number of suitably qualified staff including at least one GCP-trained sub-investigator and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

2.1.3 Provide documentation describing the distribution of duties and functions for the conduct of the trial.

2.1.4 Demonstrate compatibility of the workload of the investigative staff with the requirements of the study.

2.1.5 Demonstrate compliance with the planned time schedule for the study.

2.1.6 Indicate the number of clinical trials previously performed and their nature (e.g. phases of clinical trials).

2.1.7 Indicate the proportion of time allocated to clinical trial work versus other activities e.g. teaching, administration, routine clinical work.

2.2 Planning for participant recruitment should be part of the overall trial design. In approving the trial, SAHPRA must satisfy itself that there are adequate resources and time available for the conduct of the trial at the site.

2.3 The purpose of the Workload Table is to inform SAHPRA of the capacity of all potential investigators to safely and effectively conduct the planned study (refer to annexure A).

3 REFERENCES

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4 UPDATE HISTORY

Date	Reason for Update	Version & Publication
April 2019	First version for External Stakeholder comment	v1, May 2019
31 May 2019	Deadline for comment	
20 July 2019	Published for implementation	v1, July 2019

Annexure A: Workload form

WORKLOAD TABLE				
Date				
Study Title				
Protocol number				
Phase of study				
Investigator (Title, Name and Designation i.e. PI or sub-I)				
Primary Employer *e.g* University, Research Unit, CRO, Private Practice of the investigator				
Area of expertise of Investigator				
Area of Study Research (*e.g*. oncology, cardiology)				
NUMBER OF CURRENT CLINICAL TRIALS OF INVESTIGATOR'S INVOLVEMENT				
Role (Principal Investigator/Co-PI or Sub-Investigator)	**Number of participants responsible for in actively recruiting clinical trials**	**Number of participants responsible for in follow-up clinical trials**	**Number of actively recruiting clinical trials**	**Number of clinical trials in follow-up clinical trials**
Principal /Co-Investigator				
Sub-Investigator				
ESTIMATED TIME PER WEEK				Hours
Clinical trials		Clinical work (patient contact)		
		Administrative work		
Organisation 1 (e.g. Private practice / University / Governmental)		Clinical / Routine work		
		Teaching/Research		
		Administrative work		
Organisation 2 (e.g. Private practice / University / Governmental), if applicable		Clinical / Routine work		
		Teaching / Research		
		Administrative work		
Organisation 3 (e.g. Private practice / University / Governmental), if applicable		Clinical / Routine work		
		Teaching / Research		
		Administrative work		
Total				

Investigator signature: _____ Date:_____