DEPARTMENT OF HEALTH
Republic of South Africa

SAHPRA
South African Health Products Regulatory Authority

CAPACITY BUILDING AND TRANSFORMATION IN CLINICAL TRIALS RESEARCH IN SOUTH AFRICA

This document has been prepared to serve as a guideline for preparation of applications to conduct clinical trials in South Africa. It represents the South African Health Products Regulatory Authority's current thinking on capacity building and transformation for clinical research in South Africa. It is not intended as an exclusive approach and Authority reserves the right to request any additional information and may make amendments in keeping with the knowledge which is current at the time

Version 1 published for comment	March 2018
Due date for comment	30 April 2018

MRS P NKAMBULE
ACTING CHIEF EXECUTIVE OFFICER

TABLE OF CONTENTS

1 PREAMBLE

South African Health Products Regulatory Authority (SAHPRA) is committed to the building of research capacity of health care professionals as well as transformation with regard to research activities throughout the country. The objective of this document is to articulate the Authority's understanding of capacity building and transformation so that SAHPRA, the pharmaceutical and medical device industry (applicants/sponsors), and investigators in clinical trials share a common understanding of the task of building the capacity of previously disadvantaged groups of South Africans, providing opportunities for healthcare and scientific graduates to acquire the necessary skills to conduct clinical trials, and promoting transformation in clinical research.

2 BACKGROUND

The South African landscape for clinical trials was noted to have grown by as much as 40 % between 1997 and 1998 (Christley, 1998).[1] It is safe to speculate that such growth would have followed an upward trajectory since 1998. This is reflected in practical terms, in the present rate of applications from the pharmaceutical and medical device industry for the conducting of clinical trials in South Africa. Fear that the growth in clinical research applications in South Africa might outstrip capacity to deal with such increase was highlighted by Burgess and Sulzer (2010).[2] Furthermore, although close to 85 % of the South African population is dependent on services provided by public health institutions, the vast majority of applications to conduct clinical trials are directed at private sector sites. In addition, there are many young South African healthcare and scientific graduates, and other professionals who are in need of opportunities to develop the skills of conducting clinical research.

To assist in addressing these challenges, it is necessary for all stakeholders involved in clinical research to embrace transformation and capacity building to increase formalised training of young graduates, encourage healthcare and scientific professionals to become clinical trial investigators and facilitate full involvement of both private and public sector healthcare institutions.

3 CAPACITY BUILDING AND TRANSFORMATION DEFINED

Capacity building in the South African context is defined as an evidence-driven process of strengthening the ability of individuals, organisations and systems to perform core functions sustainably, and to continue to improve and develop over time. In 1991, the term capacity building evolved to become "community capacity building" in the lexicon of the United Nations Development Programme (UNDP).[3] The organisation, therefore, defines capacity building as a long-term continual process of development that should include all stakeholders, including ministries, local authorities, non-governmental organisations, professionals, community members, academics and others. Capacity building thus focuses on the need to use a country's human, scientific, technological, organisational, institutional and resource capabilities to address issues confronting effective development in a country. The goal of capacity building is therefore to tackle challenges related to policy and methods of development, while considering the potential, limits and needs of the people of the country concerned. In the South African context, this includes addressing the historically disadvantaged groups marginalised from mainstream research activity along race, gender and other parameters. The UNDP[3] has further emphasised that capacity building needs to be implemented through a three-pronged strategy: at an individual level, at an institutional level and at the societal level.

Transformation is defined as a process of holistically changing perceptions through the actions of individuals, organisations and other stakeholders to ensure increased access and opportunities for all South Africans, particularly all women and the youth. The UNDP[3] as well as the World Health Organisation (WHO)[4] have

consistently incorporated the concept of transformation into their global programmes, especially in low-middle income countries. These two global players (UNDP[3] and WHO[4]) define transformation as a long-term, continuous process of development that involves all stakeholders with the primary aim of attempting to bridge the gap between developed and developing societies.

As the principle of capacity building is enhanced so too must all the elements of transformation. If transformation is achieved, it will translate into human capital development; equitable resource distribution; elimination of skills imbalances across the demographic divides, and enhanced competencies for clinical research.

4 BUILDING CAPACITY FOR CLINICAL RESEARCH IN SOUTH AFRICA

SAHPRA has consistently encouraged a "capacity building" component in a clinical trial application. It is an expectation that speaks directly to the national imperative for enhancing research throughout the country. The overall objective of capacity building as envisaged by SAHPRA is the need to increase the pool of healthcare and scientific professionals in South Africa. These will be the individuals that will form the backbone of the human capital that will guarantee future clinical research performance in South Africa.

Capacity building should not be seen as purely a redress for demographic imbalance in the South African society. Its main thrust should be a concerted effort by all stakeholders including government, the pharmaceutical and medical device industry, clinical research organisations (CROs) and academia, to develop and recruit young, skilled medical and other professionals into the practice of conducting clinical research. In the process, the profile of the clinical research professional cohort needs to be transformed to better reflect the gender, race and other demographic representation in South Africa.

The following steps, among others, need to be undertaken in order to achieve the objectives of capacity building and transformation:

4.1 Partnerships between government, the pharmaceutical industry, academic institutions and individuals, be encouraged and strengthened with a common focus on increasing the number of medical and scientific professionals that will be involved in clinical research.

4.2 Where possible, all stakeholders be encouraged to engage academic institutions to develop and include in their curriculum the teaching of subjects related to "Clinical Research & Regulatory Sciences".

4.3 Young graduates from all sectors of society be encouraged and sponsored to undergo training and acquire the necessary expertise for the conducting of clinical research.

4.4 Training and periodic re-training be undertaken by healthcare professionals at every clinical research centre so that those involved in clinical trials can acquire further competence.

4.5 Uniform standards with appropriate standard operating procedures be implemented across all sites.

4.6 The number of trial sites be increased thus augmenting patient recruitment potential and contributing towards capacity building.

5 APPLICATIONS FOR CLINICAL RESEARCH IN SOUTH AFRICA

To support capacity building and transformation applications for clinical research, applications should include evidence and activity plans to build capacity at each study site as well as enhancing research activities and skills of professionals from previously disadvantaged groups. In addition, the application should provide evidence and plans to effect transformation in line with national legislation. It must be noted that although training in Good Clinical Practice (GCP) forms part of capacity building, it is only one component thereof.

To support transformation and capacity building it is thus proposed that:

5.1 If a trial is to involve four or more trial sites (multi-centre clinical trials), a minimum of 25 % of the sites should be public institution(s) unless there is a clear justification why this is not possible. All attempts to include public institutions in a multi-centre clinical trial must be properly documented, and where any one such institution has declined participation, the applicant must provide written proof of such request and provide reasons given by such institutions for declining to participate in the clinical trial.

5.2 Applicant/Sponsor should ensure that the research process in no way compromises prioritisation or quality of care of patients, is not disruptive to routine clinical procedures and that patients receive the same standard of care regardless of where services are provided.

5.3. Public institutions should derive some benefit for hosting research which could include the training of staff in an area directly related to their work, or the donation of equipment needed for the provision of clinical services.

5.4 The sponsor/applicant is encouraged to ensure that selected trial sites include a diverse demographic distribution of all healthcare professionals who possess the required qualifications and experience. If this is not the case, the site, the sponsor and the applicant are required to provide reasons for such and describe steps to be taken to ensure redress.

5.5 Both the sponsor/applicant and the clinical trial site should ensure that previously disadvantaged members of staff at all levels are given well defined roles that will enhance acquisition of expertise for future involvement in the conduct of clinical trials.

5.6 Efforts must be directed at encouraging the appointment and training of previously disadvantaged personnel at all levels of any clinical trial site (public institutions and private research sites) that will enhance the full participation by such individuals in the conduct of clinical trials, and a necessary budget item be included for this purpose.

The sponsor/applicant must have policy in place, choose site that are complaint and assist sites to comply to Capacity Building and Transformation.

Note that non-compliance may delay the approval of the study.

6 REFERENCES

Christley, H.M. 1998. Conducting clinical trials in South Africa. Applied Clinical Trials, September. Vol 7(9): 56 – 59.

Burgess, L.J. and Sulzer, N.U. 2010. Clinical trials in South Africa: need for capacity building and training. South African Medical Journal. Vol 100(7): 402.

United Nations Development Programme. Defining Capacity Building. Archived on 17 August 2017 from: http://www.gdrc.org/uem/capacity-define.html.

World Health Organization. 2017. Ten years of Transformation: Making WHO fit for purpose. Accessed on 01 September 2017 from: http://www.who.int/about/who_reform/ten-years-transformation/.

7 UPDATE HISTORY

Date	Reason for Update	Version & Publication
Nov 2017	First version for External Stakeholder comment	v1, March 2018
30 April 2018	Due date for comment	