Opportunities and Challenges in Clinical Trials, South Africa

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health
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Health
REPUBLIC OF SOUTH AFRICA

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INTRODUCTION (1)

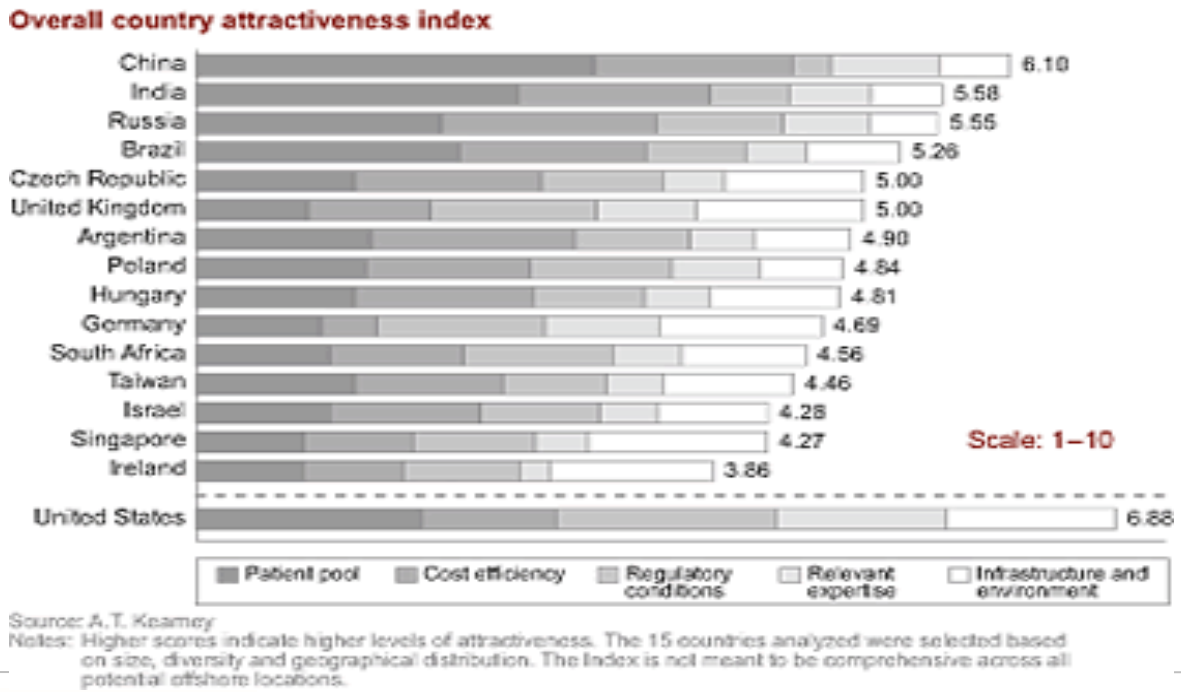
Background to Clinical Trials

- South Africa provides unique, highly attractive research environment
- Diverse population
- Well developed skills, expertise and infrastructure and moderns healthcare facilities
- Increasing research activity and competition for research
- Over-researched communities
- Most trials in private sector

INTRODUCTION (2)

South Africa is an attractive location to perform clinical trials

FIGURE 1
China and India are the most attractive locations to perform clinical trials outside of the United States



Source: A.T. Kearney
Notes: Higher scores indicate higher levels of attractiveness. The 15 countries analyzed were selected based on size, diversity and geographical distribution. The index is not meant to be comprehensive across all potential offshore locations.

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LEGISLATIVE FRAMEWORK

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

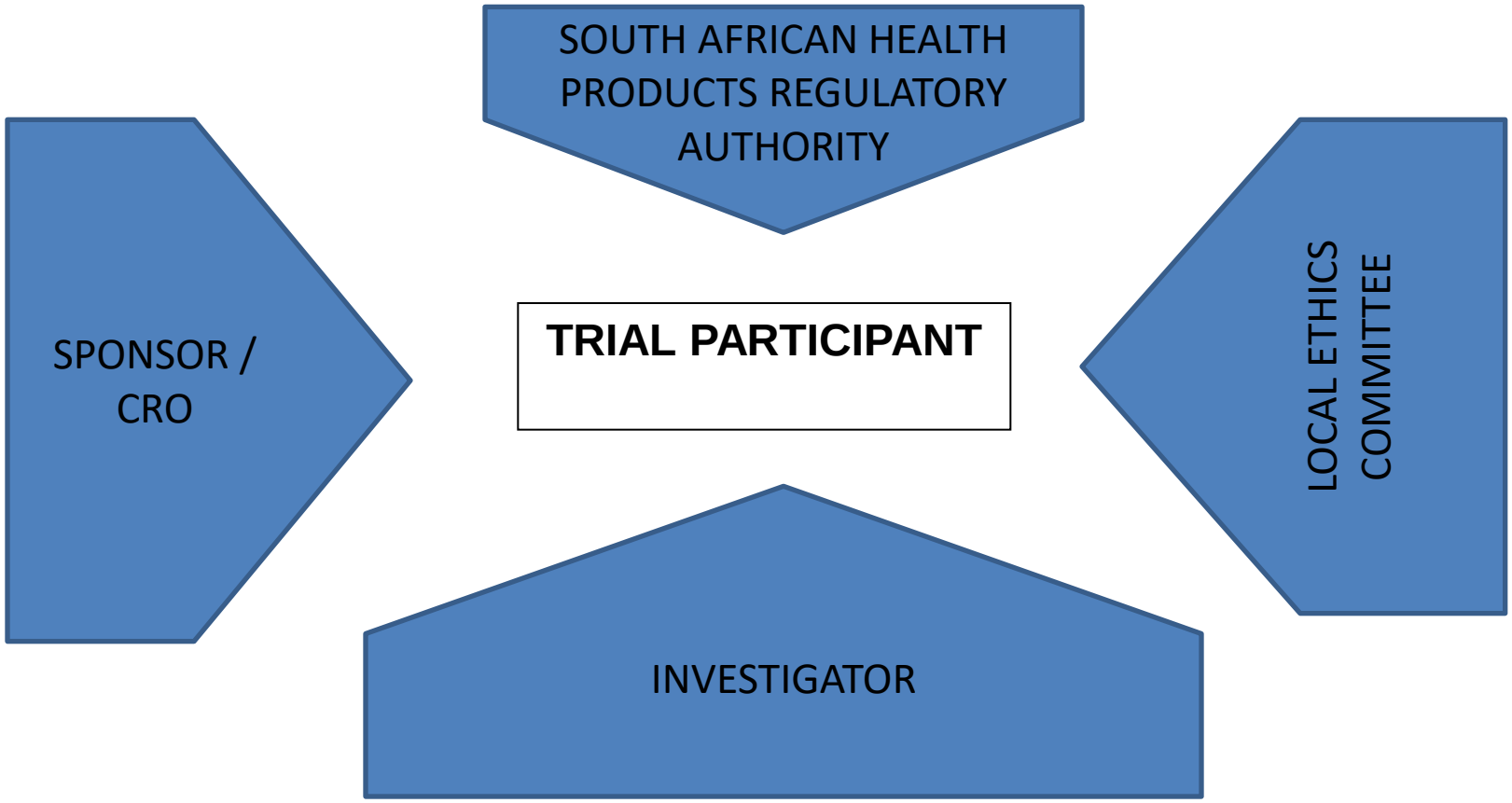
NATIONAL HEALTH RESEARCH ETHICS COUNCIL (NHREC)

REGULATION OF CLINICAL TRIALS

LOCAL ETHICS COMMITTEE

SA GCP AND OTHER INTERNATIONAL GUIDELINES

Stakeholders in clinical trials



CURRENT REGULATORY CHALLENGES WITH CLINICAL TRIALS (1)

- Capacity Building and Transformation

  - Lack of capacity Building and Transformation
  - Most trials in private sector
  - Over researched communities
  - Lack of awareness of clinical trials
  - Decline in number of experienced investigators
  - The number of PI has declined 11 % globally, 20% in the USA (Centrewatch, 2011)
  - High turnover of investigators – only 27% of PIs participate in a second trial (Traynor, 2014)

  - Age of investigators is increasing (Traynor, 2014)
    - ❖ Poor institutional support
    - ❖ Lack of formal training programmes
    - ❖ Lack of protected time for research
    - ❖ Work balance, time requirements, reporting of SAEs (Corneli et al, 2017)

CURRENT REGULATORY CHALLENGES WITH CLINICAL TRIALS (2)

- Harmonization and collaboration
  - Minimal harmonization
  - Need of Collaborative efforts

- Complexities of studies
  - Complex study designs
  - Cancer studies- although holds potential but other patients with co-morbidities are excluded
  - Genes and genomic studies and stem cell studies

- Minimal care after research
- Lack of insurance to cover participants
- Lack of understanding in completion of clinical trials protocol and documents – particularly investigator initiated trials – protocol development done elsewhere

CURRENT REGULATORY CHALLENGES WITH CLINICAL TRIALS (3)

- Lack of standardization of GCP certificate
  - No agreement on course content and method of assessment

OPPORTUNITIES (1)

- Developing Capacity Building guidelines to address issues of capacity building
  - involvement of young professionals and experts multi-sectorial, HDIs, inclusion of public sector sites and academic institutions
    - ✓ Skill transfer and succession planning
    - ✓ build human capital
- Establishment of Co-Principal investigator – non-medical healthcare professionals to have an opportunity of being a PI.

- Medical schools to introduce concept of clinical trials as a career opportunity
  - increase interest, awareness and exposure to clinical research
  - Introduce Master's Degree in Clinical Research
  - incorporate the clinical research as part of the curriculum

- A need to collaborate with various stakeholders
  - Multi-sector involvement – academia, public health sector, industry and NGOs

OPPORTUNITIES (2)

- strengthened relationship between SAHPRA and NHREC
- A SAHPRA representative on NHREC

- Enabling framework to guide researchers
- Less stringent regulatory constraints

- Reliance: SA member of AVAREF since in inception in 2006 which is a platform aimed at improving the regulatory oversight of interventional CT being conduct in Africa
  - ❖ AVAREF- provide regulatory authorities with expertise, information sharing and capacity building
    Joint review of clinical trials applications and GCP inspections
    Standardization of clinical trial application tools, including GCP guidelines
- Bi-annual meeting with Stakeholders – started expanding to Ethics Committees and Academia

OPPORTUNITIES (3)

- Proposed roadshow – Training and workshops
- Working on electronic systems to improve the timelines
- Need for new innovative medicines to combat the public health issue as well as diseases such as cancer, HIV and other immune diseases, and other rare disease
- Access - Care after research and
  - Section 21 of the MRSA
- Clinical trials and sites to be spread across the country
- Source funding and establishment of more research sites and facilities

THANK YOU