SOUTH AFRICAN NATIONAL CLINICAL TRIALS REGISTRY (SANCTR)

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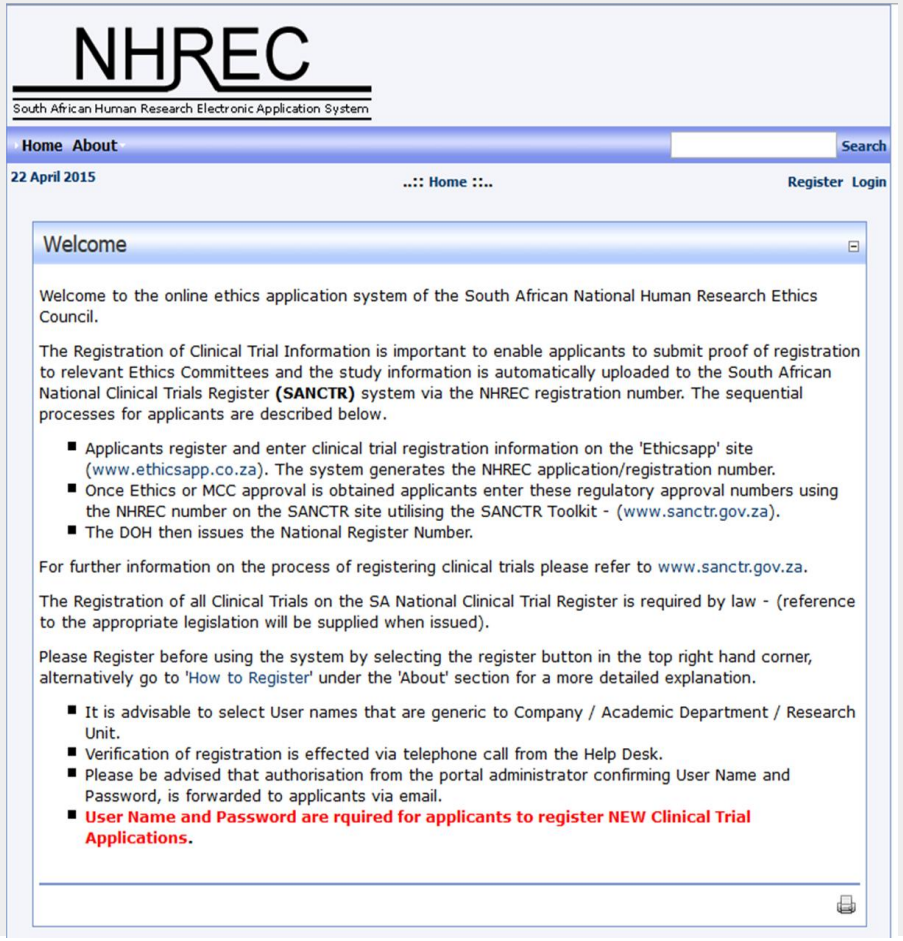
South African Clinical Trials Registry (SANCTR)

- Establishment of SANCTR follows International Calls for registration of clinical trials
- Department of Health commissioned establishment of a clinical register in 2005
- November 2005 the Department of Health issued a statement that as from 1st December 2005 all new clinical trials to be conducted in the country must be registered in the South African National Clinical Trials Register

Access to current SANCTR database



SANCTR

- SANCTR serves as tool for monitoring and managing conduct of clinical trials in South Africa

- Registration on SANCTR requires that a trial is approved by a Research Ethics Committee and meets the requirements of the National Regulatory Authorities.

- In addition, SANCTR seeks to facilitate registration of trials in accordance with the ICTRP initiative requiring prior entry of clinical trials in a public registry as a condition for publication

South African Good Clinical Practice Guideline, 2006, 2nd edition

The World Health Organization (WHO) and Clinical Trial Registration

- WHO hosts the International Clinical Trials Registry Platform (ICTRP)
- The WHO ICTRP is not a clinical trials registry but a platform that collects data from partner registries
- The Pan African Clinical Trial Registry (PACTR) is a partner registry for the African continent
- WHO ICTRP
    - is a platform facilitating registration of a minimum 24-item data set
    - provides a searchable one-stop portal for registered clinical trials

World Health Organization (WHO): 24-item data-set

1. **Primary Registry and Trial ID Number**
2. **Date of Registration in Primary Registry**
3. **Secondary Identifying Numbers**
4. **Source(s) of Monetary or Material Support**
5. **Primary Sponsor** and if applicable **Secondary Sponsor(s)**
6. **Contact for Public Queries**
7. **Contact for Scientific Queries**
8. **Principle Investigator Contact Information**
9. **Public Title**
10. **Scientific Title**

WHO 24-item data-set

11. Countries of Recruitment
12. Health Condition(s) or Problem(s) Studied
13. Intervention(s)
14. Key Inclusion and Exclusion Criteria
15. Study Type
16. Date of First Enrollment
17. Target Sample Size
18. Recruitment Status
19. Primary Outcome(s)
20. Key Secondary Outcomes

WHO 24-item data-set

21. Ethics Review

22. Completion date

23. IPD Sharing Statement

24. Summary Results

What is a clinical trial register?

A trial register is a database in which key administrative and scientific information about planned, ongoing and completed trials, with enough information to identify that trial's existence, are stored

Why register a clinical trial?

- Reduction of publication bias/selective reporting
- Fulfill publication mandate
- Allows for transparency thus enhancing public trust
- Reduce duplication of research and limited resources

Ethical obligation for trial registration

- Clinical trial registration can assist a researcher fulfill ethical obligations.
  - Adhere to the South African Good Clinical Practice Guideline
  - Ensure transparency and information dissemination
- Enhance public trust in the conduct of clinical research (experiments should serve the public good)

SAGCP guideline 2006. 2nd edition

What types of trials should be registered?

- For the purposes of registration, the WHO defines a clinical trial as:

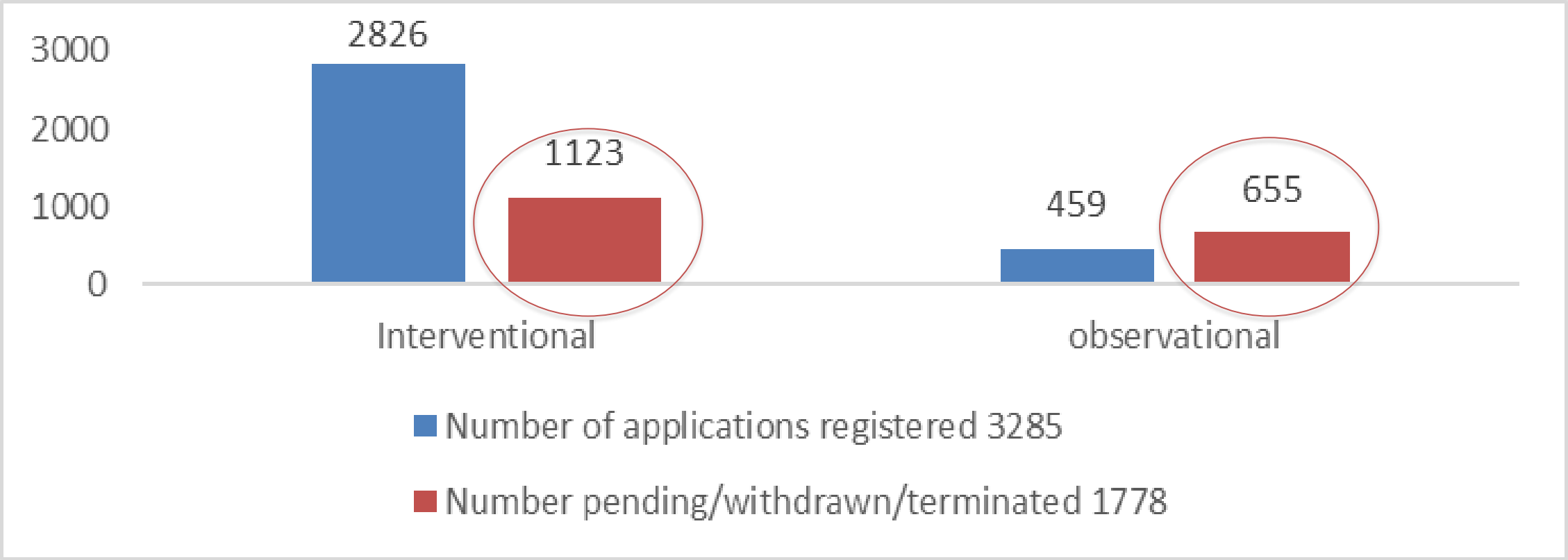
  Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

- Prospective registration
  - Before the trial starts (also known as, “prospectively”)
  - Allows for a trial’s outcomes and protocol to be tracked all the way through the course of the trial

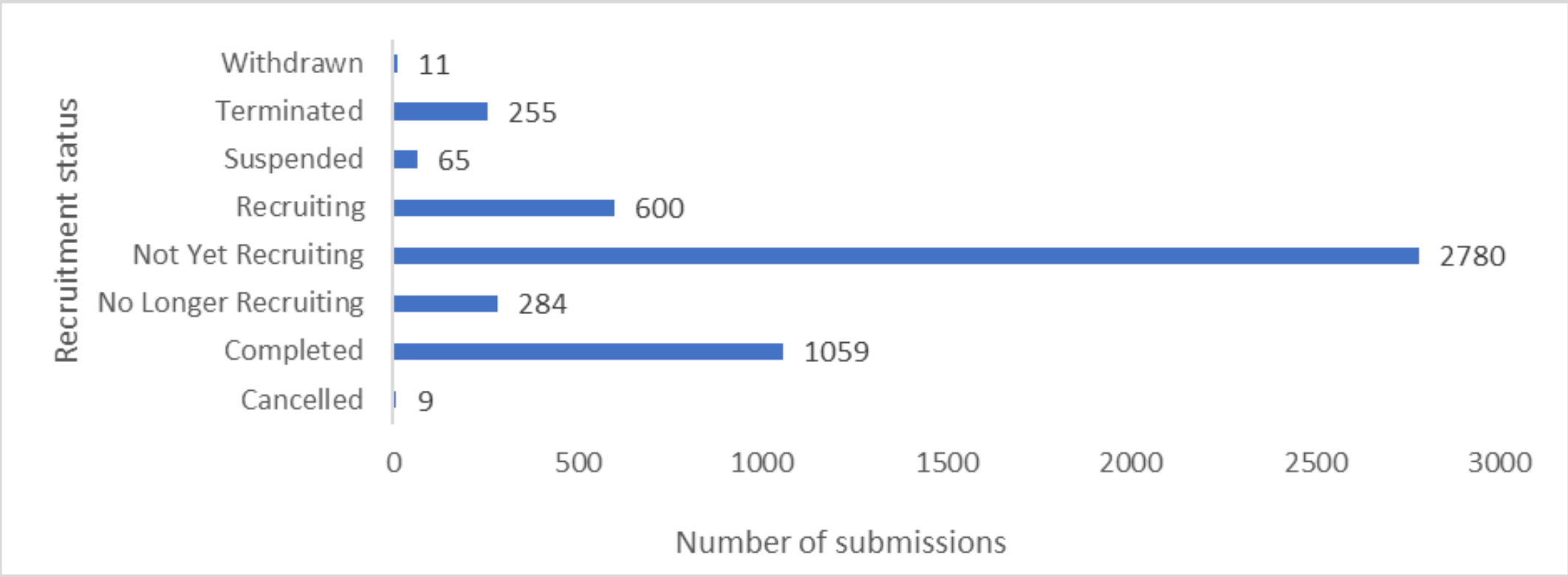
SANCTR Progress

- SANCTR was developed by Wits Health Consortium (WHC)
- SAMRC approached by the DoH in 2015 to redevelop the database
- SAMRC already houses the WHO Primary Register (PACTR) which conforms to the WHO data requirements.
- SANCTR is in a process of being redeveloped. The redevelopment process includes the following activities:
  - Data migration from WHC to SAMRC
  - Understanding the process flow of registration in SANCTR
  - Stakeholder consultation to ensure that SANCTR meet the needs for the country while conforming to the international standards for registry

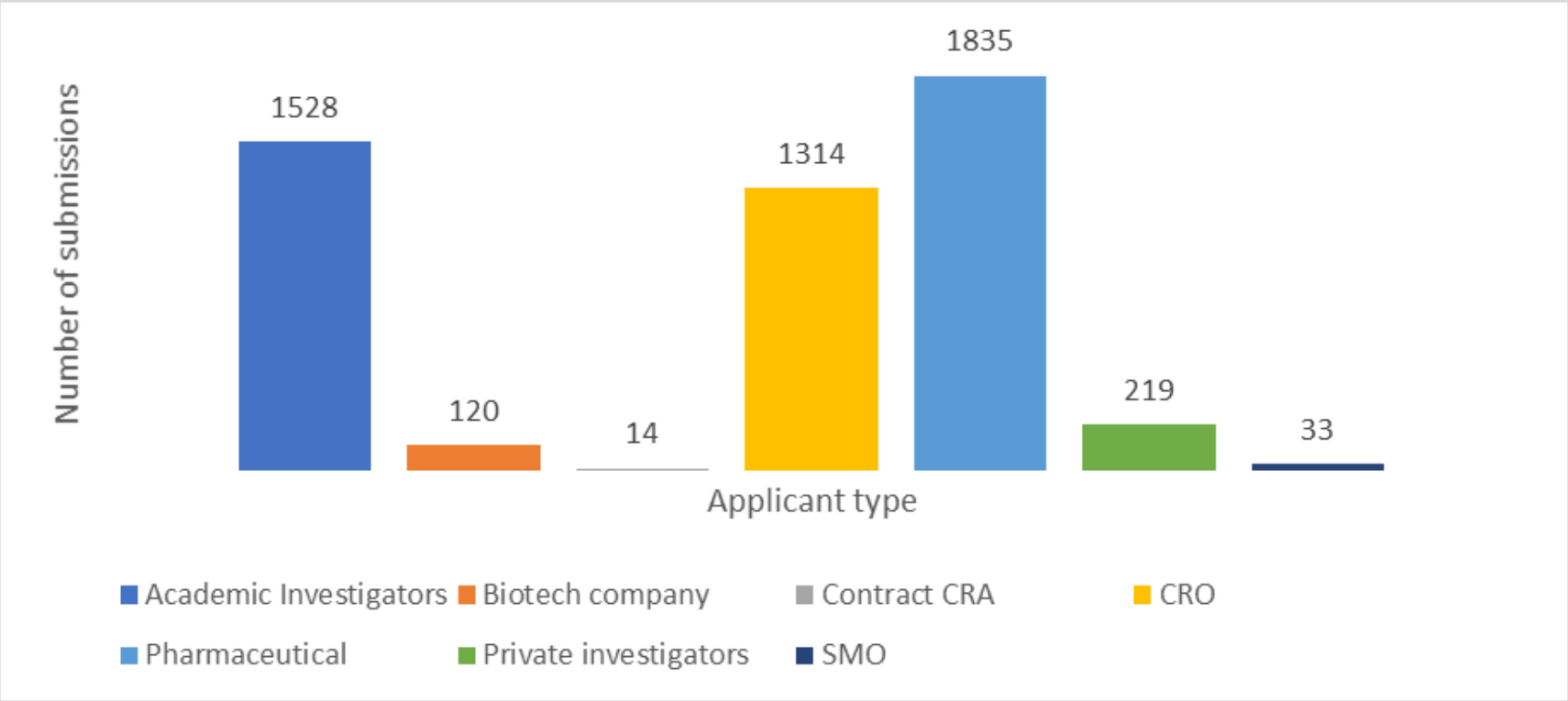
Current stats in SANCTR database



Status of trials in SANCTR



Who is submitting applications?

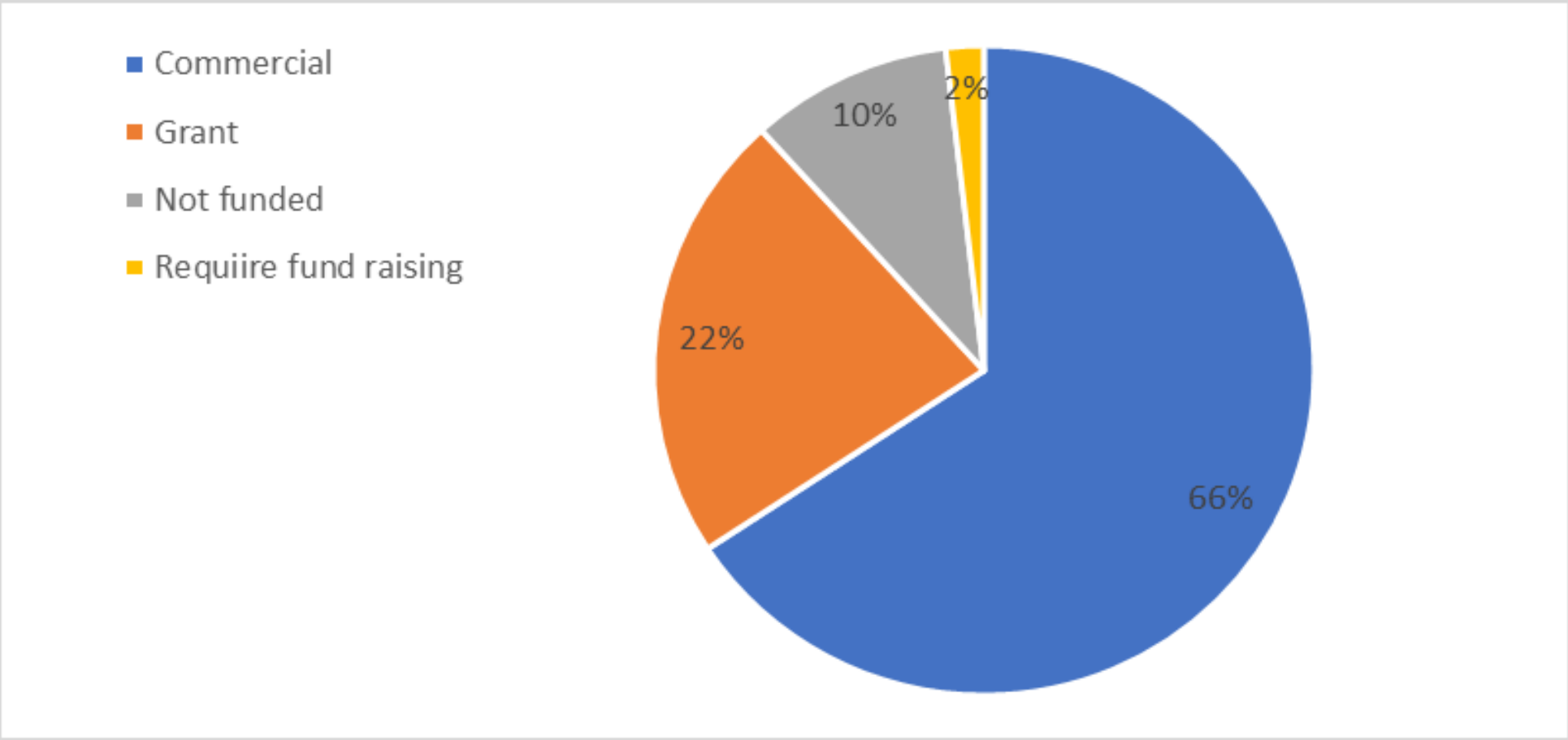


CRO – Contract Research organisations

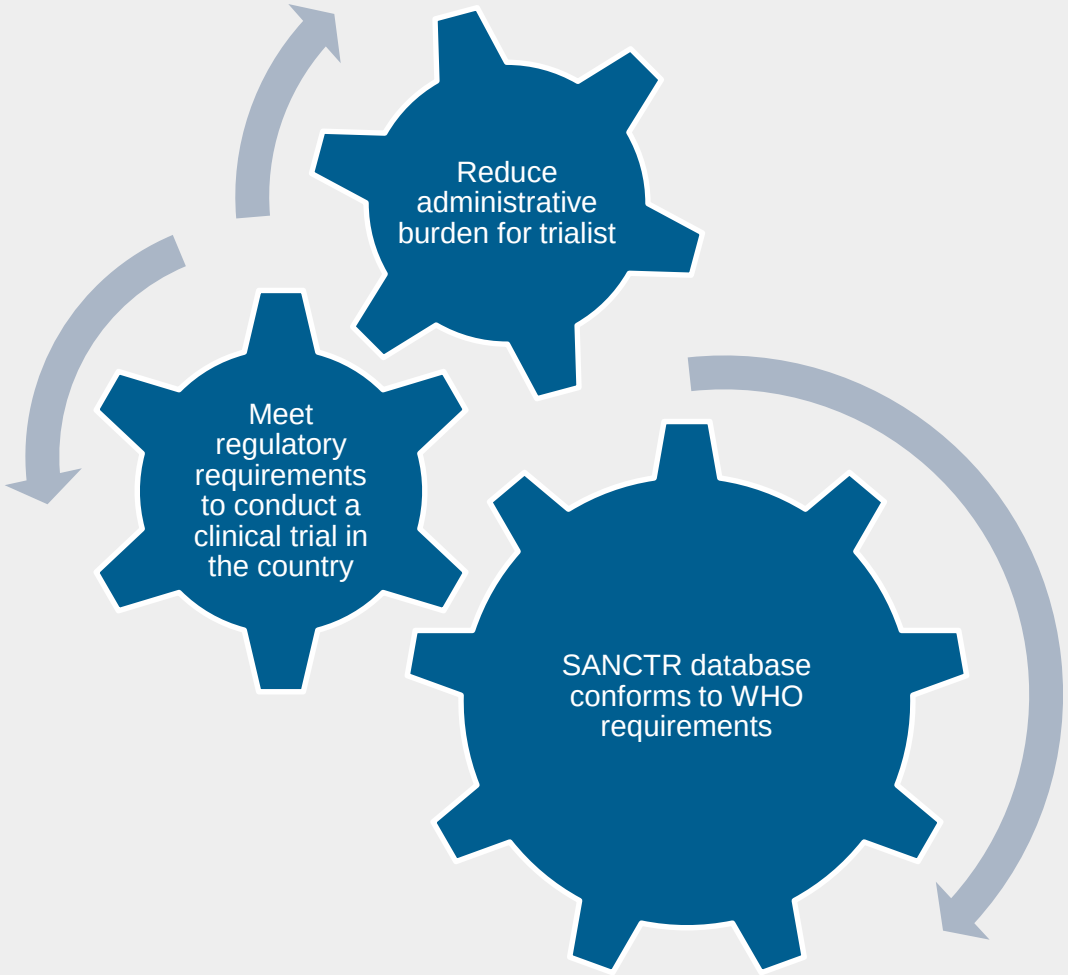
SMO – Site Management organisations

CRA – Clinical Research Associates

Who is funding trials?



Why we need to collaborate?



Consultation with various stakeholders play an important role in shaping the redevelopment of SANCTR registry

Acknowledgement

Steering Committee Members

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Questions and Discussion