



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



The screenshot shows the SANCTR website home page. At the top left is the South African Department of Health logo and the text "health Department: Health REPUBLIC OF SOUTH AFRICA". Below this is the "South African National Clinical Trial Register" title. A navigation bar includes "Home Resources", "Your Rights", "Investigator Information", and "SA Clinical Partners Trials". A search bar is present on the right. The date "Wednesday, April 22, 2015" is displayed on the left, and "Login" is on the right. The main content area features a "Welcome to SANCTR" section with a close button. The text explains the register's purpose, its international context, and the benefits of a central publicly accessible clinical trial register, including promoting collaboration, assisting in trial identification, reducing publication bias, and promoting the best use of limited resources. It also mentions the SA National Clinical Trials Register as an important tool for monitoring and managing new clinical trials and notes that as of December 1, 2005, all new clinical trials must be registered in the SANCTR database.

health
Department:
Health
REPUBLIC OF SOUTH AFRICA
South African National Clinical Trial Register

Home Resources Your Rights Investigator Information SA Clinical Partners Trials Search

Wednesday, April 22, 2015 ...: Home Login

Welcome to SANCTR

The South African National Clinical Trials Register provides the public with updated information on clinical trials on human participants being conducted in South Africa. The Register provides you with information on a trials purpose; who can participate, where the trial is located, and contact details.

The South African National Clinical Trials Register forms part of international calls for making trial information publicly available. The International Committee of Medical Journal Editors, which includes peer reviewed journals from around the world, recently made a statement that from 1 July 2005 no trials will be considered for publication unless they are included on a research register. The World Health Organisation has begun the push for clinical trial registration with the initiation of a Clinical Trials Register platform. Similarly, the global pharmaceutical industry has recently released plans to make trial data more publicly available.

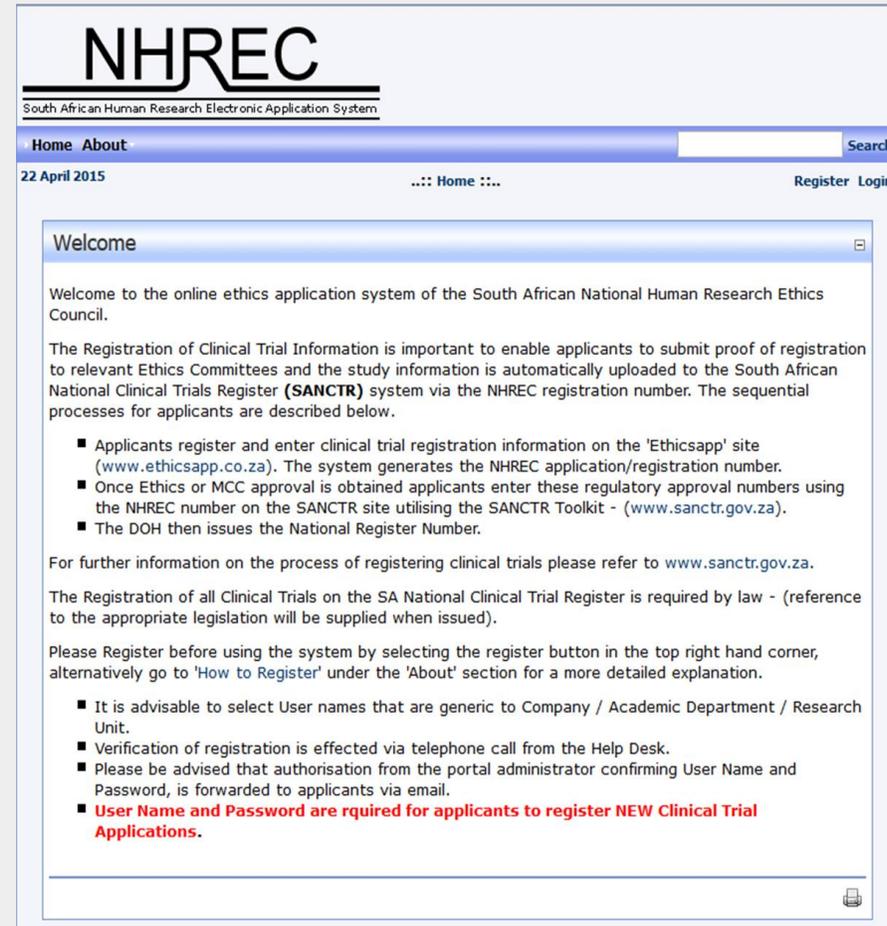
The benefits of a central publicly accessible clinical trial register are numerous. They include:

- Serves to promote collaboration among researchers, the private sector and the community through the sharing of research information;
- Assists people to identify clinical trials they can participate in;
- Decreases publication bias; reduce duplication of research efforts;
- Promotes best use of limited research resources; and
- Contributes to global efforts to reduce / eliminate disease.

The SA National Clinical Trials Register is an important tool for monitoring and managing new clinical trials. The questions being investigated, findings of studies as well as mapping of locations, funders, funding, research institutions and progress towards developing new capacity in the area are some of the issues that the register can assist the research community in addressing.

In November 2005 the Department of Health issued a notice that as from the 1st December 2005 all new clinical trials to be conducted in the country must be registered in the South African National Clinical Trials Register. The notice also explained that trials that started recruiting as of 1st July 2005 must also be registered.

You may want more information on clinical trials before seeing what trials are being done in South Africa. If so, refer



The screenshot shows the NHREC website home page. At the top is the "NHREC" logo and the text "South African Human Research Electronic Application System". Below this is a navigation bar with "Home About" and a search bar. The date "22 April 2015" is displayed on the left, and "...: Home ... Register Login" is on the right. The main content area features a "Welcome" section with a close button. The text welcomes users to the online ethics application system and explains the registration process. It lists three steps: 1) Applicants register and enter clinical trial registration information on the 'Ethicsapp' site (www.ethicsapp.co.za). 2) Once Ethics or MCC approval is obtained applicants enter these regulatory approval numbers using the NHREC number on the SANCTR site utilising the SANCTR Toolkit - (www.sanctr.gov.za). 3) The DOH then issues the National Register Number. It also provides further information on the registration process, states that registration is required by law, and asks users to register before using the system. A final note states that it is advisable to select generic user names and that verification is effected via telephone call from the Help Desk. A red warning states: "User Name and Password are required for applicants to register NEW Clinical Trial Applications."

NHREC

South African Human Research Electronic Application System

Home About Search

22 April 2015 ...: Home ... Register Login

Welcome

Welcome to the online ethics application system of the South African National Human Research Ethics Council.

The Registration of Clinical Trial Information is important to enable applicants to submit proof of registration to relevant Ethics Committees and the study information is automatically uploaded to the South African National Clinical Trials Register (**SANCTR**) system via the NHREC registration number. The sequential processes for applicants are described below.

- Applicants register and enter clinical trial registration information on the 'Ethicsapp' site (www.ethicsapp.co.za). The system generates the NHREC application/registration number.
- Once Ethics or MCC approval is obtained applicants enter these regulatory approval numbers using the NHREC number on the SANCTR site utilising the SANCTR Toolkit - (www.sanctr.gov.za).
- The DOH then issues the National Register Number.

For further information on the process of registering clinical trials please refer to www.sanctr.gov.za.

The Registration of all Clinical Trials on the SA National Clinical Trial Register is required by law - (reference to the appropriate legislation will be supplied when issued).

Please Register before using the system by selecting the register button in the top right hand corner, alternatively go to 'How to Register' under the 'About' section for a more detailed explanation.

- It is advisable to select User names that are generic to Company / Academic Department / Research Unit.
- Verification of registration is effected via telephone call from the Help Desk.
- Please be advised that authorisation from the portal administrator confirming User Name and Password, is forwarded to applicants via email.
- **User Name and Password are required for applicants to register NEW Clinical Trial Applications.**

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:

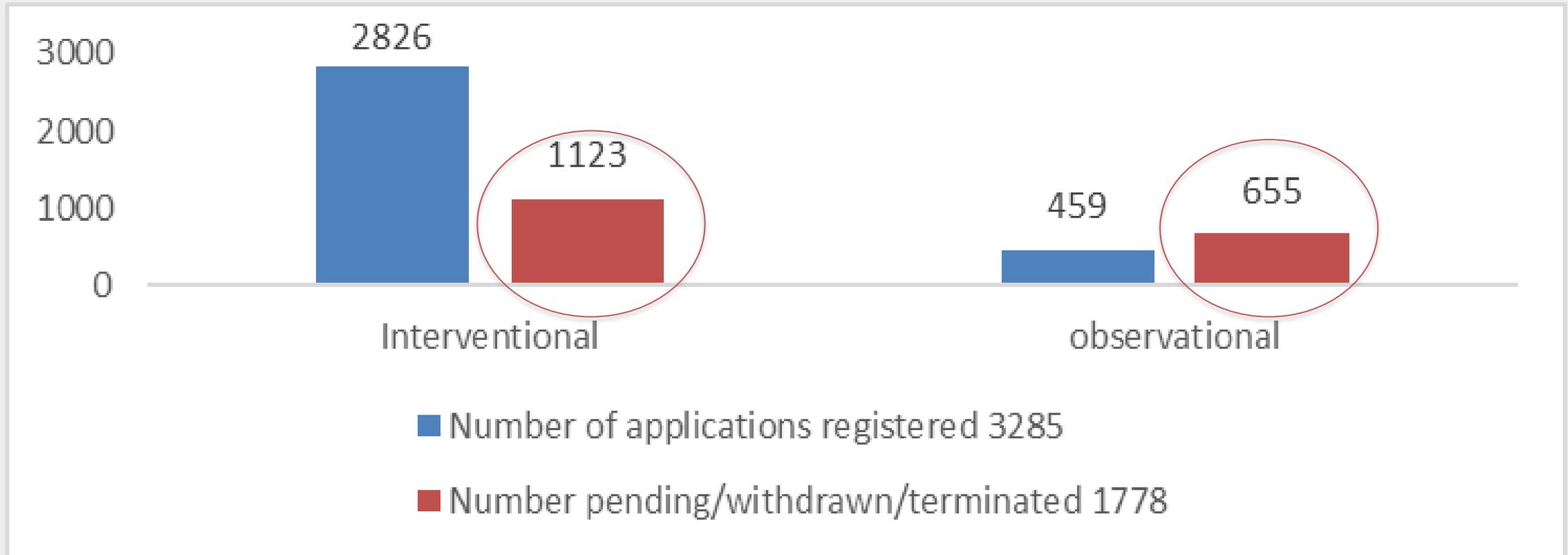
Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

- 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

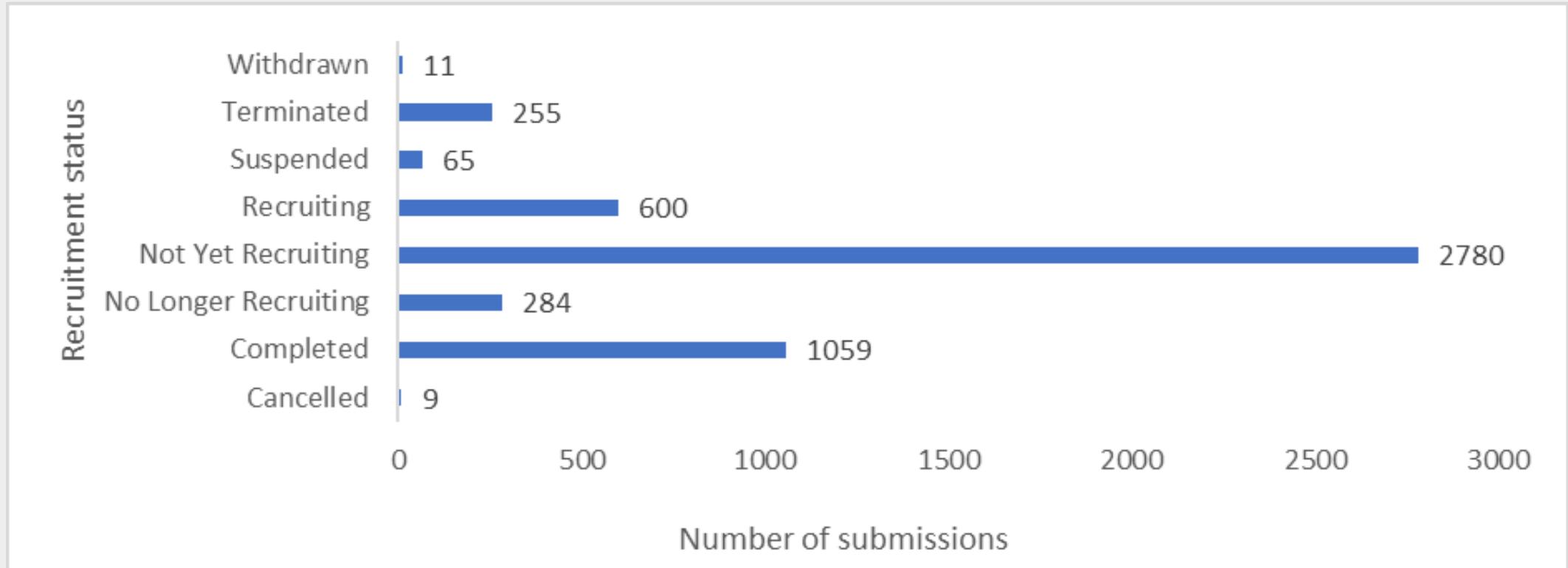
SANCTR Progress

- 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

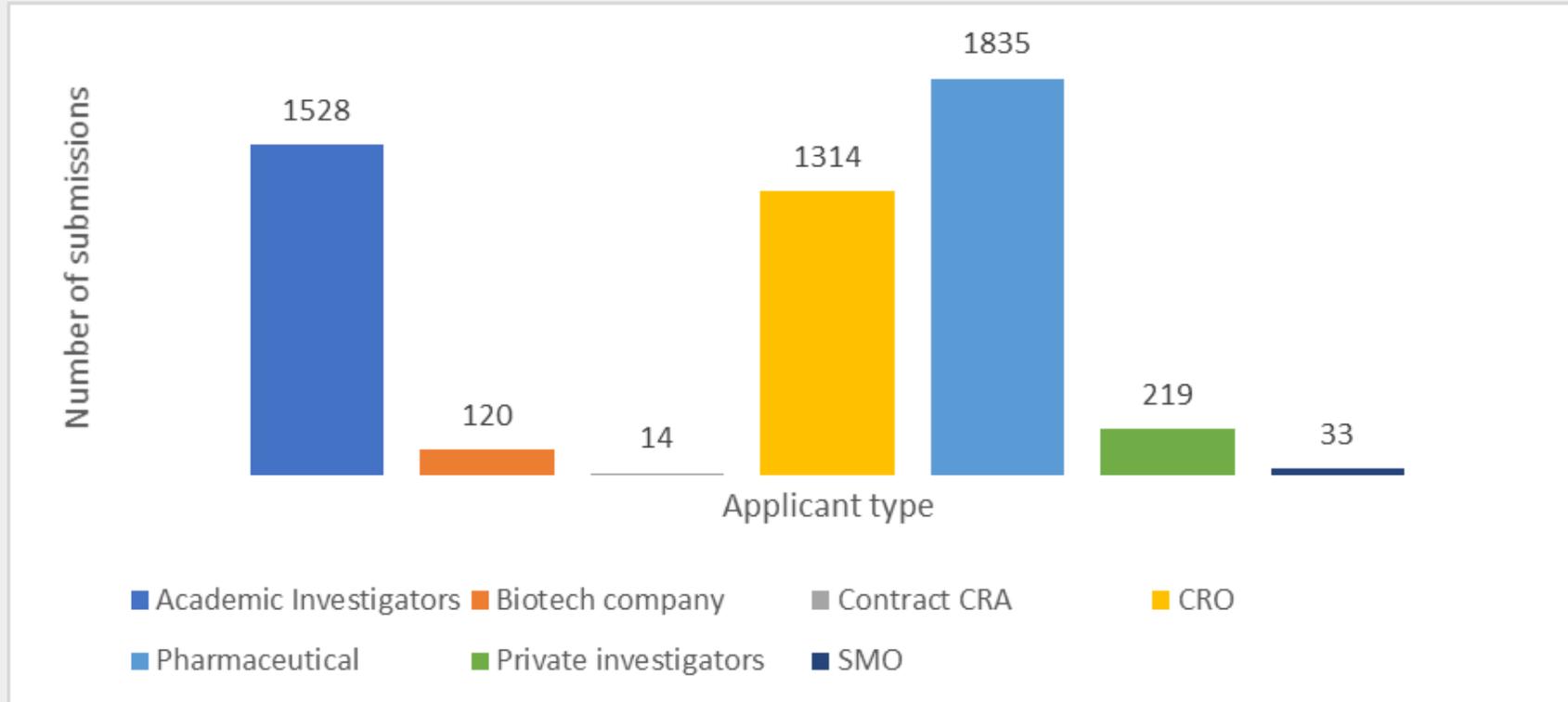
Current stats in SANCTR database



Status of trials in SANCTR



Who is submitting applications?

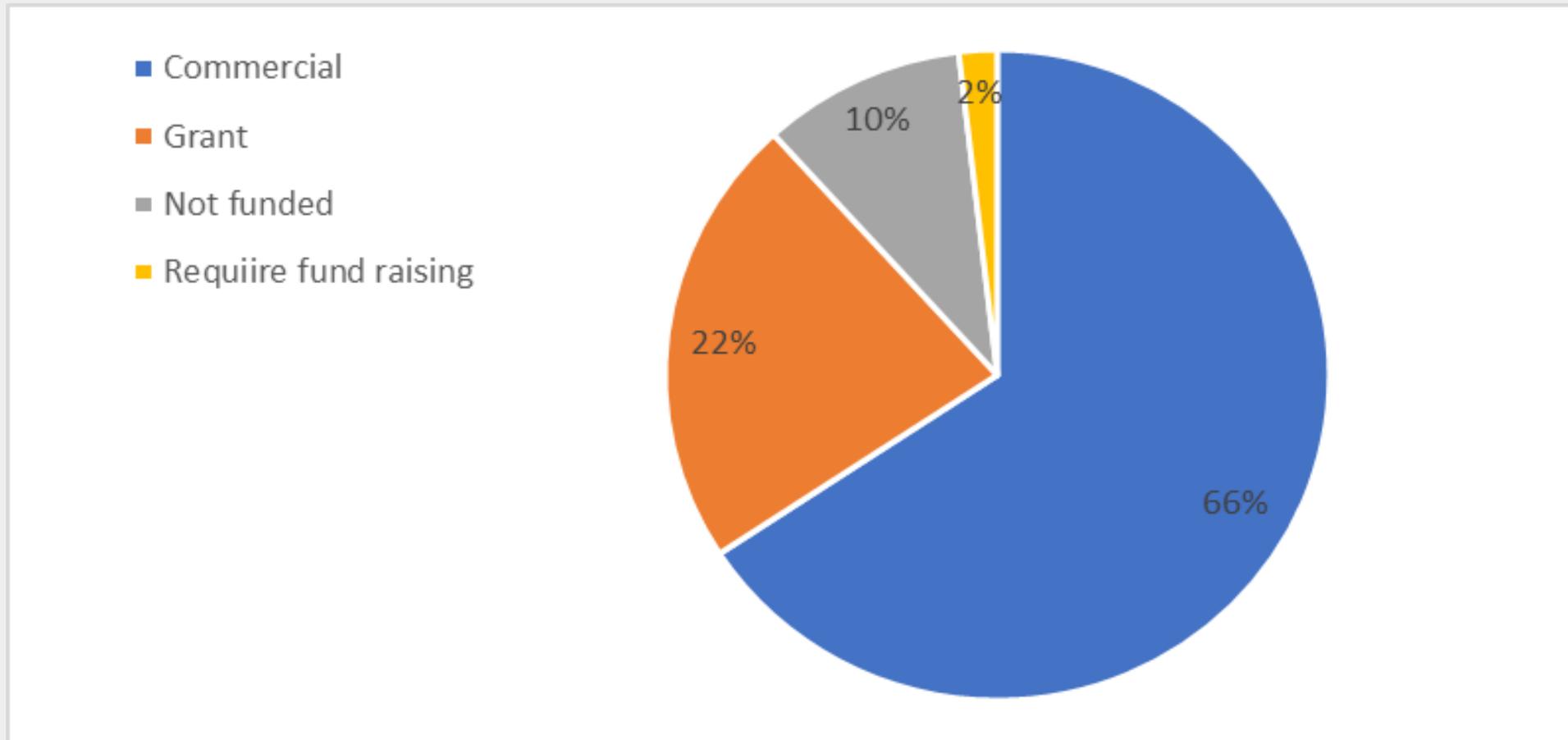


CRO – Contract Research organisations

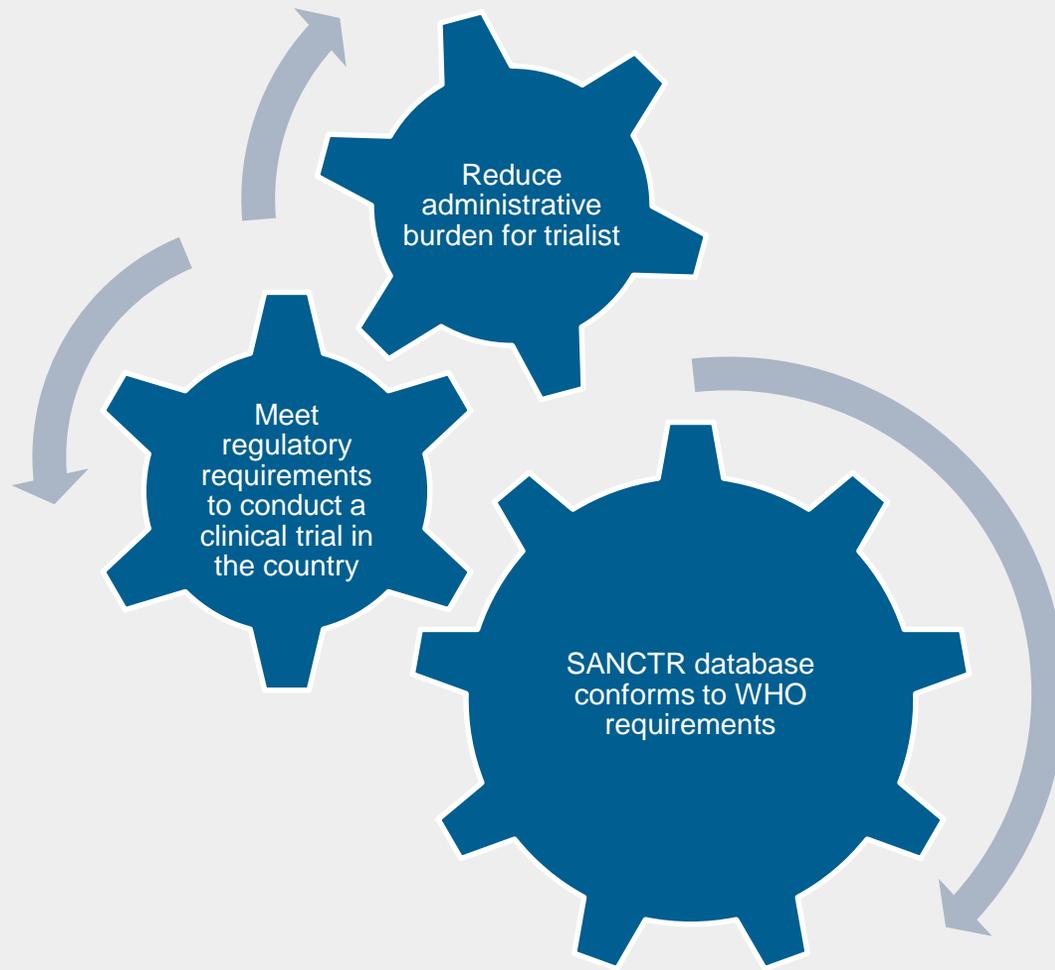
SMO – Site Management organisations

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

Surname	Name	Institution
Zondi	Thulile	NDoH
Muthivhi	Tshilidzi	NDoH
Nkambule	Portia	SAHPRA
Spotose	Thozama	NDoH
Kredo	Tamara	PACTR and CSA
Pienaar	Elizabeth	PACTR and CSA
Ndwandwe	Duduzile	PACTR and CSA
Charls	Patrick	SAMRC IT
Ross	Keith	SAMRC IT
Kgasi	Mpho	NDoH
Malinga	Lesibana	NDoH
Diale	Dora	SAHPRA
Padayachee	Thesandree	HST
Burgess	Theresa	NHREC

Funder

National Department of Health

Questions and Discussion