IPD sharing plan statement: A Clinical Trial Registry Perspective

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Introduction

Data sharing has been increasingly recognized as a vital prerequisite for scientific research. Hence it is advocated that prospective clinical trials be registered in a clinical registry such as Pan African Clinical Trial Registry (PACTR) and South African Clinical Trial Registry (SANCTR) in an effort to reduce publication and reporting bias. The World Health Assembly resolution has made it a point to enforce sharing the results of trials in the public domain. To promote clinical trial data transparency, PACTR and SANCTR registries collect information on IPD sharing statements as part of the registration process.

Aim

We seek to examine the reporting of Individual Participant Data (IPD) sharing plan statements in PACTR, the only African WHO primary registry as well as the national registry SANCTR.

Methods

We searched and downloaded data in excel format in the clinical registry from 06 September 2022 and 21 September 2022 respectively. The total number of records reviewed was n = 2295. The search output from the registry was populated in an excel book for analysis. The random sampling was done using excel random sampling and the rationale behind was to reduce cost and achieve greater speed given the timeframe and working with large data. We assessed the researchers' responses on the IPD sharing statement field for the studies registered from 2019 to the date of the search. We analyzed the IPD sharing statements collected as part of the reporting field in the registries. Furthermore, we did a random sampling and extracted the IPD sharing statements from those records. When registering a study, the researchermust indicate whether there is a plan to make IPD data collected in the study, including data dictionaries, available to other researchers, and we will do a descriptive analysis of the findings.

Furthermore, we searched the database for each selected record and downloaded the records separately to extract the following data items: IPD sharing statement description (initial IPD statement). Those studies that indicated an intent to share IPD by selecting "Yes" under the optional protocol registration field entitled "IPD Sharing" (n = 2246) were further analyzed for the IPD description statement. Two researchers independently extracted data from all selected records included in the study in Microsoft Excel. To demonstrate the level of understanding of the IPD sharing statement and willingness to share IPD by the researcher, we described the number of trials with the initial IPD sharing statement (own statement).

Results

Our clinical registry search identified 2295 trial records. After random sampling of 10% of records using an excel workbook, 230 records were included for the analysis. An intention to share IPD trial records in (Figure 1) is the total number of trials registered between 2019-2022 and in (Figure 2) the sampled number of records. After reviewing the records, 115 free-text IPD descriptions were captured (see table 1).

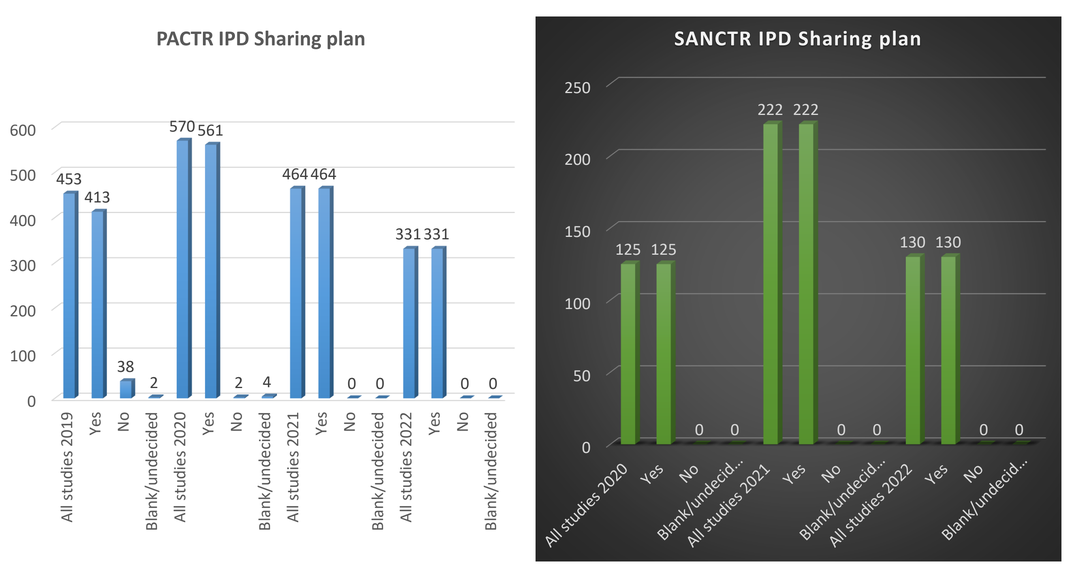

Figure 1: Individual Participant Data (IPD) sharing plan statements in our registries

The graphs in Figure 1 shows the number of studies who indicated intent to share IPD by year

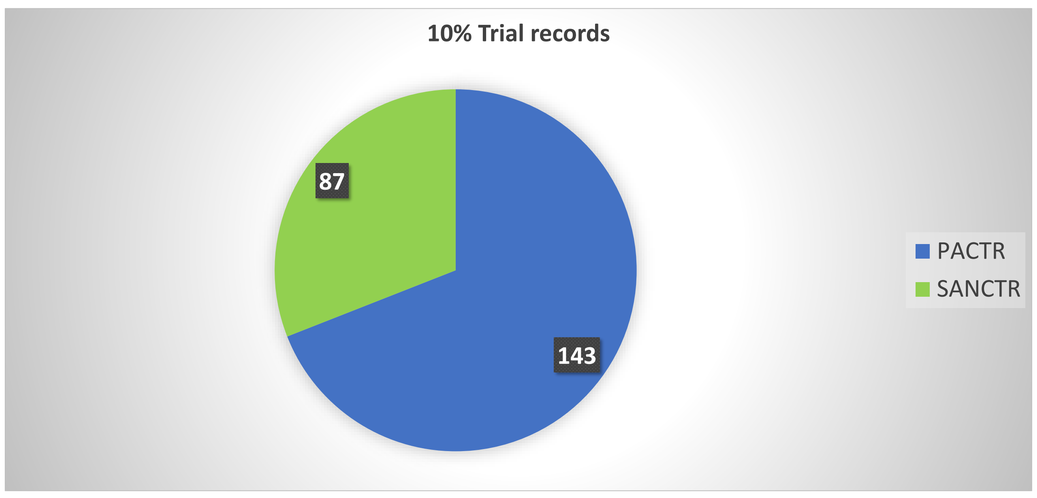

Figure 2: Individual Participant Data (IPD) sharing plan statements in our registries

The figure above shows the randomly selected (10%) sample that was analyzed to assess the researchers' responses on the IPD sharing statement field for the studies registered from 2019 to the date of the search.

Table 1: IPD sharing described in the 10% of the record sample

IPD sharing statement (own statement)	n	%
The IPD will include patients' demographic information	4	3.47
The data is available from the study's principal investigator	3	2.60
Summary results	15	13.04
A full excel sheet of data will be available	15	13.04
No information	55	47.82
Qualified external researchers may request IPD	3	2.60
An integrated clinical study report will be available	3	2.60
The privacy statement is included in the consent form	3	2.60
The sponsor is committed to sharing with qualified external researchers	12	10.43
Regardless of the outcome of a trial	2	1.73
Total	**115**	**100**

The table above shows the free-text descriptions of sharing plans and we found that 115/230 had different descriptions compared to the ICMJE and WHO recommendations.

Discussion and Conclusion

Based on our observation, data sharing still appears to depend on the enthusiasm of the lead researcher, despite it being widely agreed that IPD should be easily available. The gap in evidence base impact of IPD sharing remains a challenge in the African region. Thus, high-level evidence is needed to assess whether researchers understand the impact of data sharing when they are conducting their research. Moreover, as the registry and other stakeholders start to require IPD sharing, researchers must adapt to these requirements to communicate their work in the science space. Sharing the data can play an important role in increasing transparency and reproducibility of science in the research community.

In conclusion, there are still multiple hurdles that still need to be overcome in order to facilitate more cooperation, collaboration, and sharing by researchers.

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