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 results of trials in the public domain. To promote clinical trial 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 researcher must 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).

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.

References


Acknowledgments

The author would like to acknowledge colleagues who assisted to produce the poster: Duduzile Ndwandwe, Lindi Mathebula, Pumeza May, and Alice Thabetha. The author’s work is supported by the South African Medical Research Council and Cochrane South Africa.