TRIAL DATA SHARING POLICY

FIND's mission is to turn complex diagnostic challenges into simple solutions to overcome diseases of poverty and transform lives. One of the key contributions to realizing this mission is the generation of robust clinical data to support regulatory and WHO clearance for new diagnostic tools so that they can be made available to the populations FIND serves, and can be used by national disease programmes and Ministries of Health in the most impactful manner.

At the same time, FIND seeks to contribute to scientific advancement through sharing of data and supports the FAIR (Findability, Accessibility, Interoperability and Reusability) Guiding Principles that have been developed for scientific data management and stewardship (see FIND's Global Access Policy). Through its Code of Conduct and Ethics, FIND is bound to the principles of transparency, open communication, and scientific integrity, *inter alia*.

FIND's organizational commitment to these goals demands that it follow clinical research best practices, including information-sharing. Nonetheless, an overriding organizational responsibility, and therefore guiding consideration, is the protection of all study participants and of the vulnerable populations that comprise FIND's target market (see FIND's Safeguarding Policy).

1. Purpose

FIND has been registering its clinical trials and has had a public policy on disclosure of results and data as of January 2017[1]. This policy document serves to consolidate FIND's approach to ensuring the rapid and accurate registration of clinical trials, the sharing of data, and the communication of study results to the wider scientific and public health communities. This policy includes extracts from existing policies[2] and is complimentary to, but does not replace in any part, FIND's policies and procedures on conducting clinical trials in compliance with Good Clinical Practice (GCP).

2. Scope

This policy document applies to all clinical trials that FIND sponsors, including those where it may act as a co-sponsor. "Clinical trials" here refers to clinical studies that involve the enrolment of participants, formal protocol development with IEC/IRB clearance, assigning specimens from human participants to one or more health-related interventions to evaluate a biomedical outcome (based on NIH and WHO definitions). These trials should follow GCP guidelines.

[1] Policy and Guidelines for working with Private Sector Partners: https://www.finddx.org/wp-content/uploads/2018/11/Private-Sector-Partners-Policy_PL-02-08-01_V1.1_November2018.pdf

[2] Code of Conduct and Ethics; Global Access Policy; Policy and Guidelines for working with Private Sector Partners

A note on the scope: While this policy statement focuses on clinical trials as defined above, FIND, as a signatory to the WHO-ICTRP Joint Statement is in full alignment with the statement that "…transparency and reduction of waste and reporting bias are important for other types of research including public health intervention studies, observational studies, implementation research and pre-clinical studies…" FIND pursues best practices for these types of research categories, including early, open-access publication, and providing access to meta-data.

3. Approach

The organization requires that all staff and consultants who work on interventional clinical trials adhere to the following principles:

- Register all such interventional clinical trials prior to first enrolment or as soon as possible thereafter (FIND has selected NIH's https://clinicaltrials.gov/).
- Update trial registry as appropriate when trial is completed and/or terminated.
- Work towards summary results disclosure within 12 months of study completion.
- Submit all trial data for publication within 24 months of trial completion.
- Include the Trial ID or registry identifier code/number in all publications of clinical trials.
- Favor immediate, unrestricted, online access to peer-reviewed and published research papers, free of any access charge and with maximum opportunities for reuse.
- Provide appropriate attributions, citations and references, including acknowledgement of the generation of data in all publications.
- Make data used to reach the conclusions of a manuscript (e.g., related metadata and methods) available for review, in line with the practice of leading journals.
- Facilitate the ability of WHO and other public sector bodies to cross-check data.
- Meet all donor requirements for disclosure.

Notwithstanding the principles listed above, FIND will neither publish, nor request publication of, any information that would otherwise be inconsistent with the confidentiality obligations of FIND or its partners. This includes patient confidentiality choices, as defined in individual Informed Consent Forms (ICF).

4. Monitoring and policy review

- FIND will make publically available the results of annual monitoring and evaluation of adherence to this policy as of end 2018.
- FIND will revisit this policy in light of changing practices and contexts at least once every three years.