



**MEMORANDUM OF
UNDERSTANDING**

BETWEEN

**TANZANIA MEDICINES AND MEDICAL DEVICES
AUTHORITY (TMDA)**

AND

NATIONAL INSTITUTE FOR MEDICAL RESEARCH (NIMR)

FOR DATA SHARING

DATA SHARING AGREEMENT

S/N.	DATA SHARING AGREEMENT	
1.	Organizations	This Data Sharing Agreement is entered drawn up between Tanzania Medicines and Medical Devices Authority (TMDA) and National Institute for Medical Research (NIMR)
2.	Purpose of the Agreement	<p>The purpose of this agreement is to facilitate data sharing between TMDA and NIMR aiming at verification of conformity of clinical trials on matters related to;</p> <p>a. New Clinical Trial registration and amendment approval status by TMDA b. Clinical Trial Ethical Clearance status by NIMRS</p> <p>The requested data sharing is expected to speed up the process of clinical trial registration and amendment to reduce costs and time of getting the data, and to eliminate duplication of clinical research, and challenges in tracking recruitment status and study completion.</p>
3.	Project Description	N/A
4.	Period of Agreement	This Agreement commences on this day..... of, 2023 and will end on (N/A) or unless terminated/extended by mutual agreement of both parties.
5.	Description of Data Requested by TMDA from NIMR and Vice Versa (i.e., Requested by NIMR from TMDA)	<p>a. Hereunder are the data items being requested from NIMR by TMDA during the initial submission of the trial (alert) and after clearance (i.e., data items to be shared from NIMR to TMDA): -</p> <ul style="list-style-type: none"> i. Primary Identification number issued by REIMS to the trial after completion of application before the Issuance of the Ethical Clearance (so that TMDA can be alerted in advance) ii. Protocol Number of the study iii. Ethical Clearance after trial being cleared by NIMR iv. Principal Investigator v. Clinical Trial Sponsor <p>b. And, hereunder are the data items being requested from TMDA by NIMR (i.e., data items to be shared from TMDA to NIMR):</p> <ul style="list-style-type: none"> i. Certificate of approval to conduct a clinical trial
6.	Data Custodian Responsibility and data stewardship	<p>This section establishes the responsibility for the maintenance of data security. This should include the secure process for transmitting the file and any file format. If there are special circumstances regarding data access, they can be specified here.</p> <p>a. NIMR develop the formal user access provisioning to assign, monitor or revoke access rights as specified under</p>

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		<p>User Access Rights Guide.</p> <p>b. TMDA develop the formal user access provisioning to assign, monitor or revoke access rights as specified under User Access Rights Guide</p>
7.	Roles and responsibilities	<p>a. TMDA Responsible Personnel:</p> <p>Manager of ICT, Manager for Clinical Trial and Pharmacovigilance (MCTP), and Director of Medicines and Complimentary Products from TMDA</p> <p>b. NIMR Responsible Personnel:</p> <p>ICT Manager, Head of Section Health Research Regulation Section, Director of Research Information and Regulatory Affairs, Director General</p>
8.	Permissible data use, linking and sharing under this agreement	<p>Data Sharing Agreement</p> <p>a. NIMR under this Data Sharing Agreement, grants absolute rights and permissions to TMDA for its specified information systems to access and use the data being requested for its internal business operations only. TMDA is not allowed to provide or grant access to the raw data to another institution, third party, or the public.</p> <p>b. TMDA under this Data Sharing Agreement, grants absolute rights and permissions to NIMR for its specified information systems to access and use the data being requested for its internal business operations only. NIMR is not allowed to provide or grant access to the raw data to another institution, third party, or the public.</p>
9.	Timing and frequency of updates.	<p>The data being requested for sharing shall be updated as specified under Regulation 55(b) of the e-Government Regulations, 2020.</p>
10.	Constraints on Use of Data	<p>Data supplied by NIMR is the property of NIMR and shall not be shared with third parties without the written permission of NIMR. Data requestor (TMDA) shall not sell or use, internally or externally, for any purpose not directly related to the scope of work defined in this agreement without the written permission of NIMR.</p>
11.	Data Security and Confidentiality	<p>The data being requested as mentioned above, shall be transferred in an end-to-end encrypted computer network and shall be for facilitating official business processes only. The data (or item thereof), in its raw format, is strictly prohibited from public or third-party access.</p>

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12.	Dissemination	This section describes a review of any results to be disseminated, including a review to make sure that third-party researchers protect the confidentiality of individuals when publishing findings. Such restrictions should not allow arbitrary or unwarranted suppression of data but be limited to protecting the privacy rights of individuals. It may also specify proper citation of the data source or any disclaimer required on the report.
13.	Indemnification/ Dispute Resolution	This section describes that in the case of legal claims against any of the parties to the agreement, normal legal rules and principles will apply, and states that if one party becomes aware of a claim against the other, they should inform the other party promptly.
14.	Termination and Modification	Include the conditions under which the agreement can be terminated. Note that this clause also includes directions on how data are to be disposed of after termination. In case of termination or modification, either party shall issue three months' notice of termination or such modification. Termination shall be upon fundamental breach of either party and modification shall be upon agreement of both parties.

By the signatures of their duly authorized representative below, **NIMR** and **TMDA**, intending to be legally bound, agree to all the provisions of this Data Sharing Agreement.

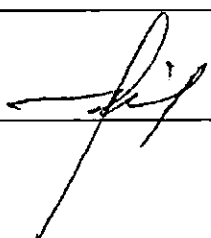
For and on behalf of
**Tanzania Medicines and Medical
Devices Authority (TMDA)**

Name: Adam M. Fimbo

Title: Director General

Place: Dar-es-Salaam

Date: 3/8/2023

Signature: 

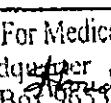
For and on behalf of
**National Institute for Medical Research
(NIMR)**

Name: Said S. Aboud

Title: Director General

Place: Dar es Salaam

Date: 09/08/2023

Signature: 
National Institute For Medical Research
Headquarters
P. O. Box 9653
Dar es Salaam