EDCTP Contract N^{0} RIA2020EF-2918

Rapid diagnostics for COVID-19: manufacturable in Africa to increase affordability, improve epidemic preparedness and strengthen local resilience

Deliverable report

Deliverable number	D9.2
WP no/title	WP9 Dissemination and Communication
Deliverable title	Data management Plan
Responsible partner	UCAM
Dissemination level	(PU = Public, CO = Confidential) PU
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History of changes:

Date	Version no	Comments
01/10/2019	1	Version transfer from Annex 1 following start of project.
10/01/2021	1	Reviewed without change
23/01/2022	1	Reviewed without change

List of content

Partner	Contribution to this deliverable
UCAM	Formulated the plan and developed it to final version.
Other partners	Provided input

1 Status of the Deliverable

This deliverable presents the data management plan and maintains it. It is complete.

2 Summary of the results (max. 1-2 pages)

This deliverable presents the data management plan and maintains it. The present version is derived from the plan submitted with the application.

3 Description of work performed and obtained results

3.1 Description of the data

3.1.1 Type of study

Four studies generating data will be conducted during the course of this project:

Study 1: Clinical evaluation of new diagnostic test

Study 2: Laboratory evaluation of new enzyme constructs

Study 3: Prototype development of scFv's

Study 4: Economic evaluation of local manufacturing and route to market in Ghana.

3.1.2 Types of data

The types of data that will be collected include:

- Clinical data during clinical evaluation of new diagnostic tests
- Laboratory data during enzyme and scFv development and production
- Laboratory data during test evaluation with new enzymes
- Cost, resource and impact data during economic evaluation

3.1.3 Format and scale of the data

The data will be stored in standard file formats (e.g. Word, Excel, databases, Matlab, jpg images etc). These formats enable file sharing and long-term revalidation of the data

3.2 Data collection / generation

New data collection is required because diagnostics will be used and developed for which no data currently exists and accurate information on epidemiology, clinical features, and laboratory diagnosis of Sars-Cov-2 is not currently available in Ghana. It is also necessary to store these data long term in order to provide context for the interpretation of new data as it becomes available. New data collection is also required to fuse information from the technological innovation of the diagnostic test with clinical data, analysis of economic frameworks including trade policies, industrial development strategies, business models and intellectual property; technological trajectories and contextual technology fit; and socio-cultural and political influences on priority-setting and technology adoption. Little data currently exists examining the benefits of local manufacture of health technologies. Such information may emerge from the preliminary data generated in this study.

3.2.1 Methodologies for data collection / generation

The data will be collected / generated as follows:

- Clinical data – will be obtained from the sample records in study 1 above
- Laboratory data – will be obtained from the experimental records of studies 1, 2, and 3 above

- Epidemiological data will be obtained from laboratory records at the testing laboratories (study 1)
- Economic data – economic data that we will cover are non-personal information unless case studies are used (which will be hypothetical).
- Secondary data on diagnostic impact will be obtained from the expert input and review of the literature.
- Other secondary data will be obtained by investigators and research assistants through a review of online articles, reports and datasets.

For any personal information data, the existing policy at NMIMR and KCCR will be used to retain anonymity. For broader macro based data, there is no specific issue. Data will be recorded with source transparency, methodology in processing the data will be recorded clearly explaining the interpretation of the data processing results. Original data sets will be stored as described above for future scrutiny

3.2.2 Data quality and standards

Clinical data collection will be performed in accordance with Good Clinical Practice guidelines. The consistency and quality of data collection / generation will be controlled and documented through data entry validation (clinical data). Laboratory data collection will follow good laboratory practice and subject to full and robust error analysis, ensuring adequate repeat data and presentation of the data to peer review in publication

3.3 Data management, documentation and curation

3.3.1 Managing, storing and curating data.

Data will be stored in secure electronic databases that are only accessible to authorised members of the research team. Data will be backed-up regularly in accordance with local institutional policies and procedures during the course of the study and in the short / medium term. Person identifiable information will not normally be accessible, but may be available to members of the research team who are also involved in front line testing. Data will be anonymised as soon as it is practical to do so

3.3.2 Metadata standards and data documentation

We will document the methods used to generate the data, analytical and procedural information, document the provenance of data and their coding, and detailed descriptions for variables. The clinical metadata produced from the study will be linked to the laboratory in a fully anonymised fashion. This will eventually be made available to other researchers for analysis

3.3.3 Data preservation strategy and standards

The clinical / laboratory research data will be stored in secure electronic databases at the University of Cambridge, Danish University of Technology, Kumasi Centre for Collaborative Research in Tropical Medicine (KCCR), University of Ghana, Kwame Nkrumah University of Science and Technology (KNUST), AVOMA for 5 years after study closure. The data will be arranged under the project name, with a folder structure representing the respective workpackages,

3.4 Data security and confidentiality of potentially disclosive information

3.4.1 Formal information/data security standards

Data from this will be collected and stored in accordance with the data management policies of the University of Cambridge,Danish University of Technology, Kumasi Centre for Collaborative Research in Tropical Medicine (KCCR), University of Ghana, Kwame Nkrumah University of Science and Technology (KNUST), AVOMA. Platforms will be ISO 27001 and GDPR compliant.

3.4.2 Main risks to data security

For the clinical evaluation studies, data and samples will be collected by clinicians who have legitimate access to patient identifiable information. Data will be entered into secure electronic databases that are only accessible to these clinical staff. Data will be anonymised as soon as it is practical to do so, prior to it being available for use in the testing trial and data analysis. Patient confidentiality will be maintained and study participants will not be identifiable in any presentations or publications arising from this research. Any further distribution or sharing of data will be with the anonymised data sets.

3.5 Data sharing and access

Deposited data will be stored securely in databases maintained by University of Cambridge, Danish University of Technology, Kumasi Centre for Collaborative Research in Tropical Medicine (KCCR), University of Ghana, Kwame Nkrumah University of Science and Technology (KNUST). Data generated from the engineering and synthesis of new proteins will be submitted to the Protein Data Bank in Europe, once protein structure is fully determined

3.5.1 Suitability for sharing

Data from the clinical studies will be shared in accordance with the data management policies of the University of Cambridge, Danish University of Technology, Kumasi Centre for Collaborative Research in Tropical Medicine (KCCR), University of Ghana, Kwame Nkrumah University of Science and Technology (KNUST) and in line with the open access policy for H2020 and the requirement to share data within 30 days. The data will be pre-prepared in anonymised form for both storage and sharing as required.

3.5.2 Discovery by potential users of the research data

We will follow FAIR Data principles (https://www.force11.org/group/fairgroup/fairprinciples) Potential users will be able to discover the data and request access through the Principal Investigators and the Steering Group. Access to data will be available within 30 days after it has been generated, through open access and will also be published through primary publication.

3.5.3 Governance of access

The decision to supply data will be made by the Principal Investigators and the Steering Group according to 5.2. In the event of appeal the request will be referred to consideration by the committee responsible in the institute where the request has been made.

3.5.4 The study team's exclusive use of the data

Data collected during the project will remain exclusively within the study team for 30 days after it has been generated and will be published in primary manuscripts arising from the research.

3.5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

Personal data will be anonymised as soon as it is practical to do so. Data collected during the project will remain exclusively within the study team until after publication of the primary manuscripts arising from the research. The procedures for the clinical trials will follow a consent procedure, which includes known risks disclosure and has been agreed by the necessary ethics boards. There will be a consortium agreement and exploitation agreement that will describe ownership of intellectual property and an exploitation plan will be produced at the end of the project for the further adding of value to the data.

3.5.6 Regulation of responsibilities of users

External users will be bound by data sharing policies of the University of Cambridge, Danish University of Technology, Kumasi Centre for Collaborative Research in Tropical Medicine (KCCR), University of Ghana, Kwame Nkrumah University of Science and Technology (KNUST), AVOMA

3.6 Responsibilities

The Principal Investigators have overall responsibility for study-wide data management, metadata creation, data security and quality assurance of data. However, the co-investigators will be responsible for data management, metadata creation, data security and quality assurance of data at their sites and are bound to follow the principle laid out in this document.

3.7 Relevant institutional, departmental or study policies on data sharing and data security

Institutional Data Policy & Procedures will be followed eg: University of Cambridge (https://www.data.cam.ac.uk/)