D9.2 – Plan for Exploitation and Dissemination of Results

Project Information

Grant Agreement Number	RIA2020EF-2918
Project Full title	COVID-19 Diagnostics for Africa
Project Acronym	AfriDx
Funding Scheme	EDCTP
Start Date of the Project	October 1, 2020
Duration	15 Months
Project Coordinator	Deborah Oluwasanya (UCAM)
Project Website	https://www.afridx.ceb.cam.ac.uk

Deliverable Information

Deliverable Number	9.2
Deliverable Title	Plan for Exploitation and Dissemination of Results
WP Number	9
WP Leader	UCAM
Nature	Public Report
Authors	Kayla Kret (UCAM)
Contributors	Jenny Molloy (UCAM)
Reviewers	Lisa Hall (UCAM)
Contractual Deadline	January 31, 2021
Delivery Date to EC	

Dissemination Level

PU	Public	✓
RE	Restricted to a group specified by the consortium.	

Document Log

Version	Date	Author	Description of Change
1.0	20/01/2021	Kayla Kret	First draft of document
2.0	30/03/2021	Jenny Molloy	First Revision
3.0	18/04/2021	Lisa Hall	Second Revision

Table of Contents

1. Executive Summary

This document is the deliverable "9.2: Plan for Exploitation & Dissemination of Results" of the European & Developing Countries Clinical Trials Partnership (EDCTP) funded project "AfriDx: COVID-19 Diagnostics for Africa" (AfriDx). The Plan for Exploitation and Dissemination of Results (PEDR) summarises the consortium's strategy and concrete actions performed so far related to the protection, dissemination, and exploitation of the project results as well as to serve as a guideline for activities to be carried out in the upcoming months of the project. This is a public deliverable and will be made available on the public website.

This report corresponds the first release of the PEDR, however updates will be made towards the midterm reporting (M8) and end of project (M15).

This document describes two main sections, the dissemination and exploitation of results, which are separately reported in Dissemination Strategy and Exploitation Plan.

Section A of this PEDR describes the Dissemination actions taken so far and strategy going forward in order to demonstrate the impact and the added value of the project to the EDCTP and European Union. These dissemination activities will be performed over the lifetime of the project. Within this section, the target audience will be identified as well as the timing of the dissemination activities. The tools and management of dissemination will also be described here as well as partner roles.

Section B of this PEDR describes the Exploitation Plan and provides a summary of exploitable results and actions taken so far. As the Exploitation Plan will be adapted during this project, this first release describes the strategy that was outlined in the proposal.

The PEDR is structured in 4 chapters. Beyond this Chapter 1 executive summary, Chapter 2 gives a brief introduction to the AfriDx project and its aims and objectives, Chapter 3 describes the dissemination strategy, and Chapter 4 describes the exploitation strategy. Within the appendices, further information can be found relating to the partner information and contact points.

2. Introduction

Management of people movement, containment of disease spread, and care of the ill requires correct diagnosis of COVID-19 and information about the person's stage in the disease pathway. This project will provide reliable diagnostic systems for the clinical diagnosis of COVID-19 in Africa from first infection through to recovery and immunity. The diagnostics will be developed to become manufactured locally in low resource environments, without major capital investment, using unique biological reagents produced in Africa.

To deliver these aims and objectives we will:

- Conduct a trial of a prototype POC LAMP (PATHPOD) for detection of viral RNA(SARS-Cov-2) in the COVID testing laboratories in Ghana
- Develop a production process for local manufacture in Ghana of the required biological materials at low cost which could contribute to enabling production of a version of PATHPOD in Africa for Africa (the AfriDx)
- Screen and isolate scFv's for a serology antibody titre test, to produce an immunoassay (AfriMx) for late-stage infection and post infection immunity
- Train skilled and minimally skilled personnel to understand and perform testing
- Connect with local enterprise in Ghana and develop a plan for exploitation and the route to market for the low cost AfriDx and AfriMx diagnostics.

NMIMR, KCCR are supporting the frontline of SARS-Cov-2 testing in Ghana using RT-qPCR. Their capacity at the start of the pandemic was ~1500 tests/day and they seek a faster lower cost solution without compromise in accuracy or precision. RT-qPCR is slow, and the costs (typically >$10/test) are not sustainable for long term testing. Point of care (POC) diagnostics are only achieved in Africa with significant external grant-aid support. The average annual expenditure on health in low-income countries is <$40 per capita. Local production capabilities are therefore a vital component of any solution as exemplified in May 2019 when WHO, UNIDO, UNCTAD, UNAIDS, UNICEF and The Global Fund released a joint statement promoting local production of medicines and health technologies.

This project will give sub-Saharan Africa the technology, tools and training which will strengthen its capacities to manage outbreaks, both directly and through improved *in-country* manufacturing capability for healthcare diagnostics. Socioeconomic long-term independence from external grant-aid to supply diagnostics and development of a local manufacturing infrastructure will emerge.

3. Section A: Dissemination Strategy

3.1. Target Audience

A preliminary list of targets includes: [A] stakeholders with interest inhuman health and public health preparedness for epidemics, [B] Ghanaian, EC, and international regulatory bodies [C] Ghanaian Health Authorities, [D] Ghanaian and EC industry and SMEs, [E] end-users, [F] scientists, [G] media reporters and [H] the general public.

The target groups listed below are considered essential for this project:

- [A] World Health Organization (WHO) is a specialized agency of the United Nations that is central in the monitoring of epidemic diseases and has also–in cooperation with EMA and FDA-developed and issued guidelines for emergency approvals for diagnostic tests to be used in the present outbreak of coronavirus COVID-19 (2019-nCoV).
- [B] Ghana Food and Drugs Authority (FDA) who regulate IVDs in Ghana in addition to the EMA and FDA for which CORONADX is preparing documents to submit an Emergency Use Authorisation for the PATHPOD system.
- [C] Ghana Ministry of Health delivers the enhanced surveillance plan and measures to control and prevent further spread of COVID-19 in Ghana and provide information and intensive public education.
- [D] Industry organisations representing the medical device manufacturing industry such as the Association of Medical Diagnostics Manufacturers (AMDM) that serves as an educational resource for regulatory submissions and other compliance information related to the *invitro* diagnostic industry. Also, local diagnostic developers such as Incas Diagnostics or other medical device distributors who may assist with route to market and seeking local production partners.
- [E] Ghana Association of Medical Laboratory Scientists is an association of key scientists who share experiences at the front line of medical laboratories including the use of diagnostics. They will represent a cohort of end-users and thereby provide essential feedback about the deployment of testing.
- [F] Relevant scientists will be targeted through diagnostics conferences and publications as detailed below and in WP9 Communication and Dissemination. We will also look for relevant networks in the African Academy of Sciences or Ghana-based network the African Science Initiative among other peer-based organisations and learned societies.
- [G] Media reporters will be targeted from national Ghana Press such as the Daily Graphic and Ghanaian Times along with communication to European and international outlets through the UCAM and DTU press offices. The scientific press can also be targeted for press

releases e.g., Nature News and technology or medicine-focused media such as STAT News or QUARTZ.
- [H] Cambridge-based Naked Scientists produce world-recognised radio shows and podcasts, we will also be proactive in providing information to groups working directly to address health misinformation e.g., Africa Check, Fact Check Ghana, particularly around COVID-19 testing.

3.2. Dissemination Timing

Throughout the project, different levels of dissemination will commence. During the initial phase of the project, dissemination will include the partners identifying channels and routes that may be beneficial to the project. This will also include the development of the website and the social media, channels provision of on-line training materials and web-based presentations.

In the mid-term phase of the project, most of the communication of the project will be via the website and the social media channels. This will include news articles and press releases through the website. The social media channels will create awareness of these articles and press releases and draw the audience to the website. Additionally, it is expected that the partners notify the communications teams at their institutions to generate press releases.

In the final phase of the project, all partners are expected to participate in dissemination of the project results through published papers in journals and conference attendances. By this point, the audience for the social media channels will be refined and more aligned with the project objectives. The social media channels will continue to be used to generate public awareness and draw the audience back to the website. The results and news articles will be the only new additions to the website as the other sections will have been completed prior to this phase.

3.3. Dissemination Management

Management of dissemination of the project will be carried out by all members. UCAM will lead the dissemination and ensure that all activities represent AfriDx and the partners in good light. All partners are expected to participate in social media engagement and contribute to website content.

3.4. Basic Tools

1.1.1. Project Handbook

The Project Handbook acts as a simple signposting guide for the participating members for contact information, work packages including lead institution, and deliverables including lead partner. The project budget can also be found within the Project Handbook. The Project Handbook was completed for deliverable D1.1 in Month 4.

3.4.1. Identity Logo

A graphic logo and visual identity have been created as described in deliverable D9.1.

The logo contains the title of the project and incorporates several factors of the project. The rough shape and outline of SARS-Cov-2, the map of Africa, and a closed ring of circles representing the unity of the African Nations have been incorporated into the logo.

Figure 1: AfriDx logo.

3.4.2. Website

The website will be the main access point to key information about the project and its outcomes, making any public materials generated in the project openly accessible. To ensure maximum public outreach, a website has been developed under the University of Cambridge webservices with the project name, AfriDx, in the URL to increase traffic. The website has been developed and will be managed by the partners at University of Cambridge. The website will be updated regularly as the project progresses through the deliverables and work packages.

The full URL of the website is:
https://afridx.ceb.cam.ac.uk/

The website has several sections for public access:

- Brief project introduction, aims, and objectives.
- Consortium information, including the institutions and partners, links to partners' websites, and contact information.
- Access to public project deliverables (reports, interviews, blogs, videos, etc.).
- Other information such as upcoming events, conference attendances, news items, etc.

The website references the funding bodies, EDCTP and EU, on each page through their logos and grant reference number. Additionally, the AfriDx logo will be found on every page.

The website is part of deliverable D9.1 as a portion of the visual identity and website.

3.4.3. Press Releases

At least two press and news releases focusing on specific project milestones will be produced and distributed in addition to journalistic articles and 2 interviews, addressing a wider lay audience of 1000s of readers.

3.5. Project Communication Plan

3.5.1. Social Media

Several key social media channels have been identified for public outreach for this project. Namely, the use of Twitter and LinkedIn will provide platforms to audiences and communities interested in the AfriDx initiative. All partners will be responsible for generating content for social media and increasing the reach of social media posts. The social media channels will be managed by UCAM.

The Twitter handle for this project is (@afri_dx). On this platform, the research groups from partners will be followed to increase awareness of their research. Their link with their institution will also act as an “influencer” to increase the public outreach. The Twitter platform will allow for easy and quick sharing of news, events, and updates in the project.

LinkedIn will be used to reach a commercial audience. Similar information will be shared on this platform as Twitter but will likely gain a different audience.

3.5.2. Publication in Journals and Conference Proceedings

Publications and conference presentations will be targeted according to the direction of the findings and will take advantage of complimentary conference and journal special issue topics. Publication will be open access. Possible targets for academic dissemination include publications such as: Lab-on-chip journal, Biosensors and Bioelectronics journal, Analytical Chemistry, Nature Biomedical Engineering, Eurosurveillance, Nature communication, Clinical Chemistry, Frontier microbiology, Small, Biomaterials, ACS Sensors.

The outcome of the project will be presented at relevant conferences and if successful it is already anticipated that it will be presented in invited and plenary presentations at the postponed Analytix 2020 and the International Meeting on Chemical Sensors. This is an important study for all members of the consortium who are enthusiastic to contribute to the challenge of diagnostics and will be promoting and reporting the outcomes at all opportunity. No budget has been assigned to attendance at these meetings in this project, but students will be funded to attend from other sources and members of the consortium will also be able to participate in conferences with other funding. In view of the crisis in testing, all the resources associated with this project have been invested in developing and delivering the testing.

3.5.3. Networking and Conferences

Project partners will be encouraged to present outcomes at a range of local and international conferences and junior team members will be specifically encouraged to present talks and posters e.g., Analytix 2020 and the International Meeting on Chemical Sensors, the biennial EDCTP Forum in 2020.

3.5.4. Workshops

In the framework of WP7 activities, regular virtual training workshops in Ghana will be planned to familiarise end-users with the use of RT-LAMP-based point of care assays and the local production of enzymes.

We will deliver four training workshops during WP2 and WP8. We have assumed that all training will need to be carried out online but that there will be a possibility to conduct hands-on sessions with local participants and instructors only. In WP2 researchers directly involved in the PATHPOD study will be trained then in WP8 there will be workshops with open calls for participation. Examples of potential courses will be: i) a course for researchers and health care workers to conduct PATHPOD point of care assays for SARS-Cov-2 tests, safely and effectively; ii) a course for Ghanaian researchers and potential private sector partners to locally manufacture Boon-RT, -BST and -scFV; ii) a course for Ghanaian researchers to use the AfriDx-KIT to develop further diagnostic assays for other diseases. Outputs of WP8 such as training materials will be public and Open Access.

3.5.5. Outreach Activities

Fact or Myth informational posts, video interviews and work with the Naked Scientist in the UK, participation in Science Festivals, will act as outreach activities. The goal will be to provide information about testing and diagnosis, including the differences between viral RNA testing and an antibody test, and where and when the different tests would be used.

The aim of our public communication will be transforming complex jargon around COVID-19 testing into clear, transparent, and easy-to-understand messages, increasing the public understanding of how COVID-19 is diagnosed through adaptation of the “Fact or Myth?” posts developed for the PATHPOD in Europe.

3.6. Monitoring Impact

The impact and effectiveness of the activities will be monitored through dedicated web analytics and software tools measuring online and social media outreach and engagement. Together with the assessment of qualitative feedback from direct exchange with stakeholders this will allow us to assess the level of awareness and acceptance of the project results as well as providing information about the reach of the communication. Indicators will be detailed in the Communication and Dissemination (C&D) Plan within the PEDR. Monitoring pre-established indicators on an on-going basis will allow us to fine-tune the communication strategy throughout the project by revising and aligning it to our expected impacts and priority stakeholders.

4. Section B: Exploitation Plan

4.1. Exploitable Results

Key exploitable results are the outputs generated during the project which can be used to create impact, either by the project partners or by other stakeholders. This includes results that are directly exploitable (e.g., inventions, prototypes, services) as well as results that have potential for further impact on research, innovation, and policy (e.g., knowledge, technology, processes, networks, reports)

The exploitable results of the project are expected to be:

- ER1: Proven direct application of the PATHPOD system to COVID testing in Ghana
- ER2: Local manufacturing process for PATHPOD reagents in Ghana, with background knowhow transferred from UCAM to KNUST
- ER3: Open Access educational resources on use and manufacturing of LAMP tests and reagents
- ER4: Proof of concept for an antigen test based on single chain antibodies (AfriMx)

4.2. Exploitation Management

The purpose of exploitation management is to maximise the positive use of exploitable results for scientific, societal, or economic purposes. This includes management of innovation, intellectual property, data, and stakeholder engagement. This section details management of each of the exploitable results listed above and complements the Dissemination Strategy and Data Management Plan.

ER1: Application of the PATHPOD system to COVID testing in Ghana

- Type: Product and process
- Innovation: this is the first multi-site deployment of LAMP-based COVID testing in Ghana.
- Benefits: faster and lower cost testing enabling rapid clinical decision making which benefits both clinicians and patients. Increased testing can improve individual and public health outcomes.
- Technology Readiness level: Instrument with pre-available reagents-TRL7 (system prototype demonstration in operational environment). With local reagent manufacture TRL4 (component laboratory validated).
- Technical challenges: adaptation of processes to local environment and local health system.

- Time to market: estimated 24 months but limited by appropriate regulatory pathway being available in country of manufacture.
- Protection and IPR issues: to be determined.

Exploitation Plan

Exploitation of AfriDx results is likely to be influenced by the acute COVID-19 situation, so a non-conventional fast-track business plan may influence the route to exploitation. In the first phase, which will be supported by the grant, the AfriDx consortium will provide Ghana partners with collection devices, PATHPODs and chips, and train partners in Ghana. They will then develop a training programme with local services in clinical trials so validation of the PATHPOD POC workflow can be initiated at the earliest. The AfriDx consortium will also investigate the patent situation in Ghana to learn if any license needs to be obtained and establish freedom to operate.

We will aim to follow-up the whole study by seeking additional funding for larger trials with volunteer recruitment (WP6-follow on) that would provide a clearer pathway to regulatory approval.

The next phase of bringing these diagnostics to market in Ghana will require further translational research grants or philanthropic funding in the first instance, with a view to innovation funding and investment as the technology readiness level increases.

ER2: Local manufacturing process for PATHPOD reagents in Ghana, validated at KNUST.

- Type: Process
- Innovation: technology is novel for industrial production of diagnostics.
- Benefits: faster supply chain and potentially lower cost enabling more diagnostic tests to be performed or resources to be saved for other health spending. Increased testing can improve individual and public health outcomes.
- Technology Readiness level: TRL4
- Technical challenges: quality assurance
- Time to market: estimated 36 months, but limited by regulatory pathway
- Protection and IPR issues: to be determined

Exploitation Plan

A local partner in Ghana (or other sub-Saharan African country) will be sought for business partnership on production. Essential is this partner has or can in relatively short time, establish production of enzymes under controlled conditions preferably under ISO 13485. If not possible, at least under IS0 9001, with a committed intention to upgrade to ISO 13485. AfriDx, led by partner TATAA, will negotiate reciprocal supply agreement with the local Ghana partner that secures Ghana access rights to use the PATHPOD technology and supply agreement for collection devices, PATHPODs and chips, while TATAA obtains supply agreement to purchase the enzymes produced by the Ghana partner.

Terms shall be commercial, but being reciprocal, which opens the possibility to agree long term contracts and large volumes, attractive terms to both parties could be agreed. The partner can be offered exclusivity against certain milestones and conditions, including setting up production in time, introducing adequate quality control, reaching certain minimum production capacity, certain employment conditions, and maximum pricing for the local market.

The further development of local manufacturing capabilities (WP7) leading to commercial supply of enzymes from within sub-Saharan Africa is expected to help catalyse a biotechnology industry and an increase in job opportunities.

The next phase of manufacturing diagnostics for the market in Ghana will require further translational research grants or philanthropic funding in the first instance, with a view to innovation funding and investment as the technology readiness level increases.

ER3: Open Access educational resources on use and manufacturing of LAMP tests and reagents

- Type: Educational resources
- Innovation: N/A
- Benefits: increased skills and knowledge for health care workers, clinicians, scientists, and innovators on relevant testing technologies. For manufacturing, capacity building for exploitation of ER2, ER4 and other biotechnologies.
- Technology Readiness level: N/A
- Technical challenges: effective delivery of material through virtual / online platforms due to lack of travel and in-person training because of COVID.
- Time to market: N/A
- Protection and IPR issues: none

Direct delivery of educational materials during the project will be undertaken by the AfriDx partners. To facilitate exploitation by others we are making the materials available under open licenses and will host them on online platforms for ready access and use by educators and by innovators, scientists, and students directly.

ER4: Proof of concept for an antigen test based on single chain antibodies (AfriMx)

- Type: Product
- Innovation: single chain antibodies (scFVs) enable easier manufacturing than monoclonal, opening the possibility of local production of lab-based or rapid antigen tests.
- Benefits: rapid testing for homes and workplaces, increased options for large scale testing compared to nucleic acid tests. Can work in conjunction with other testing as part of an effective track and trace and/or surveillance system.
- Technology Readiness level: TRL3 (experimental proof of concept)
- Technical challenges: selection of appropriate scFV, immunoassay sensitivity and optimisation, transfer of manufacturing process to local production.
- Time to market: 4+ years
- Protection and IPR issues: to be determined

As this exploitable result will only be at TRL3, it will require follow-on work to further develop the proof-of-concept immunoassay. In the meantime,, AfriDx will investigate any IP and regulatory issues that would need to be considered in future exploitation. The advice on the uses of immunoassays is developing, as part of an effective COVID management strategy in Ghana, Africa and elsewhere in the world. This will better target future work on their application that is more useful from a public health perspective in the context of the Ghanaian health system and could have broader application.

5. Appendix

5.1. AfriDx Consortium

Coordinator	**Country**

University of Cambridge	United Kingdom
Participants	
Danish Technical University	Denmark
Kumasi Centre for Collaborative Research in Tropical Medicine	Ghana
Kwame Nkrumah University of Science and Technology	Ghana
Noguchi Memorial Institute for Medical Research	Ghana

5.2. Contact Points

General Queries
afridx@ceb.cam.ac.uk

Project Coordinator
Deborah Oluwasanya
do361@cam.ac.uk
University of Cambridge

For more information, please visit our website:
https://afridx.ceb.cam.ac.uk/