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D1.17 Dissemination and exploitation plan

Title of the Project: BCG vaccine to reduce absenteeism due to infectious diseases of health care workers during the COVID-19 pandemic. A multi-center randomised controlled trial

Acronym: BCG-COVID-RCT

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Deliverable 1.17 Dissemination and exploitation plan

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Project website: https://www.sdu.dk/en/forskning/edctp

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1. Introduction

This report is the public D1.17 Dissemination and Exploitation Plan of the BCG-COVID-RCT project entitled *BCG vaccine to reduce absenteeism due to infectious diseases of health care workers during the COVID-19 pandemic. A multi-center randomised controlled trial*, produced as part of Work Package 1 – Administration and overall scientific coordination. The present project has received funding from the European Union's EDCTP2 Programme under Grant Agreement No RIA2020EF3049.

The Plan has been developed with the purpose of providing Dissemination and Exploitation (D&E) guidelines to consortium partners and stakeholders. The plan provides details for D&E actions to be undertaken both during the project and after it has finished and should be seen as a tool to harmonize and synchronize strategies/plans across consortium partners.

The Trial is registered on ClinicalTrials.org with registration number NCT04641858, released on November 22, 2020.

2. Background

2.1 General objectives and progress of the clinical trial

The COVID-19 pandemic challenges available hospital capacity. This is augmented by absenteeism of health care workers (HCW). Bacille Calmette-Guérin (BCG), a vaccine against tuberculosis, has been shown to induce protective non-specific effects against other infections; a plausible immunological mechanism has been identified in terms of "trained innate immunity". Several trials across the world have therefore been initiated to study if BCG can reduce the incidence and/or severity of COVID-19 have been initiated. African studies are needed. Even with the availability of specific COVID-19 vaccines, it is relevant to study if BCG can reduce the risk of infectious diseases due to its large availability, the very low risk of side-effects and its potential to confront future variants of COVID-19.

BCG-COVID-RCT is a clinical trial sponsored by the University of Southern Denmark testing the hypothesis that BCG and ameliorate the damaging effects of COVID-19. It is currently being conducted within a consortium involving researchers from NOVA University in Lisbon, National Institute of Public Health in Guinea-Bissau, Cape Verde University in Cape Verde, and the Manhiça Center for Health Research in Mozambique. The vaccine trial was envisioned to be conducted in the three African countries Cape Verde, Guinea-Bissau, and Mozambique. Since no legal framework for conducting a clinical trial in Cape Verde existed, the Cape Verde leg of the trial has been changed to an observational study which is ongoing, while the trial is as well currently ongoing in Guinea-Bissau and Mozambique.

Inclusions in both the observational study and the trial have been completed and follow-up data is currently being collected (expected to be finished by July 2022).

Aside from the objectives of the main trial, e.g., answering the research question as to whether BCG vaccination can reduce absenteeism among health care workers, several observational studies based on the large dataset are planned, and this D&E plan covers strategies and actions for all output from the consortium.

As an integrated plan for the analysis of trial results, appropriate data transfer approvals have been obtained to share trial data with an international consortium, ALL-IN-META-BCG-CORONA, which maintains a running meta-analysis gathering BCG trial data from around the world that tests the same research question.

2.2. Objectives of the D&E plan

The aim of the D&E plan – led by University of Southern Denmark (SDU) – is to communicate and disseminate the project data and results in the most optimal way. The BCG-COVID-RCT will produce data of potential interest to a wide range of audiences, including (but not limited to) researchers, participants in the trials, people at-risk of severe COVID-19, health care providers, community members, international organizations and policy-/decision-makers.

The communicative activity is thus vital to promote and ensure the dissemination of the BCG-COVID-RCT results to guide policy and has the following objectives:

- Disseminate information about BCG-COVID-RCT, its objectives and outcomes.
- Facilitate collaboration and information exchange between stakeholders, scientific communities, patient groups, the general population and international organizations such as WHO.

- In case of a significant effect of BCG against COVID-19 or on overall health, promote the use of the results of BCG-COVID-RCT in developing and revising guidelines for vaccination of adults at increased risk of severe COVID-19 and/or death from other causes, such as health care workers and the elderly.
- Create effective bilateral communication channels with stakeholders, academia, researchers, and the public as a whole.
- Disseminate the final results (exploitation) of the project to target audiences like stakeholders, academia and researchers, and the public.

3. Strategies for communication, dissemination, and exploitation

3.1. What constitutes communication?

In the present project, we intend to use strategic and targeted communication measures for promoting the action itself and ensure dissemination to a multitude of audiences, including the media and the public. When possible and where there is interest, we will engage in a two-way exchange. This increases chances of reaching out to society as a whole and to more specific audiences of interest. Communication is for us thus in this sense:

- Strategically planned (not only *ad hoc*) and agreed upon within the consortium, when necessary
- Identifies and sets clear communication objectives.
- Involves pertinent messages, the right media for the message in question, and means.

3.2. What constitutes dissemination?

Dissemination is important but not always desirable. A wrong interpretation and regular misinformation can be disseminated widely; this problem has been amplified during the COVID-19 pandemic and is now substantial. As a consortium of researchers from a host of countries, conducting a randomized controlled vaccine trial in Africa, how our results are disseminated and in which channels is crucial, along with their interpretation. With dissemination we intend that **our** scientific interpretation of the results of the action is widely available (public disclosure) by appropriate means, including scientific publications and appropriate summaries. Our goals include:

- Transfer of knowledge and results where they can make best use.
- Maximize the impact of the research, enabling the value of the results to be potentially wider than the original focus (e.g., a possible outcome could be more emphasis put on the adult BCG vaccination scar rate, due to the derived importance that the project might highlight).
- Sharing essential elements of good research practices including the research training and capacity building embedded in the project, which has a wider scope and use not limited to COVID-19.
- Prevent results from being lost/disregarded.
- Strengthen and promote the profile of the project and organizations involved, highlighting both the capacity building performed and the ability for said organizations to conduct a complex, large multi-country RCT.
- Raise awareness of EU's EDCTP foundation in Lusophone Africa among researchers and the public.

3.3. Communication versus dissemination

Communication is a way to inform about the project and results, reach out to society and show the benefits of research to multiple audiences, beyond the project's own community thus including the

media and the public. Dissemination enables the use and uptake of results (hence it deals only with results and not with the project structure) targeting audiences that may use the results in their own work, e.g., peers (scientific or the project's own community), industry and other commercial actors, professional organisations, policymakers.

3.4. What constitutes exploitation?

Exploitation is the scientific utilisation of results in further research activities other than those covered by the action concerned, such as developing, creating, and marketing a product, process, technique or policy, or creating and providing a service. Exploitation can thus be commercial, societal, political, or for improving public knowledge and action.

3.5. Dissemination versus exploitation

While dissemination is a way to describe and make available results – which are not restricted due to the protection of intellectual property, security rules or legitimate interests so that they can be used by the audience. Exploitation is the important action to make use of the results, for scientific, societal, or economic purposes by groups and entities that are making concrete use of results. Consortium members shall thus make best efforts to exploit the results it owns, or to have them exploited by another legal entity.

4. Strategies to communicate with important targets

Project results will be communicated (where/if relevant) to relevant stakeholders for whom the findings are of potential use, and these may include (subject to changes and local adaptations):

- Local and National level authorities, including Ministries of Health, Institutes of Public Health, Regional Health Bureaus, Heads of relevant vaccination programs and the Ethical Committees that approved the trial.
- Trial participants that opted in on receiving the results of the trial by email.
- All health institutions (hospitals and health centers) that participated in the trial in Guinea-Bissau and Mozambique and in the observational study in Cape Verde.
- The scientific community, through dissemination of the results in the peer-reviewed scientific literature.
- Scientific congresses, likely including the Optimmunize meeting in November 2022: https://www.sdu.dk/en/forskning/dias/research-projects/optimmunize-2022 .
- Sharing results/summaries of the trial data (along with a link to the published article) on Twitter and LinkedIn.
- Continued collaboration and data sharing with the ALL-IN-META-BCG-CORONA consortium; meta-analysis results will be disseminated where appropriate.
- Policymakers: Their role in promoting utilization of the project's results is beyond doubt, as they are the ones that influence and maintain vaccination policies worldwide. While harder to reach, our approach as members of the ALL-IN meta-analysis framework mentioned above will allow us to communicate and disseminate also within these channels, especially if the trials identify a strong effect of BCG.
- The funding agency EDCTP.

The proposed communication channels used to disseminate findings will be reviewed and updated periodically during the course of the trial and major changes will be communicated to all consortium members to align the communication strategy.

4.1 Internal and external communication

Communication is a key element of the BCG-COVID-RCT project, necessary to achieve its main objectives, both within and outside the consortium. Communication should be social - visual - transparent - inclusive - collaborative. As mentioned, our communication strategy is open to changes over time in order to adapt to possible evolutions in both external and internal scenarios, aiming to respond to public and expert communication requirements. Our strategy therefore addresses two levels of communication, that can overlap and may evolve in time, but all in all needs to be considered separately:

- Internal communication within the project consortium. BCG-COVID-RCT partners have complementary perspectives, knowledge, and experiences: communication among them is a sort of laboratory where the capacity of inter-sectorial exchanges can be built and proofed. D&E thoughts and plans can be panned out and mature at the frequent consortium meetings in a forum that consists both of younger researchers and professors, spanning thus different age groups and nationalities that carry different perspectives on communication, dissemination. We aim for mutual learning in order to address effectively scientific and societal challenges and hold biweekly meetings both within the consortium and within the project steering group
- External communication involving stakeholders (including WHO, health authorities, patient groups, NGOs, industry etc.) and the general public

Internal/external communication strategies will also intersect with strategies for horizontal communication to other scientists and strategies for more vertical communication to other stakeholders and the public, including local communities. Strategies for horizontal communication to other scientists include the following:

- To consortium members through mainly the regular Zoom meetings and email
- Through consortium members to other scientists, collaborators and policy-makers mainly in their respective countries (Cape Verde, Denmark, Guinea-Bissau, Mozambique and Portugal)
- Peer-reviewed publications of results; dissemination of these as outlined above
- Conference participation (both EDCTP and other scientific conferences)
- Seminars with other research groups

Strategies for vertical communication to stakeholders (including WHO, health authorities, patient groups, NGOs, industry etc.) include:

- Reports and publications.
- Information and news shared on the project webpage: https://www.sdu.dk/en/forskning/edctp
- Conferences
- Seminars with stakeholders

Strategies for public communication, including local communities:

- Printed media where possible and if widely used.

- Radio/TV if necessary and appropriate.
- Information shared on the project webpage: https://www.sdu.dk/en/forskning/edctp
- Summary/posts of project results in lay-man language shared on Twitter and LinkedIn
- Lectures and seminars open to the public.

5. Dissemination and exploitation management

Communication, dissemination and exploitation activities will be led by SDU's prof. Christine Stabell Benn, supported by prof. Inês Fronteira. Postdoc Frederik Schaltz-Buchholzer and student assistants Arthur Diness will assist with developing the material to be used (writing summaries, updating webpage etc.). All four work in close collaboration with all consortium members who are all involved in discussions regarding communication strategies. Major announcements/publications will be done only after acceptance by the steering group (in case of differences of opinion, a vote will be performed to accept/reject a proposition).

6. Website and media

The project website, https://www.sdu.dk/en/forskning/edctp, is hosted securely on SDU servers and represents one of several tools for external communication. It is used to publish project deliverables and other outputs such as newsletters and notices. Products of the project (e.g. course material from meetings/workshops, leaflets, posters, pictures, progress reports on the trial).

Snapshot:

The website follows these communication guidelines: clarity of language, addressing both experts and the general public, transparency, interaction with different parts of society, plenty of pictures, videos, links to videos with previous consortium course material, and so on and is completely open access. A part-time student assistant, Arthur Diness, has assisted the study team with developing the webpage and now maintains the page with regular updates.

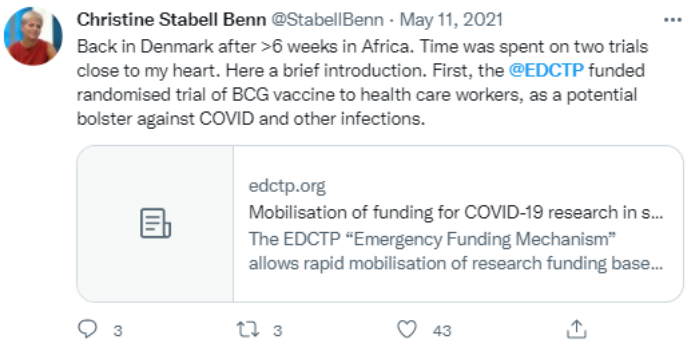
The plan is that the fully developed website will contain the following sections:

- The Project (with description of PREGART project and the trial);
- Partners;
- Contacts;
- Library with key documents with public dissemination level produced by the project are available;
- Deliverables, introduced by a short summary;
- Material presented during meetings, seminars, workshops (capacity building);
- Archive of published papers from the project (links and abstracts);
- Lectures/presentations at conferences and meetings;
- Events;
- News about the project;
- Press reviews.

6.1 Social media

Activity on social media such as Twitter and LinkedIn and additional communication/dissemination of scientific research is now practically a daily routine for scientists. It is becoming an increasingly important tool to reach the citizens where they are, replacing traditional media such as television and newspaper. This is also a trend in Sub-Saharan Africa.

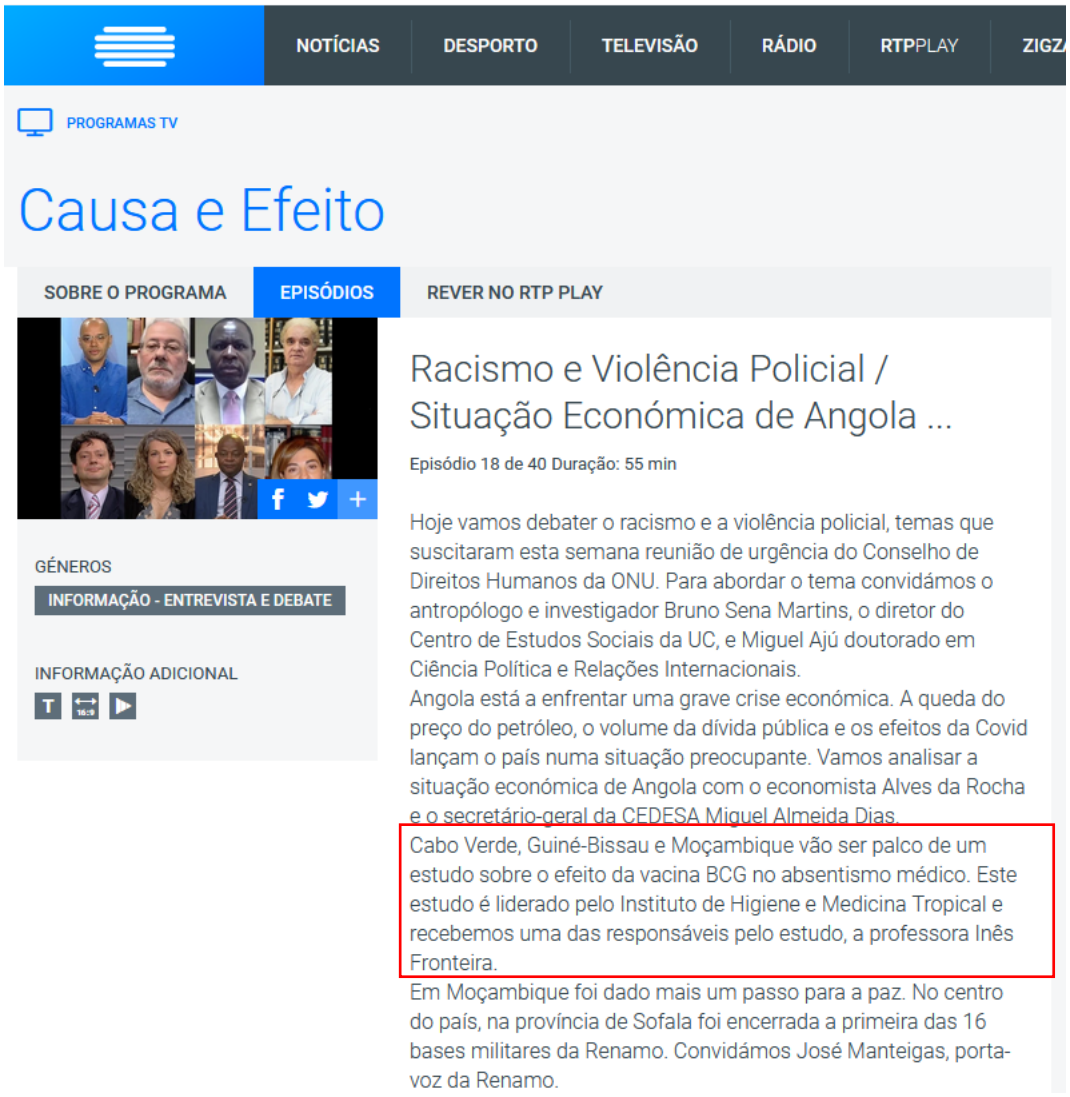
We have chosen not to open specific Twitter or LinkedIn accounts for the present project, but rather to make use the established accounts of scientists affiliated with the project, since there are several researchers with well-established accounts that have large followings, for which reason project results communicated through these channels reaches a large and substantial crowd of both scientists and laymen interested in vaccine research.



Professor Christine Stabell Benn's official Twitter account and an example of a project-related Tweet to Professor Benn's followers.

6.2. Other Media

Presentation of the study in the Portuguese broadcast channel RTP Africa in May 2020, by Prof. Inês Fronteira.



7. Scientific communication

COVID-19 represents an acute global public health problem not yet resolved after more than two years. Any scientific evidence related to prevention of COVID-19 should therefore reach a wider range of audiences, especially in the case of the well-known BCG vaccine that is widely available and have very few side-effects. Scientific communication to disseminate the trial outcomes will therefore be disseminated through multiple methods, which include articles in peer-reviewed international journals, magazines, newsletters, online outlets and if feasible also seminars, workshops, meetings, and webpages, reports, and policy briefs. This activity starts from the second year (2022). An example of relevant online media for a review of the available evidence is *The Conversation*, where several of the involved researchers have previously presented a summary of scientific findings: https://theconversation.com/old-vaccines-for-new-infections-what-we-discovered-147944

Since the project consortium consists of a broad group of researchers with established bases within both English, Portuguese, and Danish-spoken media, we will leverage this to our advantage to ensure the maximization of our impact in both Anglophone, Lusophone and Danophone channels.

Detailed scientific reports (in Portuguese and English) will be submitted to official institutions.

List of specific communicative actions taken by participant country:

Cape Verde

- Exhibition of posters in the Services and Departments of Hospitals;

- Delivery of folders about the study to health workers of the target hospitals;

- Presentation session of the study to the health care workers of the target hospitals;

- Conference BERC-Luso Project: "Biomedical Research - Its importance for the global development of a country

- I National Forum on Medical Education: "Being a researcher in Cape Verde";

- Public Health Research at Uni-CV: "Contributions to the National Health Research Agenda";

- II National Congress on Health Research: "The Challenges and Opportunities of Research in Communicable Diseases - Contributions of Health Research Centers".

Guinea-Bissau

The Bandim Health Project collaborates closely with the Institute of Public Health (INASA) in Guinea-Bissau. Results of the trial will thus be communicated to the Institute and a copy of the main trial report will be deposited in the INASA library. In case the trial shows a beneficial effect, we will work closely with the institute in order to magnify this message to increase knowledge and recognition.

Mozambique

National Kick-off meeting. Scientific Session at Manhiça Research Centre to presente the project to the research community before the start of the recruitment phase. Flyers and posters exhibition in Hospital Distrital da Manhiça (Hospital Rural de Xinavane, Centro de Saúde de Maluana, de Taninga, Malavele, Munguine, Chibucutso, Calanga, Maragra and Hospital Geral de Mavalane).

8.1. Papers in peer reviewed journals

Title	Leading author	Other authors	Journal for submission
High prevalence of SARS-CoV-2 antibody among health care workers in Guinea-Bissau	Elsi Cá	Sebastian Nielsen, Inês Fronteira, Christine Stabell Benn, Frederik Schaltz-Buchholzer	Public Health
Ethical challenges for clinical trials in Cabo Verde	Maria da Luz Lima	Inês Fronteira, António Pedro Delgado, Christine Stabell Benn, Frederik Schaltz-Buchholzer, Mohsin Sidat, Isabel Inês Araújo, Paulo Ferrinho	
SARS-CoV-2 IgG and IgM semi-quantitative assessment after Covid-19 vaccination in health care workers at Manhiça District Hospital	Lídia Nhamússua	Inês Fronteira, Abel Nhama, Sebastian Nielsen, Frederik Schaltz-Buchholzer, Christine Stabell Benn and Pedro Aide	Public Health

Prevalence of Observed BCG Scar in a Cohort of Health and Care Workers from Three Lusophone Sub-Saharian African Countries: Cross-sectional Comparative Study	Inês Fronteira	Frederik Schaltz-Buchholzer, Isabel Inês Araújo, Lídia Nhamússua, Paulo Ferrinho and Christine Stabell Benn	International Journal of Environmental Research and Public Health (submitted)
Absenteeism among HCWduring the covid-19 pandemic in three African countries: Cabo Verde, Guiné-Bissau and Moçambique	Inês Fronteira	Isabel Inês Araújo, Lídia Nhamússua, Frederik Schaltz-Buchholzer, Sebastian Nielsen, Christine Stabell Benn, Paulo Ferrinho	Human Resources for Health
The extent of dual practice during the covid-19 pandemic in three African countries: Cabo Verde, Guiné-Bissau and Moçambique	Paulo Ferrinho	João Luís Sousa, Isabel Inês Araújo, Lídia Nhamússua, Frederik Schaltz-Buchholzer, Sebastian Nielsen, Christine Stabell Benn, Inês Fronteira	Human Resources for Health
Measuring excess weight and obesity in research: comparison between BMI and visual body scale	Inês Fronteira	Isabel Inês Araújo, Lídia Nhamússua, Frederik Schaltz-Buchholzer, Sebastian Nielsen, Christine Stabell Benn, Paulo Ferrinho	Obesity

8. International events

GHTM sessions at the Institute of Hygiene and Tropical Medicine - Presentation of project sero-survey data by Dr. Elsi Cá from Guinea-Bissau

GHTM Sessions 2021CCID08 » High prevalence of SARS-CoV-2 antibody among health care workers in Guinea-Bissau, by MD Elsi Cá Silva | Bandim Health Project | Guinea-Bissau.

10th EDCTP Forum, 17-21 October 2021

Cá, E., Nielsen, S., Fronteira, I., Benn, C.S., Schaltz-Buchholzer, F. High prevalence of SARS-CoV-2 antibody among health care workers in Guinea-Bissau. Tenth EDCTP Forum, 17-21 October 2021.

Fronteira, I., Schaltz-Buchholzer, F., Nielsen, S., Araújo, I., Aide, P., Ferrinho, P., Bem, C. Prevalence of observed BCG scar in health care workers from the BCG-COVID-RCT trial. Tenth EDCTP Forum, 17-21 October 2021.

Araújo, I., Delgado, A., Mendonça, M., Monteiro, J., Benn, C., Fronteira, I., Ferrinho, P. Ethical Challenges for Clinical Trials in Cabo Verde. Tenth EDCTP Forum Equity in Research. 17-21 Out 2021. Maputo, Mozambique (online).

Optimmunize 2022

Fronteira I. Non-specific effects of vaccines (NSE): a rapid review of studies conducted in Portuguese Speaking African Countries. Optimmunize 2022 Odense, Denmark, November 9-11.

Araújo II, Santos K, Monteiro T, …, Fronteira I. Prevalence of Anti-SARS-CoV-2 antibodies among Health Care Workers (HCW) in hospitals from the islands of Santiago and São Vicente, Cabo Verde. Optimmunize 2022 Odense, Denmark, November 9-11.

17th World Conference on Public Health (may 2023)

Prevalence of observed BCG scar in a cohort of health care workers from three Lusophone sub-Saharian African countries: cross-sectional comparative study (accepted for poster presentation).

9. Video material

Within the project framework, as part of the capacity building process, four courses (in Portuguese) have been held:

Fundamentals of Epidemics and Pandemics for Health Workers

Introduction to REDCap platform

Fundamentals of clinical research and RCT management

Short course on data analysis

These courses were recorded and will be shared in appropriate channels, so that they can be put into use also by other research projects and strengthen capacity across Lusophone Africa.

10. Communication at the National level to direct beneficiaries

The objective of communicating the findings with the community is to improve the level of awareness about the trial outcomes. The possible immediate beneficiaries of the project are health care workers and other at-risk populations. In the light of an evolving pandemic with new variants of concern emerging, the possible prospect of an umbrella vaccine that makes uses of the broader non-specific effects to provide relevant protection, is great. The degree to which end users benefit from the output of the action will be influenced by how well the results are communicated and disseminated, however.

In the case that a beneficial effect is shown in the trial and/or in the broader meta-analysis, which will have more power to show an effect, we will work closely with the National Institute of Public Health in the three consortium countries. In case the appropriate institutions reach the decision to recommend BCG vaccination to at-risk populations, we will work closely with all public institutions to assist them with planning and coordination of all communicative efforts.

We will also ensure feedback regarding trial results to all participants (who opted in for feedback by the time of the inclusion interview) and to all participating health care facilities (hospitals and health centres).

11. Visibility of EU and EDCTP logos

The European flag appears as standard on all related dissemination action as well the logo of the funding Agency, EDCTP. In addition to the logos, all publications will include the following text: "*This project is part of the EDCTP2 Program supported by the European Union RIA2020EF3049*".

12. Conclusive remarks

This report details the Dissemination & Exploitation (D&E) plan for the corresponding deliverable 1.17 in the EDCTP-funded BCG-COVID-RCT project. This plan summarizes already designed strategies and describes D&E actions already taken, while also setting the frame for future actions. The document provides guidelines to consortium partners and should be used with the aim of harmonizing all communication and dissemination activities both at the international and national/local level.