



Sustainable eThics Reviews of digital heAlth Technology dEsiGn In sub saharan afriCa (STRATEGIC)

D1.1

Scientific Coordination Plan

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List of acronyms/abbreviations

Abbreviation	Explanation
DHTs	Digital Health Technologies
EDCTP	European and Developing Countries Clinical Trials Partnership
EUREC	European Network of Research Ethics Committees
GHS	Ghana Health Service
LETS	Université de Yaoundé
LUMSA	Libera Università degli Studi Maria Ss. Assunta di Roma
NECs	National Ethics Committees
NRAs	National Regulatory Authorities
RDD	Research and Development Division
STRATEGIC	Sustainable eThics Reviews of digital health Technology dEsiGn In subsaharan afriCa
SSA	Sub-Saharan Africa
UoN)	University of Nottingham
UEM	Universidade Eduardo Mondlane

EXECUTIVE SUMMARY

This plan describes the goals of the scientific coordination in the STRATEGIC project and the strategies for achieving them. The document provides clarity on the specificities of scientific coordination as a component of the overall management structure of the project. The document outlines the process that will be employed to ensure that all scientific activities and outputs are achieved in a timely manner. By implementing this Scientific Coordination plan led by Ghana Health Service, STRATETIC project aligns with the overall objectives of EDCTP. This plan is closely related to other deliverables such as D1.2; D1.3; D7.1 and D7.2.

1. Introduction

The Sustainable eThics Reviews of digital health Technology dEsiGn In sub-Saharan afriCa (STRATEGIC) Project aims to develop processes and training programs on the ethical evaluation of digital health technologies used for clinical research and trials in sub-saharan Africa. Starting with understanding key strengths, gaps, needs and contexts of DHTs in terms of regulations, especially as regards National Ethics Committees (NECs) and National Regulatory Agencies (NRAs). Although there is a focus on the 3 countries that represent that three major languages of English (Ghana), French (Cameroon) and Portuguese (Mozambique), it is hoped that the research will have a wider impact in Africa and Europe. Scientific coordination in STRATEGIC involves setting and overseeing the research objectives, ensuring they align with the overall mission of the EDCTP project. Through the scientific coordination process, STRATEGIC hopes to:

- Ensure smooth collaboration and effective communication among the partners.
- Be able to track the progress of research activities, ensuring they align with the planned timelines and quality standards.
- Ensure that project activities adhere to relevant ethical standards and guidelines
- Make sure that project outputs and deliverables are of high quality
- Ensure that risks and challenges are adequately identified and mitigated
- Ensure that STRATEGIC maintains strategic and regular communication with the EDCTP Secretariat, ensuring alignment with the overall goals of the funding body.

1.2 The Consortium:

The consortium comprises of 7 partners; four in Europe and 3 in Sub-Saharan Africa (SSA). The partners of the Consortium are the University of Nottingham (UoN -UK), the European Network of Research Ethics Committees (EUREC - Gemany), the Universidade Eduardo Mondlane (UEM - Mozambique), and the Libera Università degli Studi Maria Ss. Assunta di Roma (LUMSA - Italy), Université de Yaoundé (LETS - Cameroon) and Ghana Health Service (GHS - Ghana). The SSA partners have relevant roles in all the workpackages in a way to encourage collaboration and effectiveness.

2. Leadership Structure

STRATEGIC is unique because it has 3 partners leading the consortium. The University of Nottingham is responsible for project management, while the Ghana Health Service serves as the scientific coordinator. The University of Bonn serves as the financial lead and is the link to the Project Officer for the European and Developing Countries Clinical Trials Partnership (EDCTP).

The Scientific Coordinator (GHS) is responsible for overseeing all scientific activities across the consortium. Each partner has a designated scientific lead who acts as the liaison for the institution. The Scientific Coordinator works closely with these leads to ensure that tasks are executed efficiently and in line with project goals.

3. Collaboration and Communication

Scientific Coordination in STRATEGIC seeks to ensure smooth collaboration among project partners to foster synergy and efficiency and facilitate effective communication through regular updates, meetings, and reporting mechanisms.

Approaches:

Monthly Consortium Meetings: Regular virtual meetings are held, with each WP presenting progress updates and challenges. This is led by UoN and GHS. WPs also organise regular meetings to discuss methodological choices and strategies for achieving WP objectives. In-person meetings will be organized at key milestones of the project.

Project Management Tool: A collaborative project management platform (MS Teams) is used to manage documents, timelines, and deliverables. This tool is maintained by the University of Nottingham and all project partners and researchers have been granted access.

Partner Communication Plan: The Scientific Coordinator has a communication plan for all partners to receive timely updates and that information flows smoothly between teams. Ghana Health Service (GHS) has assigned each partner a liaison that is regular communication to provide support and address any open questions.

4. Tracking Progress and Ensuring Timely and Quality Outputs

The Scientific Coordination implemented for STRATEGIC also ensures that research activities align with planned timelines and quality standards as well as be able to monitor deliverables to ensure their timely submission and high quality.

Approaches:

Approaches to achieve the above include;

Gantt Chart and Milestones: STRATEGIC has a detailed Gantt chart outlining all research activities, milestones, and deliverables that guide project activities.

Quality Assurance: Internal peer reviews of scientific deliverables are carried out to ensure they meet quality standards before submission. The STRATEGIC quality assurance plan is detailed in D1.3. Any deviation from planned timelines will trigger a formal assessment and corrective action plan. UoN has the responsibility of ensuring that the quality assurance plan is implemented. All key deliverables (e.g., scientific publications, policy briefs, reports) will undergo an internal review process. Lead partners responsible for each deliverable will coordinate reviews using the quality assurance plan. When appropriate, the STRATEGIC Stakeholder Advisory Board (SAB) will be consulted to review major scientific outputs. Additionally, high standards for data collection, storage, and analysis will be applied to ensure the integrity and reproducibility of research findings. The use of standard operating procedures (SOPs) for data handling will be required for some data collection activities.

5. Ethical Compliance and Standards

The STRATEGIC scientific coordination also helps to ensure adherence to ethical standards and guidelines for all research activities.

Approaches:

Ethical Approval: All partners involved in human research will secure the necessary ethical approvals from relevant ethics committees before starting any research.

Ethical Monitoring process: An ethical monitoring process has been established to review the ethical aspects of the project regularly. This process will ensure compliance with EDCTP guidelines, local laws, and international ethical standards such as the Declaration of Helsinki and the General Data Protection Regulations as well as other Data Protection regulations.

Informed Consent: All surveys, interviews and other primary research processes will ensure informed consent procedures are in place and that participants' rights and data privacy are respected.

5. Risk Management and Mitigation

STRATEGIC takes risks serious and through SC, it hoped that risks can be identified early and their impact on the project mitigated. How this can be achieved in the project is detailed in deliverable D7.2. A comprehensive risk register is maintained, listing potential risks and corresponding mitigation strategies. Risk assessment will be carried out every 6 months and contingency plans will be updated accordingly.

6. Strategic Communication with EDCTP Secretariat

STRATEGIC intends to maintain regular and strategic communication with the EDCTP Secretariat to ensure alignment with project goals and funder expectations. In addition to this, relevant projects to STRATEGIC's goals within EDCTP will also be engaged in strategic ways.

Approaches:

- ***Regular Updates:*** The Scientific Coordinator will provide the EDCTP Secretariat with regular updates on project progress, including interim and final reports.
- ***EDCTP Events:*** The consortium will participate in events organised by the EDCTP Secretariat to discuss progress, address challenges, and realign strategies if necessary.

7 Summary of Document

This document has presented the scientific coordination goals that will be carried out in STRATEGIC, and the approaches adopted to achieve them. It has also indicated clearly the roles and responsibilities. The document is expected to dispel ambiguity about the roles of partners and spell out the role of each member of the team for each partner.