



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

D7.2

Risk Register

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Abstract	This deliverable outlines the methodology for identifying, assessing, and managing risks throughout the STRATEGIC project's lifecycle. It details key potential risks related to project implementation, including technical, financial, and operational challenges, and provides mitigation strategies to minimise their impact.
Key Words	Ris Register,

Revision History

Version	Date	Author(s)	Reviewer(s)	Notes
0.1	04.09.2024	Damian Eke (UoN)	Persampieri, Loredana (LUMSA)	First Draft
0.2	23.09.2024	Damian Eke (UoN)	Lisa Haeberlein (EUREC)	Second Draft

Executive Summary

The STRATEGIC Risk Register provides a comprehensive overview of potential risks associated with the project, along with strategies for their identification, assessment, mitigation, and ongoing management. The overall aim is to ensure that the project is executed smoothly by anticipating potential challenges and addressing them in a timely manner. The key objectives include;

- Identification of risks: This document systematically identifies risks across all project phases (relevant to project tasks, deliverables and milestones as well as KPIs), including technical, financial, regulatory, and operational risks. These risks are categorised to streamline tracking and mitigation efforts.
- Risk Assessment and Impact Analysis: Each identified risk is evaluated in terms of its likelihood of occurrence and potential impact on project objectives.
- Mitigation Strategies: For each significant risk, appropriate mitigation measures are outlined, aiming to reduce both the probability of occurrence and the impact.

1. Introductions

STRATEGIC consortium recognises a risk register as a critical tool for project management. It is a tool that enables the identification and assessment of potential risks before they become issues, allowing the project team to take preventive actions. It provides clear understanding of risks and helps the project partners and stakeholders to make informed decisions regarding resources, timelines, and project scope, ensuring actions are aligned with potential challenges. The STRATEGIC risk register provides a structured way of communicating risks across the project team and to stakeholders. This promotes transparency and keeps everyone aligned on potential issues and mitigation strategies. This document supports continuous monitoring of risks throughout the STRATEGIC lifecycle. It enables the consortium to adjust strategies in real-time, ensuring the project remains adaptable to emerging risks. In essence, the risk register is essential to maintaining STRATEGIC's stability, reducing uncertainties, and ensuring that objectives are met on time and within budget.

2. Potential Risks

Some potential risks already identified for the STRATEGIC project can be grouped into technical, financial, and operational risks.

2.1 Technical Risks

2.1.1 Lack of Technical skills for data analysis and other project activities

Description: There is a possibility that researchers within the consortium may not have the required knowledge to undertake qualitative data analysis and / or use technical tools for data analysis (e.g NviVo and SPSS).

Probability/Impact Levels: Medium/Medium

Mitigation Strategy: To address this, training sessions on methods (data collection and analysis) are planned by the scientific coordinator (GHS).

2.1.2 Lack of internet connectivity

Description: Due to budgetary constraints and the distribution of the project partners (in Europe and Africa), most of STRATEGIC's activities happen virtually. However, many of the African partners have internet connectivity problems.¹

Probability/Impact Level: Medium/Medium

¹ Internet connectivity is often a challenge in Africa: <https://subtelforum.com/massive-internet-outages-have-been-reported-across-africa/>

Mitigation Strategy: To mitigate this, STRAEGIC's fortnightly consortium meetings have been extended to 2 hours. This ensures that internet disruptions do not prevent essential discussions. African partners also continue to work towards possible local solutions. Non-sensitive documents are also shared with partners with connectivity problems to ensure offline access.

2.2 Financial Risks

2.2.1 Financial instability affecting partner contributions

Description: Project partners may experience financial instability beyond the project that affects their contributions to project activities and outcomes. This may limit a partner's ability to allocate sufficient staff, resources, or equipment to the project, which can reduce their overall contribution. Partners facing prolonged financial difficulties may withdraw from the project, unable to fulfill their obligations. This could leave critical gaps in expertise, resources, or regional knowledge, requiring a restructuring of the project and causing delays or additional costs in finding new partners.

Probability/Impact Levels: Low/High

Mitigation Strategy: If a partner faces significant financial challenges, STRATEGIC will consider reallocating their responsibilities to other partners who are more financially stable, either temporarily or permanently. This could involve redistributing certain tasks or deliverables.

2.2.2 Lack of travel Budget: Due to lack of travel budget, the EUREC Office team who will develop the training materials will not be able to carry out trainings in the three pilot sites Mozambique, Ghana and Cameroon.

Probability/Impact Levels: Low/Medium

Mitigation Strategy: With support from partners, local consortium members could conduct onsite train-the trainer sessions. UEM could conduct onsite pilot tests in Mozambique, GHS in Ghana and UY1 for Cameroon. Alternatively, all partners can pilot tests within their own institutions or national training centers, ensuring wider coverage and practicality. Also, EUREC will plan a webinar to guide partners through the training materials and their implementation.

2.3 Operational Risks

2.3.1 Ineffectiveness of STRATEGIC's responsible innovation framework

Description: Considering the diverse cultural dynamics of Africa and the EU, there is a risk of ineffectiveness of proposed STRATEGIC's responsible innovation framework. This can be due

to lack of stakeholder engagement and maybe because of a rigid framework that doesn't allow for adaptation across different regions and contexts of innovation in clinical research and trials. This could result in a lack of adoption or resistance from key actors, undermining the overall effectiveness of the framework. If the framework is not well-integrated with regulatory contexts, organisations may find it difficult to apply, reducing its practical relevance.

Probability and Impact Levels: Low/High

Mitigation Strategy: STRATEGIC will use a well-reasoned and suitable stakeholder engagement methodology that ensures holistic stakeholder mapping and engagement/involvement. STRATEGIC will conduct inclusive and continuous stakeholder engagement throughout the development and implementation of the framework (cf WP3, 4, 5 and 6). This involves workshops, consultations, and collaborative platforms that bring together diverse actors, including industry, policymakers, academia, and civil society. Regularly updating the framework to reflect changes in EU/AU policies, standards, and regulations related to innovation, sustainability, and ethics. Engagement with policymakers (particularly RECs and NECs) to ensure coherence with existing regulatory frameworks. Project partners will ensure that the framework is clear, concise, and user-friendly, with accessible languages (English, French and Portuguese) and well-defined guidelines = breaking down complex concepts into easy-to-understand steps or components.

2.3.2 Low quality of deliverables and possibilities of underperformance

Description: Like in all EU projects with partners in different countries who work under different professional and academic standards, languages and communication styles, cultural approaches to time management, reporting, and hierarchical structures, regulatory environments, and expectations, possibilities of low-quality deliverables and underperformance can arise. This can lead to some partners falling behind on deliverables or producing work that doesn't meet the EC's quality standards. For instance, currently, one partner – UEM, is behind on coordinating activities and deliverable timelines.

Probability/Impact Levels: Medium/High

Mitigation Strategy: To address this, STRATEGIC has developed a shared framework of quality standards and deliverable expectations at the beginning of the project. Most of this is contained in STRATEGIC's Quality Assurance Plan (D1.3). This plan includes quality reviews of all deliverables that start a month before the final submission deadline. It also contains guidelines, and specific criteria for assessing deliverables. This process also includes the development of a deliverable template. There are uniform expectations on deliverables and other outputs which ensure consistency in the quality of deliverables across all partners, minimising misunderstandings.

2.3.3 Partners leaving the project

Description: Again, like in any EU project STRATEGIC also faces the possibility of partners leaving the project. This can pose significant risks to the project's success, including delays, loss of expertise, and disruption in the continuity of work. When a partner leaves, the project loses the specific expertise, knowledge, and skills that they contribute, which could create gaps in key deliverables or milestones. The departure of a partner may disrupt workflows, especially if the partner was responsible for managing specific work packages or leading coordination efforts. Remaining partners may be forced to take on additional responsibilities, leading to resource strain, overburdening, and possibly reduced quality of outputs. In STRATEGIC – a project involving EU and African partners - the departure of a partner could result in the loss of important local or regional knowledge, particularly in the case of African partners who understand specific regional contexts, or communities.

Probability/impact Levels: Low/High

Mitigation Strategy: To address this, STRATEGIC has a collaborative project management principle where three partners are part of the coordination team (GHS, UoN and UBO). This is well detailed in the Scientific Coordination plan [D1.1]. WPs and tasks are designed with flexibility, allowing for the reassignment of responsibilities if a partner leaves. It is ensured that there is no task only one partner is engaged with. This way other partners are familiar with the tasks and processes so they can step in if necessary. Additionally, both UoN and UBO have extensive experience in EU project coordination and contribution to EU projects. This risk register will also be regularly reviewed and updated.

2.3.4 Insufficiency of identified networks and platforms

Description: EU-based platforms that are mentioned in the GA, such as iRECS, TREE, ENERI, and others may not sufficiently cover medical research ethics for training African stakeholders.

Probability/impact Levels: Low/Medium

Mitigation Strategy: Make training materials accessible on identified African platforms and use existing EU platforms to distribute training content further and ensure access to African stakeholders.

2.3.5 Inaccessibility of Training Materials:

Description: Developed training materials and other project outputs may not be accessible to stakeholders considering differences in languages and target audiences from different regions.

Probability/impact Levels: Low/High

Mitigation Strategies: Depending on the comprehensiveness of the materials, translations could be provided internally by the consortium or allocated budget for external agencies. However, desk research in D5.1 has revealed that materials in English might give access to a broad audience.

Training needs assessment will further investigate the language issue. The consortium has the capacity to translate the materials in three languages: English, Portuguese and French.

2.3.6 Lack of Stakeholder participation STRATEGIC activities

Description: There is a possibility that stakeholders may not participate in some of STRATEGIC's activities such as the train-the-trainer programme and the policy roundtable.

Probability/impact Levels: Low/High

Mitigation Strategy: STRATEGIC will employ a number of approaches including social media campaigns, production of a promotional video that will help to engage stakeholders and increase participation in both online and onsite events including training activities.

3. Review of the Risk Register

STRATEGIC will ensure that the risk register is up to date and reflects any changes in the project's environment, especially as new risks emerge, or previously identified risks are mitigated. Therefore, there will be a regular review of the risk register by partners (every 6 months). Partners and WP leaders will be requested to update the register. For high-priority risks, the register will include contingency plans that specify how the project will respond if the risk materialises. The risk register also includes a mechanism for incorporating lessons learned from previously mitigated risks to improve future risk management. This will ensure that the register is not static but is a living document that evolves with the project. Capturing lessons from successfully mitigated risks (or failed mitigations) helps improve future risk management practices.

3.1 Risk Status

The STRATEGIC risk register will be continuously updated with the status of each risk (e.g., possible, active, mitigated). This allows for real-time tracking of risks as the project evolves.