AFRICAI-RI: A Pan-African Research Infrastructure for Collaborative Biomedical Imaging and Artificial Intelligence

Deliverable D1.4:

Study Initiation Package (Stakeholder and Community Engagement)

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Version log

Issue Date	Version	Involved	Comments
24 Nov 25	V0.1	Elena Marbán, Maria Maixchens (ISGLOBAL)	First draft.
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02 Dec 25	V0.3	Elena Marbán, Maria Maixchens (ISGLOBAL)	Comments received and report updated.
03 Dec 25	V1	Cecilia Kessler, Lidia Garrucho Moras, Karim Lekadir (UB)	Revised and corrected final version.

Acronyms

Name	Abbreviation
Sub Saharan-Africa	SSA
Artificial Intelligence	AI
Chest Ultrasounds	CUS
Chest X-rays	CXR
Consolidated Framework for Implementation Research	CFIR
Tuberculosis	TB
Focussed Group Discussion	FGD
Graphical Processing Units	GPUS
Healthcare	HC
Neglected Tropical Diseases	NTDs
Point of Care	POC
Rapid Diagnostic Tests	RDTs
Semi-Structured Interview	SSI

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Executive Summary

This Study Initiation Package outlines the framework, methodology, and operational procedures that will guide stakeholder and community engagement activities within the AFRICAI-RI project. AFRICAI-RI aims to co-create the first federated, multi-institution imaging data infrastructure in SSA, enabling secure, privacy-preserving, and context-appropriate development of AI tools for the diagnosis of respiratory infections. This deliverable defines the approach for gathering insights from clinical study participants, healthcare providers, policymakers, community representatives, and industry actors across ten SSA countries.

The report presents a mixed-methods study design structured across three stages: (1) stakeholder mapping; (2) qualitative and quantitative data collection through interviews, focus group discussions, surveys, and observations; and (3) stakeholder workshops focused on refining the AFRICAI-RI platform. Detailed procedures for sampling, recruitment, harmonised participant identifiers, data management, analysis, and reporting are provided to ensure consistency across sites. Ethical considerations, data protection requirements, and governance mechanisms are addressed in alignment with GDPR, national regulations, and international research standards.

This package also identifies anticipated risks and corresponding mitigation strategies, highlighting data confidentiality, participant well-being, and technical challenges related to federated learning and multimodal data integration. The study is expected to generate critical insights on the acceptability, feasibility, appropriateness, and sustainability of an open AI imaging repository in SSA. These findings will directly inform platform design, governance structures, and future implementation strategies.

Overall, this deliverable provides the operational foundation needed to ensure meaningful stakeholder participation, ethical conduct, harmonised data practices, and a community-centred approach throughout the AFRICAI-RI project. The methodologies and tools presented here will support informed decision-making and promote trust, transparency, and long-term sustainability of AI-enabled diagnostic innovations across the region.

1. Background

Infectious diseases such as tuberculosis (TB) and pneumonia (PNA) are among the biggest contributors to mortality in sub-Saharan Africa (SSA) (1). Infectious diseases disproportionately affect populations living in poverty, exacerbated by challenges such as malnutrition, overcrowding and high rates of HIV (2). Timely screening and diagnosis of these pathologies remains a challenge, with studies indicating TB remains undetected in about half of the individuals using passive case finding methods and in over 90% under active screening approaches (3).

There is a growing demand for rapid and accurate diagnostics that can be used outside laboratories, at the point of care (POC) level (4), supporting triaging practices in fragile health systems, where diagnostic resources are typically scarce. POC technologies often require less infrastructure and processes, thus, are promising solutions for those in remote areas, to release the burden from healthcare (HC) systems (4).

While chest X-rays (CXR), chest ultrasounds (CUS) and lung ultrasonography (LUS) offer accessible imaging modalities for respiratory pathologies in SSA, the region suffers from a severe shortage of healthcare providers (HCPs) with the basic skills to interpret such scans for respiratory disease detection. Artificial Intelligence (AI) has shown immense promise for enhancing access to healthcare, as it is able to analyse complex data such as medical images (11), thus potentiating the widescale utility of CXR and LUS in settings where skilled staff are lacking.

However, the vast majority of these technologies have originated from, and are tailored to the needs of, high-income countries. While in Europe some strategic funding initiatives have facilitated the establishment of medical repositories, Africa stands on the other side of this technological divide, with no comparable imaging repositories. This deficit poses a substantial barrier to aggregating African imaging datasets and developing AI solutions that address Africa-specific imaging challenges. AI technology offers significant promise in meeting this critical clinical need by enabling automated image interpretation in under-served SSA regions with high rates of TB, PNA and HIV (2,11). However, the lack of open repositories providing secure access to large imaging collections for training the AI tools has significantly hindered the much-need AI development in SSA.

The AFRICAI-RI project aims to address these challenges by co-creating the very first federated, multi-institution imaging data infrastructure for Africa, ensuring it is carefully tailored to meet local needs and contexts. Key to this project is the implementation of a decentralized federated learning system that eliminates the need for data transfers, thereby enhancing privacy, building trust, and encouraging wider participation. The project will establish a federated network of secure storage systems and graphical processing units (GPUS) distributed 10 SSA sites (Senegal, The Gambia, Ghana, Nigeria, Gabon, Mozambique, Malawi, DR Congo, Uganda and Ethiopia), empowering local researchers with new capabilities for conducting advanced research in AI and medical image analysis. A customised, user-friendly data curation toolkit will be developed to accommodate the diverse local conditions, particularly variations in image data formats and quality standards.

Dedicated hacking challenges and open data calls will be organised for testing the security and integrity of AFRICAI-RI's federated data network, continually enhancing the infrastructure, and further increasing public trust. With the proposed infrastructure, the project will deliver new multi-centre research datasets, which will include specialised collections such as CXR for HIV-positive patients, paediatric CXR datasets, and the first extensive multi-centre LUS dataset from SSA. The AFRICAI-RI project will deliver a research infrastructure for medical imaging. This federated network of secure storage systems and graphical processing will be named in this protocol as "the AFRICAI-RI platform".

This master protocol covers the mixed-methodologies that will be conducted in the 10 SSA countries from the AFRICAI-RI Consortium. Each country will adapt this protocol to their local needs. This master protocol covers both the AI clinical diagnostic components and the social-science, data-governance, and implementation activities of the AFRICAI-RI consortium. No additional clinical interventions are introduced beyond standard of care.

2. Study objectives

The main aim of this study is to inform, support, and provide continuous feedback to optimize the design and functionality of the AFRICAI-RI platform.

The specific objectives of this study are the following:

1. To **map relevant stakeholders** for AI tools in health and disease diagnosis in SSA.
2. To explore AFRICAI-RI clinical study participants', healthcare providers utilizing the AFRICAI-RI platform and stakeholders´ perceptions on the **acceptability, adoption, appropriateness, feasibility, penetration, and sustainability** for the social, cultural, ethical, legal, clinical, technical, and policy implications of an open AI repository for respiratory disease diagnosis.
3. To assess **barriers and facilitators** for the social, cultural, ethical, legal, clinical, technical and policy implications of an open AI repository for diagnosis of respiratory infections by AFRICAI-RI clinical study participants', healthcare providers utilizing the AFRICAI-RI platform and stakeholders.
4. To **refine the AFRICAI-RI platform interface**, decision-support tools, and reporting outputs based on experts feedback.

These objectives cover all the relevant aspects from all the working groups from the AFRICAI-RI project.

3. Study design

This is a **mixed-methods study** conducted to explore barriers, facilitators and **implementation outcomes such** as feasibility, acceptability, appropriateness, adoption, penetration, and sustainability for the integration of an open AI repository for diagnosis of respiratory infections.

Following Enola Proctor et al. (2011), this study will assess six key implementation outcomes: **acceptability**, **appropriateness**, **feasibility**, **adoption**, **penetration**, and **sustainability**.

1. ***Acceptability*** refers to stakeholders' perceptions that an intervention is satisfactory or agreeable.
2. ***Appropriateness*** captures the perceived fit or relevance of the intervention to a given context or problem.
3. ***Feasibility*** reflects the extent to which the intervention can be successfully implemented within a setting.
4. ***Adoption*** denotes the initial uptake or use of the intervention.
5. ***Penetration*** refers to the extent to which it becomes integrated within the service setting and reaches its intended users.
6. ***Sustainability*** indicates the degree to which the intervention is maintained over time after initial support ends.

This study will also use the **Consolidated Framework for Implementation Research (CFIR)** to identify and analyse the **contextual factors influencing the implementation process.** CFIR provides a comprehensive structure for exploring determinants of implementation across five domains: *intervention characteristics, outer setting, inner setting, characteristics of individuals,* and *implementation process*. Applying CFIR will help capture the **barriers and facilitators** that affect how the intervention is perceived, adopted, and sustained in the study context. This framework complements the measurement of implementation outcomes (Proctor et al., 2011) by providing insight into the underlying mechanisms and contextual influences that shape implementation success.

Study population, selection criteria and recruitment

Stage 1

Stage 1 will respond to objective 1 to map relevant stakeholders for AI tools in health and disease diagnosis in SSA..

The stakeholder mapping will aim to collect contacts from the 10 SSA countries from each of these groups of stakeholders to be as diverse as possible. Once stakeholders are being interviewed in Stage 2, they will be asked to provide other stakeholders´ contact, thus a snowball sampling approach will be used (Table 1).

Table 1. Stakeholder groups to be engaged for the AFRICAI-IMPACT study

Group number	Group	Stakeholders roles
G1	ELSI	Ethics committee members, policy makers, local patent offices, national and local health technology regulators.
G2	Healthcare	Healthcare managers, clinicians, clinical researchers, radiologists, nurses, imaging technicians, IT managers and data managers
G3	Civil	Citizens, patients advocates and advocacy organizations

	society	
G4	Scientific	AI researchers, Principal Investigator of existing project, IT managers and data managers
G5	Industry	Radiology AI companies, funders, data brokers, AI developers, IT managers, data managers

Stage 2

Stage 2 will respond to objective 2 to explore AFRICAI-RI clinical study participants', healthcare providers utilizing the AFRICAI-RI platform and stakeholders´ perceptions on the **acceptability, adoption, appropriateness, feasibility, penetration, and sustainability** for the social, cultural, ethical, legal, clinical, technical, and policy implications of an open AI repository for respiratory disease diagnosis. As well as objective 3, to assess **barriers and facilitators** for the social, cultural, ethical, legal, clinical, technical and policy implications of an open AI repository for diagnosis of respiratory infections by AFRICAI-RI clinical study participants', healthcare providers utilizing the AFRICAI-RI platform and stakeholders.

The study population will consist of **stakeholders** from the five groups listed in Table 1, and **participants** from the AFRICAI-RI clinical study, including adult participants, **caregivers** of minor participants and **HCPs** utilizing the AFRICAI-RI platform.

- Adult participants and caregivers will be henceforth mentioned as "AFRICAI-RI participants".
- Individuals participating in this AFRICAI-IMPACT study will be mentioned as "Participants".

Participants will be recruited through purposive and convenience, referral/snowball sampling strategies to ensure diversity across stakeholders roles and settings. Contacts will be done in person, via email, or phone by the local team.

All study participants will be assigned a harmonised Participant Identifier (PID) using the format LOCATIONCODE_GROUPCODE_PARTICIPANTNUMBER to ensure consistency across the 10 participating countries.

- The LOCATIONCODE corresponds to the country of recruitment: SEN (Senegal), GAM (The Gambia), GHA (Ghana), NGA (Nigeria), GAB (Gabon), MOZ (Mozambique), MWI (Malawi), COD (DR Congo), UGA (Uganda), and ETH (Ethiopia).
- The GROUPCODE reflects the participant category and will follow the simplified schema: AP for AFRICAI adult participants, AC for AFRICAI caregivers, HC for healthcare workers using the AFRICAI-RI platform, and G1, G2, G3, G4, G5 for the five stakeholder groups respectively.
- The PARTICIPANTNUMBER will be a sequential three-digit number starting at 001 for each group within each country.

This coding system (e.g., *GHA_AP_012*, *UGA_AC_004*, *MOZ_HC_021*, *SEN_G3_007*) will be used in all study documentation, data collection tools, and datasets, while each site maintains a secure, local linking log to protect participant confidentiality.

Data collection and analysis will be conducted independently at each country site. ISGLOBAL will develop an initial coding tree to guide the analysis based on the CFIR framework and the SSI and FGD guides. Country partners will adapt and expand this coding tree as needed, following both inductive and deductive approaches. Each country will conduct its own thematic analysis and produce a site-level report summarizing the final coding structure, key themes, and results. These country reports will be submitted to ISGLOBAL, which will compile and synthesise the findings to conduct a multi-country comparative analysis.

Any participant records or datasets that will be transferred to ISGLOBAL will not contain personal identifiers; participant names or any information which would make the participant identifiable will be removed during data collection and data analysis. The participant will be informed that his/her personal study-related data will be used by ISGLOBAL in accordance with local data protection law and that there would not be any attempts to re-identification by the local team or ISGLOBAL. The level of disclosure must also be explained to the participant.

Participation will be voluntary, and individuals may withdraw at any point without penalty. Persons unable to consent or unavailable during data collection will be excluded. When consent is withdrawn and participant demands for their specific data (surveys and quotes) to be removed, data collected from that specific participant up to that point will be permanently removed from storage and withdrawn from data analysis.

The inclusion criteria is included in Table 2. Exclusion criteria apply to individuals who do not provide consent to participate.

Table 2. Inclusion criteria for participants in AFRICAI-IMPACT study

Target	Inclusion criteria
AFRICAI-RI participants	• **Adult participants** who have been enrolled in the AFRICAI-RI clinical study for at least **two weeks**. • **Caregivers of children** enrolled in the AFRICAI-RI clinical study for at least **two weeks**.
Healthcare providers	• HCP, including doctors, nurses and others, utilizing the AFRICAI-RI platform
Stakeholders	• Stakeholder from one of the 5 groups detailed in Table 1.

No invasive or clinical procedures will be involved in the study. Participants will receive reimbursement for local travel or refreshments in accordance with site policies. Each country's

local context or partner institution may adapt these reimbursements or provisions according to local policies and the requirements of the local Institutional Review Board (IRB).

Stage 3

Stage 3 will respond to objective 4, to refine the AFRICAI-RI platform interface, decision-support tools, and reporting outputs based on expert feedback.

Key stakeholders identified during stage 1 (mapping), including some who might have already participated in stage 2 interviews, though not necessarily, will be invited to participate in stage 3 workshops.

Sample Size

Stage 1

The stakeholder mapping exercise aims to include as many relevant stakeholders as possible across the participating countries. A **minimum of 5 stakeholders per country** will be targeted, resulting in an estimated **total of at least 50 stakeholders**.

Stage 2

The qualitative sample size will be guided by the principle of data saturation, that is the point at which no new themes or insights emerge. Based on previous empirical studies, saturation is typically achieved after approximately 12–15 interviews or 6-8 focus group discussions. Total numbers in our study will be very superior to these.

For observations, saturation will be reached once researchers have gained a sufficient understanding of behaviours and interactions in their natural setting. As achieving saturation can be challenging in practice, observation schedules will be aligned with official working hours in each country to ensure adequate coverage of daily routines and processes.

For planning purposes, we anticipate the following approximate numbers per country, Table 3:

Table 3. Sample size estimation per country

Method	Type of participant	Size per country
SSI	Stakeholder groups G1 and G2.	6 to 10 participants
FGD	1. Stakeholders group G3 2. Stakeholders group G4 3. Stakeholders group G5 4. AFRICAI-RI participants 5. AFRICAI-RI caregivers 6. AFRICAI-RI HCPs	4-5 FGD with 6-8 participants each

Survey	All SSI and FGD participants	Same participants
Observations*	Field observations at sites where the AFRICAI-RI clinical study is being implemented	15 approximately

*Field observations will be conducted only if appropriate for the local context. The exact number of FGD and SSIs will be determined based on country-specific considerations, such as stakeholder availability, local research infrastructure, and contextual needs.

Stage 3

One workshop per site will be conducted with at least **10–15 participants (key stakeholders),** either in person or online. The workshop will use participatory methods to engage stakeholders in discussions and activities. A quantitative survey will be administered before and after the workshop to assess changes in participants' knowledge, perceptions, and attitudes regarding the AI repository and its implementation.

Data collection

Stage 1

For the **mapping exercise, a form** has been developed and shared with AFRICAI-RI country partners. Each partner was asked to provide information on at least five key stakeholders per country, covering their roles, affiliations, and relevance to the project. The collected data will be standardized across all sites to ensure consistency and comparability. Responses will be automatically compiled into an **Excel file, facilitating easy management, visualization, and subsequent analysis** of stakeholder relationships and networks.

Stage 2

This stage will include **qualitative (SSI, FGD, Survey and Observation)** research to document and explore experiences and perspective on the AFRICAI-RI. There are different methodologies used in this study (Figure 1). These will be conducted with a diverse range of stakeholders, including healthcare workers, programme managers, policymakers, data and IT staff, patients, caregivers, and community representatives.

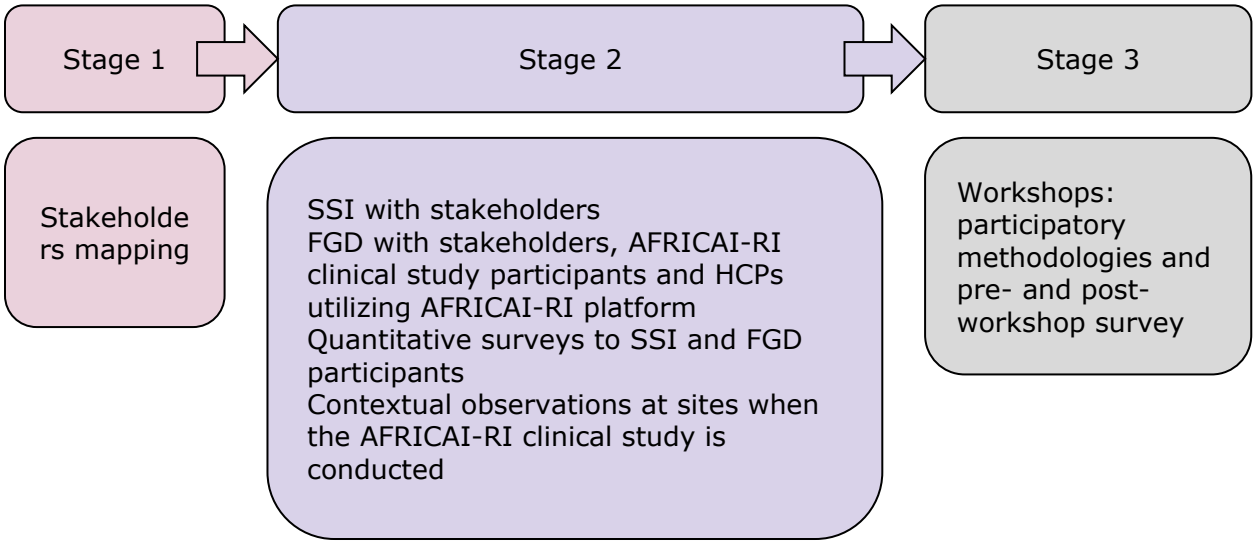

Figure 1. Methodologies used in the AFRICAI-IMPACT study per stage

All data collection tools are provided in the annexes (Annex 2-13); however, minor adjustments may be made as needed without requiring resubmission of the protocol to the ethics committee. Themes to be explored in the SSI, FGD, workshop, observations and surveys are defined within Table 4. For the purpose of triangulation, the themes will be explored by different populations.

Table 4. Themes to be explored by methodology to be applied

Implementation Theme	**Question to be explored**	**CFIR Domain / Proctor Outcome**	**Population**	**Methods**
Acceptability, Needs & Design	Understand end-user needs, clinical workflows, and potential barriers to using AI tools in disease diagnosis and an Open repository.	**Acceptability** (Proctor), **Relative Advantage** (CFIR), **Intervention Characteristics** (CFIR)	HCP, AFRICAI-RI participant, G1, G2, G3	SSI, FGD, Survey, Observations

Feasibility & Policy	Define and promote incentives (e.g., financial, academic, public good) for data sharing and use of the open repository.	**Feasibility** (Proctor), **Outer Setting - Cosmopolitanism** (CFIR), **Policy Implications**	HCP, G1, G4, G5	SSI, FGD, workshop
Adoption & Sustainability (Clinical/Tech)	Define pathways toward implementation and adoption of the AI tools in real-world practice, considering clinical features and existing IT infrastructure.	**Adoption** (Proctor), **Inner Setting Compatibility** (CFIR), **Inner Setting Implementation Climate** (CFIR)	HCP, G1, G2, G4, G5	SSI, FGD, Observations, workshop
Data Governance & Policy	Understand ethical and legal concerns (**ELSI**) regarding federated data access, processing, and long-term sustainability.	**Sustainability** (Proctor), **Inner Setting - Culture** (CFIR), **Outer Setting - Patient Needs & Resources** (CFIR)	AFRICAI-RI participant, HCP, G1, G3	SSI, Workshop
Socio-cultural Barriers & Facilitators	Assess socio-cultural **barriers and facilitators** that may affect the perceived **appropriateness** and **penetration** of the AI repository within local contexts.	**Appropriateness** (Proctor), **Penetration** (Proctor), **Outer Setting - Social Climate** (CFIR)	HCP, AFRICAI-RI participant, G3	FGD, Surveys, Observations

Technical Certification & Governance	Define African models to certify AI tools built through federated learning and address technical security requirements. Define new models for IP rights and reward sharing.	**Intervention Characteristics - Design Quality** (CFIR), **Feasibility** (Proctor)	G1, G2, G4	SSI, FGD, Workshop

Data will be analysed locally to preserve contextual nuances, and across sites to identify shared and site-specific requirements.

1. Semi-Structured Interviews (SSI)

- **Themes** to be addressed: ELSI, technical, socio-cultural and policy implications.
- Interviews may be conducted in person, online, or by phone, depending on participant preference.
- Interview guides will include open-ended questions with flexible probes to allow participants to express their views freely.
- Each interview will last approximately 30 minutes to 1'.5 hour.
- Sessions will be audio-recorded using secure, encrypted recorders or approved mobile applications, with participant consent obtained before recording. Audio files will be transferred to a secure, access-restricted server at each country site and deleted from the device once the transfer is confirmed. Transcription will be conducted locally, and all transcripts will be fully de-identified before analysis. When recording is not possible, researchers will take detailed de-identified notes.
- Interviews will be conducted in English or in local languages (e.g., Swahili, Yoruba, Portuguese, French etc.) according to participants' choices, using context-appropriate discussion guides.

2. Focus Group Discussions (FGDs)

FGDs will complement SSIs by exploring collective experiences, perceptions, and opinions about AI integration and trust.

- **Themes** to be addressed: Clinical and socio-cultural implications.
- Each group will consist of 6–10 participants and last 1 to 2 hours.
- Sessions will be facilitated by an experienced moderator with a note-taker present.
- Sessions will be audio-recorded using secure, encrypted recorders or approved mobile applications, with participant consent obtained before recording. Audio files will be transferred to a secure, access-restricted server at each country site and

deleted from the device once the transfer is confirmed. Transcription will be conducted locally, and all transcripts will be fully de-identified before analysis. When recording is not possible, researchers will take detailed de-identified notes.
- FGDs may be conducted online, by phone, or in-person.
- FGDs will be conducted in English or in local languages according to participants' choices, using context-appropriate discussion guides.

3. Quantitative Survey
All participants from SSI and FGDs will be invited to complete a survey to complement qualitative data, including the acceptability, appropriateness and feasibility survey adapted from Weiner BJ et al (13).

4. Observations
Where appropriate, non-participatory observations will be conducted to document real-world implementation of the AFRICA-RI clinical study.

- Observers will focus on clinic environments, workflow processes, time, activities and interactions between staff and patients to identify facilitators and barriers to AI adoption.
- No photographs or videos will be taken; only de-identified field notes will be recorded.
- Observations will only take place with prior site approval and after informing staff of the purpose of the activity.

Stage 3

Following Stage 2, based on study findings, **workshops** will be conducted with relevant stakeholders in each of the ten SSA countries. These workshops aim to **gather feedback** from participants and ensure that stakeholder perspectives are continuously **integrated into project design, policy alignment, and sustainability planning** for AFRICAI-RI across the region.

Stakeholders will bring together participants to collaboratively **refine system interfaces, decision-support tools, and reporting outputs.** This participatory approach ensures solutions are relevant, user-friendly, and adapted to local needs. Participatory approaches, including **Participatory Action Research (PAR) techniques**, will be employed to actively engage stakeholders in co-identifying challenges, priorities, and solutions related to AI for respiratory disease diagnostics. The workshops will provide a platform for dialogue, validation of findings from previous stages, and collaborative decision-making to strengthen local ownership and contextual relevance of the federated AI infrastructure.

For workshops, country partners will compile **narrative summaries**, and participants will complete **pre- and post-workshop surveys** to capture quantitative feedback. Each workshop will include **10 to 15 participants**, ensuring meaningful discussion while capturing diverse perspectives. These methods aim to foster stakeholder ownership, encourage

collaborative problem-solving, and ensure that project design, policy alignment, and sustainability planning are informed by local needs and contexts.

Each session will last 90–120 minutes and be held in a convenient and accessible location, or online.

Data analysis

Stage 1

For the mapping exercise, the collected data will be analysed using the **WHO stakeholder analysis framework** (14) alongside a **power mapping framework** (15). These frameworks will help identify the influence, interest, and relationships of different stakeholders ecosystems for respiratory disease diagnostics, highlighting key actors, potential allies, and areas where engagement may need to be strengthened. We will analyse basic sociodemographic factors, including stakeholders' gender and country of origin, to ensure diversity and representation across all participating sites.

Stage 2

Qualitative data analysis will be conducted using Dedoose (or equivalent qualitative data analysis software) and analysed with different qualitative methods depending on appropriateness, such methods may include **thematic analysis**. To ensure rigour and consistency, a subset of transcripts will be double-coded by multiple researchers, with any discrepancies resolved through consensus. The insights will be fed back to technical and clinical teams at defined intervals, ensuring ongoing, iterative refinement of AI components in response to real-world needs.

Quantitative data analysis will be summarized using **descriptive statistics** (means, standard deviations, and response distributions). Following the approach of Weiner et al. (13), item-level and scale-level patterns will be examined to evaluate response variability and identify any potential relationships. All analyses will be conducted using standard statistical software.

Stage 3

Data from Stage 3 workshops will be analysed using a mixed-methods approach. Narrative summaries collected by country partners will undergo **thematic analysis** to identify key stakeholder priorities, concerns, and recommendations related to project design, policy alignment, and sustainability.

Quantitative data from pre- and post-workshop surveys will be analysed **descriptively to assess changes in participants' perceptions**, with simple statistical comparisons applied where appropriate. Findings from both qualitative and quantitative sources will be triangulated to provide an integrated understanding of stakeholder feedback, highlighting both country-specific and regional insights to inform AFRICAI-RI implementation and policy guidance.

4. Ethical considerations

Ethical approval will be obtained from the coordinating institution (University of Barcelona) and from national institutional ethics committees at each participating SSA site prior to any data collection. Each site will adapt the protocol template of informed consent forms. Participants will be asked to provide written informed consent (Annex 1). Consent forms will include explicit clauses about (i) participation in the current study, and (ii) optional secondary use of data for future research. Each site will store signed consent securely for at least 5 years post-study completion, or the necessary time to be compliant with EU and local national record-retention policies.

Given the nature of the study, no clinical procedures, interventions, or biological sampling will be performed. All activities involve minimal risk and consist solely of interviews, focus group discussions, observations, and surveys. Participation will be voluntary, and individuals may withdraw at any time without any consequences. Participants will be clearly informed of their right to decline answering specific questions and to stop interviews at any point.

All data will be handled in compliance with local regulations, institutional policies, and GDPR, including de-identification; secure storage, and controlled access protocols. Only pseudonymised data will be transferred to ISGLOBAL for cross-country analysis. A data management plan will define access roles, processing rights, and procedures for ethical review of any data reuse and will be reviewed at reaching several project milestones for updates and adaptations.

Potential ethical concerns such as social discomfort, perceived power imbalances, or fear of data misuse will be mitigated through culturally sensitive engagement, trained facilitators, and transparent communication about the study's purpose, governance, and expected benefits. All participants will receive an information sheet and provide written or thumbprint-informed consent prior to participation.

5. Risk, mitigation strategies and anticipated benefits

This study is considered minimal risk, as it involves SSI and FGD. Participants will not undergo any clinical procedures, and all data will be handled in compliance with ethical and data protection standards. There is minimal risk for the participation in qualitative research as no sensitive data or topic will be discussed with the participants. The ethical risks associated with this project will be **potential social discomfort** during interviews, mitigated by optional question skipping, neutral facilitation, referral procedures for distress and termination of the interview. These risks will be continuously monitored and mitigated through technical design choices, governance protocols, human oversight, stakeholder engagement, and alignment with international standards such as GDPR and the Declaration of Helsinki. Interviewers will be trained in neutral facilitation techniques, privacy-preserving practices, and protocols for responding to participant distress.

From a technical and governance standpoint, potential risks include data confidentiality breaches, unauthorised access, or inconsistencies in data handling across countries. These

will be mitigated through secure data management procedures, pseudonymisation at source, harmonised data protection SOPs, local ethics approvals, encrypted data storage, and continuous monitoring. System-level risks associated with the federated learning infrastructure will be addressed through regular security audits, penetration testing events, and strong governance frameworks.

Conversely, the anticipated benefits of the study are substantial, including:

- Improved diagnostic support and clinical decision-making for TB and pneumonia in resource-constrained settings aligned;
- Enhanced image quality and data availability through synthesis and harmonisation.
- Strengthened infrastructure and capacity for AI-enabled healthcare in SSA;
- Broader sharing and reuse of research outputs in a secure and privacy-preserving manner.

6. Timeline

The specific timeline per country collecting data is detailed in Table 5. This study will be implemented before and during the AFRICAI-RI clinical study. The post-implementation study will be conducted by Kamuzu University of Health Science in Malawi.

The delays during this period have compressed the timeline, reduced flexibility for revisions, and required rescheduling with partners. This has created some coordination challenges and affected deliverable timelines. Mitigation measures include revised internal deadlines and closer monitoring.

Table 5. Timeline per country for the mixed-methods study

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Ethical approval																		
Mapping: Identification of stakeholders																		
Mapping: Categorization and analysis																		
Mixed-methods training																		
SSI																		
FGD																		
Quantitative survey data collection																		
Observations																		
Transcriptions																		
Qualitative analysis																		
Quantitative analysis																		

Final data analysis																	
Workshops																	
Write up of the reports and manuscripts																	

7. Dissemination

Results will be disseminated to study **participants**, key **stakeholders**, the **general public**, and the **scientific** community. For study participants, a short brief in plain language will be developed and shared at the study sites; the same material will be displayed on walls and notice boards for the general public and published at AFRICAI-RI partner websites. For stakeholders, a dedicated workshop will be organized to present and discuss the study findings. For the scientific community, results will be submitted as abstracts to at least two international conferences, and two scientific manuscripts will be prepared based on the outcomes of this study

8. Conclusion

This deliverable presents the initial framework that will guide stakeholder mapping and engagement, data governance, and implementation research within AFRICAI-RI. By outlining harmonised procedures for recruitment, data management, ethics, and mixed-methods data collection, it establishes a solid foundation for the collaborative development of the continent's first federated imaging infrastructure. The insights generated through this study will enable the project to refine platform design, strengthen community and institutional trust, and ensure that AI-driven diagnostic tools are acceptable, feasible, and sustainable across diverse African contexts. Ultimately, this framework positions AFRICAI-RI to achieve its vision of supporting equitable, secure, and context-appropriate AI innovations for respiratory disease diagnosis throughout SSA.

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10. Annexes

10.1. Consent Forms

SECTION A. BACKGROUND INFORMATION

Version and date	V_1.0 dated x of x of 2026
Title of Study	AFRICAI-IMPACT
Principal Investigator	Dr. Maria Maixenchs, Barcelona Institute for Global Health (ISGlobal)
Co-investigators	To be completed
Participating Institutions	To be completed
Protocol number	V_1.0 dated x of x of 2026

SECTION B. CONSENT FORM TO PARTICIPATE IN RESEARCH

Introduction

Greetings: My name is _____(name)_____ and I work for _____ (institution). I would like to give you information about a research study and invite you to be part of it. Several African countries are participating in this research to understand people´s perceptions in Sub-Saharan Africa for the use of artificial intelligence (AI) in diagnosis of respiratory diseases.

You are being asked to participate because you are either:

- A key stakeholder

- A participant from the AFRICAI-RI clinical study, or a caregiver of such participant
- A healthcare provider utilizing the AFRICAI-RI platform

Your opinion on this topic is very relevant for us, for designing diagnostic tools that are context-specific to your community. We are inviting you to share your thoughts, concerns, views, opinions, and preferences regarding the introduction of AI tools in respiratory disease diagnostics in sub-Saharan Africa. We believe that your insights are key to shaping the development process of current and new AI-based diagnostic tools. Please take the time to read this information carefully and ask any questions you may have. Before deciding whether to participate, you can consult with the people you consider appropriate.

Purpose of the research

Researchers have developed a new tool to support respiratory disease diagnosis using artificial intelligence (AI). This system could help us diagnose chest-images as well as other medical images, specially for tuberculosis (TB) and pneumonia.
The goal is to make it easier, faster, and more accurate to diagnose respiratory diseases. Right now, diagnosis often depends on experts carefully looking at medical images. This takes a lot of time, requires trained staff, and can lead to mistakes. This new system will help automatically identify patterns in images that could make diagnosis more reliable, less expensive, and easier to use in different health settings. We will check if the system is accepted, potentially adopted, appropriate, feasible, sustainable and potentially integrated to potentially improve diagnosis and disease surveillance. We will also explore the potential barriers and facilitators for its use.

Why is this component of the study being done?

This component of the study will help us understand the socio-cultural, ethical, technical, clinical and policy perspectives and specific needs related to the potential use of AI-based diagnostics in Sub-Saharan Africa. Your participation will provide valuable insights that will guide the development of diagnostic tools. If you choose to participate in the study, you will have the opportunity to share your thoughts, concerns, views, opinions, and preferences regarding diagnostics using AI in your country and similar countries. The new knowledge gained will enable the development of imaging AI diagnostic tools that are fundamentally inclusive, affordable, scalable, and accessible.

Voluntary participation

The participation in this study is entirely voluntary. You may also choose to stop participating in the study at any time. If you, after the interview today, decide that you do not want us to use the information provided by you, you can let us know and we will erase it and we will not include it in the analysis. Not participating will not

affect you in any way and you may continue to access care at the health facility now or in the future.

Procedure of the research

If you agree to take part in this component of the study, you will be asked to participate in an interview or focus group discussion, using a structured guide.
Note for researcher: Check and read appropriate method below:

- You are invited to participate in a one to one interview (one hour maximum).
- You are invited to participate in a focus group discussion (two hour maximum).

A researcher will take you through an interview to get your comments on your thoughts, concerns, views, opinions, and preferences regarding the introduction of AI tools, especially in resource-limited settings. These interviews will be conducted at a place convenient to you such as your office, facility, or any other convenient place. This interview will be audio recorded so that we do not miss any of your words.

What will happen to information collected from me?

This interview will take part in a private place away from others. All information obtained is confidential and will be stored in computers that are password protected located at our institution. All paper documents will be kept under lock and key. Access to information will be limited to the research team in the country and approved partners. Information will be stored for 5 years using a unique ID number; your name and date of birth will not be used, so that your identity is protected. This de-identified dataset may be used in future research studies and may be shared with other researchers.

Who has allowed this research to take place?

This research has been reviewed and approved by the Independent Scientific and Ethics Review Committee at the University of Barcelona and at _____ [University/IRB] at your country. They have agreed that this research is conducted ethically, and that participants' safety and rights have been respected.

Will there be a follow-up study?

We do not intend to contact you again after the interview, but we want to ask your permission to do so if we need to clarify any information. We also want to know if you would want to be contacted again to participate in a possible follow-up study. If we contact you, we will provide you with information about the study and allow you to decide whether to participate. Participation in any future studies will be voluntary.

What will happen to the results of this research study?

The results of this study will help us to optimize a new model for sharing medical data, using AI for diagnosis of respiratory infections. At the end of the study, we will

share relevant results with the technical team developing the AI tool. In addition, the results will be written in reports and scientific journals and presented at meetings for academic and policy discussions. These results will be shared in a summarized format; your details will remain confidential.

What will the participant data be managed?

The data will be treated with absolute confidentiality and in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016, regarding the protection of natural persons with regard to the processing of personal data and the free circulation of these data and Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights. Disassociating the data means that your information cannot be associated with you since the personal identifying data (name, surname, etc.) is replaced by a code. The dissociated information will be archived for use by project researchers and their research partners. All the results of the study will be presented in a database of the group of participants, data will never be presented individually. Below, we detail the information on the protection of personal data, please read it carefully and contact us if you have any questions:

Who is responsible for the processing of your personal data?

The local partner institution at your country _____ _____ _____ and the Barcelona Institute for Global Health (ISGlobal), CIF: G65341695, Postal address: Rosselló, 132, 6ª Barcelona (08036). Data Protection Officer, contact: lopd@isglobal.org

For what purpose do we process your personal data?

In compliance with the provisions of the General Data Protection Regulation and Organic Law 3/2018, your personal data will be used to carry out the investigation, to which you have consented to participate.

What is the legitimacy for the processing of your personal data?

The legal basis for data processing is the consent that you have provided by accepting the data processing clause. Obtaining your data is necessary to carry out the research project, without prejudice to the fact that you have the right at any time to withdraw the consents given, without this affecting the legality of the treatment carried out previously to your withdrawal.

How long will we keep your personal data?

The Researcher Institution is obliged to retain the data collected for the study according to national guidelines. Subsequently, your information will only be retained by the center conducting this study and by the promoter for other scientific research purposes if you have given your consent to do so, and if permitted by applicable law and ethical requirements.

To which recipients will your personal data be communicated?

This information will be used by the Research Group in charge of the research, who are located in each country and have an adequate level of personal data protection. The data obtained may be published in scientific repositories intended to share information between researchers in order to accelerate research. The information shared will be limited and your anonymity will be guaranteed by avoiding the publication of data that could identify you.

What are your rights when you provide us with your personal data?

You are responsible for the veracity and correctness of the data you provide us and have the power to exercise the rights of access, rectification, deletion, limitation of processing, portability and opposition of your data in accordance with the provisions of the regulations on the matter. of data protection. To exercise them, you must write to the Data Protection Officer at lopd@isglobal.org. In any case, you must attach a photocopy of your national identification document or equivalent. Finally, in addition to the possibility of exercising your rights, if you do not agree with the processing carried out or consider that your rights have been infringed, you may file a claim at any time with the local Data Protection Agency.

Are there any benefits to me for taking part?

There will be no direct benefits to you for participating in this research. However, the knowledge gained from the study may give us insights into the development of AI-based diagnostic tools that are ethically sensitive and respond to the needs of your community, which may benefit the society in general.

What are the possible risks or disadvantages of taking part?

There are minimal risks for participating in this study. Some of the possible inconveniences are the time it takes to complete the interview, individual interviews will take up to one hour/FGD will take up to two hours, and discomfort that you might feel answering some questions. There are potential risks that participants may inadvertently disclose confidential or personal information. You do not have to answer any question that makes you feel uncomfortable, and you can ask us to stop the interview at any time.

Will I receive any compensation?

There will be no compensation for participating in the study.

How are the study results communicated?

Study data may be published. However, participants will not be identified by name. A summary will be available at our study website. Any participant can search this site at any time.

Whom can you contact if you have questions?

If you have any further questions, please contact the study coordinator _____ _____.

You should also contact this person if you would like to withdraw from the study, or if you have any worries regarding your participation in this study.

You may also contact the Principal Investigator of this study, _____ at email _____ or telephone _____.

If you are happy to take part in the study, please read and sign the provided consent sign sheets. You will have a copy of this information sheet to keep.

SECTION C. INFORMATION CONSENT FORM

All of the details and goals of the study have been explained to me. I understand that the study will be a 30 minutes to 1.5 hours interview or a 1 to 2 hours focus group. I understand that these interviews may be conducted in the hospital, at my office or at another convenient place. I also understand that the interview will be audio-recorded.

I agree that all information about the study has been explained to me before consenting to participate, and that I am free to refuse participation in the study without any consequences to me.

Study participation

I agree to be a participant in the study. *(Tick the box that applies)*

☐ YES ☐ NO

Audio recording

I agree to an audio recording of the interviews

☐ YES ☐ NO

Follow-up

You may contact me in the future about this study or to invite me to participate in future studies.

☐ YES ☐ NO

Data sharing

I agree that my data with all personal details removed (eg, name and data of birth) may be shared with other researchers around the world.

☐ YES ☐ NO

Retaining data in case of withdrawal

If I withdraw from the study, I agree that stored data already collected will be kept.

☐ YES ☐ NO

Agreement to Participate

I, _____ (name of participant), have had the research explained to me. I have understood all that has been read and had my questions answered satisfactorily.

I agree to take part in this research. I understand that I can change my mind at any stage, and it will not affect my care in any way.

_____ Date: _____ Time: _____

Printed Name of Research Participant

_____

Signature/Thumbprint of Research Participant

Person who obtained informed consent from the participant

I certify that I have followed the study SOP to obtain consent from the participant.

The participant had the opportunity to ask questions and clarifications about this study and consented to participation in the study. I ensure that the participant questions have been answered satisfactorily and the information has been explained exhaustively.

_____

Name of Person who Obtained Consent

_____

_____

Signature of Person Who Obtained Consent Date

The Participant should now be given copies of the Information sheet and consent form to keep.

10.2. Data Collection Tools

10.2.1. Sociodemographic survey to participants

1. Study ID number [_ _ - _ _]
2. In which of these circumstances are you participating in this study?
    - Stakeholder
    - AFRICAI-RI clinical study participant (adult)
    - AFRICAI-RI caregiver of a minor clinical study participant
    - AFRICAI-RI healthcare worker
3. What is your age? [list of numbers from 18 to 90]
4. What is your gender? Single choice
    - Men
    - Women
    - Trans men
    - Trans women
    - Non binary
    - Prefer not to say
5. What is your country of origin?
6. What is your country of residence?
7. What is your highest level of education obtained? Single choice
    - Not completed elementary school
    - Completed elementary school

- Secondary school (9th grade)
- High school
- Professional technical education
- University or higher

8. Occupation
9. Religion

10.2.2. Stakeholders mapping: Identification of stakeholders´ survey

Introduction

This form aims to collect **contact details of stakeholders who might be relevant to the AFRICAI-RI project**. We seek to ensure diversity in stakeholders´ backgrounds and representation across different **Sub-Saharan African contexts**.

These contacts will be used to map stakeholders in AI and health in SSA. We will not contact them to participate in interviews at this stage. All interviews will later be scheduled and contacted by partners in the countries.

Please provide as **many stakeholders contacts as possible.** Feel free to complete the form multiple times. We kindly recommend that each **AFRICAI-RI country partner propose at least 1 stakeholder per each of these groups:**

1) **Ethical/Policy:** Ethics committee member / Policy makers / local patent offices / National and Local health technology regulators
2) **Healthcare:** Healthcare managers / clinician / clinical researcher / radiologist / imaging technicians / IT manager / Data manager
3) **Civil society:** citizens, patients advocate or advocacy organizations
4) **Scientific/Academic:** AI researchers / Principal Investigator of existing projects on AI and health / IT manager / Data manager
5) **Industry**: Radiology AI companies / Funders / Data brokers (Experts in data monetisation) / AI developer / IT manager / Data manager

Deadline: One week.

[Start of the Questionnaire]

[Mandatory email log in]

1. Please provide your name. *(Mandatory)*
2. Please provide your affiliation. *(Mandatory)*
3. Please provide the name of a stakeholder that could be relevant to the AFRICAI project. *(Mandatory)*

Response type: Short answer

4. Stakeholder sex *(Optional)*
Response type: Single choice

- *Female*
- *Male*
- *Other*

5. Stakeholder country of origin *(Optional)*
Response type: Short answer

6. Stakeholder country of residence *(Optional)*
Response type: Short answer

7. Please select all the roles that best describe the proposed stakeholder. *(Mandatory)*
Response type: Multiple choice (select all that apply)

1. Ethics committee member
2. Policy maker
3. Patent office
4. National or local health technology regulator
5. Healthcare manager
6. Clinician
7. Clinical researcher
8. Radiologist / Imaging technician
9. IT manager
10. Data manager
11. Citizen / Patient advocate / Advocacy organizations
12. AI researcher
13. Principal investigator of existing project
14. AI manufacturer / developers
15. Funders
16. Data brokers (experts in data monetisation)

8. Organization/s where the stakeholder works *(Mandatory)*
Response type: Short answer

9. Stakeholder online website *(Researchgate, LinkedIn profile, online personal website etc.(Optional)*
Response type: Short answer

10. Type of organization(s)*. (Optional)*
Response type: Multiple choice (select all that apply)*.*

1. *Ethics committee*
2. *Policy / Decision maker*
3. *Healthcare*
4. *Civil society*
5. *NGO*
6. *Scientific / Academic*
7. *Government / Regulatory body*
8. *Industry / Private sector / Manufacturer*
9. *Funder*
10. *Other (please specify): _____*

10. Why are you recommending this stakeholder? *(For example, because of their relevant experience or expertise in AI-based diagnostic tools, or in AI and health, previously worked together, would be interested to be interviewed, key decision-maker, leads an AI in health project, strong community link, critical voice on ethics, etc. etc.) (Optional)*
Response type: Paragraph (free text)

11. Would you like to add any other relevant information about this stakeholder? *(Optional)*
Response type: Paragraph (free text)

[End of the Questionnaire]

10.3. AFRICAI-IMPACT Semi-Structured Interview (SSI) Guide

Purpose: To identify ethical, legal, clinical, technical, and policy needs for the successful co-creation, governance, and sustainability of the AFRICAI-RI federated imaging infrastructure across Sub-Saharan Africa (SSA).

1. Introduction (5–10 minutes)

- Introduce interviewer(s) and participant.
- Briefly explain AFRICAI-RI and AFRICAI-IMPACT: This study aims to inform the design, implementation, and long-term sustainability of the AFRICAI-RI federated imaging platform in Sub-Saharan Africa. We are exploring ethical, social, cultural, technical, clinical, and policy considerations related to federated AI for respiratory disease diagnosis.

- Explain voluntary participation, confidentiality, data protection, right to withdraw.
- Explain permission to audio-record.

2. Participant Background

- Can you describe your current role and how it relates to AI, health, data governance or medical imaging?
- What is your experience with digital health systems, data sharing, or AI tools?
- How familiar are you with federated learning or decentralized data infrastructures?

3. CORE QUESTIONS FOR ALL PARTICIPANTS

(These align with: acceptability, feasibility, adoption, appropriateness, penetration, sustainability.)

Expectations and Perceived Value (CFIR: Intervention Characteristics)

- What potential value do you see in a federated platform like AFRICAI-RI for your setting?
- What concerns or hesitations would you have about adopting or working with such a system?

Contextual Factors (CFIR: Outer Setting & Inner Setting)

- What factors in your country/institution could support or hinder the use of federated AI tools?
- How do community expectations, cultural norms, or public trust influence data-related initiatives?

Implementation Climate & Readiness (CFIR: Inner Setting)

- What resources, capacities, or infrastructure are needed to make AFRICAI-RI feasible in your setting?
- Are there existing policies, workflows, or systems that would need to change to adopt this platform?

Long-Term Adoption & Sustainability (Implementation Outcomes)

- What would help ensure long-term uptake and sustainability of the AFRICAI-RI platform?

- What risks or threats could jeopardize its continued use after initial project?

4. THEMATIC MODULES BY STAKEHOLDER GROUP

MODULE A — G1: ELSI, POLICY & REGULATORY STAKEHOLDERS

(Use this section only for ethics committees, policymakers, regulators, decision makers, patent office staff.)

Ethical, Legal, Social & Cultural Issues (ELSI Theme)

- What ethical issues arise when institutions participate in federated learning and cross-country AI research?
- How should privacy, confidentiality, and community trust be protected when data never leave local sites but models are shared?
- Are current national ethics or data governance frameworks adequate for federated infrastructures?
- What additional safeguards or oversight mechanisms would increase trust among institutions and publics?

Policy & Regulatory Alignment (Policy Theme)

- What national or regional policies may facilitate or hinder the use of federated AI platforms?
- How should regulatory bodies approach certification of AI models trained through federated learning?
- What guidance would be needed to harmonise cross-border participation?

Governance & IP Models (Technical + Policy Theme)

- How should intellectual property and benefits be shared for collaboratively developed AI models?
- What governance structures (committees, rules, audits, decision-making processes) would ensure fairness and accountability?
- What incentives—regulatory, academic, or public-good oriented—could encourage institutions to share data for federated learning?

MODULE B — G2: INDUSTRY, AI/IT, FUNDERS, DATA BROKERS & TECHNICAL EXPERTS

(Use this section only for companies, developers, IT/data managers, funders, and technical teams.)

Technical Infrastructure Needs (Technical Theme)

- What technical challenges could affect your ability to participate (e.g., computing power, data quality, bandwidth, interoperability)?
- What features should be included in the data curation toolkit to handle heterogeneous imaging data across the 10 SSA sites?
- What expectations do you have regarding system uptime, security, and reliability?

Model Development, IP & Incentives

- How should intellectual property, credit, and rewards be allocated for models trained collaboratively through federated learning?
- What business, scientific, or operational incentives would encourage industry or developers to participate in AFRICAI-RI?
- What are your concerns about data monetisation, model sharing, or benefit-sharing?

Security, Testing & Certification

- How useful are activities such as hacking challenges or open data calls to validate the system's security and integrity?
- What technical standards or certification pathways would make AI tools produced through this platform trustworthy and usable in practice?

Implementation & Sustainability

- What type of local capacity building (skills, infrastructure, partnerships) would be necessary for long-term participation?
- How do you see your organisation's role evolving as AFRICAI-RI matures into a long-term research infrastructure?

5. CLOSING QUESTIONS (All Participants)

- What are your top recommendations to ensure that AFRICAI-RI is ethical, equitable, and sustainable?

- Is there anything we haven't discussed that you consider essential?
- Is there anything else you would like to add or highlight about challenges or opportunities in this initiative?

Thank the participant for their time and contribution, and provide contact details for follow-up.

10.4. AFRICAI-IMPACT Focus Group Discussion (FGD) guide

Purpose: To explore perceptions, needs, barriers, and opportunities related to ethical, socio-cultural, clinical, technical, and policy dimensions influencing the implementation and adoption of the AFRICAI-RI platform and AI tools.

Target groups:

1. G3 Citizens / Patient advocates / Advocacy organizations, and G4 AI researchers / Principal Investigators
2. G5: Healthcare managers / clinicians / clinical researchers / radiologists / imaging technicians
3. AFRICAI-RI participants and caregivers of minor participants
4. HCPs utilizing the AFRICAI-RI platform

1. Introduction (5 minutes)

- Welcome participants and introduce facilitators.
- Explain purpose of the discussion and expected duration (1-2 hours).
- Emphasize voluntary participation, confidentiality, and respectful dialogue.
- Obtain verbal consent (and permission to record).
- Quick round of introductions: name, role, and experience with AFRICAI-RI (if any).
- Briefly explain AFRICAI-RI and AFRICAI-IMPACT: This study aims to inform the design, implementation, and long-term sustainability of the AFRICAI-RI federated imaging platform in Sub-Saharan Africa. We are exploring ethical, social, cultural, technical, clinical, and policy considerations related to federated AI for respiratory disease diagnosis.

2. Warm-up Question (5 minutes)

- When you hear about using AI in healthcare or medical imaging, what comes to mind?

3. Core Discussion Themes (40–50 minutes)

Facilitators to select or adapt specific prompts based on the stakeholder group.

A. Experiences, Needs, and Expectations

- What value do you expect to see from this project?
- What needs or challenges exist in your community/clinic/work that tools like AFRICAI-RI could help address?

B. Ethical, Social, and Trust Considerations (especially relevant for G3+G4, participants, caregivers)

- What concerns do you have about sharing medical images with partners in other countries? And with AI? Which are the concerns regarding data privacy or data protection?
- What would help you increase trust for HCPs to use your medial images with AI for disease diagnosis?

C. Clinical and Workflow Perspectives (especially for G5 and HCPs using the platform)

- How could AI tools fit into your current clinical workflows?
- What factors could facilitate the use of an Open AI shared repository for respiratory diagnosis, such as the AFRICAI-RI platform?
- What factors could be a barrier for its use (for the Open AI shared repository for respiratory diagnosis, such as the AFRICAI-RI platform)?
- What training or support would be needed for HCPs?

D. Technical and Data Governance Considerations

- What technical challenges (connectivity, equipment, data quality, interoperability) might affect implementation?
- What governance structures would make you feel confident about how models and data are managed?
- How should responsibilities be shared across institutions?

E. Adoption, Sustainability, and Community Engagement (especially relevant for G3+G4, participants, caregivers)

- What factors would support or hinder longer-term adoption?
- What role should communities, researchers, and clinicians play in decision-making?
- How can communication and engagement with participants or the public be improved?

4. Closing Reflections (10-15 minutes)

- If you could give one recommendation to ensure AFRICAI-RI succeeds and is trustworthy, what would it be?
- Is there anything that was missed or anything you would like to add?

Thank the group for their time and contributions.

10.5. Acceptability, appropriateness and feasibility survey

Final version of the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM)

GENERAL INSTRUCTIONS: These measures could be used independently or together. The IAM items could be modified to specify a referent organization, situation, or population (e.g., my clients). Please check and report the psychometric properties with each use or modification.

Acceptability of Intervention Measure (AIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The AFRICAI-RI Open AI repository for diagnosis of respiratory infections meets my approval.					
2. AFRICAI-RI Open AI repository for diagnosis of respiratory infections is appealing to me.					
3. I like AFRICAI-RI Open AI repository for diagnosis of respiratory infections.					
4. I welcome AFRICAI-RI Open AI repository for diagnosis of respiratory infections.					

Intervention Appropriateness Measure (IAM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. AFRICAI-RI Open AI repository for diagnosis of respiratory infections seems fitting.					
2. AFRICAI-RI Open AI repository for diagnosis of respiratory infections seems suitable.					
3. AFRICAI-RI Open AI repository for diagnosis of respiratory infections seems applicable.					
4. AFRICAI-RI Open AI repository for diagnosis of respiratory infections seems like a good match.					

Feasibility of Intervention Measure (FIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. AFRICAI-RI Open AI repository for diagnosis of respiratory infections seems implementable.					
2. AFRICAI-RI Open AI repository for diagnosis of respiratory infections seems possible.					
3. AFRICAI-RI Open AI repository for diagnosis of respiratory infections seems doable.					

4. AFRICAI-RI Open AI repository for diagnosis of respiratory infections seems easy to use.					

Pragmatic Qualities:

- Readability tested by substituting "This EBP" for "Insert Intervention." Flesch reading ease score (and grade level) is 95.15 (5th grade) for AIM, 99.60 (5th grade) for IAM, and 94.17 (5th grade) for FIM.
- No specialized training is needed to administer, score, or interpret the measures.
- Cut-off scores for interpretation not yet available; however, higher scores indicate greater acceptability, appropriateness, or feasibility.
- Norms not yet available.
- Scales can be created for each measure by averaging responses. Scale values range from 1 to 5. No items need to be reverse coded. Good measurement practice: assess structural validity to confirm the unidimensionality of each measure and calculate alpha coefficient to ascertain reliability.
- There is no cost to use these measures.
- Time to complete: less than 5 minutes per measure.

10.6. Pre-workshop survey

Purpose: To assess workshop participants' initial knowledge, perceptions, and attitudes regarding the AFRICAI-RI repository before the workshop.

Instructions: Please rate the following items on a scale of 1 to 5 (1 = Strongly disagree, 5 = Strongly agree).

Section 1 — Knowledge

1. I understand the overall purpose of the AFRICAI-RI initiative.
2. I am familiar with the concept of an Open AI biomedical imaging repository for respiratory diagnosis.
3. I know how imaging data could be used to train or validate AI models.
4. I am aware of the ethical considerations related to data sharing for AI.

Section 2 — Perceptions

5. I believe an AI imaging repository could improve healthcare delivery in Africa.
6. I think such a repository could strengthen biomedical research collaborations across countries.
7. I feel that data governance frameworks in my country are adequate for AI initiatives.

Section 3 — Attitudes

8. I feel positive about participating in or supporting the implementation of an Open AI imaging repository for respiratory diagnosis in SSA.
9. I trust that communities and health institutions can benefit from sharing imaging data.
10. I am comfortable with the idea of cross-border data sharing if proper safeguards are in place.

10.7. Post-workshop survey

Purpose: To measure changes in workshop participants' knowledge, perceptions, and attitudes following the workshop.

Instructions: Rate the same items on a scale of 1 to 5.

Section 1 — Knowledge

1. I now have a clear understanding of the AFRICAI-RI initiative.
2. I am familiar with the concept of an Open AI biomedical imaging repository for respiratory diagnosis.
3. I can explain how imaging data contribute to AI training and validation.
4. I understand the ethical and regulatory considerations discussed during the workshop.

Section 2 — Perceptions

5. I believe the AI imaging repository is feasible to implement in my context.
6. I think it will support equitable and collaborative research across Africa.
7. I feel confident in the data governance approaches presented during the workshop.

Section 3 — Attitudes

8. I am motivated to contribute to or support the AFRICAI-RI implementation.
9. I trust that safeguards can ensure responsible and ethical data sharing.

10. I feel more confident engaging communities or colleagues about the repository.

Section 4 — Workshop Feedback

11. The workshop content was clear and relevant.
12. The participatory methods helped me engage with the topic.
13. I would recommend similar workshops to other stakeholders.

Open Questions:
14. What was the most useful part of the workshop?
15. What additional support or information would you need going forward?

10.8. Guide for field observations

Purpose: To observe routine clinical workflows and contextual factors affecting the use and implementation of the AFRICAI-RI platform, without collecting identifiable information.

Preparation:

Introduce yourself to staff, explain the purpose ("to understand workflows around imaging and data use"), obtain verbal permission, and confirm appropriate areas for observation.

Workflow & Processes:

Note how imaging procedures are conducted; how images are stored, curated, or transferred; how and when the AFRICAI-RI platform is used; points where staff encounter delays, confusion, or improvisations.

Technology & Equipment:

Observe condition and use of imaging devices, computers, connectivity, electricity stability; staff interactions with the platform interface; any technical limitations affecting workflow.

Human Roles & Interactions:

Identify who performs which tasks; how staff communicate or coordinate around imaging and data processes; clarity of roles; visible workload or workflow pressures.

Socio-Cultural & Contextual Factors:

Record how patients or caregivers respond to imaging and data procedures; comfort or hesitations; cultural norms influencing consent, privacy, or communication; environmental constraints such as space or layout.

Barriers & Facilitators:

Note examples related to usability, complexity, resource availability, staff confidence or training needs, workflow compatibility, policy influences, and team dynamics.

Informal Clarifications:

Ask brief questions such as: "Which step is most challenging?" or "Has this system changed your workflow?" Avoid identifiable or evaluative questions.

Note-taking:

Record date, site, location, main activities observed, key insights, and short anonymized quotes if helpful. No names or personal identifiers. Store notes securely per project guidelines.