Process Design Table – Appendix I

Step	Description	Key Attributes	Descriptions	Feedback on Step description		Feedback on Attribute description		Any other comments Any questions?	Questions (one question, or up to 3 if necessary)	Answers
				Does the step exist in current system? (yes/no)	How does it relate to an existing step, or would it fit within a new step?	Does the attribute exist in current system? (yes/no)	How does it relate to an existing step, or would it fit within a new step?			
1. **Is there a functioning TB Recording and reporting system in place?**	Assess whether the current TB recording system consistently applies WHO-recommended case definitions and recording standards across all facilities. Identify any gaps in functionality and ensure that both WHO and national TB guidelines are followed.	Case definitions	Ensure that the system records patient types such as bacteriologically confirmed, clinically diagnosed, pulmonary (PTB), extra pulmonary (EPTB), new, relapse, and other patients as per WHO standards.	Yes	There is a functioning system in place that follows the WHO standards. The recording and reporting guidelines follow the WHO standards. There are National Guidelines in place. Case definitions are clearly outlined in the guidelines.	Yes	It will fit	Standard definitions to classify TB are clearly defined in the National Guidelines	What percentage of health facilities in your jurisdiction have a fully functional TB recording and reporting system that complies with WHO standards, and how often (e.g., annually) are these systems evaluated for compliance?	Yes, they all have. They get the forms from the NTP. They comply with WHO. They are evaluated when they are changing the guidelines, 5 years
		Recording and reporting standards	WHO sets standards for case definitions and data reporting formats. Verify whether these standards are being followed consistently across health facilities.	Yes		Yes	It will fit	Recording and reporting standards follow WHO standards and registers are used for recording		
		National guidelines in place	Ensure compliance with national TB and Leprosy guidelines, published in 2024, that are aligned with WHO's global standards.	Yes		Yes	It will fit	Guidelines are in place and they are reviewed every 5 years. They are aligned with WHO standards.	What percentage of TB cases in your facility are recorded in compliance with WHO and national TB guidelines, and how often are compliance reviews conducted (e.g., quarterly)?	100%. From people screened, the presumptive and people identified. Quarterly
		Staff capacity in TB	Ensure that healthcare workers handling TB recording and reporting are well-trained to avoid errors in data capture and management.	Yes		Yes	It will fit	All staff are trained in TB before assigned TB Roles.	What percentage of TB staff are currently trained in data reporting procedures, and how often (e.g., every 6 months) are refresher training sessions conducted?	100%. All data clerks are trained. Mentorships are done every quarter. There are also performance reviews done biannually where trainings are done
2. **Who needs to provide overall oversight and participate in decision making related to the adoption, design and implementation of an electronic and reporting system for TB?**	Assemble a multi-stakeholder steering committee, including representatives from health facilities, government, and IT. Ensure all stakeholders are fully briefed on system objectives, available resources, TB treatment workflows, and relevant information-system regulations.	Users and beneficiaries	These stakeholders are critical to the system's success, ensuring proper use and benefit distribution, especially among TB care providers and policy-makers	Yes	In the existing system, There is a technical working group that provides overall oversight TB, therefore it fits	Yes	It will fit	The current system has clear users for the system who are the health workers and the beneficiaries who are the patients and users of data	Are there key stakeholders or a steering committee that manages the system's design and implementation? Who are the designated stakeholders responsible for overseeing the TB recording system, and how frequently (e.g., annually) are their roles reviewed for clarity and accountability?	NTP, Partners, Academic institutions. There is a Technical Working Group comprised of NTP, WHO and Partners. They are reviewed quarterly. There is also HMIS that looks at DHIS2.

		TB care providers	Frontline health workers responsible for entering patient data, managing cases, and following up with patients	Yes		Yes	It will fit	Part of the Technical Working Group		
		Ministry of Health	Sets policy directives and ensures the system aligns with national health goals and provides appropriate funding.	Yes		Yes	It will fit	Part of the Technical Working Group		
		IT experts	Handle system architecture, integration, and troubleshooting to ensure that the system is scalable and secure	Yes		Yes	It will fit	Part of the Technical Working Group		
		District managers.	Responsible for ensuring compliance with guidelines, monitoring system usage, and managing data quality in their districts.	Yes		Yes	It will fit	Part of the Technical Working Group		
		National TB Program	Ensures alignment of the system with the country's TB control strategy and WHO's recommendations	Yes		Yes	It will fit	Part of the Technical Working Group		
		Laboratory networks	Feed lab test results into the system, ensuring timely diagnosis and data accuracy.	Yes		Yes	It will fit	Part of the Technical Working Group		
		Legal Experts	Ensure that the system complies with patient data privacy laws and data-sharing agreements.	Yes		Yes	It will fit	Part of the Technical Working Group		
		External agencies	Organizations such as WHO or donors who provide support, funding, or guidance for TB control initiatives.	Yes		Yes	It will fit	Part of the Technical Working Group		
3. **Establish the primary objectives of building an electronic recording and reporting system for TB care and control**	Establish clear objectives for the electronic system, with a focus on defining its design, content, and complexity.	Improve surveillance and public health	Enhance case detection, monitor trends, and provide real-time data for informed decision-making and public health interventions.	Yes	This exist in the current system. The recording and reporting system currently available has the same objectives therefore it will fit.	Yes	It will fit	Information from the current system is collected every quarter by a supervision team and the data is used improved surveillance and public health efforts	What are the primary objectives of the TB recording and reporting system at your facility?	Improve surveillance and public health, Improving Programme and resource management, Improving clinical care of individual patients. This enables to to view data in real time thereby improving the entire service.
		Improving Programme and resource management,	Optimize resource allocation and management by identifying areas with higher TB burdens through accurate and timely data.			Yes	It will fit	Information from the current system is collected every quarter by a supervision team. This consolidated data is used by NTP, Ministry of health and partners to improve and resource managememt	How effectively is the TB recording system meeting its objectives of improving surveillance, resource management, and clinical care, and what measurable outcomes can demonstrate this success in the past year?	The system is meeting the objectives but the lead times to achieve these objectives is long and not in real time., the updates are done quarterly through TB/HIV supervisions.

		Improving clinical care of individual patients	Improve patient outcomes by ensuring timely follow-up, tracking adherence to treatment, and ensuring no patients are lost to follow-up.			Yes	It will fit	The records in the register help facilities improve clinical care of individual patients	How has the system improved decision-making and patient care in the past 6 months, and what specific metrics demonstrate this improvement?	The program has used data from the supervisions to make changes like scaling up TB preventive Therapy amongst adults regardless of HIV Status, there was high TB death rates in other districts and the project implemented Quality improvement initiatives based on this data.
4. **Identify Users and Beneficiaries of the system**	Determine user roles and identify key system users, such as clinicians, lab technicians, and policymakers, to guide both the planning and implementation phases.	Who will be entering data	Health workers, clinicians, lab technicians, and surveillance officers responsible for inputting patient records, lab results, and treatment plans.	Yes	The guidelines and the current system has clear user roles and beneficiaries of the system	Yes	It Will Fit	In the current system, TBO, Clinician, Nurses, Data Clerks, Lab, M&E, HMIS are the ones that enter data	Who are the primary users (e.g., clinicians, lab technicians) of the TB system, and how often (e.g., daily, weekly) do they access the system to record or review data? Who will be entering data, using data, or receiving reports from the system? How does the system support different types of users in their roles (e.g., data entry, case management, reporting)?	TBO, Clinician, Nurses, Data Clerks, Lab, M&E, HMIS. Daily TBO, Clinician, Nurses, Data Clerks, Lab, M&E, HMIS. Daily Different roles have different registers. On electronic systems they have different interfaces according to their roles and access levels
		Who will be using data directly while interacting with the system	Health workers and clinicians use real-time data for decision-making and managing patient care.			Yes	It Will Fit	Data collected in the facilities is consolidated once a quarter and this data is used by TBO, Clinician, Nurses, Data Clerks, Lab, M&E, HMIS, NTP, District managers Ministry of Health and Partners		
		Who will be viewing or receiving reports	Policymakers, district managers, and program coordinators who use system-generated reports to make policy decisions and allocate resources			Yes	It Will Fit	Policymakers, district managers, and program coordinators who use system-generated reports to make policy decisions and allocate resources		
		Who will be extracting data for analysis	Health analysts and IT experts responsible for extracting data to identify trends and produce reports for TB surveillance and program performance evaluation.			Yes	It Will Fit	M&E Team, NTP, HMIS		
5. **Determine which Patient the system will coverage**	Clarify which patient groups will be included in the system, such as TB patients, including MDR and latent cases, and establish a rationale for their inclusion. This will inform the choice of	All diagnosed TB patients	Ensure that all diagnosed TB patients, including new and relapse cases, are covered by the system for accurate reporting.	Yes	This relates to the current system, there are categories of patients but the current system covers all patients regardless of the category	Yes	It will fit	All patients are currently enrolled in the TB recording and reporting system	Does the TB recording system cover all diagnosed patient types, including MDR-TB and latent TB, and how often is coverage updated to include new patient groups?	All patients are covered. The register categorizes every category.

	different aspects and workflows in the system design.	only MDR-TB patients	Initially, the system may focus on MDR-TB patients as a priority group before expanding to other patient categories.			Yes	It Will Fit	The system manages all diagnosed patients	Are there patient subgroups (e.g., latent TB, HIV co-infected) not currently covered by the system?	No, all TB patients are covered
		Expand coverage to all TB patients	The system should eventually cover all TB patients, ensuring nationwide surveillance of the disease.			Yes	It Will Fit	The system currently manages all diagnosed patients		
		Links to different systems	Specifies the integration of other health systems to track different TB patient sub-groups (e.g., HIV co-infected)			Yes	It Will Fit	The current system reports are used by other systems including DHIS 2 and HIV system	Does the system integrate with other health systems (e.g., HIV) for comprehensive patient coverage?	Currently, Partial integration with HIV AND DHIS2
6. **Which locations the system cover**	Assess whether the system will include all geographic areas and facility types (e.g., urban, rural, remote, public, private) or a subset. Plan accordingly to ensure comprehensive TB surveillance, with particular emphasis on including high-risk areas.	All locations and all providers of TB diagnostic and care service	The system should be implemented across all TB diagnostic and care facilities, whether public, private, or specialized (e.g., military hospitals, refugee camps	Yes	The current system is rolled out in all TB registration site so this related to the step. There is a column for the registration site and type	Yes	It will fit	The current System is in use in all TB registration sites, these include private and public facilities. They include Central Hospitals, District Hospitals, Military facilities, Prisons, Mission Hospitals and Private facilities.	Does the TB recording system cover 100% of urban, rural, and remote areas in your jurisdiction, and how frequently (e.g., biannually) is this coverage evaluated?	100% FOR ALL TB Registration sites
		Geographic location	Identify urban, rural, and remote areas where the system will be implemented to ensure comprehensive geographic coverage.			Yes	It will fit	The current system operates in all geographical locations	Does the system cover all types of facilities (e.g., public health centers, private clinics, hospitals)?	All
		Type of facility	Consider the range of facility types (public, private, military, prison, etc.) to ensure that the system is adaptable to different settings.			Yes	It will fit	The current system is in all types of facilities provided they are TB registration sites	Are there specific facility types (e.g., public health centers, private clinics) that are excluded from the system's coverage?	No
7. **Will the system be a stand-alone system or will it be integrated with other electronic systems**	Map the entire data flow process from patient intake at clinics and labs to central reporting, identifying all data entry points and ensuring smooth, real-time data transfer. Additionally, determine whether the system will be standalone or integrated with existing health information systems (e.g., HIV, pharmacy, lab management) and map the necessary integration points.	Mapping all existing paper and electronic systems	Identify current systems (e.g., HIV, lab management) that need to be integrated with the TB system for consistent and unified reporting.	Yes	This step relates to the current system. Even though it is a paper based system, information from this system is shared with other systems like DHIS 2 and HIV systems. Therefore it is not a stand-alone system	Yes	It will fit	The current system share data with DHIS 2 and HIV system. The reports from quarterly visits are used by other systems	Is the TB recording system intended to be a stand-alone system, or is there a plan to integrate with other electronic systems?	Integrated system probably with HIV, DHIS 2, Non Communicable diseases, Leprosy, EMR
		Integrate with existing systems e.g. DHIS2 or HIV System	Integrate with national health information systems (e.g., DHIS2, HIV program) to avoid data duplication and streamline reporting processes.			Yes	It will fit	Currently information is shared with DHIS 2 and HIV system.	What are the anticipated benefits of integrating the TB system with existing health information systems (e.g., DHIS2, HIV program)?	Comprehensive management for patients, will improve turnaround time
		Data Compatibility	Ensure the system's data formats are compatible with existing systems for smooth integration and interoperability.			Yes	It will fit	The current system collects patient level data while other systems like DHIS 2 require aggregated data. Patient level data can be aggregated to ensure compatibility		
		Security Requirements	Implement robust security measures, such as encryption and access control, to protect sensitive patient data from breaches.			Yes	It will fit	The current system implemented physical measures to protect data	What challenges might arise during system integration (e.g., data compatibility, security, training)?	Capacity of the people to understand the variables, data compatibility, workload for staff.

8. **What elements of paper-based recording and reporting should be maintained**	Retain critical paper records as necessary while planning for digital migration. Identify essential paper-based records (e.g., patient history, treatment plans) for transition to the electronic system, and implement a phased transition plan to ensure no data loss during the migration process.	Legal requirements	Certain legal obligations may require retaining paper-based records for a specific period before fully transitioning to a digital system.	Yes	This will fit in the existing step as we are already using the paper-based system currently	Yes	It Will fit	Patient records are required to be retained for at least 7 years before discarded.	What elements of the current paper-based recording and reporting system should be maintained during the transition to the electronic system?	We maintain all and allow to run in parallel.
		Patient well being	Ensure that critical paper-based records (e.g., patient history) are maintained for proper follow-up and patient care, especially during the transition phase.			Yes	It will fit	Patient history is important when managing the patient. Currently patient data is on paper based system therefore it is good to retain some elements	Do you believe that some data should remain paper-based for a certain period after the electronic system is implemented? Why or why not?	Yes. Most users may need capacity building. Backup
		Phased transition.	Gradually move from paper to digital systems, allowing time for healthcare providers to adjust to the new technology while minimizing disruptions to TB care.			Yes	It will fit	For future referencing and backup, phased transition is important.	How do you currently ensure that essential paper records are preserved?	They are archived in arch files and stored in lockable cabinets
9. **Is the basic unit of recording clinical data a patient, a case or a group of cases?**	Decide on the data entry units for clinical data, determining whether it will be recorded at the patient, case, or group level, and ensure consistency across the system.	Unique Patient Data (Unique personal identifiers)	Each patient should have a unique identifier to ensure accurate tracking and reporting of their health status, avoiding duplication of records	Yes	This will fit. Health workers are already dealing with both unique data and aggregated data in different systems	Yes	It will fit	The paper based system uses patient level data which is unique data	Is the unit of data entry at your facility (patient, case, or group) appropriate for accurate reporting, and how often is this reviewed to ensure optimal data management? Do you believe that recording data at a different unit level (patient vs. case vs. group of cases) would improve data management? Why or why not? What benefits do you foresee in using an alternative unit for recording data?	Patient level. They are also categorized according to the risk groups. Reviewed in the guidelines. Recording at patient level is advantageous because you have information that will help you design specific interventions that will benefit the patient Using the aggregated data will help to see the overall picture.
		Aggregated Data (sub-national or local patient identifiers)	Data can also be aggregated at the local level (district, facility) for broader analysis without losing patient-specific information.			Yes	It will fit	Patient data can be aggregated from the current system to be used in systems like DHIS 2		
10. **Determine what data items that needs to be captured**	Develop and maintain an updated data dictionary that identifies essential data variables for reporting, management, and surveillance, ensuring alignment with WHO guidelines and reporting requirements.	Programme management and TB surveillance data	Collect essential data such as patient demographics, case type, and treatment progress to monitor TB cases and evaluate program effectiveness.	Yes	It will fit in the step. Already most of this data is captured in the current paper based system	Yes	It will fit	To manage patients currently, patient demographics, case type, and treatment progress are collected to monitor TB cases and evaluate program effectiveness.	What essential data variables are captured by the TB system according to WHO guidelines, and how frequently is the data dictionary updated to reflect any changes? How do these data items align with WHO guidelines or national TB reporting standards? Are there additional data items that you believe should be included to improve patient care or program management?	Patients demographics, Occupation, TB/HIV status, TB History and other infections All reporting indicators are in conformity with the DHO guidelines Add an element on AI findings, X-RAY findings must be included.

		Patient management data items	Track individual patient information, including treatment regimens, adherence, and outcomes, to improve patient care.			Yes	It will fit	To manage patients, individual patient and treatment information is recorded and used		
		Work flow management	Data fields that track the workflow of health workers, ensuring that patients receive care at every step of the TB care continuum.			Yes	It will fit	Workflow in the current system is clear, patients are registered in different registers that determine work flow		
		system administration data items	Data related to the management of the system itself, such as user access logs and system performance metrics.			Yes	It will fit	This will need to be developed.		
		System monitoring and audit data items	Capture system performance data and audit trails to ensure system reliability and detect any misuse or inaccuracies.			Yes	It will fit	This will need to be developed		
11. **Identify who enters data, where and when will data be entered, and how do data flow within the system**	Develop a data flow diagram that identifies where and when data will be entered and how it will flow through the system, mapping the entire process from clinics and labs to central reporting.	Data entry points	Describe all the situations where data is entered, such as clinics, labs, and hospitals. Map data entry by healthcare staff (e.g., clinicians, lab technicians).	Yes	Modelling against the current system, the guidelines already defined who enters data, where and when will data be entered, and how do data flow within the system	Yes	It will fit	In the current system, data is entered at the TBO, Lab, OPD	Who will be entering data into the TB recording and reporting system?	Data entry clerks, TBO, Lab, Clinicians, Nurses
		Workload	Assess how data entry tasks will be distributed across health workers, ensuring it doesn't overwhelm their daily work.			Yes	It will fit	This must be assessed	Are there any bottlenecks or challenges in the data entry process?	In other system the issue is mainly connectivity, insufficient gadgets, capacity of staff.
		Data flow	Create data flow diagrams showing the movement of data from local health centers to district and national levels for reporting.			Yes	It will fit	Using the current workflow, dataflow diagrams can be developed from that	How does data flow from the point of data collection to reporting?	OPD or any other service delivery point (Screened) To TBO (Register and sample collection) TO Lab (testing and register and issue results) TO TBO (IF CONFIRMED TREATMENT INITIATION, contact investigation, TB Preventive therapy)
		Real-time data	Aim for real-time data transmission wherever possible, ensuring minimal delay in updates from clinics to central databases.			Yes	It will fit	This must be developed.	What percentage of TB data is entered in real-time, and what is the average delay (in hours or days) between data collection and system entry over the past 3 months? What is the typical turnaround time from data collection to reporting?	Yes it is in real time. No delay Monthly for facility. Quarterly for supervision.

12. **What data quality assurance processes are required?**	Set up data validation protocols, regular audits, and error-checking processes. Implement detailed validation checks that specify the people involved, their responsibilities, the timing of checks, the procedures followed, and the handling of records at each stage.	Data checks at the point of entry.	Implement validation protocols to ensure data accuracy and completeness during entry.	Yes	This can be related to the current system as there are quality assurance processes during supervisions	Yes	It will fit	To register a patient in the current system, you need to fill all the fields.	What data quality assurance protocols (e.g., audits, validation checks) are currently in place, and how often are they reviewed to ensure data accuracy and completeness? What percentage of data quality issues are flagged during audits, and how often (e.g., monthly) are these challenges addressed and resolved?	Data Quality Assessments, Supervisions also check registers for quality data.
		System generated alerts	Alerts should notify users when required fields are left empty, or when inconsistencies arise, such as duplicate entries.			yes	It will fit	This will need to be developed		
		Error detection algorithms	Use automated algorithms to flag errors, anomalies, or missing data for review and correction.			yes	It will fit	This will need to be developed		
		Regular audits.	Conduct regular data quality audits to identify gaps and ensure data integrity. Use manual checks and automated validation to clean the data.			yes	It will fit	Currently there are monthly and quarterly audits.		
		External data checks	Verifications performed by external bodies or during supervisory visits to ensure compliance with reporting standards			Yes	It will fit	Currently there are monthly and quarterly audits		
13. **How is feedback provided to the system?**	Design interactive user interfaces that provide real-time feedback to users at all levels, ensuring immediate notifications for data entry errors and inconsistencies.	Engaging users	Ensure the system allows for feedback loops that engage data-entry users actively, making data entry an interactive process.	Yes	In the current system, feedback is provided during audits and quarterly visits so it relates	Yes	It will fit	This must be developed. The current system does not engage users	What percentage of users receive real-time notifications for incomplete data entries, and how frequently (e.g., quarterly) are feedback loops evaluated to improve system accuracy? What challenges do users face in receiving and acting on feedback from the system?	All receive feedback but not in real time. Feedback usually happens when there are data quality checks and supervisions and that is in a month or quarter. Yes, the feedback loops are evaluated. Feedback is received late and the required changes are also done late (once a month or in a quarter)
		Real-time feedback	Build feedback mechanisms that alert users to incomplete or incorrect data entries, helping maintain data accuracy.			Yes	It will fit	This must be developed. The current system does not provide real-time feedback		

14. **What standard outputs, reports and other analyses are required?**	Identify standard outputs for each user group, including data visualizations and statistical tools, and define standard reports for stakeholders (e.g., case notifications, treatment outcomes). Specify the audience for each output or report, ensuring that visual displays such as graphs, maps of spatial and temporal trends, and potential outbreaks can be generated within the system or through external software (e.g., statistical, visualization, or GIS packages).	Data visualization	Create visual outputs such as charts, graphs, and maps for TB case trends, outbreaks, and treatment outcomes to support decision-making.	Yes	The current system presents data only, to develop reports this data must be collected and analysed	Yes	It will fit	This must be developed. The current system does not have this.	What standard reports (e.g., case notifications, treatment outcomes) are generated by the system, and how frequently are they produced and distributed to stakeholders? What additional analyses do you believe are necessary for effective TB management but are currently not available? What percentage of standard TB reports (e.g., case notifications, treatment outcomes) were delayed in the past year, and how often have these delays affected decision-making processes?	Number of client screened, Case notification, Linkage to care report, Treatment outcome Graphs, Dashboard, GIS None
		Reports	Generate standard reports such as TB case notifications, treatment outcomes, and surveillance summaries at local, district, and national levels.			Yes	It will fit	The current system produces the following reports; Number of client screened, Case notification, Linkage to care report, Treatment outcome		
		Statistical Analysis	Include tools to analyze case trends, treatment success rates, and detect potential TB outbreaks using advanced statistical software.			Yes	It will fit	This must be developed. The current system does not have.		
15. **What are the data entry screen or interface requirements?**	Consult with stakeholders to design user-friendly data entry screens and interfaces that are intuitive and familiar, ensuring they meet the needs of all users.	System language	Set up system language options based on users' preferences and comfort. Ensure that technical language is minimized for ease of use.	Yes	The current registers use English. This is a standard in Malawi	Yes	Yes	Registers and forms are in English, the official language	How often do users receive formal training on the TB recording system, and what percentage of staff have completed training in the past 12 months? What specific tools (e.g., software, dashboards) are used to generate reports, and how are they shared with relevant stakeholders? What specific features in a new TB recording system would improve your workflow and patient care, and by when should these features be implemented to optimize care delivery?	At the beginning. Then depends on need and funds availability EPI info, excel, PDF. Print and emails are used to share SMS, Email, Notification, Alerts
		Screen layout.	Ensure that screen designs mimic familiar paper-based systems to make the transition to digital easier for health workers.			Yes	It will fit	This must be carefully considered and developed.		
		Use date or time formats	Implement role-based access permissions, ensuring that only authorized personnel can view or edit sensitive patient data.			Yes	It will fit	This must be developed		

16. **How will Data Confidentiality and Security be ensured?**	Train users on data confidentiality and the importance of compliance with data protection laws. Implement robust security measures, including encryption, access control, secure data transmission, and physical security. Ensure users formally commit to these standards by signing a document outlining their responsibilities regarding data handling.	Access control Mechanisms	Implement role-based access permissions, ensuring that only authorized personnel can view or edit sensitive patient data.	Yes	The current system has some security control mechanisms, mainly physical mechanisms	Yes	It will fit	The roles are already defined. Access control mechanisms must be developed	What percentage of TB data is encrypted, and how frequently (e.g., quarterly) are security measures such as access control and encryption tested for potential vulnerabilities? What are the most common security risks encountered in the past year, and how frequently (e.g., monthly) are data security protocols updated or audited to address these risks?	With the current paper based system, there is no encryption, we rely on keeping the registers safely that only staff can access. But with electronic system, personal identifiable information needs to be encrypted Theft of machines and registers are common risks but we did not have any in the past 6 months.
		User Authentication	Use strong authentication protocols such as passwords, biometrics, or two-factor authentication to protect user accounts.			Yes	It will fit	This must be developed		
		Data Anonymization	Anonymize patient data wherever possible to protect patient identity and ensure compliance with privacy laws.			Yes	It will fit	This must be developed		
		Encryption	Encrypt data during transmission and storage to prevent unauthorized access and ensure data security.			Yes	It will fit	This must be developed		
		Physical Security	Ensure secure physical locations for servers and backups to protect against theft or damage.			Yes	It will fit	This is already implemented		
17. **What staffing is required?**	Plan for user roles and training to ensure sustainability, while defining staffing needs for the effective operation and management of the system. Develop a comprehensive staffing plan that outlines required roles and responsibilities.	User Roles	Identify necessary roles (clinicians, IT personnel, lab staff) required to operate the system at various levels (local, district, national).	Yes	This exist in the existing plan. Before establishing TB registration sites, there are staffing considerations in TB, Data and Lab	Yes	It will fit	The guidelines clearly define the user roles in TB management and these are the ones using the TB paper based system.	Are all roles and responsibilities for TB system users (e.g., data entry, analysis, reporting) clearly defined and reviewed at least once per year to ensure clarity and accountability?	Yes, they are defined in the TB guidelines and they are reviewed together with the guidelines once every 5 years.
		Staff Turnover Contingency	Plan for turnover by ensuring continuous training and maintaining a pool of trained personnel.			Yes	It will fit	There is always a plan especially for TBO for every site	What percentage of staff are trained for data entry and system maintenance, and how frequently (e.g., annually) is staffing capacity assessed to ensure adequate coverage? What challenges do you face regarding staff capacity or turnover?	All in TBO are trained. For maintenance 50% Minimal turnover in my jurisdiction
		Training	Regular training ensures that all users understand how to use the system and are aware of best practices for data entry and reporting.			Yes	It will fit	Currently, before establishing a TB site, staff are trained and every quarter, there is mentoring during supervisions		

18. **What user Support is needed?**	Establish clear response times and support mechanisms for user issues, including providing "how-to" guides or easy-to-follow standard operating procedures (SOPs), help desk or hotline services with defined response times, and a web-based discussion forum. Facilitate sharing of experiences and learning from users in other countries that have transitioned from paper-based to electronic recording and reporting.	Helpdesk services	Provide a dedicated helpdesk with clearly defined response times for addressing user issues and system troubleshooting	Yes	This relates to the current support services that are done by NTP during supervision. During these visits there is mentoring, clarifications and collection of data.	Yes	Its will fit	This must be established	What kind of technical support is available to users when there are system issues or data-related challenges? What percentage of technical support requests are resolved within the agreed service level timeframe, and what is the average resolution time (in hours or days) for the past 6 months?	With the papers based support there is supervision and mentorship from NTP. With DHIS 2 and HIV system there is helpdesk, IT technical assistance All the requests are resolved within 24 hours.
		Technical assistance	Offer written guidelines (SOPs) and real-time support to help users resolve system-related issues quickly.			Yes	It will fit.	Currently technical assistance is done through supervisions	Are there "how-to" guides or standard operating procedures (SOPs) available for users?	Yes there are guides for the job.
		Training	Ensure ongoing training sessions for new staff and refresher courses for existing staff to maintain competency in using the system.			Yes	It will fit	Currently trainings are done through normal training and mentoring		
19. **What technical support is needed?**	Plan for system administration, hardware maintenance, and bug fixes, while determining the technical support needed for the system's infrastructure and ongoing software maintenance.	System administration	Assign a dedicated team to manage day-to-day system operations, perform regular data backups, and handle system maintenance tasks (e.g., software updates, bug fixes) to ensure smooth system functionality.	Yes	This step relates with supervision visits	Yes	It will fit	This must be developed	What specific technical support (e.g., helpdesk, software updates) is available to maintain the TB system, and how frequently are maintenance and bug fixes implemented? How often do technical issues affect your ability to use the system effectively?	Helpdesk for guidance on system usage. Technical support for technical issues. If there are challenges they are fixed within 24 hours Not often
		Hardware Maintenance	Plan for regular hardware checks and replacements to prevent system failures due to outdated or faulty equipment.			Yes	It will fit	This must be developed	What specific hardware or software issues are most common, and how often do these issues disrupt TB data entry or reporting in a typical month?	The major issues that affect the system include server downtimes and network connectivity. Sometimes power failure. This may happen 3 times a month
		Fixing software bugs	Have protocols for identifying, reporting, and fixing software bugs that may disrupt system performance.			Yes	It will fit	This must be developed.		
20. **What level of service availability, response times and contingency planning is required?**	Establish business continuity plans and service level agreements that address system downtime and ensure continuity of operations through effective contingency planning.	Response times	Set acceptable response times for system issues, ensuring quick resolution to minimize downtime.	Yes	This somehow relates to the quarterly assistance facilities get	Yes	It will fit	We currently do not have this, it will need to be developed	How often does system downtime affect TB data reporting, and that is the expected response time to resolve such issues to minimize disruption? What are the acceptable response times for system issues to be resolved?	3 times a month. TB Reporting is done in real time and if the system is down it affect the reporting. But currently we rely on paper based system as the main system Within 24 hours

		Service level agreements	Define required uptime for the system to ensure constant access to health workers and prevent disruption of services.			Yes	It will fit	We currently do not have them, they must be developed	Are service level agreements in place to ensure consistent system availability?	No
		Business continuity plan	Create contingency plans for system failures, including backup servers and recovery procedures.			Yes	It will fit	We currently do not have them, they must be developed		
21. What funding is required for both start-up and routine operations	Plan for ongoing costs, including hardware, software, staffing, and services, while ensuring a long-term budget strategy that maintains the system's sustainability beyond the initial implementation phase.	capital costs	Estimate the initial investment required for system infrastructure, including hardware, software, and training	Yes	We have a plan for the current system so this relates to that.	Yes	It will fit	This need to be developed	Is there a sustainable funding plan in place for the TB recording system, and how often is funding reviewed to ensure continuity of operations?	Normally we rely on government funding which is not enough. We also have partners but they funding is not sustainable
		Hardware maintenance and replacement	Budget for regular hardware replacements to prevent system failures caused by outdated technology.			Yes	It will fit	This need to be developed		
		Software development, maintenance and licenses	Include ongoing costs for software updates, licenses, and feature enhancements			Yes	It will fit	This need to be developed	How sustainable is the system beyond the initial implementation phase?	If we have a system that does not completely rely on internet connectivity, it will be sustainable because there will be no recurring charges.
		Staffing and Project management	Ensure funding for staff salaries and project managers to maintain system functionality.			Yes	It will fit	This need to be developed		
22. How long will electronic data be retained and will they be archived?	Establish data retention policies that define retention periods, secure archiving processes, and retrieval mechanisms, ensuring secure access to archived data.	Retention policy	Define how long TB data will be retained in the system, ensuring compliance with national data storage	Yes	The current system retains data for 7 years before discarding so this relates to the step	Yes	It fits	This is defined in the guidelines. Data is retained for 7 years	What is the current data retention policy for TB patient records, and how often is this policy reviewed for compliance with national regulations?	TB data is retained for 7 years before archiving. This is included in the guidelines and reviewed every 5 years.
		Secure access	Establish processes for secure access to archived data, ensuring that only authorized personnel can retrieve sensitive			Yes	It fits	Currently data is stores securely and access is only to authorised medical personnel	How is secure access to archived data ensured?	Archived data is stored in the lockable cabinets that are in a secured stores room.
		Archiving Processes	Implement secure archiving systems for long-term storage, with easy retrieval mechanisms for historical data			Yes	It fits	Currently, archived files are stored in lockable cabinets	How long do you believe electronic data should be retained to support patient care and public health initiatives?	7 years as per guidelines, this is important because TB may recur and it is important to have patient historical data
23. How is the electronic recording and reporting software made available to users?	Determine how users will access the system based on connectivity and infrastructure needs, and plan the technical infrastructure, including servers, software, and hardware, to support this access.	User access methods	Determine how users will access the system based on internet availability, considering both online and offline functionality.	No	The current system is paper based so this does not exist.	Yes	It fits	This need to be defined	How do users access the TB system (e.g., online, offline), and what percentage of facilities face challenges due to unstable network connectivity?	For the electronic system, it is online. Currently network connectivity is in 50% of the facilities
		Connectivity infrastructure	Ensure that necessary network infrastructure (e.g., LAN, internet, mobile networks) is in place to facilitate reliable access to the system across various healthcare settings**.**			Yes	It fits	This must be defined	What technical infrastructure (computers, servers, networks) is in place at your facility for TB data collection and management?	Computers, tablets, servers, printers, phones

24. **Device Requirements**	Identify the devices users will need to access the system, ensuring compatibility, usability, and security for long-term use.	Device Requirements	Identify the types of devices (e.g., computers, tablets) that will be needed to access the system and ensure they are available across different healthcare facilities.			Yes	It fits	This must be defined	What devices (e.g., tablets, computers) are currently used for TB data management, and are there plans to upgrade or replace outdated devices within the next fiscal year?	Computers, phones, tablets, servers, tables
		Usability and security	Ensure that devices are user-friendly and secure, with appropriate measures to protect data and ensure that users can operate them with varying levels of digital literacy.			Yes	It fits	This must be defined	Are there any limitations with the hardware (e.g., aging computers, insufficient servers) that impact the efficiency of the TB system?	Aging computers, tablets and phones. Not enough gadgets for the facility.
25. **What database software is required**	Assess database functionality and compatibility with system requirements to determine the appropriate database software needed based on system needs.	Functionality	Choose database software (e.g., SQL, NoSQL) that meets system needs for scalability, security, and integration with other health data systems.	Yes	The current system does not have this	Yes	It fits	It must be defined	What database software (SQL, NoSQL, etc.) will meet the system's needs for scalability and security?	SQL
		Compatibility	The database should integrate with other systems and support interoperability with external health data sources.			Yes	It fits	It must be defined	How will the chosen database integrate with other health information systems (e.g., HIV databases, laboratory systems)? Does the database need to support real-time data updates, and how will it ensure data accuracy during transmission?	Ensuring that the chosen database is compatible with the existing databases Yes.
26. **Where will the servers be located?**	Assess server locations to ensure legal compliance and data accessibility, and decide on server placement based on legal requirements and data ownership considerations.	Data hosting legal requirements	Ensure that server locations comply with national data-hosting laws and provide easy access to data for authorized users.	Yes	The current system does not have this	Yes	It fits	This must be defined	Where should the servers be located to comply with national data-hosting laws and ensure accessibility for authorized users? How will the server location affect system uptime, data access, and security, especially in rural or remote areas?	Servers should be hosted within the country in line with the country laws. Main servers should be at the Ministry of Health datacenter. Facilities should have local servers for local accessibility If servers are located centrally, any network downtime will affect the system.
		Data Ownership	Establish clear ownership of the data stored on the servers, ensuring that access rights and responsibilities are defined for all stakeholders involved in data management.			Yes	It fits	According to the guidelines, data is owned by Malawi Government	Who is responsible for the ownership and management of data stored on TB system servers, and how often is this ownership reviewed to ensure compliance with legal standards?	NTP is responsible for servers and data ownership. This is reviewed with the guidelines.

27. **What communications networks are needed**	Plan for network infrastructure by considering LAN, internet, and mobile options, and identify suitable communication networks for effective data transmission.	Local area network, Internet and Mobile network	Implement reliable network infrastructure (LAN, mobile, internet) to ensure seamless data transmission from rural to urban healthcare facilities and support effective communication among healthcare providers.	Yes	The current system does not us communication networks. However some systems like the DHIS 2 and HIV system use this infrastructure therefore it related	Yes	It fits	This must be developed if it is not available	What communications networks are in place to support the TB system, and how often is network reliability evaluated, especially in rural areas? How efficiently is TB data transmitted from rural to urban healthcare facilities, and what percentage of data is successfully transmitted without delay each month?	Mobile networks, Government wide area networks and facility local area networks. During supervision this is reviewed TB data is effectively transmitted
		Network Reliability	Ensure that the network infrastructure is reliable and has contingency plans in place for potential outages, particularly in rural areas where connectivity may be less stable.			Yes	It fits	This must be developed	How often (e.g., monthly) does network downtime affect TB data reporting, and what percentage of facilities experience challenges with stable internet connectivity?	None
28. **What are the electrical power Needs?**	Plan for power availability and backup systems to ensure continuous operation, ensuring reliable power sources for both urban and rural areas, including backup options.	Power availability	Ensure that health facilities have reliable power sources for system operations, including alternative backup options in case of outages.	Yes	This relates to the current systems implemented at the facilities.	Yes	It fits	This must be developed	What backup power options are available at your facility to ensure continuous system operation?	Solar and Generator.
		Backup power	Install uninterruptible power supplies (UPS) and generators in health facilities to ensure that systems remain operational during power outages, safeguarding data integrity and availability			Yes	It fits	This is must be assured	Does your facility have reliable uninterruptible power supplies (UPS) or backup generators, and how often have these systems been activated to maintain functionality during power outages?	Yes. We also have solar backup