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BASED ON **CURRENT BEST PRACTICES**

MINISTRY OF HEALTH MALAYSIA

GUIDELINES ON PATIENT REGISTRY ESTABLISHMENT AND IMPLEMENTATION IN MINISTRY OF HEALTH MALAYSIA

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The successful completion of this guideline was made possible by the collective efforts and support of numerous individuals, agencies, and organizations committed to improving healthcare through patient registry systems. Their unwavering commitment to enhancing healthcare delivery is recognized and appreciated.

Our sincere gratitude goes to healthcare professionals and experts within the Ministry of Health (MOH) for generously sharing their knowledge, experiences, and insights. Their invaluable input throughout the development of this guideline has ensured its relevance, accuracy, and practicality, making it a valuable resource for healthcare practitioners.

Additionally, the guideline working group acknowledges the collaboration and support extended by all relevant external stakeholders, such as clinical specialty societies, academic institutions, or industry partners. Their partnership has enriched the content of this guideline book and facilitated its dissemination for the benefit of the wider healthcare community.

May this guideline serve as a valuable resource and catalyst for advancing healthcare quality and outcomes in Malaysia for years to come.

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DIRECTOR GENERAL OF HEALTH

FOREWORD

Patient registries in Malaysia can trace their roots to early paper-based record-keeping efforts, which gradually evolved into more advanced online platforms that not only collect data, but also distill actionable insights to stakeholders. The establishment of numerous patient registries covering a wide variety of diseases over the last few decades underscores the importance of patient registries to clinical practitioners and policymakers alike. The amalgamation of various technical expertise from a wide variety of clinical as well as non-clinical disciplines has created a collaborative environment that is reflected in the variety of ways that clinical registries in Malaysia are funded, established and operationalised.

As we brace ourselves to fully realise the potential of advancements in health information technology, there are also fundamental questions on ethics, sustainability and governance that must be addressed to ensure the success of our clinical registries. This guideline offers a comprehensive framework to empower current and future registry managers to navigate through the complexities of establishing and operating patient registries with clarity and confidence. Key principles, such as governance and technical processes involved are defined throughout the stages of planning, development, implementation as well as monitoring and evaluation of patient registries. We hope that by explaining the processes in the guideline, registry operations will be better managed, resulting in a better data collection system that will contribute to excellence in patient care.

As we embark on this journey, I sincerely hope that this guideline will be an impetus for stakeholders to fully optimise the way in which patient registries in Malaysia not only positively impact individual patient care but also enhance the resilience and collective wisdom of our healthcare ecosystem. Last but not least, I would like to extend my heartfelt gratitude to the contributors who were involved in the publication of this guideline and I wish all registry stakeholders success in their future endeavours.

Datuk Dr Muhammad Radzi Bin Abu Hassan
Director General of Health
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The increasing adoption of Information & Communications Technology (ICT) in clinical quality initiatives in Malaysia is both evidence to the increasing value of ICT in healthcare as well as the increasing capacity amongst those working in the Malaysian healthcare sector to fully leverage emerging technologies to improve patient care. Patient registry initiatives, which often began as small-scale research projects have now evolved into highly valuable data infrastructure that support many business functions within the Ministry of Health. This stride towards progress however, is not without its own set of challenges.

It is with this realisation that the Ministry of Health through its Research and Technical Support Programme has embarked on an effort to better streamline and coordinate the implementation of patient registries within the Ministry of Health. We hope that all current and prospective registry stakeholders – from clinicians, programme managers and researchers will find valuable information within the guideline to improve the implementation of their registries. With this newly established guideline, it is hoped that better-governed patient registries will not only improve care, but also inspire confidence among clinical groups and the public at large in how our data assets can be used to foster innovation and promote evidence-based care.

Finally, I would like to extend my acknowledgement to the core working group for their commitment and tireless effort in producing this guideline, as well as the multi-disciplinary group of external reviewers for their contribution in ensuring that the guideline will be relevant to all stakeholders.

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GLOSSARY

- **Data:** Data consists of raw facts, figures, or information that can be collected, processed, and analysed. In the context of patient registries, it often includes information about patients' health, medical history, and related details.

- **Governance:** Governance refers to the overall management, control, and decision-making processes that guide an organisation or system. In the context of patient registries, governance involves the establishment of rules, policies, and procedures for managing the system and using the collected data.

- **Patient:** In the context of healthcare, a patient refers to an individual who is receiving medical attention, care, or treatment.

- **Registry:** A registry is a systematic collection of data or database that stores and manages data related to patients with the focus of improving patient outcomes.

- **Scope:** Scope defines the extent or range of a particular activity, project, or initiative. In the context of patient registries, scope refers to the boundaries and objectives that outline what the registry aims to achieve and the parameters it covers.

EXECUTIVE SUMMARY

In the evolving landscape of healthcare, patient registries stand as indispensable tools for understanding disease patterns, treatment outcomes, and healthcare utilization. Information generated from patient registries are crucial to improve patient outcome and quality of care, as well as to inform and guide the formulation and implementation of health-related policies at organisation and national level.

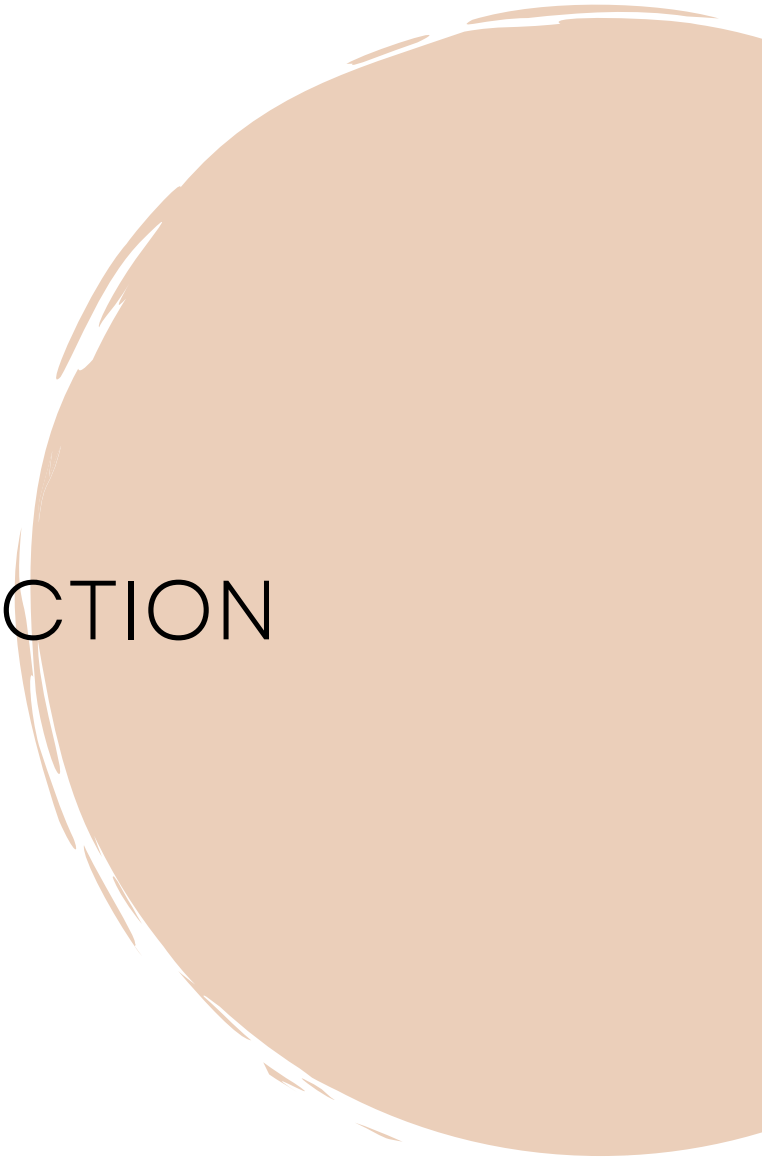
Strategic and operating principles serve as the cornerstone for the success of patient registries, emphasizing the need for strong governance and leadership, clear goals and direction, efficient use and allocation of resources, and responsible management of data and information systems. By aligning registry goals with strategic initiatives and fostering collaboration among stakeholders, organisations can ensure the registry's relevance and sustainability over the long term.

Patient registries go through different stages of life cycle - from its initial phase of establishment to its subsequent phase of sustainability. The stages of registry establishment encompass planning, development, implementation and monitoring and evaluation. Each stage is critical in its own right, requiring careful attention to detail, with stakeholder involvement and adherence to best practices. Given the dynamic nature of health, the design of patient registry systems need to be flexible to adapt and allow for iterative improvement and expansions.

Central to the effectiveness of a patient registry is the systematic management of data according to the data life cycle, which encompasses data collection, validation, management, storage and security, and analysis and reporting. Establishing uniform data standards and collection protocols ensures that relevant data points are captured accurately and comprehensively, laying a solid foundation for subsequent analyses and integration of data for meaningful health insights. Data governance policies and procedures guide registry operations, addressing issues such as data access, use, and sharing while ensuring compliance with regulatory requirements and ethical standards.

System governance in the context of patient registries encompasses a multifaceted approach aimed at ensuring the smooth operation, regulatory compliance, and long-term viability of the registry infrastructure. Managing registry infrastructure involves overseeing the technical components, such as software platforms, databases, and communication systems, to ensure their reliability, scalability, and interoperability with other healthcare systems.

Guidelines in general provide a prescriptive framework, offering systematic and structured directives to help achieve an intended goal. This guideline endeavours to support the establishment and implementation of patient registries within the Ministry of Health Malaysia, drawing from best practices and embracing a journey-oriented approach.



Chapter 1

INRODUCTION

1.1 What is Patient Registry

EU- PARENT (cross-border **PA**tient **RE**gistries i**N**i**T**iatives)
defines **PATIENT REGISTRY** [1] as:

".. an organised system designed to collect, analyse, and disseminate the data and information about a specific group of people defined by a particular disease, condition, exposure, or health-related service, and serves a predetermined scientific, clinical or/and public health (policy) purposes".

In a broad sense, we can understand the concept of "registry" by breaking it down into its basic building blocks:

- **Place:** A registry refers to a designated site where official records are stored.
- **Process:** It encompasses the activities involved in data collection, management and processing.
- **Time:** The processes of a registry occurs periodically over a period of time.
- **Person:** A registry involves the collection of information about individuals.

Within the context of "patient registry", the similar concept applies but specifically to patient data. The primary goal of establishing a patient registry is to enhance patient care and outcomes. Additionally, the data gathered can serve to enhance accuracy of information to support policy, research and for knowledge translation.

1.2 Patient Registry: The Malaysian Journey

Patient registries in Malaysia began as initiatives by clinicians for research purposes, and the first registry was established within the Ministry of Health (MOH) in 1992. Since then, a number of patient registries have been set up with funding sourced from research grants and clinical specialty societies, coordinated by the Clinical Research Centre (CRC).

In 2012, a situational analysis was conducted by the Malaysian Administrative Modernization and Management Planning Unit (MAMPU)* in collaboration with the CRC and Multimedia Development Corporation (MDEC) to assess the implementation of patient registries in Malaysia.

1 Methodological guidelines and recommendations for efficient and rational governance of patient registries [Electronic source] / editors Metka Zaletel, Marcel Kralj. - El. book. - Ljubljana : National Institute of Public Health, 2015.

**currently known as Jabatan Digital Negara (JDN)*

Following the situational analysis[2], attempts were made to consolidate the management of these registry systems. Some were integrated into the Patient Registry Information System (PRIS) and included in the Malaysian Health Data Warehouse (MyHDW) infrastructure, while the remaining registries were managed by Health Informatics Centre (HIC) through subscription of third party software. These initiatives helped the Ministry of Health (MOH) address some of the issues identified in the analysis. However, fundamental challenges persist in the areas of governance, technical aspects, and on-the-ground implementation.

Currently, several patient registries are hosted within the MyHDW infrastructure, including the PRIS and *Aplikasi Registri Pesakit* (ARP). Other registries operate independently, overseen by specific divisions or units within the MOH or managed by clinical specialty societies.

In response to the complexities in managing and governing diverse registries, an engagement meeting (*Mesyuarat Pembangunan Rangka Kerja Pengurusan Registri Klinikal Bil 1/2023*) was held on 27th September 2023. It was chaired by the Deputy Director General of Health (Research and Technical Support) and involved representatives from various registry groups. During the meeting, it was agreed that a guideline should be introduced to improve the control, implementation, and sustainability of patient registries within the MOH.

1.3 Overview of Guideline

This guideline is developed by incorporating elements from two established frameworks as the foundation for best practices in patient registry governance; namely:

- **EU-PARENT - Joint Action cross-border Patient Registries INiTiatives**[1]
- **Framework for Australian Quality Registries**[3]

To ensure its relevance, the guideline is tailored to the local Malaysian context by consulting with key stakeholders, taking into account the current workflows, procedures, and existing laws and policies both within and outside the MOH Malaysia.

1 Methodological guidelines and recommendations for efficient and rational governance of patient registries [Electronic source] / editors Metka Zaletel, Marcel Kralj. - El. book. - Ljubljana : National Institute of Public Health, 2015.
2. Clinical Research Centre, Patient Registries in Malaysia: A Situational Analysis.
3. Australian Commission on Safety and Quality in Health Care, Framework for Australian clinical quality registries - a national standard for clinical safety and quality data collections and reporting Second Edition. Sydney. ACSQHC, December 2022.

1.4 Applicability of Guideline

This document is relevant to various stakeholders involved in patient registries:

- **Interest groups planning to establish, develop and subscribe to a patient registry system**: They include those aiming to create and advance a registry for research, or other purposes. The registry could be a newly developed system, an existing data collection system, or an international registry platform that the interest group seeks to join.
- **Entities responsible for running and maintaining registries**: This encompasses personnel tasked with the operation, maintenance, and governance of patient registries.
- **Stakeholders of the registry**: These are individuals or groups with a vested interest in the registry, including healthcare providers, researchers, policymakers, and patient advocacy groups.

Chapter 2

PRINCIPLES AND ATTRIBUTES OF PATIENT REGISTRY

2.1 Strategic and Operating Principles

Strategic principles act as guiding values that influence every aspect of patient registry operations. The following principles have been adapted from the Australian Framework for Clinical Quality Registries[3].

1. **Strong governance structure with unified quality improvement framework**

   Patient registries should be built upon sound governance arrangements with strong clinical leadership and established with a demonstrated framework for quality improvement in health and the healthcare system.

2. **Maximise value to public expenditure and healthcare system**

   Patient registries that receive public funds to operate should strive to meet their objectives through optimal use of resources and provide valuable insights for the improvement of healthcare delivery.

3. **Effective collection and management of data and information**

   Patient registries should aim to strike a balance between comprehensively capturing information and only collecting what is necessary and needed. Data should be captured in a timely manner to ensure that the information is relevant and up-to-date, to support accurate assessments and interventions.

4. **Responsible custodianship of patient data**

   Responsible custodianship of patient data entails ensuring the ethical, secure, and confidential handling of this information throughout its lifecycle. Patient data should be treated with utmost respect and safeguarded from corruption, unauthorised access and unintended use.

5. **Bridging healthcare gaps through accountable data sharing and accessibility**

   Patient registry data should be made accessible to authorised individuals and cater to the needs of stakeholders in healthcare. Accessibility promotes collaboration, research, and informed decision-making across healthcare stakeholders.

6. **Robust governance of data and system**

   Patient registry utilises systems to collect patient data. National data governance arrangements and best practice infrastructure are crucial to foster a culture of accountability and transparency and to provide support for comprehensive data usage, information generation, and reporting, monitoring and management of clinical practice variance.

7. **Minimizing process redundancy through interoperability**

   Interoperability refers to the ability of systems to seamlessly exchange and make use of information. This is so as to ensure that data remains consistent across different systems, with minimal duplication of work and data collection burden.

3. *Australian Commission on Safety and Quality in Health Care, Framework for Australian clinical quality registries - a national standard for clinical safety and quality data collections and reporting Second Edition. Sydney. ACSQHC, December 2022.*

2.2 Attributes of Patient Registry

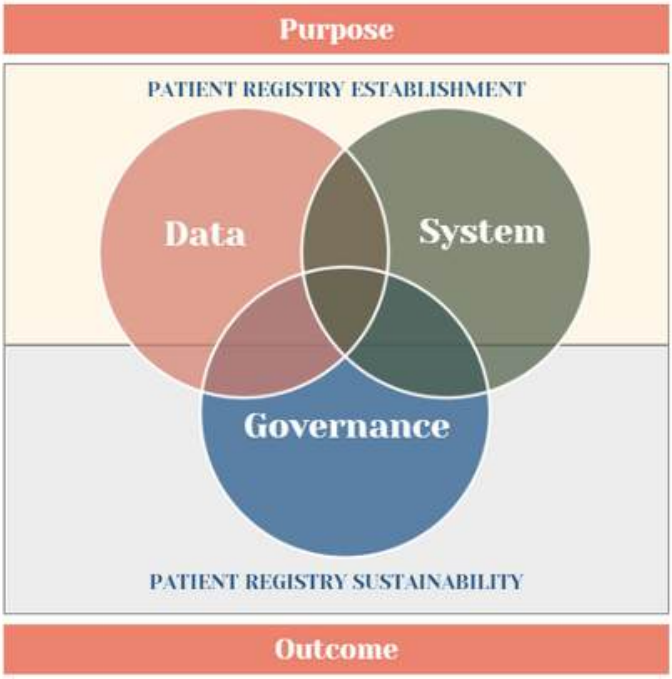


Figure 1: Attributes of Patient Registry

The three **essential components for effective operations of a patient registry** - from its establishment to its implementation, management and sustainability - are **data, system** and **governance.**

Data forms the foundation of any patient registry. The accuracy and reliability of a patient registry are directly linked to the quality of the data collected. The data should be comprehensive, standardized, and securely stored to maintain its trustworthiness. Additionally, data validation and error checks are vital to ensure its accuracy.

The technological infrastructure supporting the patient registry - the **system** - is another critical component. This includes the software and hardware necessary for data collection, storage, analysis, and reporting. The system should be user-friendly, scalable, and capable of integrating with existing healthcare information systems to streamline data entry and retrieval processes. Regular updates and maintenance are necessary to keep the system running smoothly and to adapt to evolving technological requirements and standards.

Patient registry **governance** encompasses the intricate organizational structures and processes that steer and ensure the registry's ethical operation, transparency, and compliance with pertinent regulations and best practices. Crucial to compliance are components such as securing institutional support and approval for both the development and ongoing operations of the registry. Governance also revolves around actively encouraging stakeholder participation, rigorously ensuring data accuracy, prioritizing stringent security measures, and upholding robust data protection standards. Collectively, these elements constitute the bedrock for effective and responsible patient registry management, fostering trust, accountability, and the reliable utilization of healthcare data.

Specific Governance Aspects

- **Framework for Objectives Achievement:** Governance structures provide a framework for setting and achieving registry objectives. This involves securing necessary resources, defining performance metrics, and ensuring the registry's long-term sustainability.
- **Procedures and Methods:** Governance establishes clear procedures and methods for registry establishment and operation, including defining the registry's purpose, scope, data collection methods, target population, study plan, and protocol.
- **Influence on Data Quality:** Governance ensures that data collection methods are standardized, data integrity is maintained, and information is accurately reported and shared with relevant stakeholders.
- **Legal Compliance:** Governance ensures that the registry complies with all legal prerequisites, including data privacy laws, consent requirements, and regulations governing the use of healthcare data.
- **Interoperability:** Governance promotes interoperability, allowing for seamless exchange of data and information among stakeholders. This involves gradually integrating the registry with existing systems and processes to improve functionality and collaboration.

- **Education and Training:** Governance mandates adequate education and training for registry staff in protocols, data collection methods, analysis techniques, and privacy legislation. Continuous training and updates are necessary to ensure staff competency and compliance with best practices.
- **Resource Planning and Financial Sustainability:** Governance oversees resource planning and management, including human, physical, and financial resources.
- **Self-Assessment:** Governance implements quality assurance activities to identify and address data quality issues. This includes regular self-assessment processes, quality control measures, evaluation mechanisms, and continual improvement initiatives to enhance the registry's performance and reliability.

The key stakeholders engaged in the processes related to patient registry system include the initiators, often referred to as the Primary Investigator (PI), Subject Matter Experts (SMEs), Information Technology (IT) officers, Statisticians, and representatives from funding agencies. These stakeholders must have a clear understanding of the registry's purpose and work collaboratively to establish a framework that would enable them to achieve the registry's intended objectives. There should also be mechanisms in place to ensure the registry's sustainability in the long run.

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Chapter 3

STAGES OF PATIENT REGISTRY

A patient registry progresses through various phases and stages throughout its lifecycle. These encompass **two primary phases: Establishment** and **Sustainability.**

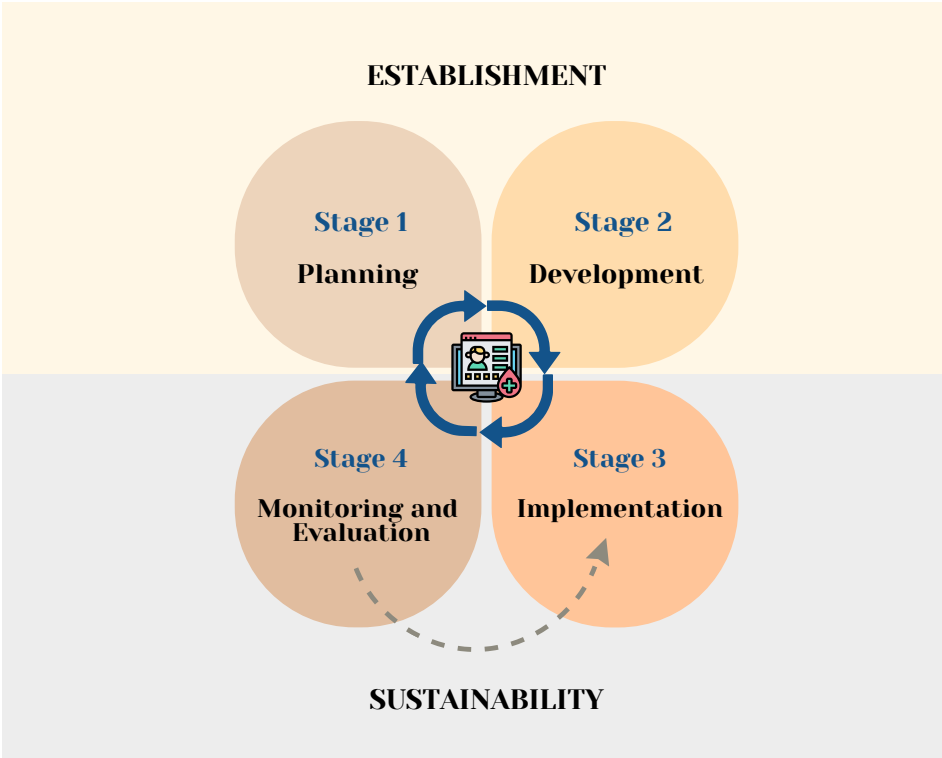

Figure 2: Key Phases and Stages within the Patient Registry Life Cycle

The **Establishment Phase** converts an idea and concept into its actual inception and is divided into two key stages:

(a) Stage 1: Planning

During the planning stage, several key considerations need to be carefully evaluated. The planning and preparation process should take into account of the followings:

- **Assessment of needs:** A thorough assessment of needs should be conducted, including evaluation of existing systems and objectives of data collection must be clearly defined.

- **Feasibility study:** A feasibility study is undertaken to gauge the practicality and viability of implementing the registry. Factors such as resource availability, potential challenges, and logistical considerations should be carefully evaluated to ensure successful execution.
- **Data life cycle:** The key stages of the data life cycle, from collection to analysis and dissemination should be outlined and main activities in each stage are defined.
- **Regulatory compliance:** Protocols for regulatory compliance are established to ensure adherence to relevant acts and regulations. This includes defining procedures for obtaining informed consent from participants and implementing measures to safeguard patient privacy and confidentiality.
- **Stakeholder engagement:** Key stakeholders are actively engaged to gather input, address concerns, and foster collaboration. This inclusive approach ensures that diverse perspectives are considered and that the registry's design and implementation reflect the needs and priorities of all stakeholders involved.

(b) Stage 2: Development

This stage translates the conceptualisation of the registry system into system development, ensuring alignment with the current context and functionality requirements. This stage involves several critical steps:

- **Defining system requirements:** Clear definition of the system's technical specifications and functional requirements is needed. This involves considering interoperability with existing systems and scalability for future expansion. Key considerations include system features, user-friendliness, security measures such as encryption, and access control mechanisms.
- **Vendor evaluation:** Thorough evaluation of potential vendors is essential to ensure the selection of the most suitable partner for system development and ongoing support. This process involves assessing factors such as expertise, experience, reliability, and compatibility with organizational needs and standards.

Once a patient registry is established, the attention shifts towards maintaining its operations and ensuring its long-term viability. The **Sustainability Phase** focuses on maintaining the registry over time, emphasising continuous training for individuals and teams, and refining processes for ongoing data collection, analysis, and dissemination of information. Furthermore, fostering collaboration and securing consistent funding is integral to maintaining the patient registry. This phase can be further categorised into two pivotal stages:

(a) Stage 3: Implementation

The Implementation stage focuses on ensuring the smooth operation of the registry in its day-to-day functions, encompassing the necessary resources and processes to maintain the data life cycle, from input (data) to output (information). Key considerations for successful implementation include:

- **Establishing a core team:** Forming a dedicated team responsible for overseeing the registry's operations and ensuring adherence to established protocols and procedures.
- **Governance:** Implementing governance structures and processes to oversee the registry's operations.
- **Data migration:** Assessing the need for migrating data from existing systems to the new registry platform.
- **Personnel training:** Providing comprehensive training to registry personnel to ensure they are proficient in using the system effectively and adhering to data collection and management protocols.
- **Standard Operating Protocols and Documentation:** Developing user manuals and establishing data sharing protocols.

(b) Stage 4: Monitoring and Evaluation

Monitoring and evaluation is essential to ensure the registry fulfils its intended purpose and operates according to established quality assurance processes. The following components are crucial considerations:

- **Audits:** Establish regular audits to assess registry processes and data quality, including completeness, timeliness, and accuracy.
- **Performance metric monitoring:** Monitor system performance to identify any issues or inefficiencies. This includes assessing system uptime, response times, and overall reliability.
- **Regular evaluation and feedback:** Create a feedback mechanism to enable users to report issues, provide suggestions for improvement, or raise concerns.
- **Mechanism to improve and sustain:** Implement a structured process for continuous improvement based on feedback, audit findings, and performance monitoring.

The subsequent sections in this chapter will provide a step-by-step guide for individuals seeking to establish a patient registry. This guide will be organized by phases and key stages in sequential order. Each stage will include important considerations based on best practices to ensure that guiding principles are consistently applied throughout each significant milestone of the patient registry establishment and implementation.

Establishment of Patient Registry

3.1 Stage 1: Planning

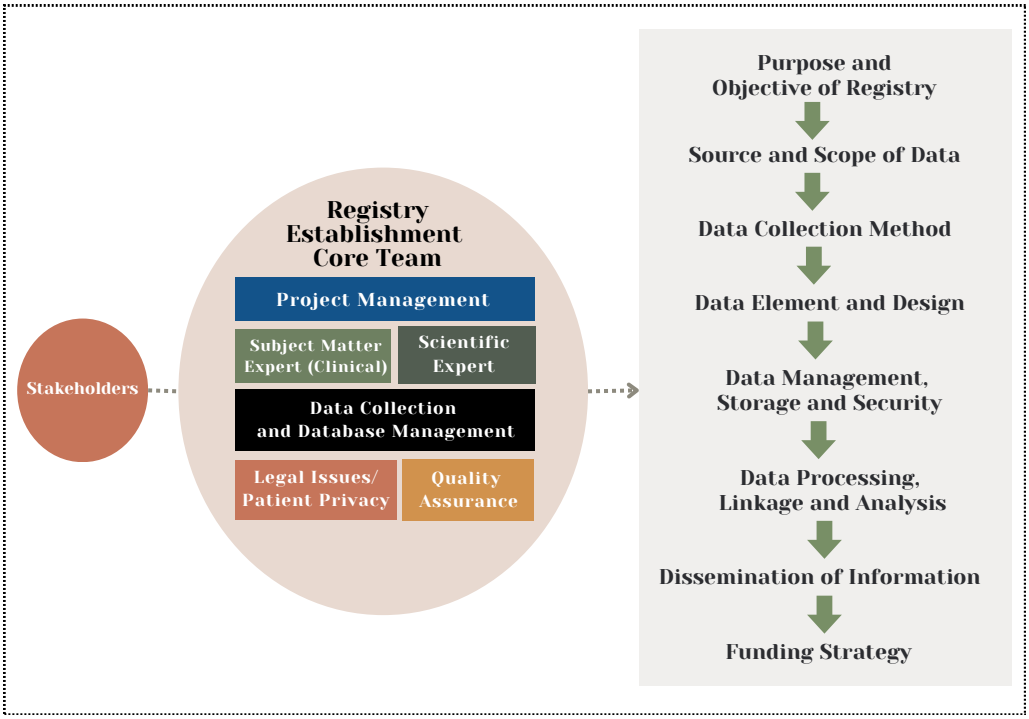

Figure 3:Planning a patient registry through the lens of data lifecycle

(a) Setting up a Core Team for Registry Establishment

- Establishing a core team is the primary step in setting up a registry. This team is responsible for tasks ranging from planning to developing, deploying, and sustaining the registry system. Their initial responsibilities include developing a comprehensive proposal plan to establish the registry system.
- In the context of the Ministry of Health, an endorsement by the Head of Program/Specialty/Service is required to establish the core team
- A core team typically consists of individuals with diverse expertise, including project management, data analysis, software development, and domain-specific knowledge related to the registry's focus area. The following are some of the domain expertise needed and their respective functions:

i. **Project Management**
   - Oversees the entire registry project.
   - Coordinates between different domain experts.
   - Ensures the project stays on schedule and within budget.

ii. **Subject Matter Expert (Clinical)**
   - Provides in-depth knowledge and expertise in the clinical aspects of the registry.
   - Decides on the content and module of the registry and involved in the preparation of the business requirement.

iii. **Scientific Expert**
   - Provides in-depth knowledge and expertise in the informatics and analytical aspects of the registry.
   - Ensures scientific relevance and accuracy of the data points being captured and analyzed.

iv. **Data collection and database management**
   - Handles the technical aspects of data collection, storage, and retrieval.
   - Designs data collection procedures.
   - Plans a secure and scalable database architecture.
   - Establishes plans to ensure data quality and integrity.

v. **Legal issues/patient privacy**
   - Addresses legal and ethical considerations regarding patients' rights, privacy, and confidentiality.
   - Ensures compliance with relevant laws and regulations.

vi. **Quality assurance**
   - Ensures the accuracy, reliability, and overall quality of the registry data and processes.
   - Develops a quality assurance framework involving plans for audit and quality control measures, including data quality and error.

Stakeholder Engagement

- It is vital to engage pertinent stakeholders early in the planning stage and throughout the proposal development phase to incorporate diverse perspectives, interests, and needs effectively.

(b) Defining the Purpose and Objective of the Registry

- Establishing a registry necessitates a clearly defined purpose. A helpful starting point is to ask: "Why does the registry need to exist?"
- Some common purposes for establishing a registry include:
  i. Describing the natural history of a disease.
  ii. Determining the clinical or cost effectiveness of a procedure or treatment.
  iii. Assessing safety or harm associated with a particular intervention.
  iv. Measuring the quality of care provided.
  v. Facilitating public health surveillance and disease control efforts.
- Once the purpose is identified, it is important to further delineate it into specific goals or objectives the registry aims to achieve.

Example:

Purpose of Registry

- To determine the distribution of diabetes cases in Malaysia

Specific Objective

- To describe the demography of the population with diabetes in Malaysia
- To determine the incidence and prevalence of diabetes in Malaysia

(c) Determining the Data Scope and Sources

- The scope of data collection is intricately tied to the purpose and objectives of the patient registry. It involves identifying key disease-specific features that are crucial for achieving the registry's goals. Additionally, considering demographic information, treatment history, and outcomes may also be relevant.
- The scope of data collection is also influenced by the inclusion and exclusion criteria. These criteria define the characteristics and eligibility requirements for individuals to be included in or excluded from the registry. For example, inclusion criteria may specify certain age groups, disease diagnoses, or treatment statuses, while exclusion criteria may exclude individuals with certain comorbidities or specific medical conditions.

- Data can originate from various sources, broadly categorised into:
    i. **Primary Data Source:** Primary data sources involve collecting data directly from individual participants. This may include data from patient interviews, medical examinations and surveys. The advantage of primary data collection is the ability to gather detailed and specific information directly from patients.
    ii. **Secondary Data Source:** Secondary data sources refer to health data derived from existing data collection systems, such as electronic health records, administrative databases, or registries. Utilizing secondary data sources can supplement primary data collection efforts, providing additional insights and facilitating longitudinal analysis.
- When utilizing secondary data sources, it's essential to strike a careful balance between the interest in research and healthcare improvement, and the rights and privacy concerns of individuals. As a fundamental principle, consent must be obtained for collecting, using, or disclosing information for secondary use.

(d) Determining the Data Collection Method

- The function of a registry is highly reliant on its ability to capture the relevant data.
- Data capture should encompass the population in a representative manner. The choice between a universal or sample-based data sampling method depends on several factors, including the registry's objectives, resources, and feasibility:

    i. **Universal Sampling Method:**
        - In a universal sampling method, data is collected from all eligible individuals or cases within the defined population.
        - This approach ensures that the registry includes a comprehensive dataset representing the entire population of interest, providing a complete picture of the condition or disease under study.

- Universal sampling is particularly useful when the population size is manageable, and resources are sufficient to collect data from every eligible participant.
- However, universal sampling may be impractical or resource-intensive for large populations, leading to challenges in data collection and management.

ii. **Sample-based Sampling Method:**

- In a sample-based sampling method, data is collected from a subset or sample of the eligible population.
- This approach involves selecting a representative sample that reflects the characteristics of the broader population, allowing researchers to draw conclusions about the population as a whole based on the sample.
- Sample-based sampling conserves resources and reduces the burden of data collection, making it feasible for larger populations or when resources are limited.
- However, sample-based sampling introduces the potential for sampling bias if the selected sample is not truly representative of the population.

- Ultimately, the choice between a universal or sample-based sampling method should be guided by the specific goals, resources, and constraints of the registry. In some cases, a combination of both approaches may be appropriate, such as collecting universal data for certain core variables while using a sample-based approach for additional variables or sub populations of interest.
- Data capture methods should be designed to prevent or minimize errors during data transcription. Errors, such as incorrect recording of a patient's ID, can prevent accurate data linkage with other databases or lead to incorrect information being linked.
- Data collection should be integrated seamlessly into the clinical workflow and minimizes disruptions.

- Additional funding may be necessary to hire contracted staff for data entry, however, prioritizing collaboration in data collection and leveraging system integration is key. System integration can minimize duplication of effort and reduce the burden on the system's front-end users.
- **Modes of data collection** include:
  i. **Paper-Based** vs. **Electronic**
    - **Paper-based methods:** In this approach, data is initially collected using paper-based forms and then transferred to an electronic database. While paper-based methods may be perceived as cost-effective, they introduce an additional step in the data collection process, increasing the burden of data entry and potentially introducing errors during transcription. Moreover, managing paper forms can be cumbersome and time-consuming, leading to delays in data processing and analysis.
    - **Electronic methods:** In contrast, electronic data collection involves entering data directly into an electronic database, bypassing the need for paper forms altogether. This approach offers several advantages, including improved data accuracy, enhanced confidentiality through encryption and access controls, greater reliability, and better integration with existing clinical data sources such as electronic health records (EHRs). Additionally, electronic methods facilitate real-time data entry, enabling timely analysis and reporting of registry findings.

  ii. **Active** vs. **Passive**
    - **Active data collection:** Active data collection involves registry personnel actively gathering data from participants or healthcare providers. This may include conducting interviews, administering surveys, or extracting information from medical records. While active methods allow for direct interaction with participants and ensure data completeness, they can be resource-intensive and require trained personnel to collect and record data accurately.

- **Passive data collection:** Passive data collection, also known as notification-based methods, relies on existing systems or data sources to capture relevant information. For example, registries may receive notification data of new cases or events from healthcare facilities or disease surveillance systems. Passive methods are often more efficient and less labor-intensive than active methods, as they leverage existing infrastructure for data collection. However, passive methods may be limited by the availability and completeness of data from the external sources.
- Modern registries often employ a combination of both active and passive methods to capitalize on their respective strengths while mitigating their limitations.

(e) Designing the Data Element for Registry

- Data forms the fundamental building block of a registry; the design of the registry needs to consider the following principles:

i. **Minimalist approach**
   - Aim for minimal complexity in the dataset to reduce the burden and costs of data collection. Only collect what is needed and ensure that the system flow is simple.
   - Determine the essential variables for data collection, categorising them as mandatory, conditional, or optional.
   - Considerations need to be given on the impact of changes when modifying the data elements.

ii. **Maximise data quality**
   - Data elements need to be accurate, complete, relevant, coherent and timeless.
   - Collect data elements that can be well-defined and allow appropriate data validation.

iii. **Prioritise data confidentiality**
   - Ensure compliance with privacy principles and assess the impact of including private or confidential data.

iv. **Standard Definitions, Terminology, and Specifications:**

- Use standard definitions and terminology for data elements; to adopt standards recommended by MOH, or where no relevant MOH-recommended standard is applicable, adopt international standards published by an authoritative governing body to ensure data comparability at international level.
- Provide specifications for each data element as part of a data dictionary.
- Refer to established resources such as the Malaysia Health Data Dictionary (MyHDD)[4] published by the MOH.

(f) Data Management, Storage and Security

- Ensure proper data management through:

i. **Strategic storage decisions**

- Determine the appropriate storage location for collected data, considering factors like local storage, on-premise servers/networks, or cloud-based solutions. (refer **Appendix B** for in-house vs. subscription based model comparison)

ii. **Well-designed data architecture:**

- Develop a robust data architecture that encompasses the collection, storage, processing, and management of data.
- Components of data architecture include data models, data flow diagrams, data standards, and relationships between data elements.
- This should also follow established standards such as the Malaysian Health Reference Data Model (MyHRDM) for data architecture design.
- This must also include alignment of the planned registry with MOH's Enterprise Architecture, to ensure that the registry adopts MOH's business objectives.

iii. **Robust backup procedures:**

- Establish backup procedures to enable data recovery and business continuity plans.

4. *Malaysian Health Reference Data Model (MyHRDM), Kementerian Kesihatan Malaysia Tahun 2017*

- Regular backups are essential for maintaining data integrity and availability in the event of system failures or disasters.

iv. **Role-based data access:**
   - Implement role-based access control to restrict data access based on user roles and privileges.
   - Ensure access levels align with users' responsibilities and data sensitivity.

- The database should be designed based on best practices in information modelling, with the resulting database design optimised for querying and analysis.

Data Security Measures

- Implement robust physical and technical safeguards in data collection, storage, transmission, and access.
- Security measures should include data encryption, access restrictions, data backups, and de-identification methods.
- Security protocols should be continuously reviewed and revised.
- Implementation of security measures should include both data and systems perspectives and consider **sensitive data management.**
- If identifiers are required for data linkage or follow-up, obtain appropriate consent from patients.
- Implement data anonymization techniques to protect patient privacy.
  i. Options include **one-way dissociation** (anonymization), which makes it virtually impossible to trace back to the patient's identity.
  ii. **Two-way dissociation** (reversible dissociation) allows tracing back to the patient's identity using specific keys and procedures.
- For **System Access Controls**, consider implementing the following measures:
  i. **User Authentication:**
     - Utilise secure authentication methods to verify the identities of users accessing the system.
     - Implement two-factor authentication, requiring users to provide two forms of verification before gaining access.

ii. **Role-Based Access Control (RBAC):**

- Define specific roles and responsibilities within the system and assign appropriate access levels based on users' job functions.

iii. **Audit Trails:**

- Maintain detailed audit trails to record and monitor user activities within the system.
- Audit trails enable the tracking of user interactions, providing visibility into who accessed the system, what actions were taken, and when they occurred.

Data access should be clearly defined with a user matrix and comply with the User Access Control Policy[5] and Guidelines by the MOH Malaysia.

(g) Data Processing, Linkage and Analysis

- Data processing, linkage, and analysis facilitates accurate interpretation and utilisation of collected data.
- Purposes of Data Linkage:
  i. **Merging records from different providers:**
     - Identify and merge records from various databases corresponding to the same individual to avoid duplicate counting.
  ii. **Enhancing information in a dataset:**
     - Adds fields from a second dataset to the records in the primary dataset.
     - Inaccurate linkage methods can result in a database riddled with missing data from unlinked records, impacting the reliability and complexity of subsequent analyses.
- Prior to data linkage, datasets should undergo data cleaning to resolve issues related to different data formatting.

5. *Garis Panduan User Access Control Policy (UACP), Kementerian Kesihatan Malaysia Tahun 2011*

Statistical Analysis Plan

- When planning a clinical registry, it's essential to have robust statistical analysis plans to manage descriptive and inferential objectives, address potential biases effectively, and handle missing data appropriately.
- The choice of statistical methods and tools should be aligned with the specific nature of the data and the research questions posed by the registry's stakeholders.

(h) Dissemination of Information

- The following are the **general principles for effective dissemination** of information:

i. **Comprehensibility:**
   - Ensure that the information is presented in a manner that is universally or internationally comparable and easily understood by the target audience.

ii. **Relevance:**
   - Choose infographic tools—such as tables, graphs, or maps—that best support and enhance the analysis. Avoid using tools that do not add value to the interpretation of the data.

iii. **Feedback from health professionals**
   - For long-term population-based registries, it is essential to regularly share descriptive analyses with health professionals to foster ongoing cooperation.

iv. **Monitoring and progress reports:**
   - For clinical registries, periodic safety data and intermediate analysis reports can provide insights into disease progression and project progress.

v. **Efficient use of data:**
   - Adhere to the principle of collecting data once and using it multiple times, ensuring timeliness and relevance.

vi. **Data visualisation:**
   - The right tools should be used in accordance to the objectives, the right type of plots is used to represent the data.

vii. **Data interpretation:**

- Declare bias; data interpretation should be done within the acknowledged limitations.

(i) Funding Strategy

- The source of funding can significantly influence how the registry's outputs are perceived. Thus, securing funding involves continuous assessment of funding needs, emphasizing sustainability and should span the entire lifecycle of the patient registry system, addressing legal aspects and conflict of interest.
- When planning to develop a patient registry system, it's essential to deliberate on the initial development costs and the ongoing expenses tied to hosting and maintenance.
- The funding models that could be explored is summarized in the next table (refer **Table 1**).

Table 1:Funding Models for Patient Registry System and its Implications

Source of Funding	Scope	Potential Funds	Advantage	Limitation
MOH	• **System Development** • **System Upgrades/ Expansions**	**MOH/NIH**	• Complete ownership of IP and source code (i.e. CRF, system architecture, application & data) by MOH. • Aligns with existing policies and strategic planning.	• Subjected to priority criteria for funding approval.
	• **Operation & Maintenance**	**MOH/NIH**		
	• **Subscription of proprietary software** (commercial off-the-shelf or customised software)	**MOH/NIH**	• Benefit from a tailored system without the burden of initial development costs and need for resources.	• IP and source code of the content and system are NOT owned by MOH; but data is still within MOH full control.
non-MOH*	• **System Development** • **System Upgrades/ Expansions**	• **Governmental organization** • **Non-Governmental organization** • **Private hospital** • **Clinical Societies** • **Government-linked organizations** • **Pharmaceutical companies** • **International agencies**	• Sharing of resources and talent pool through project collaboration. • Encourage innovation by taking into account perspectives from others beyond health.	• IP and source code of the content and system MAY NOT be owned by the MOH, subject to the agreement of the participating parties. • Coordination challenges might arise. • Data is handled by other parties, subject to Non-Disclosure agreement. • Potential conflicts of interest, need for clear contractual agreements related to data ownership and usage.
	• **Operation & Maintenance**			
	• **Subscription of proprietary software** (commercial off-the-shelf or customised software)		• Benefit from a tailored system without the burden of initial development costs and need for resources.	• IP and source code of the content and system are NOT owned by MOH. • Coordination challenges might arise. • Data is handled by other parties, subjected to Non-Disclosure agreement. • Potential conflicts of interest, need for clear contractual agreements related to data ownership and usage.

****Special consideration*** **applicable to MOH**

- In situations where initial development of registry system is funded by non-MOH entities/parties but with transference of complete ownership of IP and source code (i.e. CRF, system architecture, application & data) to MOH thereafter:

    i. There is a need to **declare it as a gift, subject to approval based on funding value** (refer to *Garis Panduan Permohonan Kelulusan Penerimaan Hadiah Bukan Tunai untuk Kegunaan Jabatan di Kementerian Kesihatan Malaysia (1 Dis 2023)*)[6].

    ii. Other modes of external funding with transfer of complete ownership to MOH would involve the setting up of an Akaun Amanah (refer to *Pekeliling Perbendaharaan WP 10.4/2013 - Tatacara Pengurusan Akaun Amanah Yang Ditubuhkan Di Bawah Seksyen 9 Akta Prosedur Kewangan 1957 (Akta 61)*)[7] or through Public-Private Partnership (refer to *Garis Panduan Kerjasama Awam-Swasta, Jabatan Perdana Menteri Malaysia 2009*)[8].

6. *Garis Panduan Permohonan Kelulusan Penerimaan Hadiah Bukan Tunai untuk Kegunaan Jabatan di Kementerian Kesihatan Malaysia, 1 Disember 2023*
7. *Pekeliling Perbendaharaan WP 10.4 Tatacara Pengurusan Akaun Amanah, Seksyen 9 Akta Prosedur Kewangan 1957.*
8. *Garis Panduan Kerjasama Awam-Swasta, Jabatan Perdana Menteri Malaysia 2009.*

3.2 Stage 2: Development

Figure 4: Key considerations during developmental stage of patient registry

(a) Interoperability

- Interoperability is defined as "the ability of two or more systems or components to exchange information and to use the information that has been exchanged"[9].
- Within the context of patient registries in Malaysia, this refers to the ability of registry systems to exchange information and use the information in a meaningful way, either with other registries or with other information systems.
- The benefits of prioritising interoperability in the planning and implementation of registry systems can be summarised as follows;
  i. **Reducing duplication of work:**
     Building upon existing data collection systems ensures that registry users are not obliged to enter data that had otherwise been collected at other data collection points during a patient's process of care. This will minimise the burden of data entry on field staff.
  ii. **Data quality:**
     The ability of a registry system to receive and use information from another data collection system also ensures that errors arising from manual data entry are kept to a minimum, whilst ensuring data consistency across different systems in use within MOH as a single organisation.
  iii. **Comparability:**
     Utilising readily-collected information instead of collecting

9. *IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries (New York, NY: 1990)*

anew also ensures that data can be compared across different systems and different time points. Utilising standards or information collected that comply with international standards also enable international comparability and sharing.

iv. **Enhanced collaboration:**
Seamless exchange and use of information will also provide opportunities for collaboration within the ministry as well as with external parties, leading to a sense of shared responsibility over data quality and data governance.

- Interoperability can be attained by adopting standards, which are agreed-upon industrial norms. For the seamless interoperability between a patient registry and other registries or information systems, there are several categories of standards that must be given due consideration within the information architecture of a registry system during system development, namely:
  i. **Identifier standards:** These are code sets that uniquely identify an entity (either physical or imaginary) or natural person involved in health data collection, either as data subjects, healthcare service providers or an attributable entity involved in healthcare, such as a facility where healthcare takes place. An identifier may be issued by an authoritative organisation (as in the case of MyKad number), or automatically generated by a system (as in the case of MyHDW's Virtual Patient Identifier). Some examples include;
     - **Patient Identifiers:** MyKad numbers issued by Jabatan Pendaftaran Negara, Master Person Index generated by a health information exchange, Virtual Patient Identifier generated within MyHDW.
     - **Provider Identifiers:** Malaysian Medical Council's Full Registration Number for registered medical practitioner, Malaysian Dental Council's Full Registration Number for registered dental practitioner.
     - **Facility Identifiers:** Ministry of Health's Health Facility Code.

ii. **Messaging/syntactic standards:** These are standards that dictate how electronic messages are structured to ensure that a receptive system is able to break a message into appropriate information chunks and subsequently enable the use of smaller units of information by the different components or sections of the system. Some examples include;
    - **HL-7 Fast Healthcare Interoperability Resources (HL7 FHIR)** for the exchange of information between health information systems.
    - **Digital Imaging and Communications in Medicine (DICOM)** for the exchange of medical imaging data.

iii. **Terminology/semantic standards:** These are structured vocabularies, terminologies, code sets and classification systems to represent certain concepts used within the health domain. These standards help different information systems share a common understanding and definition of health concepts. Some examples include;
    - **International Classification of Diseases (ICD)** for morbidity and mortality classification.
    - **International Classification of Health Interventions (ICHI)** for clinical procedures and other health interventions.
    - **Systematized Medical Nomenclature for Medicine - Clinical Terminology (SNOMED-CT)** for the representation of clinical concepts.
    - **Logical Observation Identifiers Names and Codes (LOINC)** for identifying medical laboratory observations.
    - **Malaysia Drug Code (MDC)** for the identification of medicinal substances.
    - **Data Dictionary Sektor Awam (DDSA)** for code sets to represent concepts that may be needed within the non-clinical component of registry data but are important for the demographic profiling of registry data subjects, such as gender, nationality and ethnicity.

iv. There are also other types of standards that are not specifically covered by this guideline that will confer additional advantages to a registry system including those related to practices in information security, such as ISO 27799:2016 - Health informatics.

v. As health informatics standards involve interdisciplinary expertise and its use may evolve with time, registry managers are encouraged to seek technical advice to ensure successful adoption and implementation of these standards. Within the MOH, this falls within the remit of the Standards Unit, Health Informatics Centre, Planning Division.

(b) Ethical and Legal Aspects

- Patient registries involve data collection from individual patients (human subjects) receiving care at a healthcare facility. Striking the right balance between registry needs, patient rights and legal requirements is fundamental to building a trustworthy relationship between organizations and the individuals whose information they handle.

Patient rights and consent

- The transparency surrounding the collection, utilization, and safeguarding of personal information is a critical aspect of responsible and accountable data management.
- It is the right of every patient as an individual to be informed of what is being collected, for what purpose and how the data would be processed and used.
- There are two models of consent for the collection of registry data:
  i. **Opt-in:**
     - Opt-in consent involves obtaining permission directly from individuals before their personal information is collected, processed, or disclosed.
     - This approach requires individuals to actively and knowingly grant permission, often through clear and unambiguous

statements, checkboxes, or other actions.

- By opting in, individuals consciously agree to the specific terms outlined in the privacy policy or data collection notice.
- This method places a strong emphasis on empowering individuals with control over their personal data and ensures that organizations respect user privacy preferences.
- Opt-in consent is particularly important in situations where sensitive or private information is involved, fostering trust and accountability between individuals and data custodians.

ii. **Opt-Out:**

- Opt-out consent, on the other hand, operates on the assumption that individuals are presumed to agree to the collection and use of their personal information unless they actively express a desire not to participate.
- In this scenario, individuals are automatically enrolled or included in data processes, and they retain the option to opt out or withdraw their consent at any time.
- This approach is often employed in less sensitive contexts, where the default expectation is that users are willing to share their information for common and expected purposes.
- While opt-out consent can streamline certain processes, it requires careful communication to ensure individuals are aware of their options and can easily exercise their right to opt out.
- Clear and accessible mechanisms for opting out should be provided to uphold transparency and respect for individual privacy preferences.

- The choice between the two approaches of consent depends on the nature of the information being collected, the context of its use, and the expectations of individuals involved. The consent model adopted for implementation at the clinical setting is subject to approval by the ethical committee.

Data Protection and confidentiality

- Compliance and adherence to data protection regulations are crucial. Non-compliance could lead to serious legal consequences, including the potential termination of the registry project.
- The following are the data protection regulations and some existing organizational policies with regards to patient data collection/usage relevant to the Malaysian context and need to be considered together in the development of the registry:
  i. Personal Data Protection Act (PDPA)[10].
  ii. Official Secrets Act 1972 (Akta Rahsia Rasmi 1972)[11].
  iii. *Garis Panduan Pengendalian dan Pengurusan Rekod Perubatan Pesakit Kementerian Kesihatan Malaysia 2023*[12].

Mandatory disclosure

- The design of data collection workflow must also consider existing legal, regulatory or administrative requirements for the reporting of certain conditions and healthcare activities.
- The design of registries must avoid duplication of mandatory notifications and more importantly, must not result in non-adherence to official notification requirements.
- Some relevant mandatory disclosures are contained in the following documents;
  i. Private Healthcare Facilities and Services Act 1998 (Act 586)[13].
  ii. Prevention and Control of Infectious Diseases Act 1988 (Act 342)[14].
  iii. *Surat Pekeliling KPK Malaysia Bil 2/2020: Arahan Notifikasi Kes-Kes Kanser Secara Atas Talian*[15].

Data ownership, access, sharing and intellectual property (IP) rights

- It is important to address issues of data ownership, access, and intellectual property rights. Securing intellectual property (IP) rights within patient registries is essential for establishing ownership and providing legal recourse against unauthorised access, modification, or replication of source codes. This ensures the integrity and security of the registry system. IP rights also extend beyond software to

10. *Personal Data Protection Act (2010).*
11. *Official Secret Act 1972 [Act 88] (Akta Rahsia Rasmi 1972 [Akta 88]).*
12. *Garis Panduan Pengendalian dan Pengurusan Rekod Perubatan Pesakit Kementerian Kesihatan Malaysia 2023.*
13. *Private Healthcare Facilities and Services Act 1998 (Act 586).*
14. *Prevention and Control of Infectious Diseases Act 1988 (Act 342).*
15. *Surat Pekeliling KPK Malaysia Bil 2/2020: Arahan Notifikasi Kes-Kes Kanser Secara Atas Talian.*

include data collection instruments and analytical methodologies. Expert guidance is recommended to navigate these complex areas.

- In registries where development and implementation involve different collaborators, there is a need to clearly outline ownership, access, sharing, and IP rights in a policy document. This document should also address procedures for data protection in the event of project termination.
- Registry committee should have clear processes for accessing and retrieving data from the external hosting environment, especially in the event of terminating the hosting agreement or transitioning to a different solution.
- Data sharing agreements should be implemented as additional safeguards against inappropriate use of information. Legally enforceable obligations should ensure appropriate and secure use of personally identifiable information.
- The physical location of the data servers may have legal and compliance implications. Registry committee must be aware of MOH specific requirements regarding where patient data can be stored and adhere to these regulations (refer to *Dasar Keselamatan ICT Kementerian Kesihatan Malaysia, v 5.0*)[16].

(c) Approval Mechanisms

- The creation and setting up of a new patient registry system require thoughtful considerations as it has resource implications to the organization with regards to people, funding and system. At the same time, there is a need to strike a balance between fulfilling a scientific/policy need and safeguarding the interest and rights of the patient.
- As such, approval mechanisms are put in place to serve as a check and balance, to safeguard the interest of different parties as far as possible. From a governance perspective, it provides a structure to guide organizational decision making, accountability, transparency and enforcement.

16. *Dasar Keselamatan ICT Kementerian Kesihatan Malaysia, v5.0, 2019.*

- The following will be the **approvals required for the setup of new registries within the MOH:**

  i. **Approval of the need for the establishment of a patient registry** by the relevant Head of Service (refer **Figure 5.1** and **Appendix A**).

  ii. **Approval of the scientific merits and ethics** by the Registry Data and Information Governance Committee (refer **Figure 5.1** and **Appendix A**).

  iii. **Project approval for setting up ICT system in MOH facilities** by the ICT approval committees (JPICT/JTI/JTISA), depending on project scope and value (refer to *Surat Pekeliling Am Kementerian Kesihatan Bil. 1/2016: tatacara pelaksanaan Projek ICT di Kementerian Kesihatan Malaysia (KKM)*)[17] (refer **Figure 5.2**).

  iv. For patient registry systems utilizing cloud infrastructure, risk assessment must be carried out prior to obtaining project approval for setting up ICT system and comply with the guidelines on cloud computing in the public sector published by the Chief Government Security Officer (CGSO)[18].

17. *Surat Pekeliling Am Kementerian Kesihatan Bil. 1/2016: tatacara pelaksanaan Projek ICT di Kementerian Kesihatan Malaysia (KKM).*
18. *SPA Bil 2 Tahun 2021 Garis Panduan Pengurusan Keselamatan Maklumat Melalui Pengkomputeran Awan (Cloud Computing) dalam perkhidmatan awam*

Process Flow:
Establishment of New Patient Registry in Ministry of Health Malaysia (1)

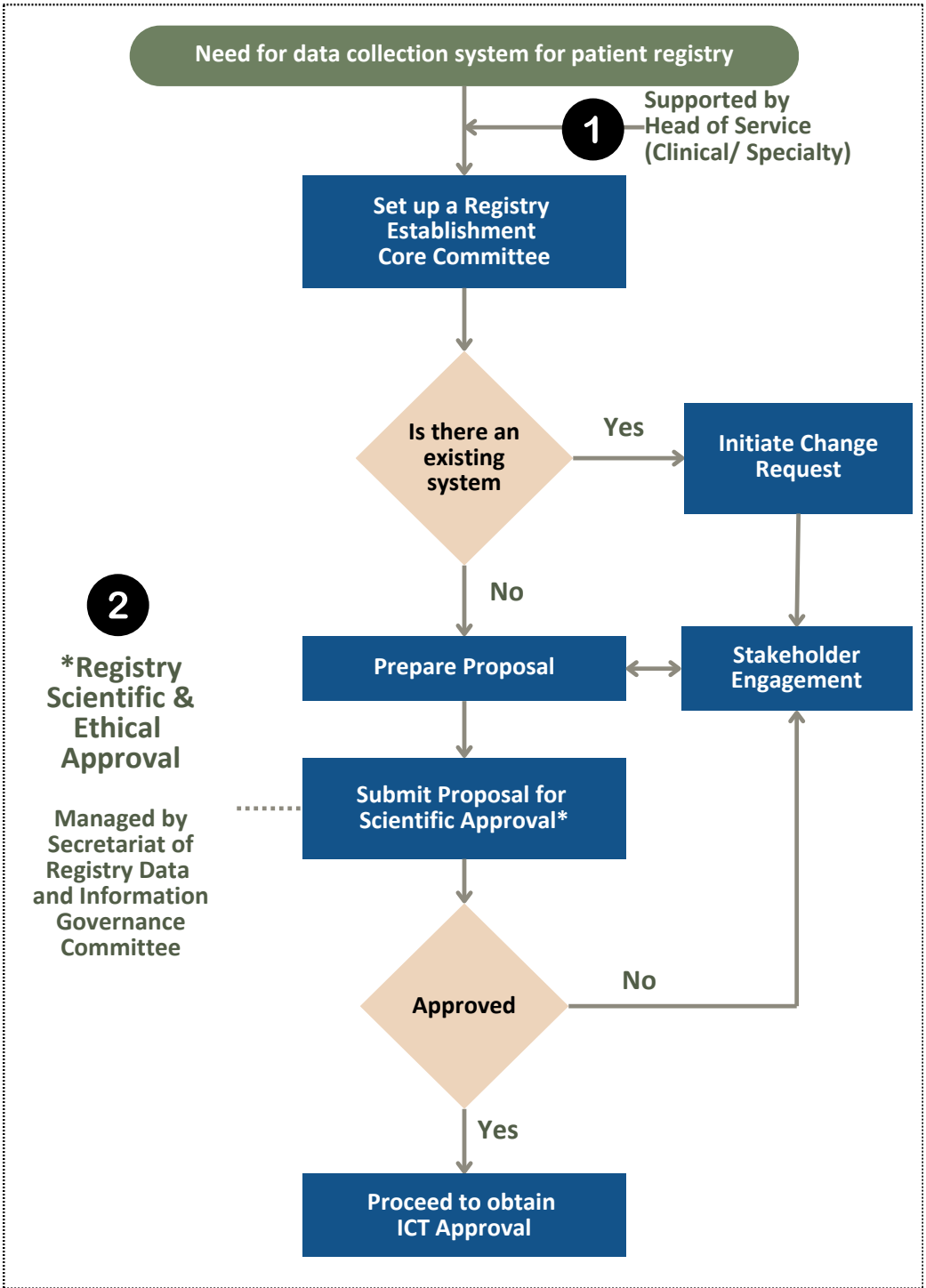

Figure 5.1: Process Flow Diagram for Scientific Approval for Patient Registry Establishment in Ministry Of Health Malaysia

Process Flow:
Establishment of New Patient Registry in Ministry of Health Malaysia (2)

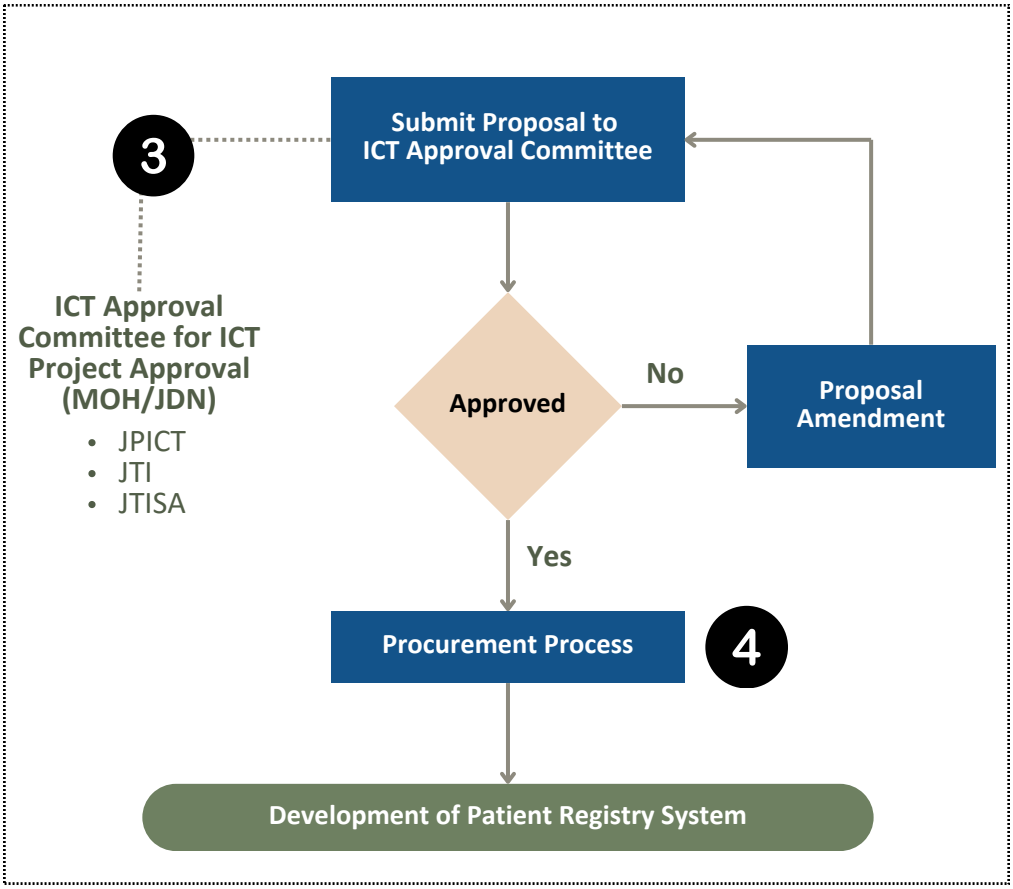

Figure 5.2: Process Flow Diagram for ICT Project Approval for Patient Registry Establishment in Ministry Of Health Malaysia

Note:
JPICT : Jawatankuasa Pemandu ICT
JTI : Jawatankuasa Teknikal ICT
JTISA : Jawatankuasa Teknikal ICT Sektor Awam

Sustainability of Patient Registry

The sustainability of a patient registry hinges on various factors, including securing continuous funding and resources, maintaining stakeholder engagement, implementing robust governance structures, ensuring data quality and integrity, adapting to technological advancements, and addressing regulatory compliance requirements. The following are key elements that needs to be considered:

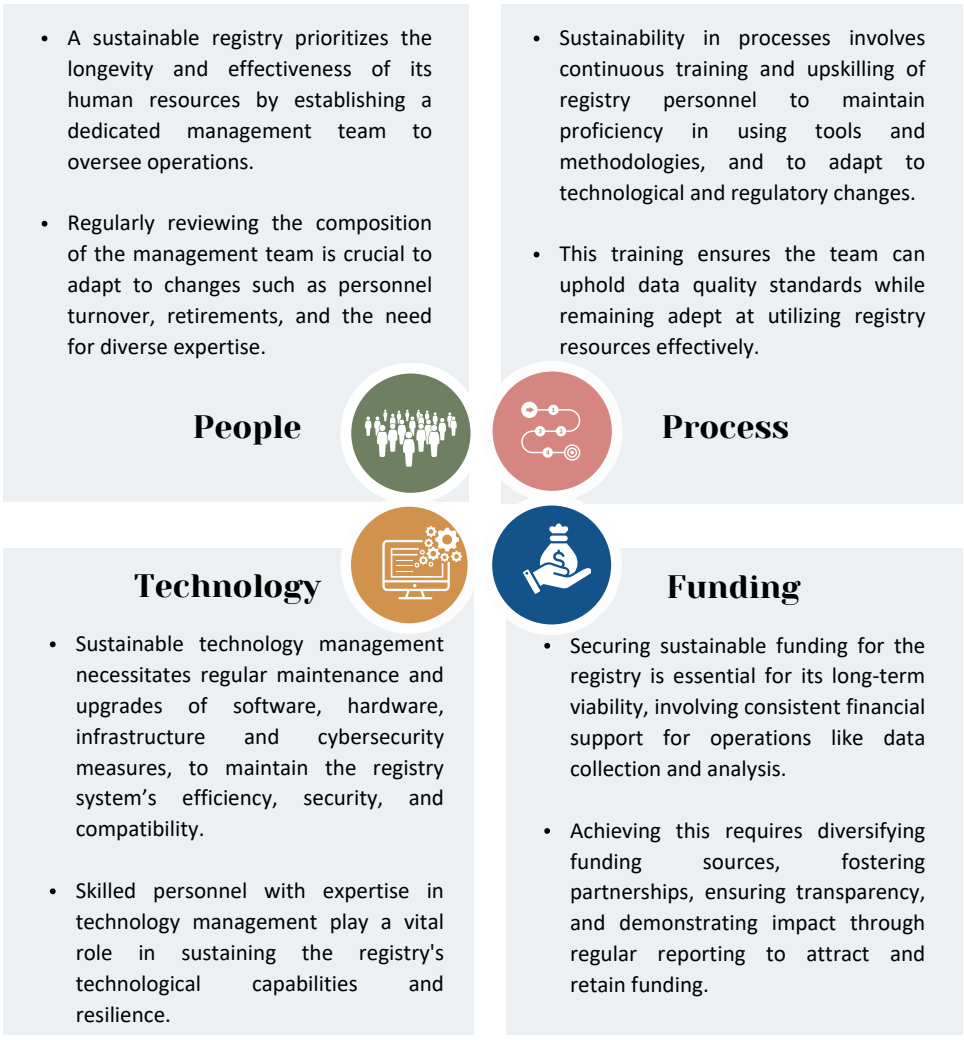

Figure 6: Key elements contributing to the sustainability of a patient registry

By effectively addressing these elements in its implementation, patient registries can remain relevant and impactful in facilitating research, improving patient care, and informing healthcare decision-making over the long term.

3.3 Stage 3: Implementation

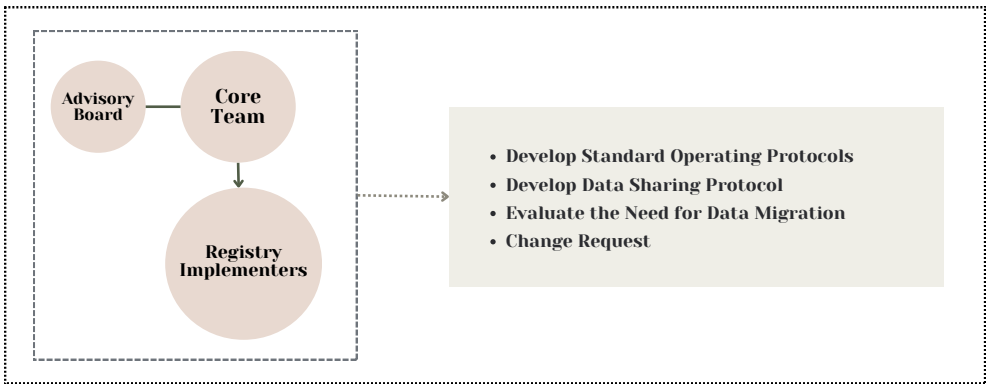

Figure 7: Implementation of patient registry post development

(a) Establish Registry Management Committee

- During implementation, establishing a Registry Management Committee is crucial for the effective execution of a patient registry. This committee is composed of three distinct entities, each fulfilling a specific function within the project management framework:

i. Registry Core Team

- The core team is responsible for the early planning, development, and deployment stages of the registry system. They also continue on to oversee various aspects of registry implementation, including data collection, analysis, quality assurance, and stakeholder engagement. Additionally, they determine the registry's direction and assess the need for content revisions and reporting extent.

ii. Registry Implementers

- The registry implementer team initiates the operations of the registry system at data collection sites, handling responsibilities such as recruiting and training data entry personnel, verifying data, and providing ground-level feedback on implementation issues.

iii. Registry Advisory Board

- The registry advisory board provides oversight and guidance for the execution of the patient registry. It serves

as an independent body that advises on the execution and reviews the needs for changes in the existing patient registry system or changes involving the initial direction and purpose of the registry. Members of the advisory board should be independent of the core team, and should declare no conflict of interest.

(b) Develop Standard Operating Protocols

- User manuals and documentation contribute to the overall success and effectiveness of the registry by ensuring adherence to standardised practices.
- Detailed manuals and documentation play a pivotal role in fostering consistency and accuracy across the registry, thereby enhancing data quality and reliability.
- Additionally, they serve as the essential training tools for onboarding new team members, enabling them to quickly grasp their roles and responsibilities within the registry framework.

(c) Develop Data Sharing Protocols

- Developing Data Sharing Protocols is essential to govern how data collected through the registry is shared with external parties. These protocols establish clear guidelines and conditions for data sharing to ensure compliance with data privacy regulations and protect patient confidentiality and security. They outline who can access the data, for what purposes, and under what conditions. Additionally, the protocols include measures to safeguard patient privacy and security during data transmission and storage.

(d) Evaluate the Need for Data Migration

- The evaluation of the need for data migration should consider factors such as data continuity, operational efficiency, data quality, and integration requirements. While data migration may entail upfront effort and resources, the benefits of preserving valuable

information, streamlining operations, and improving data quality justify the investment.

- Transitioning data from existing systems to the new registry ensures that valuable information from previous records is preserved and remains accessible. This continuity of data is crucial for maintaining historical records, tracking patient outcomes over time, and facilitating longitudinal analysis.
- A well-executed data migration process streamlines operations by consolidating data into a single database. This consolidation simplifies data management tasks, reduces redundancy, and minimizes the need for manual data entry or reconciliation across multiple systems. By centralizing data within the new registry, administrative burden is reduced, and operational efficiency is enhanced.
- Data migration also allows for the standardization and normalization of data from various sources, ensuring consistency and accuracy within the registry. By cleaning and validating data during the migration process, errors, inconsistencies, and duplications can be identified and corrected, improving data quality and reliability.

(e) Change Request

- Patient registry systems are dynamic systems that evolve with time. Regular assessment and adaptation are vital for ensuring the long-term sustainability and impact of the registry.
- As healthcare practices, technology, and regulatory requirements evolve, the need for modifications to data collection methods, data elements, or system functionalities becomes apparent. Change requests serve as formal proposals to introduce these modifications into the registry system.
- Once a change request is submitted, it typically undergoes a structured review process at tier 3 and tier 2 committees (refer **Figure 8**) to assess its feasibility, impact, and alignment with the registry's objectives and standards. This review process may involve

evaluating factors such as the potential benefits of the proposed change, the resources required for implementation, any associated risks or challenges, and the timeframe for implementation.

3.4 Stage 4: Monitoring and Evaluation

Monitoring and evaluation (M&E) is integral to ensuring the effectiveness and sustainability of patient registries. This process involves monitoring and assessing the registry's performance in terms of output, impact, and alignment with its goals and objectives. Regular assessments and adjustments contribute to continuous improvement and risk mitigation, ensuring the registry's long-term viability.

Auditing is a critical component of M&E, focusing on systematically reviewing registry processes and data against predefined standards or criteria, including adherence to regulatory requirements. Audit provides valuable insights for improving registry operations and reliability.

Key aspects of M&E

- **Data Quality Assurance:** The audit process ensures that data collected and stored in the registry meet predefined standards of validity, completeness, consistency, and reliability.
- **Registry Analysis Report**: A common indicator of registry activity is the number of publications produced. Reports generated from the analysis of registry data provide insights into the registry's performance, adherence to objectives, and data quality. Impactful reports serve as evidence that the registry remains a valuable resource for research, analysis, and decision-making.
- **Performance Metrics:** These metrics serve as quantifiable measures to evaluate the effectiveness and efficiency of the patient registry. By defining and tracking key performance indicators (KPIs), stakeholders can assess various aspects of its operation and impact. Some common performance metrics include data entry rate, retrieval efficiency, user satisfaction, and overall system reliability.

Types of Audits

- Audits conducted for registry systems typically focus on ensuring data quality, system integrity, and adherence to regulatory standards. The frequency of audits for registry systems should be determined based on a combination of regulatory requirements, risk assessments, organisational policies, system changes, continuous monitoring practices, and industry best practices.

Two type of audits exist:

i. Internal Audit

- Carried out by members of the registry project management team who are familiar with its operations and objectives.
- Follow a predefined plan and use specific indicators to identify potential errors or areas of improvement within the registry.
- Customised to align with the specific goals and objectives of the registry, ensuring that they address relevant areas of concern effectively.
- Some common types of internal audits include data quality, system security, workflow process, and issues with system.

Table 2: Example of Indicators used in Internal Audit

No	Indicator	Frequency of reporting	Generator	Content	Recipient
1	Percentage of missing data	Monthly	Data collection sites	Aggregated findings; trends in outcomes and patterns of practice	Core Team of Registry Management Committee
2	Submission rate	Monthly			
3	Non-compliance to data entry protocols	Monthly			

ii. External Audit:

- Conducted by third-party auditors who are not directly associated with the registry. This independence ensures an unbiased assessment of the registry's processes and data.
- Adhere to predefined criteria or standards for evaluation, which may include regulatory requirements, industry best practices, or specific guidelines set forth by governing bodies.
- Offer impartial evaluation of the registry without internal bias or conflicts of interest.
- They commonly assess compliance with organizational policies, governance, and internal controls.

Table 3: Example of Indicator used in External Audit

No	Indicator	Frequency of reporting	Generator	Content	Recipient
1	Information dissemination	yearly	Core team	Publication/ reports/ poster	Registry Data and Infomation Governance Committee
2	Number of trainings conducted	yearly	Core team		
3	Submission rate	yearly	Core team		

Implementation of Monitoring & Evaluation

- **Routine vs. Sporadic**
  - **i. Routine Methods:** These are assessment approaches that are implemented regularly due to their simplicity and cost-effectiveness. They are suitable for ongoing monitoring of key performance indicators or basic quality assurance checks.
  - **ii. Sporadic Methods:** Sporadic assessment methods, on the other hand, are more complex and are used intermittently. These methods may involve in-depth analyses or comparisons with independent cases to ensure completeness or accuracy.

Chapter 4

MINISTRY OF HEALTH MALAYSIA: DATA AND SYSTEM GOVERNANCE FOR PATIENT REGISTRY

A well-defined governance structure is vital for the successful implementation of a patient registry. Governance structure provides a defined framework to oversee the operation and management of the registry. This includes defining roles and responsibilities, decision-making processes, and protocols for resolving issues or conflicts that may arise during its establishment and implementation.

The MOH Malaysia adopts a 3-tier governance structure for patient registry establishment and implementation (refer **Figure 8**). Each individual level has their own separate leadership and ecosystem represented by different groups of people, differentiated by their roles and functions. The activities within the ecosystem are carried out independently from each other. Concurrently, each tier is also connected through a hierarchical level of reporting for selected and pre-defined activities, to maintain accountability and transparency.

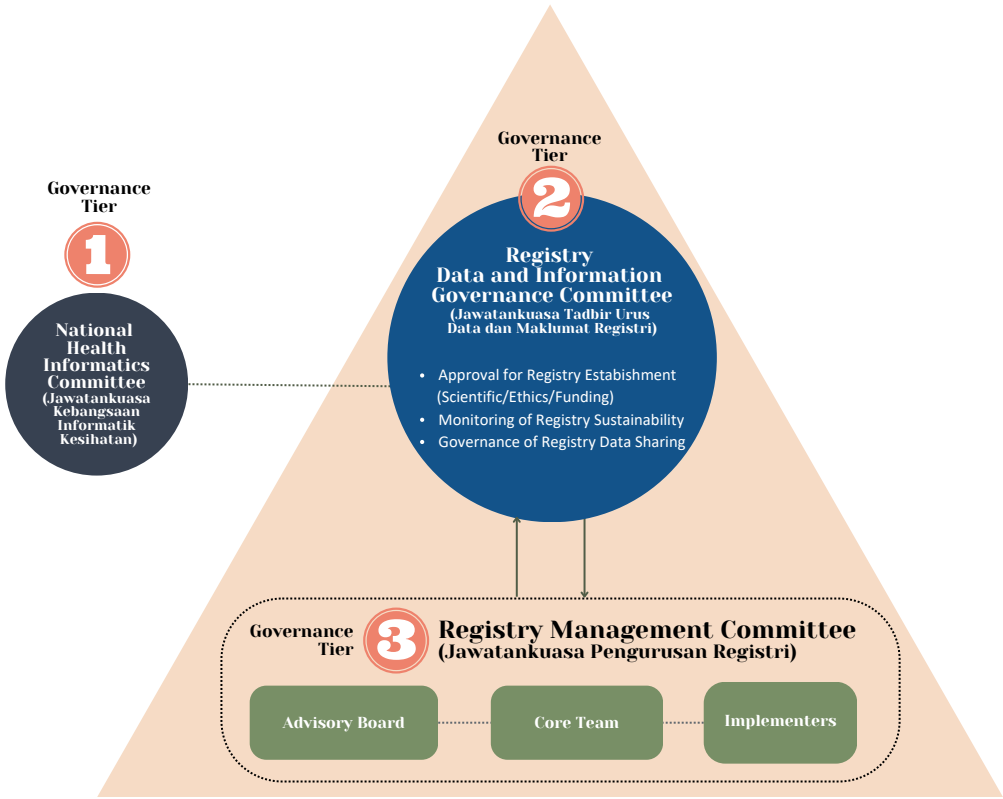

Figure 8: Three-tiered governance structure for patient registry establishment and implementation in Ministry of Health Malaysia

- **Tier-1 governance ecosystem** is represented by the **National Health Informatics Committee *(Jawatankuasa Kebangsaan Informatik Kesihatan JKKIK)***, chaired by the Director General of Health. The committee provides overarching oversight to all matters relating to health informatics within the MOH Malaysia and functions as an avenue to manage ownership, accountability and access where health data and information are concerned.

- **Tier-2 governance ecosystem** is represented by the **Registry Data and Information Governance Committee (*Jawatankuasa Tadbir Urus Data dan Maklumat Registri*)**, chaired by the Deputy Director General of Health (Research & Technical Support). This committee oversees the governance of data and information at the national level. Its primary function is to facilitate the establishment and implementation of patient registries within the MOH Malaysia. This includes evaluating the scientific and ethical merits of proposed registries, as well as monitoring and evaluating their sustainability over time. The committee reports its findings and recommendations to JKKIK.

- **Tier-3 governance ecosystem** is represented by the **Registry Management Committee.** Within this ecosystem, the head of the registry has authority over the arrangement, allowing for flexible work arrangements within registry groups to meet diverse needs. This structure also facilitates internal alignment and needs assessment, ensuring resources are used effectively and redundancies are minimized. Best practice recommends a core team to establish and sustain the patient registry, implementers to manage its operations, and an advisory board, including Clinical/Specialty Heads of Service, to provide subject matter expertise and governance.

(refer **Appendix D** for specific **Term of Reference**)

4.1 Data Governance

Data governance is needed to guide authority in making decisions about data; it provides the basis upon which those decisions are made. Data governance functions should include defining accountabilities, prioritizing investment requirements, establishing policies, implementing processes, setting standards, managing risks, and monitoring performance related to data throughout its lifecycle[19].

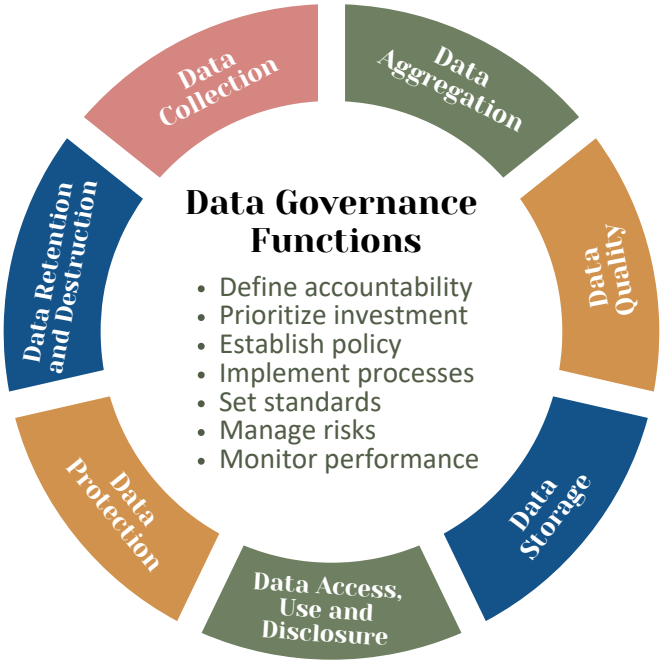

Figure 9: Functions of Data Governance

Data governance will be based on the overarching governance policy of MOH. The policy ensures the privacy, security and confidentiality of data in the patient registry system. In addition to protection against data leaks, the governance policy also ensures the accuracy and integrity of data to support evidence-based decision-making.

The following table (refer **Table 4**) provides a summary of the key roles involved within the planning, oversight, and control over management of data and the use of data and data-related resources, together with their respective key responsibilities.

19. *Understanding Data Governance in Public Health – Version 1.0*

Table 4: Key Roles and Responsibilities in Data Governance

No	Roles	Responsibilities
1	**National Health Informatics Committee** *(Jawatankuasa Kebangsaan Informatik Kesihatan*)	To provide policy and strategic directions for the development and implementation of patient registry. *Managed by appointed secretariat
2	**Registry Data and Information Governance Committee** *(Jawatankuasa Tadbir Urus Data dan Maklumat Registri)*	Oversight of the strategic decision making by the Registry Management Committee, including establishment approvals for establishment of new patient registries and monitoring of patient registries for sustainability. *Managed by appointed secretariat
3	**Registry Management Committee** *(Jawatankuasa Pengurusan Registri)*	**Core Team** Strategic decision making at Clinical/Specialty level and oversight of Registry Implementation Committees, define and ensure documentation of standard operating procedures, data sharing protocols, user training. **Implementers** Implementation of patient registries; from the clinical, technical and operational aspects, ensure the implementation of standard operating procedures and data sharing protocols. **Advisory Board** Advises and provides guidance to the execution of the patient registry, independent of the core team.
4	**Research Committees** • **NMRR** • **JPP-NIH** • **MREC**	Approval of secondary use of data from registries by external parties or for research purposes or outside of the original/intended purpose of the patient registry.

Note
NMRR : National Medical Research Register
JPP-NIH : Jawatankuasa Penilaian Penyelidikan (for research grant)
MREC : Medical Research & Ethics Committee

Data Sharing

The true value of registry data is realized when it is transformed into meaningful insights that inform policymaking, enhance healthcare service delivery, and improve population health. This can be achieved through responsible data sharing among authorized parties, who use the data to drive improvements in healthcare outcomes. Robust governance practices for data sharing should uphold ethical standards, protect sensitive information, and maintain security, while also fostering meaningful collaboration among health stakeholders.

The **data sharing matrix** (refer **Table 5**) is build upon the following principles and premises:

- Aggregated and anonymized granular data should be made accessible and available for sharing among relevant stakeholders in health, with proper data sharing protocols put in place.
- Non-anonymized granular data may include sensitive data that would allow the identification of patients, hence would require extra considerations and mechanisms for data sharing to safeguard patient data confidentiality.
- Registry data originates from the patient, and the success of a registry system depends heavily on the registry management committee, which plans, manages, and oversees daily operations. The sustainability of the registry is supported by those who fund and maintain the system, monitor its activities, and provide necessary human resources and facilities. The data collected is used to inform policy, generate new knowledge through research, and benefit patients broadly. Therefore, all parties involved share responsibility and accountability for the data.
- Data is deemed as a strategic asset to all stakeholders in health. Accountability and transparency should remain central to the processes and decision making related to data sharing, with check and balance mechanisms put in place. The goal is to achieve a balance in autonomy, enabling flexibility and empowering decision-making at the registry management level, while also ensuring mechanisms are in place to safeguard the interests of healthcare stakeholders.

The following data sharing protocol is applicable to:

- Patient registry system owned and managed by MOH Malaysia
- Patient registry system funded by MOH Malaysia
- Patient registry system utilizing any form of patient data obtained from facilities owned by MOH Malaysia
- Patient registry system managed by MOH personnel

Table 5: Governance of Patient Registry Data Sharing by Requester and Data Granularity Level

<table>
<tr><th rowspan="2">Requester</th><th rowspan="2">Type of Data</th><th colspan="4">Levels of accountability</th></tr>
<tr><th>Director General of Health</th><th>Registry Data and Information Governance Committee</th><th>Registry Management Committee</th><th>NMRR & MREC</th></tr>
<tr><td rowspan="3">Divisions and Agencies under MOH</td><td>Aggregated</td><td></td><td>Consulted</td><td>Accountable & Responsible</td><td rowspan="12">*Secondary data usage of registry data with a specific research question and intention to present/publish in scientific platforms need to abide to “Guidelines for Conducting Research in Ministry of Health (MOH) Institutions & Facilities”

This applies to:
• Research undertaken by MOH personnel or involving MOH personnel as a team member,
OR
• Research conducted in MOH institutions/ facilities
OR
• Research using MOH data/patient/ sample/ personnel as subject
OR
• Research funded by MRG</td></tr>
<tr><td>Granular (without PII)</td><td></td><td>Consulted</td><td>Accountable & Responsible</td></tr>
<tr><td>Granular (with PII)</td><td></td><td>Accountable</td><td>Responsible</td></tr>
<tr><td rowspan="3">Other Ministries/ Government agencies</td><td>Aggregated</td><td></td><td>Consulted</td><td>Accountable & Responsible</td></tr>
<tr><td>Granular (without PII)</td><td></td><td>Consulted</td><td>Accountable & Responsible</td></tr>
<tr><td>Granular (with PII)</td><td>Informed</td><td>Accountable</td><td>Responsible</td></tr>
<tr><td rowspan="3">Researchers from Universities and Other Local Agencies</td><td>Aggregated</td><td></td><td>Consulted</td><td>Accountable & Responsible</td></tr>
<tr><td>Granular (without PII)</td><td></td><td>Consulted</td><td>Accountable & Responsible</td></tr>
<tr><td>Granular (with PII)</td><td>Informed</td><td>Accountable</td><td>Responsible</td></tr>
<tr><td rowspan="3">International Researchers</td><td>Aggregated</td><td>Informed</td><td>Accountable</td><td>Responsible</td></tr>
<tr><td>Granular (without PII)</td><td colspan="3" rowspan="2">Data sharing to international parties are to abide to
Pekeliling Kemajuan Pentadbiran Awam (PKPA) Bilangan 2 Tahun 2021 Dasar Perkongsian Data Sektor Awam
with Bahagian Dasar dan Hubungan Antarabangsa (BDHA) consulted</td></tr>
<tr><td>Granular (with PII)</td></tr>
<tr><td rowspan="3">Others, including members of the public</td><td>Aggregated</td><td>Informed</td><td>Accountable</td><td>Responsible</td></tr>
<tr><td>Granular (without PII)</td><td colspan="4" rowspan="2">No granular data to be shared with third parties unless with explicit consent from subject or required by law</td></tr>
<tr><td>Granular (with PII)</td></tr>
</table>

Note
PII : Personally Identifiable Information

Role	Explanation
Informed	Party is to be notified by the accountable party, in formal documentation and in regular intervals, either alongside or after the approval of the request. Where needs arise, the informed party may be consulted by the accountable party before the final decision of approval is made.
Consulted	Party is to be notified alongside by the requester (in formal documentation) prior to the decision being made by the accountable party. The accountable party must seriously consider the advice by the consulted party but the final decision on approval lies with the accountable party.
Accountable	Party is responsible to ensure that data sharing is done up to required standard, makes final approval on request.
Responsible	Party is responsible to ensure that all activities related to data sharing request are coordinated (including engaging stakeholders, obtaining all necessary approvals, organising consultations, performing data extraction and documenting correspondences).

Additional Note: The data sharing protocol applies to all request based on the type of requester and data granularity aforementioned, with the exception of circumstances that may require non-disclosure of data such as when it involves data with national sensitivity and national interest, and when there exist prior formal agreements with external collaborators or funding bodies on non-disclosure of data. However, prior to making such exceptions, legal advisors should be consulted, with decisions explicitly documented in writing.

4.2 System Governance

System governance focuses on the overall management, oversight, and optimization of the technical infrastructure, processes, and resources supporting the patient registry system. This includes the technology infrastructure (hardware and software), approval and procurement mechanisms for ICT system development, system support and maintenance and system change and upgrades. The conduct of matters related to ICT domains for patient registry establishment and implementation involving the Ministry of Health Malaysia will need to abide by the overarching policies within the MOH Malaysia and *Jabatan Digital Negara* (formerly known as MAMPU).

Table 6: Governance related to Patient Registry System and Infrastructure in Ministry of Health Malaysia

Purpose	Guideline	URL
ICT Project and Procurement Approval including Hardware and Software The level of approval required depends on the scope, type (hardware vs software), value and category of the (development or maintenance) of the project.	*Surat Pekeliling Am Kementerian Kesihatan Bilangan 1 Tahun 2016 Tatacara Pelaksanaan Projek ICT di - Kementerian Kesihatan Malaysia (KKM)*[17]	https://www.moh.gov.my/index.php/database_stores/attach_download/681/115
Guideline for Cybersecurity Management of Cloud Infrastructure	*SPA Bil 2 Tahun 2021 Garis Panduan Pengurusan Keselamatan Maklumat Melalui Pengkomputeran Awan (Cloud Computing) dalam Perkhidmatan Awam*[18]	https://www.jpm.gov.my/images/surat_pekeliling/2021-SPA_BIL2_-_Garis_Panduan_Pengurusan_Keselamatan_Maklumat_Melalui_Pengkomputeran_Awan_Cloud_Computing_Dalam_Perkhidmatan_Awam.pdf
Procurement of Cloud Infrastructure	*PK 2.6 Perolehan Perkhidmatan Pengkomputeran Awan (Cloud) Sektor Awam*[20]	https://ppp.treasury.gov.my/sub-topik/fail/221/muat-turun

17. Surat Pekeliling Am Kementerian Kesihatan Bilangan 1 Tahun 2016 Tatacara Pelaksanaan Projek ICT di - Kementerian Kesihatan Malaysia (KKM).
18. SPA Bil 2 Tahun 2021 Garis Panduan Pengurusan Keselamatan Maklumat Melalui Pengkomputeran Awan (Cloud Computing) dalam perkhidmatan awam.
20. PK 2.6 Perolehan Perkhidmatan Pengkomputeran Awan (Cloud) Sektor Awam.

Guideline for ICT Project Management	*Pekeliling Transformasi Pentadbiran Awam BIL. 3 Tahun 2018, Panduan Pengurusan Projek ICT Sektor Awam (PPrISA) by MAMPU*[21]	https://sqa.jdn.gov.my/index.php/ms/garis-panduan/garis-panduan-pengurusan-projek-ict-prisa
Guideline for System Development of Patient Registry *Once system is developed, it has to be registered as "Aset Tak Ketara"	*Buku Kejuruteraan Sistem Aplikasi Sektor Awam (KRISA) by MAMPU*[22] *Tatacara Pengurusan Aset Tak Ketara Kerajaan'-Pekeliling Perbendaharaan Malaysia: AM 7.1*[23]	https://sqa.jdn.gov.my/index.php/ms/garis-panduan/garis-panduan-pembangunan-aplikasi-krisa https://ppp.treasury.gov.my/topik/fail/45/muat-turun
Operation and Maintenance	*Surat Pekeliling Ketua Setiausaha Kementerian Kesihatan Malaysia BIlangan 5 Tahun 2019 - Tatacara Pengurusan Penyenggaraan ICT Kementerian Kesihatan Malaysia*[24]	https://www.moh.gov.my/index.php/database_stores/attach_download/312/360
Change Request	*Surat Pekeliling Am Kementerian Kesihatan Bilangan 1 Tahun 2016 Tatacara Pelaksanaan Projek ICT di - Kementerian Kesihatan Malaysia (KKM) - KKM.100-1/6/1 (8)*[17]	https://www.moh.gov.my/index.php/database_stores/attach_download/681/115

21. *Buku Kejuruteraan Sistem Aplikasi Sektor Awam (KRISA) by MAMPU. (*JDN)*
22. *Tatacara Pengurusan Aset Tak Ketara Kerajaan-Pekeliling Perbendaharaan Malaysia: AM 7.1.*
23. *Pekeliling Transformasi Pentadbiran Awam Bil. 3 Tahun 2018, Panduan Pengurusan Projek ICT Sektor Awam (PPrISA) by MAMPU. (*JDN)*
24. *Surat Pekeliling Ketua Setiausaha Kementerian Kesihatan Malaysia BIlangan 5 Tahun 2019 - Tatacara Pengurusan Penyenggaraan ICT Kementerian Kesihatan Malaysia*

Chapter 5

APPENDIX AND BIBLIOGRAPHY

Appendix A:
Process flow and Criteria for Evaluating the Suitability of Patient Registries for Establishment and Implementation in Ministry of Health Malaysia

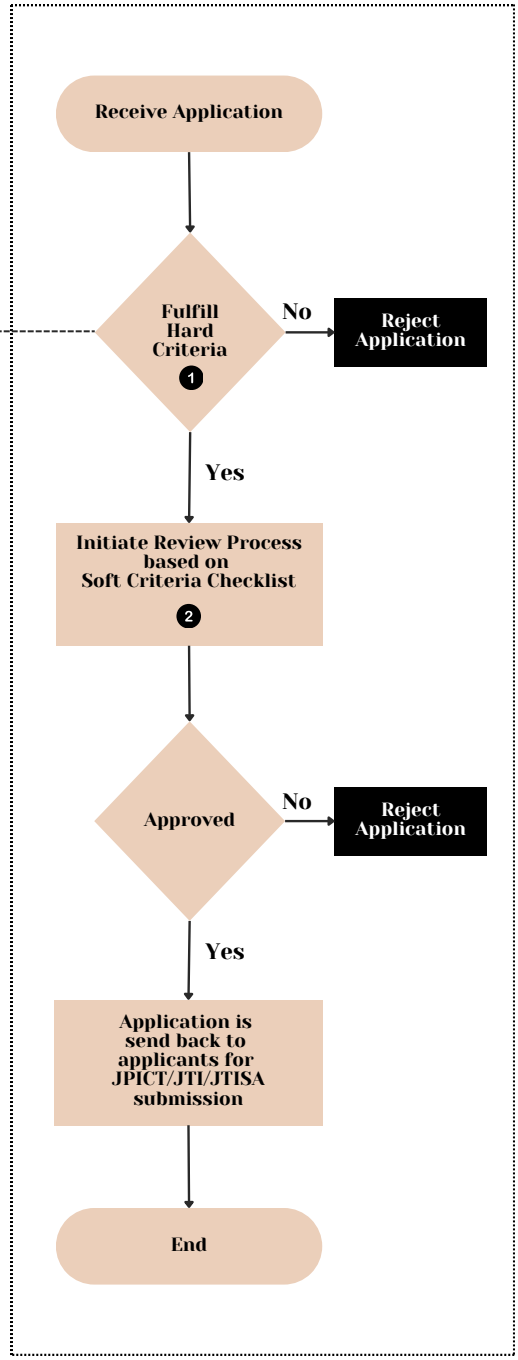

Figure 10: Workflow for review process by Registry Data and Information Governance Committee (*managed by Secretariat) using the Hard Criteria and Soft Criteria Checklist

1

Hard Criteria

Criteria for Patient Registry

- **Data collection of individual patients grouped by** one or more of the following:
  - (a) Exposure
  - (b) Specific Disease/Condition
  - (c) Specific Procedure/Treatment
- Data collected has to be **related to patient-related outcome**
- Data collection at **National Level (planned as multi-centre involvement)**

Administrative Criteria

- There is **no existing system within Ministry of Health Malaysia**
- Decision made within the clinical/specialty/service that there is a **need to set up a new registry (supported by Head of Service)**

Appendix A:

Process flow and Criteria for Evaluating the Suitability of Patient Registries for Establishment and Implementation in Ministry of Health Malaysia

2

Evaluation with Soft Criteria Checklist

Documents required to be submitted to Secretariat of Registry Data and Information Governance Committee

- **Registry Establishment and Implementation Proposal**
- **Case Report Form**
- **Data Element Definition**
- **Budget Justification**
- **Patient Information Sheet**
- **Letter of Support from Head of Service/ Head of Program**
- **System Architecture** (*additional for those with existing system and require change request)

Soft Criteria Checklist

(adapted from EURRECa checklist for quality evaluation of Rare Disease Registry)

Aspect	Scope	Items
Management Team	Has a management team been identified with their respective roles and responsibilities defined?	• Project Management • Subject Matter Experts • Scientific Experts • Database Management • Ethical, Legal and Privacy Issues • Quality Assurance **Select the range of expertise that is present within the management team of the registry*
Collaboration	Are there collaborations with parties outside of Ministry of Health (MOH)?	• Ministry of Higher Education (MOHE) • Professional Societies and Assocations • International Agencies
	What is the nature of collaboration for MOH?	• Data Sharing • System Provider • System User • Funder

Aspect	Scope	Items
Priority	Does the registry address prioritised issues?	• 12th Malaysia Plan: Health Research Priority (12MP-HRP) or equivalent • Sustainable Development Goals (SDG) • Rare disease initiatives **Any of the following purposes must be included:* • *Describe the natural history of the disease* • *Determine the clinical effectiveness of a procedure/treatment* • *To measure quality of care*
Governance: Core Team	Is the management team supported by a steering committee or a project governing board?	• Clinicians • Informatics • Patient representative • Statistics • Epidemiology • Ethical, legal and privacy issues **Select the range of expertise that is present within the steering committee of the registry*
Governance: Stakeholders	Who are the stakeholders involved in the registry activities?	• Clinicians • Patient representative • Researchers • Public authorities • Private companies * Select the range of stakeholders that are involved in interacting with the registry
Governance: Ethics	Does the registry have ethical approvals?	• Yes • Not required, mandate for data collection • Not existing and required

Aspect	Scope	Items
Governance: Data access	Does the registry manage the request for data access in a transparent way?	• **Yes** (i) in existing policy (ii) no specific policy • **No**
Governance: Data sharing	Does the registry share and exchange data with other data collection systems?	• **Yes** (i) National (ii) International • **No**
Governance: Consent management	Does the registry have an informed consent and participant information sheet?	**Model** • Opt-in consent • Opt-out consent **Dissemination** • Poster • Online notice • Patient information sheet
Data sources	Does the registry have a clear list of personnel who act as data sources for entering the clinical information?	• Data entered by the clinician responsible for the case • Data entered by patients • Data entered by other health professionals • Data entered by the administrator • Automatic data transfer
Data collection	Does the registry data collection involve primary collection or secondary use of data?	• Primary • Secondary use • Combination

Aspect	Scope	Items
Subject eligibility	Does the registry have standardised inclusion/exclusion criteria that a patient must meet?	• **Yes** • **No** *is imperative that the clinical condition or event can be identified systematically.
Case Report Form	Is the case report form developed based on best practice, standard guidelines and by consensus of experts?	• **Yes** • **No** • **Local design**
Data Elements	Is there a list of data elements with a clear definition?	• **Yes** • **No**
Outcome measures	Does the registry collect patient-centred outcome measures?	• **Yes** • **No** *There must be evidence that a well-executed sequence of care can improve patient outcomes for the selected clinical condition
Interoperable	Are standards used for data elements?	• **Yes** • **No**
Database management	What are the types of format/system used for data storage?	• **Relational database** • **Cloud database** • **NoSQL** • **HDFS** • **Single file**

Aspect	Scope	Items
Database management	Are backups stored separately and regularly?	• **Yes** • **No**
Software development	Does the registry software have a modular multi-tier architecture?	• **Yes** • **No**
	Is the registry based on open-source software?	• **Yes** • **No**
	Does the software have a web interface?	• **Yes** • **No**
	Is the registry available on a mobile interface?	• **Yes** • **No**
	Does the system have an interface that allows patient interaction?	• **Yes** • **No**
	Is the interface available to other Health Information Systems (HIS) to exchange data?	• **Yes** • **No**
	Does the system have data collection purposes other than for outcome-based analysis?	• **Yes** • **No**

Aspect	Scope	Items
Security	Is a pseudonymous patient identifier created by the system?	• **Yes** • **No**
	Does the system have a procedure in place in case of a personal data breach?	• **Yes** • **No**
	Does the system have a procedure in place to erase personal data when requested to?	• **Yes** • **No**
	Do only authorised users have access to data?	• **Yes** • **No**
	Does the system utilise secure web server communication through encrypted data transfer?	• **Yes** • **No**
	Can sensitive data be stored encrypted in the database?	• **Yes** • **No**
	Does the system have an audit trail module to track the activities of all users?	• **Yes** • **No**
	For systems utilizing cloud-based infrastructure, is there sensitive data being shared and has it obtained risk assessment and approval from CGSO?	• **Yes** • **No**

Aspect	Scope	Items
Data quality	Does the registry have a procedure for checking data quality (e.g. accuracy, missing, duplicate records)	• **Yes** • **No**
Data audit	Does the registry have a data audit system?	• **Yes** • **No**
Documentation	Does the registry provide an operation manual, including standard operating procedures?	• **Yes** • **No**
User training	Does the registry provide training for the operational registry team?	• **Yes** • **No**
	Does the registry provide training for registry users?	• **Yes** • **No**
Funding	Does the registry have a clear policy to ensure long-term sustainability?	**Types of funding:** • MOH (New) • MOH (Existing) • Other Government Agencies • Professional Societies • International Agencies Select *MOH (New) if requesting funds from MOH* **Fund coverage:** • System development • System maintenance • Training • Data migration • Data integration • Change requests **Declaration of conflict of interest?** • Yes • No

Appendix B:
System Development vs Subscription

	System Development and Maintenance	Subscription
Customisation	The system can be designed to meet specific business needs and requirements	Off-the-shelves system with constrained feature and functionality customisation
Integration	The system can be designed and developed with a focus on seamless integration with existing internal systems and databases	Outgoing or incoming integration may incur additional costs and security risks
Security Control	MOH can implement and control its own security measures, ensuring that the system adheres to the security policies and standards. Regular security audits, code reviews, and adherence to security best practices are crucial to mitigate these risks.	External hosting introduces concerns about data security and privacy. The registry committee must ensure that the external hosting solution complies with regulations governing the storage and processing of patient data to avoid legal consequences. The risk of a data breach exists, and the registry committee must assess the security measures the hosting provider implements. Additionally, they should have contingency plans and response mechanisms to promptly address potential breaches.
Organisational Culture	The system can be designed to align closely with the MOH's culture, workflows, and business processes	The system's inherent flow needs to be learned and adapted by the MOH.
Skill Gaps	MOH may face difficulties finding and retaining skilled developers, architects, and system administrators. If key personnel leave the organisation, there may be challenges in finding replacements with similar expertise	Developers and resources are managed by the vendor, and the fees are usually included as part of the subscription services.

	System Development and Maintenance	Subscription
Scope Creep	There is a risk of scope creep, where additional features or functionalities are continuously added during development, extending the project timeline and potentially increasing costs.	The development stage can be skipped.
Support and Maintenance	MOH must have processes in place for addressing bug fixes, updates, and user support to ensure the system's continuity.	Registry users may experience service interruptions or downtime if the external hosting provider faces technical issues.
Ownership	Data and systems are owned by MOH. MOH has full control of the location of system hosting.	MOH may have less direct control over the infrastructure and physical location of the data when it is hosted externally. Clarifying data ownership, access rights, and control mechanisms with the hosting provider are crucial.

Appendix C:
Scenarios that Require Additional Funding

Considerations for various scenarios requiring additional funding:

Change request

A change request may be needed to incorporate additional data fields or modify existing ones to align with prevailing health issues or evolving healthcare needs.

Data migration

During the implementation of the patient registry system, historical patient records from legacy systems may need to be migrated to the new system to maintain a comprehensive patient history and facilitate continuity of care.

System integration

System integration ensures seamless connectivity with existing healthcare infrastructure. The patient registry system may need to integrate with electronic health records (EHRs) or existing registry systems to provide a comprehensive view of patient information and streamline healthcare workflows.

User training

Training ensures that healthcare professionals are well-versed in using the patient registry system. New hospital staff members need comprehensive training to navigate the system efficiently, input data accurately, and utilize the system's features.

Appendix D:
Term of Reference: 3-Tier Governance for Patient Registry Establishment and Implementation in Ministry of Health Malaysia

Tier 1: National Health Informatics Committee

(Jawatankuasa Kebangsaan Informatik Kesihatan - JKKIK)

- To provide policy and strategic directions for the development and implementation of patient registries.

Tier 2: Registry Data and Information Governance Committee

(Jawatankuasa Tadbir Urus Data dan Maklumat Registri)

1. Develop and review policies and guidelines related to data and information governance for patient registries within the Ministry of Health Malaysia.
2. Establish procedures for reviewing and approving proposals for the establishment of patient registries, including assessment of scientific and ethical merits.
3. Ensure that patient registry activities adhere to ethical principles and guidelines, including obtaining informed consent from participants and protecting their privacy and confidentiality.
4. Develop and implement mechanisms for ensuring the quality, accuracy, and completeness of data collected within patient registries.
5. Establish protocols and procedures for safeguarding patient registry data, including encryption, access controls, and cybersecurity measures to prevent unauthorized access or breaches.
6. Develop guidelines for sharing and exchanging data between patient registries and other healthcare information systems, ensuring compliance with data protection regulations and privacy laws.
7. Monitor the performance and effectiveness of patient registries, including regular evaluation of registry activities, outcomes, and impact on patient care and research.
8. Foster collaboration and coordination among stakeholders involved in patient registry activities, including healthcare providers, researchers, policymakers, and patient advocacy groups.
9. Provide expert advice and guidance to registry sponsors, investigators, and other stakeholders on data governance issues and best practices in patient registry management.
10. Identify opportunities for continuous improvement in data governance processes, policies, and infrastructure to enhance the effectiveness and sustainability of patient registries.

Tier 3: Registry Management Committee

(Jawatankuasa Pengurusan Registri)

1. Develop and oversee the implementation of the registry's strategic plan, including setting objectives, defining priorities, and monitoring progress towards goals.
2. Determine resource allocation priorities, including budgetary decisions, staffing requirements, and technology investments, to support the registry's objectives.
3. Identify and mitigate risks associated with registry operations, data security, and compliance, and develop contingency plans to address potential challenges.
4. Oversee data management policies and procedures, including data collection, storage, sharing, and analysis, to ensure data integrity, privacy, and security.
5. Foster collaboration and communication with key stakeholders, including patients, healthcare providers, researchers, and policymakers, to solicit input, address concerns, and promote transparency.
6. Monitor and evaluate the registry's performance against established metrics and benchmarks, and make recommendations for improvement as needed.
7. Establish quality assurance processes to ensure the accuracy, completeness, and reliability of registry data, including regular audits and validation checks.
8. Develop training programs and educational resources for registry staff and stakeholders to enhance their understanding of registry objectives, protocols, and best practices.
9. Conduct periodic evaluations of the registry's impact on patient care, research outcomes, and healthcare policy, and prepare reports for dissemination to stakeholders and funding agencies.
10. Identify opportunities for continuous improvement in registry operations, technology infrastructure, and stakeholder engagement, and implement strategies to enhance registry effectiveness and sustainability.
11. Provide governance oversight for the patient registry, ensuring compliance with regulatory requirements, ethical standards, and organizational policies.

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