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Author(s)	Nikolaos Ntampakis (MINDS), Georgios Tsoumplekas (MINDS), Christos Vasilakis (MINDS), Vasileios Gavresis (MINDS), Nikolaos Moschos (MINDS), Dimitra Dichala (MINDS), Ioannis Makris (MINDS), Ilias Sinisioglou (MINDS) Chang Sun (UM) Janaki Raman Rangarajan (VPH)
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[1] **Type**: Use one of the following codes (in consistence with the Description of the Action):
R: Document, report (excluding the periodic and final reports)
DEM: Demonstrator, pilot, prototype, plan designs
DEC: Websites, patents filing, press & media actions, videos, etc.

[2] **Dissemination level**: Use one of the following codes (in consistence with the Description of the Action)
PU: Public, fully open, e.g. web
SEN: Sensitive, limited under conditions of the Grant Agreement

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List of Abbreviations and definitions

AI	Artificial Intelligence
CT	Computed Tomography
D	Deliverable
EHR	Electronic Healthcare Records
FAIR	Findable, Accessible, Interoperable, and Reusable
GDPR	General Data Protection Regulation
HTA	Health Technology Assessment
MDSW	Medical Device Software
M	Month
MAB	Multi-disciplinary Advisory Board
NDA	Non-Disclosure Agreement
SDQF	Standard Data Quality Framework
T	Task
WP	Work Package

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Executive Summary

This deliverable demonstrates the work carried out for the Standard Data Quality Framework (SDQF) regarding the REALM platform.

The first step was to collect and find out what technical teams and users need. Surveys, interviews, and expert feedback were used for this purpose. Requirements collected include functional requirements (e.g., data and model uploads), security requirements (e.g., user privacy and encryption), and ethical requirements (e.g., fairness and transparency). These will allow the platform to operate effectively within real healthcare environment and be compliant with EU legislation.

Moreover, key stakeholders and players, including hospitals, research institutions, health industries and developers, regulators (including Health Technology Assessment (HTA) agencies) and patient groups, were identified. Understanding their roles and needs ensured that the platform will be effective and ethical with real end-users.

Additionally, a Standard Data Quality Framework (SDQF) was developed by adapting quantitative and qualitative dimensions developed for assessing the quality of medical data from the QUANTUM consortium[3], an EU-funded project on defining health data quality labels in the context of European Health Data Space (EHDS). This framework enables the assessment of how broad, accurate and useful medical datasets used for evaluation of AI-based Medical Device Software (MDSW) are, which is critical in validating AI models for healthcare applications.

Overall, this deliverable outlines the foundation for designing a secure, fair and effective AI test platform by combining strong legal, technical and ethical requirements with definite user and system requirements.

[3]QUANTUM: An EU-funded project in the context of EHDS that aims to create a common label system for Europe that guarantees the quality and utility of datasets for scientific and health innovation purposes - https://quantumproject.eu/about-us/.

1 Introduction

This deliverable provides the overall methodology, processes and outcomes related to the elicitation and validation of user and system requirements for the development of the REALM platform. These requirements were gathered through a combination of processes, taking into account EU and national legal frameworks, ensuring a comprehensive understanding of what the platform must deliver across the healthcare AI ecosystem.

REALM aims to build a novel platform for the transparent evaluation of AI models for MDSW creators that is fully compliant with the General Data Protection Regulation (GDPR). As part of this objective, it is essential to align platform development with real-world needs, expectations, and constraints, across clinical, technical, legal and ethical dimensions. This report outlines the structured approach followed to achieve this alignment, under WP4.

1.1 Purpose of the Deliverable

The objective of this deliverable is to document the process and result of the requirements engineering process for the REALM platform. It outlines how the user requirements and system expectations were elicited, analysed and validated to ensure that the platform can meet the demands of a complex healthcare and regulatory environment.

Additionally, the deliverable identifies the security and privacy requirements for the development of medical systems and software in the REALM platform. They are mapped onto both EU and national legal frameworks, i.e., the GDPR and medical device regulations. The functional requirements outlined in this document summarize all the major attributes that are to be implemented by the REALM solution. These include both the behavioural aspects of the system and the expected functionality of its components, tools, and applications.

1.2 Relation with Other Work Packages, Tasks and Deliverables

This deliverable is part of WP4 “RWD & Synthetic Data Repository” and directly influences the design and architecture of the REALM platform carried out in T3.1. It also directly informs the technical implementation in WPs 3, 4, and 5 as well as the platform’s integration in WP6. The identified requirements also align with the objectives of WP2, particularly in terms of legal compliance and ethical considerations.

Moreover, this work supports the deliverable D3.1 “The Federated REALM Architecture”, upcoming outputs related to platform testing and validation. It provides a reference framework to ensure consistency across all development activities and ensures that all technical components are aligned with real user needs and policy frameworks.

1.3 Structure of the Document

The deliverable is structured as follows:

- **Section 1 – Introduction:** outlines the purpose of the deliverable. Describes the connection with other work packages and the overall structure of the document.
- **Section 2 – Methodology:** describes the methodology structure followed for collecting user and system requirements, including stakeholder engagement and validating input through a multi-disciplinary advisory board.
- **Section 3 – User Requirements:** provides the validated list of requirements of the user, along with Security & Privacy Requirements as well as Ethical, Privacy & Data protection Requirements.
- **Section 4 – System Requirements:** provides the system requirements for the REALM platform.

- **Section 5 – Stakeholders & Actors in the Medical Domain:** presents and analyses the stakeholders and actors involved during the development phase and after the platform's deployment
- **Section 6 – Standard Data Quality Framework:** Introduces a novel framework consisting of quantitative and qualitative dimensions for a multi-aspect evaluation of medical datasets in terms of their suitability for utilization in the validation of AI-based MDSW. Indicative results for a specific use-case are also presented.

This structure allows readers to understand not only what requirements were gathered, but also how they were identified, validated and connected to the broader REALM development process.

2 Methodology

The development of any software platform, especially in sensitive and highly regulated domains like healthcare, is based on a clear and well-structured methodology. One of the most important parts of the process is the gathering and validation of requirements and stakeholders' identification. That way, we ensure that the platform responds not only to functional needs but also to legal, ethical and operational expectations. Following a clear methodology, as shown in Figure 1, for the requirements collection process, we can reduce the risks, align stakeholder expectations and guide the technical design to produce a platform that is trustworthy and usable.

Regarding the REALM platform, a four-phase methodology was adopted in order to structure and coordinate all relevant activities. These phases include:

- User Requirements Collection
- System Requirements Collection
- Stakeholder Identification
- Creation of a Multi-disciplinary Advisory Board (MAB)

The process was developed to provide a participatory, inclusive approach that reflects the diversity of stakeholders within the medical sector, from clinicians and AI developers to legal experts and patient advocates. Each stage was supported by templates, formal feedback mechanisms and direct engagement with partners and third parties. The goal was to ensure that the REALM platform responds to real-world needs while complying with European standards such as GDPR and medical device regulations.

The diagram below summarizes the step-by-step process followed in the methodology:

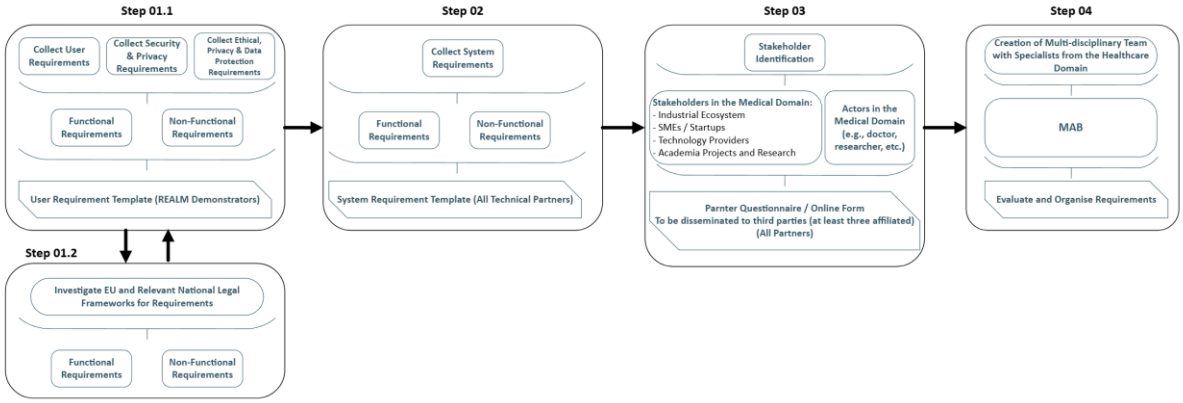


Figure 1: Overview of the requirements elicitation and stakeholder identification methodology.

2.1 User Requirements Collection

The first step in the strategy was the gathering of user requirements from the project demonstrators and partners. This was undertaken in two phases in an effort to capture operational needs as well as legal restrictions.

Step 01.1 – Input from Demonstrators: Demonstrator sites provided feedback on the platform functionalities that will be useful for them. Specifically, in the first step, three categories of requirements were collected: user requirements**,** security & privacy requirements, and ethical, privacy, and data protection requirements. These included tools for model uploading, certification workflows, output visualisation, account management, communication and collaborative workspaces. Requirements were classified as functional (what the system should do) or non-functional (performance, usability, privacy, etc.) in alignment with their priority level. All inputs were collected

using a User Requirements Template (see Annex: REALM User Requirements Template) to ensure consistency and completeness across partners.

Step 01.2 – Legal and Regulatory Compliance: Concurrently, legal experts performed an analysis of EU regulations like GDPR and relevant national legislation to determine additional ethical, privacy and data protection standards. These legal requirements were also mapped into system characteristics and constraints in order to meet European regulations and best practice, giving that way, input to Step 02. This legal and regulatory analysis gave critical input to the requirement gathering process (Step 01.1), namely to the identification of constraints and non-functional requirements related to data protection, privacy, and system accountability. This ensured that legal considerations were embedded in the requirements gathering process.

By integrating these two steps, we made sure that REALM is not only developed to meet users' needs but also made to operate legally and ethically in the complex health domain.

2.2 System Requirements Collection

The second step of the collection methodology is to gather the system requirements. Following the collection of user needs, the focus shifted to defining what the platform must do technically in order to fulfil those needs. This step will support the technical implementation of each REALM components.

This step engaged technical partners to describe the infrastructure, technologies and performance expectations for REALM components.

Each partner filled in a System Requirements Template (see Annex: REALM System Requirements Template), specifying the following elements:

- Minimum hardware requirements (CPU, RAM, storage),
- Software dependencies and programming environments (e.g., Python, PostgreSQL, Apache Spark, Kubernetes),
- Containerization and deployment specifications.

These system requirements directly correspond to the modular design of the platform, enabling scalable deployment, AI orchestration, explainability (XAI), synthetic data generation and secure federated data access. This establishes a rich technical foundation that has the system in operation while protecting the sensitive healthcare domain.

2.3 Stakeholder Identification

Recognizing that REALM is not just a technical platform but one that impacts and is influenced by many groups, this step focused on mapping out all key stakeholders. These include individuals, institutions, or organizations that interact with or are affected by the platform. This specific step was supported by two different processes. The first one was a targeted literature review and the second one was a direct engagement activity through an online survey.

Specifically, a literature review was conducted during M9 to gain a better understanding of the role and expectations of stakeholders toward AI in healthcare and in particular regarding explainability, trust and ethics. The review included a total of forty-eight sources, consisting of scientific papers, white paper and online articles from different institutions. To conduct the review, we used tools such as Google Scholar, PubMed, and Scopus, and searched for articles using keywords including *medical stakeholder*, *medical actor*, *stakeholders in the medical domain*, *actors in the medical domain*, *AI in healthcare ethics*, *explainable AI stakeholders*, and *trust in medical AI*. The literature helped to reveal typical categories of stakeholders and actors such as researchers [1], clinicians [2], regulators [3],

developers [4] and patient groups [5] and brought to the spotlight the requirement of technical and non-technical stakeholders' participation. The literature also underscored the role of transparency and XAI in making a contribution towards establishing trust within stakeholder communities.

Additionally, a questionnaire (see Annex: REALM Stakeholder & Actor Questionnaire) for REALM was designed and distributed to the Work package leaders during M15, who were also asked to gather responses from affiliated third parties. The questionnaire collected information on stakeholder roles, expectations of AI in medicine, and potential interactions with the REALM platform. This input landscaped more accurately and confirmed many of the groups mentioned in the literature review. Based on these combined inputs, stakeholders were assigned into four. These layers include core users who directly use the platform, like hospitals and research centres; oversight and regulatory organizations which interpret findings and track compliance; influence and advocacy stakeholders and indirect stakeholders who leverage the insights of the platform for purposes of decision-making, e.g., professional societies and insurers. This classification, which was depicted in an onion diagram, which is described in Section 5.1, showing how different actors engage with the platform and with each other.

2.4 Creation of Multi-Disciplinary Advisory Board

The final step of the methodology is the creation of a multi-disciplinary team with specialists from the healthcare domain. Under this step and in order to further strengthen the development process, an MAB was formed. The MAB includes clinical experts, researchers, legal professionals and other domain specialists. The scope of this board was threefold:

- To review the requirements compiled in the previous steps,
- Validate their accuracy and relevance,
- Prioritize and order them by practical relevance.

The MAB played a key role in the identification of duplications, mediation of competing demands, and keeping the final list of functionalities and features in touch with the realities of healthcare practice and regulation. The 1st MAB meeting took place virtually in September 2024, engaging eight specialists. Their ongoing input allows for flexible iteration and ensures that the REALM platform remains up to date.

3 User Requirements

Building on the analysis presented in Section 2.1, a comprehensive set of the platform's requirements has been gathered to ensure the successful development and deployment of REALM. These requirements are organized into three distinct yet interconnected categories: **user requirements**, **security & privacy requirements**, and **ethical, privacy, and data protection requirements**. Each category addresses specific aspects of the platform's functionality, user experience, and compliance with relevant standards, offering a holistic framework for its development. Note that the same categorization has been used in the listing of REALM's requirements in MS3, *"Availability of the User & Stakeholder, Security & Privacy Requirements to Be Met by REALM",* delivered in M12, as well as in D3.1, *"The Federated REALM Architecture",* delivered in M28.

Overall, categorizing the requirements is crucial since it provides a structured approach to addressing the diverse needs of the REALM platform, helping to break down complex considerations into manageable components. Additionally, separating user needs, security concerns, and ethical obligations facilitates a focused and targeted development process, ensuring that each area receives the necessary attention and resources to meet its specific goals and requirements. Finally, this organization also enables clearer communication between stakeholders, from developers to end users, and ensures that no critical aspect is overlooked during the development process.

3.1 User Requirements

This section outlines the user requirements that guide the development of the REALM platform, ensuring it meets the operational needs, expectations, and regulatory contexts of its key stakeholders. The requirements span both functional capabilities, such as model and data upload, certification workflow management, account and role configuration, output visualization, and internal communication, and non-functional expectations**,** including usability, performance, interoperability, data privacy, and multilingual support. Moreover, special attention is given on enabling a streamlined and secure user experience, fostering collaborative environments, and ensuring transparency throughout critical processes like model evaluation, certification, and user interaction with infrastructure.

Table 1 summarises REALM's user requirements.

Requirement	Title	Description	Type	Priority
REALM_UR_01	Presenting results	The REALM system must be able to provide, present and visualise the results of processes to the RIANA Dashboard.	Functional	High
REALM_UR_02	Ask for approval	The REALM system must ask for the approval of the administrator, when necessary, before proceeding to interventions on the infrastructure.	Functional	High
REALM_UR_03	Automated Segmentation	The REALM platform must integrate demonstrator's automated segmentation functionality to facilitate rapid and accurate lung tumor segmentation in CT scans.	Functional	High
REALM_UR_04	User-Friendly Interface	The REALM platform should have an intuitive interface that	Non-functional	High

		allows clinicians to efficiently navigate and utilize the demonstrator tool.		
REALM_UR_05	Workflow Integration	The REALM platform must facilitate seamless integration of the demonstrator tool into the clinicians' current workflows, including necessary installations and setup in various systems at the clinical site(s).	Functional	High
REALM_UR_06	Visualize output	The REALM system must be able to visualise the HTML output in a web browser.	Functional	Medium
REALM_UR_07	Parse output	REALM system must be able to parse and assess the JSON output.	Functional	High
REALM_UR_08	Database	REALM should integrate all requirements for updating the PharmCAT database (e.g., guidelines, drugs, etc.).	Functional	Low
REALM_UR_09	Create Account	User should be able to create an account with the minimum relevant information needed and secured password.	Functional	High
REALM_UR_10	View login / account information	User should be able to preview login and account information.	Functional	High
REALM_UR_11	Retrieve login information	User should be able to retrieve login information.	Functional	High
REALM_UR_12	Update login/account information	User should be able to update login and account information.	Functional	High
REALM_UR_13	Delete account	User should be able to delete their account.	Functional	High
REALM_UR_14	User guide	There should be a full documented user guide explaining the platform, the functionalities, processes objectives, etc. as well as a FAQ.	Non-functional	High
REALM_UR_15	User roles	User should have clearly specified roles with associated rights / permissions.	Non-functional	Medium
REALM_UR_16	User organization	(Verified admin) user should be able to create an organisation and add other users into the organisation.	Functional	Medium
REALM_UR_17	Users' collaborative environment	Users from a same organisation should be able to work in a collaborative environment according to their appropriate rights.	Non-functional	Medium

REALM_UR_18	Data upload	User should be able to upload and re-upload proprietary data.	Functional	High
REALM_UR_19	Model upload	Users should be able to upload and re-upload models on the platform.	Functional	High
REALM_UR_20	Model information	Minimum information about be model should be provided, in particular, the type of technology (Generative AI vs algorithmic AI) and how it has been developed.	Functional	High
REALM_UR_21	Event log	All actions, communications, inputs, etc. should be logged and a full history should be available for the users.	Non-functional	Medium
REALM_UR_22	Processing time	The platform should have minimal processing time.	Non-functional	High
REALM_UR_23	Dashboard	The platform should have an ergonomic summarizing clickable dashboard, with all relevant data / actions required / communications / organization / etc.	Functional	High
REALM_UR_24	Automated communication email	All status update / action required / communication update / etc. should trigger an automated email to all the users of the organisation that are related to this event based on user's roles.	Functional	High
REALM_UR_25	Communication / messaging	An internal communication / messaging system should be put in place to communicate with relevant people.	Functional	Low
REALM_UR_26	Language	Users should be able to use the platform in any official language	Non-functional	Medium
REALM_UR_27	Contacts persons	Persons of contacts should be clearly identified and reachable in acceptable delay.	Non-functional	Low
REALM_UR_28	Journey	It should be clear to organisations at what step of the process they are.	Functional	Medium
REALM_UR_29	Process steps	Steps should be clearly identified so the users exactly know where their application is and what are the status of these steps.	Functional	Low
REALM_UR_30	Process timings	Timings should be estimated and provided to users (average timing based on all applications). In addition, timings for each step should be	Functional	Low

		continuously recorded to update those average process timing.		
REALM_UR_31	Focus on long timing	If an application has an abnormal process timing, the platform should be able to ask the relevant persons to focus on the task or process and make sure everything is ok.	Functional	Low
REALM_UR_32	Assessment Criteria	It should be clear to the users what type of assessment, with what type of data, and what criteria are used to validate / assess the model.	Non-functional	High
REALM_UR_33	Reports	Clear report from model assessment should be given to the users, pointing out what passed and what failed plus a 'human written' specific note explaining and motivating exactly and clearly the outcomes of the assessment. (Not an automated report).	Non-functional	High
REALM_UR_34	Data format and interoperability	If using data format "standards" (there is no real standards and there will always be new standards), the platform should clearly explain what data format will be used, should implement relevant 'APIs' or data exchange system, document everything including the expected flow, make sure it works. This is crucial and get very complex.	Non-functional	High
REALM_UR_35	Data standards updates / and general updates	The platform should make sure that models that have been uploaded in a specific way (standards etc.) can still be used if platform updates or data format updates are realised.	Functional	High
REALM_UR_36	Model programming language	The platform should not restrict the programming language of the model uploaded. It is actually important that the model assessed is as close as possible to the model that will be used as a medical device.	Non-functional	High
REALM_UR_37	Implication	It should be clear what the implications of this assessment are for the models.	Non-functional	Medium
REALM_UR_38	Information Related to the	Introduction to the system for the Interested User applying to	Functional	High

	Services Provided. 1. Objectives and Services 2. Who can apply 3. Eligibility Criteria 4. Selection Criteria 5. How to apply a. Application template b. Support to applicants Data privacy policy	certify an ML/DL predictive algorithm/ system.		
REALM_UR_39	Instructions download	Detailed instructions for offline viewing and preparation.	Functional	Medium
REALM_UR_40	Application form 1. Sign up form 2. Login form 3. Application submission	Register interest to use the system.	Functional	High
REALM_UR_41	Application Approval 1. Invitation link (Organization) a. Support info (human) if needed 2. User (Organization) login a. Model provider Role b. Data provider Role Admin Role	Application approval process and Login procedure comprising different roles including Admin, Data and Model (algorithm) provider roles.	Functional	High
REALM_UR_42	User In 1. View Models list (organization specific) 2. View Data list (organization specific) 3. Upload Model (to be certified) 4. Upload auxiliary dataset 5. Check for Anonymity Provide	As soon as the User is logged in, there will be a list of already uploaded models from the same organization/ authority and another list of available/ indicative datasets linked to specific models. The dataset can be used for an initial model validation and as the basis for Synthetic data generation if needed. Anonymisation should be ensured. If not provided there must be an option/ tool for dynamic anonymization.	Functional	Medium

	Anonymization process (if needed)			
REALM_UR_43	Certification Workflow 1. Start Process 2. Email User on Status updates (Progress) 3. Output Report 4. Visualization Next steps (if any description)	Overview of the Certification progress. Updates to the User.	Functional	Medium
REALM_UR_44	Account Creation	The future user should be able to create an account from the log in page of the dashboard.	Functional	High
REALM_UR_45	Role Definition	The future user should be able to create an account with a specific user role.	Functional	High
REALM_UR_46	User Login	The future user should be able to log in to their created account.	Functional	High
REALM_UR_47	Language selection	The user should be able to select the language in which to see the dashboard from the logging page.	Functional	Low
REALM_UR_48	Human contact	A way to contact someone in charge of the dashboard should be visible on the dashboard without being logged in.	Functional	Medium
REALM_UR_49	User in organisation	All model developer account should be linked to an organization.	Functional	High
REALM_UR_50	Organisation's director	All organization should have at least one director account with extended right such as deactivating an account or remove access to part of the dashboard.	Functional	High
REALM_UR_51	Register organisation	There should be a process for a developer account to register an organisation by providing administrative papers such as the status of the company.	Functional	High
REALM_UR_52	User account permission	The permissions associated to an account associated to an organisation should be customisable by the director of the organisation.	Functional	High
REALM_UR_53	Models overview	All models registered by the dashboard should be visible on a page.	Functional	High

REALM_UR_54	Certification timeline	For each model submission, show a timeline showing the past, current, and future steps.	Functional	Medium
REALM_UR_55	Email alert	If an action is required or a certification process has ended, an alert should be sent by email to the person responsible for the action.	Functional	Medium
REALM_UR_56	Certification summary	Have a publicly available page displaying a summary of the certification result for each model.	Functional	Medium
REALM_UR_57	Extended certification report	After the certification process, an extended report recording the strengths and weaknesses found in the model should be available on the dashboard and downloaded as a pdf.	Functional	Medium
REALM_UR_58	Anonymous aggregation of certification data	If the data obtained during the certification process can only be used when anonymized for internal improvement purpose.	Functional	High
REALM_UR_59	Explanation certification	For models with explainable prediction, it must be possible to certify the model and the explanation independently.	Functional	Medium
REALM_UR_60	Certification data versioning	The certification given to a model must include the version of the data generating algorithm used during the certification.	Functional	High
REALM_UR_61	Create and Configure Model flow	It should be possible to create and configure Model flows in the platform for their asset evaluation.	Functional	High

Table 1: Summary of REALM's User Requirements

3.2 Security & Privacy Requirements

This section defines the comprehensive security and privacy requirements essential to the REALM platform's trustworthy and compliant operation. The platform is designed to protect sensitive personal and medical data through rigorous controls such as encryption of databases and communications, secure user authentication (including 2-factor authentication), controlled access to systems and outputs, and full anonymization or pseudonymization of real-world data. It incorporates privacy-by-design and privacy-by-default principles, ensures compliance with data protection regulations such as the GDPR, and supports mechanisms for user rights such as data erasure. Additional measures include secure data transmission, continuous integrity monitoring, non-disclosure agreement (NDA) enforcement, protection against unauthorized access, and strict handling of proprietary and certification-related data. Combining all of the above together, these requirements ensure the confidentiality, integrity, availability, and lawful processing of all data handled within the platform.

Table 2 summarises REALM’s security & privacy requirements.

Requirement	Title	Description	Type	Priority
REALM_SPR_01	Database security	All databases where personal data are stored in the REALM System must be encrypted, access to them must be restricted and authentication required to access such data.	Functional	High
REALM_SPR_02	Minimum Systems Configuration	The REALM System shall install only updates and functionalities which are essential for the functioning and security of the system.	Non-functional	High
REALM_SPR_03	Data Anonymization	The REALM platform must support the complete anonymization of CT scans to protect patient privacy before processing them through the demonstrator system.	Non-functional	High
REALM_SPR_04	Secure Data Transmission	The REALM platform should ensure secure transmission and storage of data, safeguarding it from unauthorized access and potential breaches.	Non-functional	High
REALM_SPR_05	Database security	All databases where personal data are stored in the REALM System must be encrypted, access to them must be restricted and authentication required to access such data.	Functional	High
REALM_SPR_06	Minimum Systems Configuration	The REALM System shall install only updates and functionalities which are essential for the functioning and security of the system.	Non-functional	High
REALM_SPR_07	Output with sensitive information	The output contains sensitive information. REALM should guarantee that the output will be treated following the same security requirement as the input used for evaluating demonstrator.	Non-functional	High
REALM_SPR_08	Non-disclosure agreement (NDA)	All actions, inputs, communications, etc. from users or organisation should always remained under a non-disclosure agreement between the REALM system (and managers) and the organisation/users; and an official NDA should be signed by all parties involved (or be part	Non-functional	High

		of the general conditions when creating account).		
REALM_SPR_09	Data encryption	All communications, data, information, etc. should be securely encrypted.	Non-functional	High
REALM_SPR_10	Proprietary data	Security around proprietary data should be ensured at all times and not shared.	Non-functional	High
REALM_SPR_11	Data / Process Integrity	Integrity of all the data (i.e.: make sure data is not 'broken') and also of all the processes (i.e.: make sure all assessment processes do what they are intended to do) should be ensured and assessed continuously.	Non-functional	High
REALM_SPR_12	Encrypted & secure communication	All communication should use encryption Any website, application or server must incorporate state-of-the-art security rules, not only on network communications but also on authentication and infrastructure.	Functional	High
REALM_SPR_13	Avoid manipulation and deception of the users, while also enabling them to make independent and well-informed decisions.	Abstain from designing and operating their interfaces in a manipulative or deceitful manner or in a way hindering service recipients´ ability to make independent and informed choices.	Non-functional	Low
REALM_SPR_14	System not accessible from unauthorized users.	Incorporate solutions compliant with data protection requirements (privacy by design), and ensure that only personal data necessary for the purpose are processed (privacy by default).	Non-functional	High
REALM_SPR_15	Use of code quality metrics tools	Code quality metrics tools should be considered.	Non-functional	Low
REALM_SPR_16	Any data processing will be performed considering the balance between legitimate interest and fundamental	System developers and parties maintaining the system at any point handle or process any type of personal data, they should balance their legitimate interest with the fundamental rights and freedoms of the data subjects whose data they will be processing.	Non-functional	Medium

	rights of users/individuals			
REALM_SPR_17	A data subject exercises its right of erasure and/or restriction to the processing	Data Provider must ensure to remove the data from any database and stop sharing.	Functional	High
REALM_SPR_18	All data handled will be fully anonymized	System developers and parties will respect fundamental rights and freedoms of the data subjects whose data they will be processing and incorporate solutions compliant with data protection requirements (i.e., GDPR).	Non-functional	High
REALM_SPR_19	Encrypted communication	All communication should use encryption.	Functional	High
REALM_SPR_20	Data privacy	The information resulting of a certification process must not be shared with other organisations.	Non-functional	High
REALM_SPR_21	Lost credential	The user should be able to reset their password if necessary.	Functional	High
REALM_SPR_22	Compromised credentials	The user must be able to block a compromised account if necessary.	Functional	High
REALM_SPR_23	2-factor authentication	The user should be able to activate a 2-factor authentication system for added security.	Functional	High
REALM_SPR_24	Non-sensitive synthetic data security	The non-sensitive synthetic data should be stored in trusted data repositories meeting appropriate security standards.	Functional	High
REALM_SPR_25	Real-world data security	The real-world data should be anonymized and stored in encrypted servers with controlled access and strict authentication mechanisms in place.	Functional	High
REALM_SPR_26	Highly sensitive real-world data security	The highly sensitive and identifiable real-world data shall be stored in a secure and encrypted storage. The transfer of data may happen only through encrypted channels and after anonymisation or pseudonymisation.	Functional	High
REALM_SPR_27	Data security	Data need to be backed up regularly to prevent data loss and ensure recovery if necessary.	Functional	High

REALM_SPR_28	GDPR compliance	All personal data should be collected with consent and shall be de-identified and anonymized before sharing in order to mitigate the privacy breach risks.	Non-functional	High

Table 2: Summary of REALM's Security & Privacy Requirements

3.3 Ethical, Privacy & Data protection Requirements

This section outlines the ethical, privacy, and data protection requirements critical to the responsible development and deployment of the REALM platform. These requirements go beyond technical implementation, reflecting the platform's commitment to fairness, transparency, accountability, and respect for individual rights. Specifically, they ensure ethical use of AI, particularly in sensitive domains like medical imaging, by addressing concerns such as algorithmic bias, informed consent, data provenance, and regulatory compliance (e.g., GDPR). Overall, through these requirements, the REALM platform emphasizes rigorous data governance practices, ethical oversight, and inclusive design to protect patient rights and foster trust among users, especially when dealing with personal health data and automated decision-making systems.

Table 3 summarises REALM's ethical, privacy & data protection requirements.

Requirement	Title	Description	Type	Priority
REALM_ER_01	Database security	All databases in REALM must be evaluated, ensuring there is no unwanted bias in the data.	Non-functional	High
REALM_ER_02	Ethical Use of AI	The REALM platform must ensure that the demonstrators adhere to ethical considerations in AI usage, promoting fairness, and avoiding biases in its tumor detection and segmentation algorithms.	Non-functional	High
REALM_ER_03	Informed Consent	The REALM platform should facilitate the process of obtaining informed consent from patients whose data will be used, ensuring transparency and respect for individuals' rights.	Non-functional	High
REALM_ER_04	Unbiased Database	All databases in REALM must be evaluated, ensuring there is no unwanted bias in the data.	Non-functional	High
REALM_ER_05	Verify ethical approval	At the time of data inclusion and/or analysis, REALM systems and/or the user should verify ethical review process and approval as appropriate for the application.	Non-functional	High
REALM_ER_06	Data provenance / bias	Data should not be biased; data should come from safe and identified source with quality factor.	Non-functional	High

REALM_ER_07	Data Consent	It should be checked whether the consent of use of the data was granted.	Non-functional	High
REALM_ER_08	Data reuse	It should be sure that data is not reused or re-uploaded multiple times.	Non-functional	High
REALM_ER_09	Fairness & transparency	Assessment should be fair and transparent to the users; so, should the users when uploading any information on the platform for assessment.	Non-functional	High
REALM_ER_10	Ethical Use of AI	Provide safeguards against overconfidence and overreliance on any of the data manipulation AI provisions.	Non-functional	High
REALM_ER_11	Follow the UI/UX Design guidelines and recommendations	Ensure universal design for accessibility, explicability specifically for non-technical end-users for understanding of AI and data manipulation.	Non-functional	High
REALM_ER_12	Display a disclaimer on how the data and AI functionalities will be used	Clearly communicate which audiences the platform and the data manipulation and AI functionalities are intended for.	Non-functional	High
REALM_ER_13	Respect patients' rights (regardless of circumstances of individuals, e.g., illegal immigrants) in deploying AI or implementing comprehensive assessment protocols and ethical guidelines.	Ensure that AI technologies are developed and deployed with a strict adherence to fundamental human rights, including privacy and non-discrimination.	Non-functional	High
REALM_ER_14	Align with regulatory obligations for the certification process	System developers are clear about the regulatory obligations with regards to data manipulation and the deployment of AI functionalities.	Non-functional	High
REALM_ER_15	Ensure standards used and comply with legal and regulatory requirements, such as data protection laws (e.g., GDPR)	System developers and other stakeholders (e.g., data providers) adhere to clear design and data standards.	Non-functional	High

REALM_ER_16	Prevent overfitting	The certification process must prevent the possibility of overfitting the model on the certification dataset.	Functional	High
REALM_ER_17	Ensure unbiased dataset	The dataset use for the model's evaluation should be unbiased for gender, socio-economic status, ethnic group, and age.	Functional	High

Table 3: Summary of REALM's Ethical, Privacy & Data Protection Requirements

4 System Requirements and Architecture Blueprints

Following the detailed presentation of the user requirements that will guide the development of the REALM platform, the next step was to clearly define the system requirements. These requirements will form the foundation for the platform's infrastructure and will guide the technical implementation of each REALM component, based on the identified needs and the resources required to ensure smooth operation.

This section outlines the system requirements necessary for the effective deployment and operation of the REALM platform. As a modular, AI-driven solution for evaluating MDSW across heterogeneous healthcare data sources, REALM requires specific hardware and software resources for each major component to support its flexible architecture and advanced data processing capabilities.

System requirements define the specifications that outline what a software system must accomplish and the constraints under which it must operate. They form the foundation for design, development, testing, and deployment activities. Typically documented in the early stages of the software development lifecycle, these requirements help ensure that the final product aligns with the needs of both users and stakeholders.

The system requirements for REALM have been detailed in Section 2.2. Building on that analysis, Table 4 outlines the requirements that must be met by the integration server to support several of REALM's key components. These requirements are organized by architectural module and include detailed specifications for computational resources (CPU, memory, and storage), external software dependencies, supported programming environments, technology stacks, and containerization needs. Overall, this information is intended to guide technical teams including system administrators, MLOps engineers, and software developers in provisioning infrastructure and configuring environments that meet REALM's performance, scalability, and compliance requirements.

Component	Hardware Requirements	RAM Usage	Max Storage	Programming Language	External Source Dependencies	Tool Version	Docker Image
Data Middleware Stack	> 8-16 CPU cores / machine	> 8GB / machine	> 500 GB	Python	Apache Spark, Kubernetes, Apache Kafka	Apache Spark 3.5.0, Kubernetes cluster >= 1.24,	Yes
Blockchain	> 16 CPUs	16 GB	> 500 GB	Python, Go, Solidity, TypeScript	Ethereum, Polygon testnet, thirdweb/Alchemy SDK	Python 3.x, Solidity 0.8.x, Go 1.22.x, TypeScript 5.x	Yes
AI Orchestrator	> 4 CPUs	16 GB	-	Python	Kubernetes, Kubeflow Pipelines SDK	Kubeflow Pipelines >= 2.0	Yes

Data Repository	4 CPUs	> 8 GB	> 500 GB	SQL	PostgreSQL	Postgre SQL >= 14	Yes
Docker Registry for Components	4 CPUs	> 8 GB	> 160 GB	-	Harbor	Harbor >= 2.0	Yes
Post-Market	8 CPUs	16 GB	> 160 GB	Python	-	Python 3.x	Yes
XAI	8 CPUs	16 GB	> 160 GB	Python	-	Python 3.x	Yes
AI Utilities	8 CPUs	16 GB	> 160 GB	Python	-	Python 3.x	Yes
AI Monitoring	8 CPUs	16 GB	6 GB	Python	-	-	No

Table 4: Summary of REALM's System Requirements

Based on the information provided in the above table, it is evident that the hardware and software requirements across REALM's major architectural components support a system built for scalability, performance, and data-intensive processing. Components such as the Data Middleware Stack, Blockchain, and AI modules such as XAI, Post-Market Surveillance, and AI Utilities demand between 8 and 16 CPU cores and at least 16 GB of RAM, underscoring their compute-intensive nature. In contrast, components like the Docker Registry and Data Repository require only 4 CPUs and 8 GB of memory, indicating that their roles are less computationally demanding and more focused on storage and access operations.

Additionally, storage requirements across the platform are uniformly high, with most components needing over 160 GB of storage and some, like the Blockchain and Data Middleware Stack, requiring more than 500 GB. This showcases that REALM is designed to manage substantial volumes of data, consistent with its role in evaluating AI-based MDSW using large-scale healthcare datasets. The only exception is the AI Monitoring component, which has a relatively minimal storage footprint, indicating a lightweight operational scope focused on logging and evaluation metrics.

From a software development perspective, Python is the dominant programming language across the platform, used in nearly all major components. This consistency enables streamlined development, integration, and maintenance which is particularly important in AI-centric systems. On the other hand, Blockchain diverges from this trend by incorporating Go, Solidity, and TypeScript alongside Python which reflects its multifaceted integration needs, including smart contract development (Solidity), backend performance (Go), and frontend/SDK interaction (TypeScript).

Moreover, containerization is a foundational design principle in REALM, with all components—except for AI Monitoring—packaged and deployed as Docker images. This approach promotes modularity, portability, and streamlined deployment across environments by orchestrating these components into fully functional pipelines using Kubernetes and Kubeflow Pipelines.

REALM also leverages a modern cloud-native technology stack that includes widely adopted tools such as Apache Spark, Kubernetes, Kubeflow Pipelines, and Harbor. These external dependencies enable distributed processing, orchestration, and secure storage which are essential features in the context of AI software evaluation for healthcare. The platform also integrates blockchain infrastructure via Ethereum and the Polygon testnet, using SDKs like thirdweb and Alchemy, which adds transparency, traceability, and tamper-evidence which are also critical factors in regulated medical software ecosystems.

Finally, each component specifies versions for key tools and dependencies, with the overarching goal of making REALM secure, high-performing, and compliant with evolving industry standards. This is achieved by ensuring compatibility, reproducibility, and simplified long-term maintenance.

Note that the RIANA dashboard, which serves as the main visualization and user interaction layer of the REALM platform, is excluded from Table 4. Unlike other components that perform data processing, orchestration, or storage functions, RIANA operates as a lightweight front-end interface that leverages existing infrastructure rather than introducing significant standalone system demands. Its deployment relies primarily on standard web server resources and browser-based rendering, and it consumes output from other REALM modules rather than generating or transforming large volumes of data independently. As such, its hardware and software footprint are minimal and context-dependent, typically tailored to the hosting environment rather than requiring dedicated infrastructure.

In addition to outlining baseline requirements, this section also highlights considerations for environments ranging from local development to production-scale deployments, including containerized and cloud-native scenarios. Figure 2 provides a comprehensive visual representation of the REALM platform's system architecture, detailing all its major components and the underlying technologies that support them. This diagram is strategically included here to enhance the understanding of the system requirements presented in Table 4 by illustrating how the different components interconnect and what software tools are employed to realize their functionality.

Note that the same architectural diagram has also been included in D3.1, *"The Federated REALM Architecture",* delivered in M28, where it serves as a foundational reference for discussing REALM's architecture. Its inclusion in the current deliverable aims to reinforce the alignment between functional design and technical infrastructure planning.

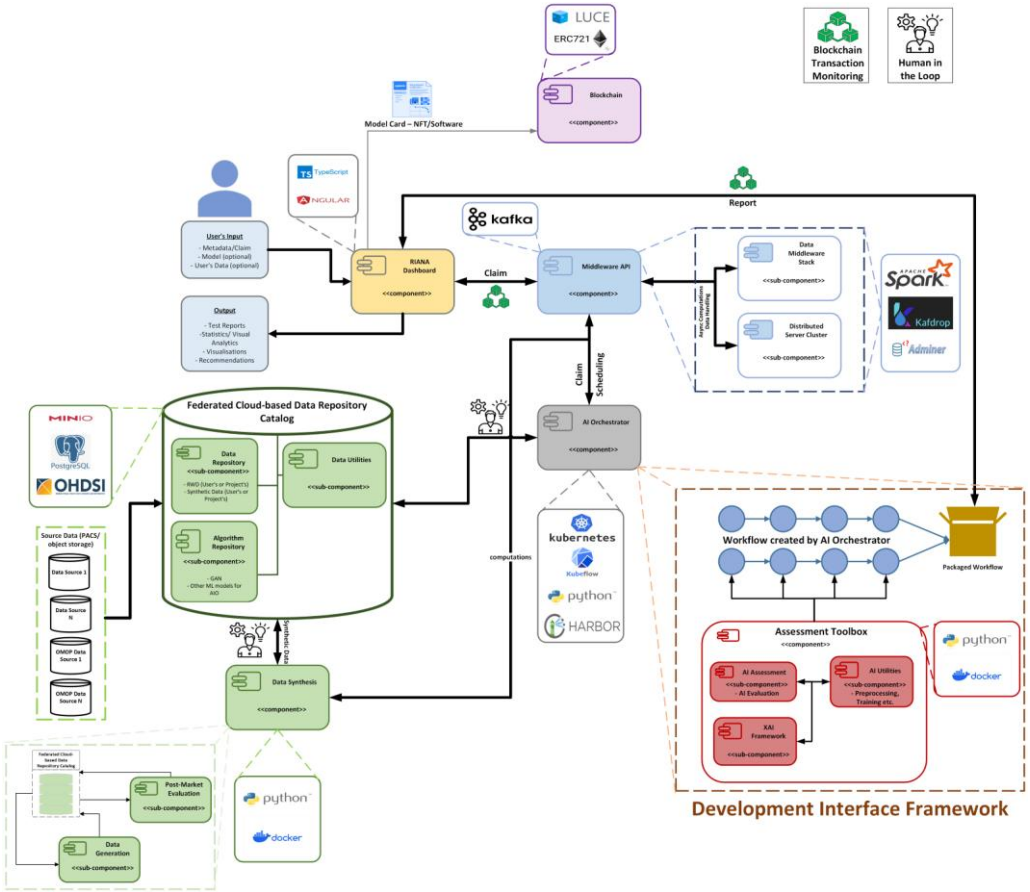


Figure 2: Overall REALM Architecture along with the Major Technologies

REALM's architecture showcases a tightly integrated but modular system built with a cloud-native and container-first approach. The **RIANA Dashboard**, built using Angular and TypeScript, offers a lightweight, browser-accessible frontend tailored for user interaction rather than data processing. It connects to backend services via a **Middleware API**, which leverages Apache Kafka for asynchronous communication and Apache Spark for distributed data processing, forming the core of the **Data Middleware Stack**.

This **Middleware Stack** is also tightly coupled with a **Distributed Server Cluster** that enables horizontal scaling and fault tolerance for high-throughput, low-latency data workflows. Technologies like Kubernetes and Apache Spark ensure the resilience and scalability of this layer, which is vital for handling real-time and batch data pipelines.

The **AI Orchestrator**, constructed with Kubeflow Pipelines running on Kubernetes, manages the execution of AI workflows across components. It coordinates processes such as data synthesis, evaluation, and model explainability, relying on containerized Python scripts to define modular and reusable pipeline steps. Supporting this is Harbor, which functions as the Docker registry, hosting versioned container images required by different orchestration tasks.

Data handling is further enhanced through a **Federated Data Repository** that integrates real-world datasets formatted in OMOP and stored in a PostgreSQL-based system. The **Data Utilities** component is responsible for preprocessing, visualization, and data transformation tasks, while the **Data Synthesis** component leverages advanced generative models to produce modality-specific data.

To ensure regulatory robustness and post-deployment reliability of AI-based MDSW, REALM includes a comprehensive **Assessment and Regulatory Toolbox** that spans subcomponents such as **AI Assessment**, **Post-Market Evaluation**, and **XAI Framework**, each implemented using Python and executed via Kubeflow. These components are computationally demanding, thus justifying the high system specifications listed earlier.

Finally, the **Blockchain** module, which is distinct in its multi-language implementation (Go, Solidity, TypeScript, and Python), supports traceability, auditability, and data provenance using Ethereum and Polygon networks. SDKs such as thirdweb and Alchemy facilitate seamless interaction with decentralized infrastructure, reflecting the platform's emphasis on trust and compliance in medical AI evaluation.

5 Stakeholders & Actors in the Medical Domain

In parallel with defining the various user and system requirements for REALM, it is essential to clearly identify and analyse the stakeholders and actors involved both during the development phase and after the platform's deployment. Before presenting a comprehensive list of those involved in REALM, it is beneficial to first provide clear definitions of what is meant by *stakeholders* and *actors* in this context:

- A **stakeholder** in the architecture of a system is an individual, team, organisation, or classes thereof, having an interest in the realisation of the system. This definition includes people both inside and outside the organization, such as end users, customers, project managers, developers, testers, support staff, suppliers, and even those responsible for maintaining or operating the system once it is deployed.
- An **actor** is an external entity, such as a person, organization, hardware device, or another system, that interacts directly with the system being developed. Actors represent the roles played by these entities, rather than specific individuals or devices, and they always exist outside the system boundary. They can initiate interactions with the system, such as triggering use cases, provide input, or receive output.

Stakeholders and actors differ primarily in their relationship to the system and their involvement throughout the project. Stakeholders may influence requirements, constraints, or goals without interacting directly with the system. Actors, in contrast interact with the system (either directly or indirectly) to achieve specific goals. While all actors are stakeholders, not all stakeholders are actors. Additionally, stakeholders may be involved at various stages of the project lifecycle, whereas actors are typically relevant during system operation and are defined in relation to the system's boundary.

Given that REALM is a platform designed for the evaluation of AI-based MDSW, it is expected to involve a diverse group of stakeholders and actors. These may include AI model developers, researchers, clinicians, regulatory bodies, and organizations that stand to benefit from such evaluations, such as insurance companies and patient advocacy groups. As a result, it is clear that individuals and entities with varying levels of expertise in fields such as medicine, artificial intelligence, and law will engage with the platform. Therefore, it is essential to clearly define both the stakeholders and actors involved in REALM, along with their objectives and the ways in which they are expected to interact with the platform. Doing so will significantly support the design of REALM in a way that better meets the needs of these groups. Section 5.1 outlines the identified stakeholders, while Section 5.2 focuses on the actors anticipated to interact with the REALM platform.

5.1 Stakeholders in the Medical Domain

Building on the methodology introduced in Section 2.3, this section provides a more detailed overview of the stakeholders involved with the REALM platform. Based on both the literature review and the results gathered from the "Stakeholder Analysis Feedback Form for the REALM project" questionnaires, the following stakeholders have been identified: (a) Healthcare Organizations (Health Services/Hospitals), (b) Health Industries / Business & Innovation Clusters, (c) Research Centres / Universities, (d) Governments / Regional – Authorities, (e) Oversight / Regulatory / Notified Bodies, (f) Patient Groups / Healthcare Consumer Groups, (g) Non-profit Groups / NGOs, (h) Health Technology Assessment (HTA) Agencies, (i) Health Professional Societies, (j) Healthcare Networks, (k) Professional Consortia, and (l) Insurance Companies.

Given the diverse range of stakeholders involved in REALM, their interactions with the platform are expected to vary significantly. While all are connected to the medical domain, they come from different professional backgrounds and possess varying levels of technical expertise. As a result, their expectations of REALM and the ways in which they engage with it are likely to differ.

Figure 3 presents an onion diagram of REALM's stakeholders, organizing the involved parties into four concentric layers according to their proximity to AI model development, data interaction, and decision-making processes. Specifically, the following layers are identified:

- **Layer 1 - Core Users / Direct Platform Operators:** This group comprises stakeholders who engage directly with the REALM platform. They contribute AI models, perform evaluations, and use the results to refine those models. Their high level of involvement is driven by a direct need to leverage REALM's technical capabilities, including federated evaluation, interpretability, and privacy-preserving mechanisms. Stakeholders in this layer include **Healthcare Organizations (Hospitals, Health Services)**, **Research Centres and Universities**, **Health Industries and Business & Innovation Clusters**, as well as **Healthcare Networks**.
- **Layer 2 - Regulatory and Oversight Bodies:** These stakeholders play a critical role in assessment, regulatory validation, and compliance enforcement. While they do not develop models themselves, they are essential to ensuring the platform operates within legal and ethical frameworks. Their focus lies in interpreting the outcomes of evaluations, such as model explainability and compliance metrics, rather than engaging directly with technical components. This layer includes **Governments / Regional Authorities**, **Oversight / Regulatory / Notified Bodies**, and **HTA Agencies**.
- **Layer 3 - Influence and Advocacy Stakeholders:** This group represents societal and ethical interests, including patient rights and broader social impacts. Their interaction with the platform centres on advocacy, fairness assessments, and accountability in the use of AI. Though not technically involved, they provide essential oversight from a rights- and ethics-based perspective. Stakeholders in this layer include **Patient Groups / Healthcare Consumer Groups**, **Non-profit Groups / NGOs**, and **Professional Consortia**.
- **Layer 4 - Indirect Stakeholders / Decision Support Users:** These stakeholders benefit from insights generated by the platform but are not involved in its technical operation. They use REALM-derived information, such as clinical AI evaluation and fairness outcomes, to inform decisions, particularly in areas like insurance or professional guidance. However, they are not active participants in the AI model development lifecycle. This layer includes **Insurance Companies** and **Health Professional Societies**.

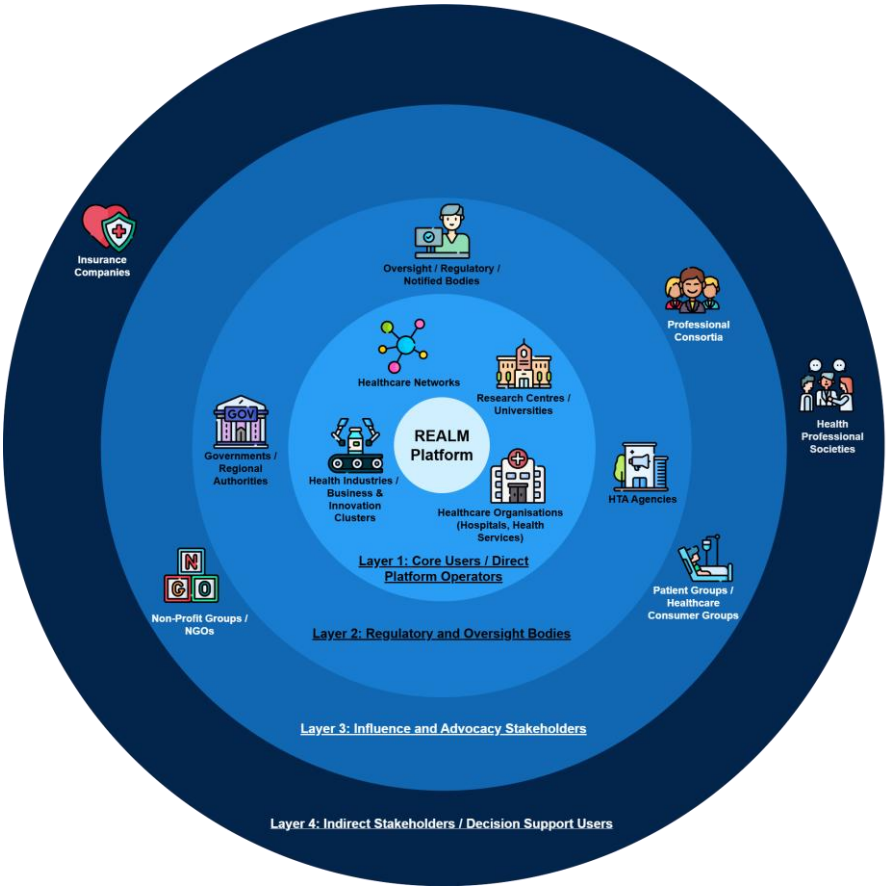


Figure 3: Onion Diagram of Stakeholders in the Medical Domain

5.1.1 Healthcare Organizations (Health Services/Hospitals)

Healthcare organizations, such as hospitals and health services, have a key role in providing integrated medical care, from prevention and treatment to emergency care and rehabilitation. They are central to maintaining high standards of patient safety, clinical effectiveness, and quality of care.

As core users of the REALM platform, these organizations can securely contribute real-world health data while preserving patient privacy. Through their direct engagement with the platform, they are able to evaluate the performance, robustness, and interpretability of AI models in clinical settings. This enables them to assess how well AI tools align with clinical needs and to support the refinement of those tools for safer and more effective deployment in healthcare practice.

5.1.2 Health Industries / Business & Innovation Clusters

The healthcare industry, including pharmaceutical companies, medical technology firms and AI-driven start-ups, constitutes a pillar of medical innovation. Business and innovation clusters within this sector are at the core of developing cutting-edge healthcare technologies and enhancing efficiency in service delivery.

As direct users of the REALM platform, these stakeholders can test, refine, and validate their AI-based MDSW using a suite of tools for performance evaluation, robustness checks, and XAI. REALM's secure and privacy-preserving environment supports these innovators in building trustworthy and high-performing AI systems that meet clinical needs, align with ethical and legal standards, and are better positioned for regulatory readiness.

5.1.3 Research Centres / Universities

Research centres and universities are key drivers of medical innovation, bridging the gap between theoretical research and clinical application. They foster the development of novel healthcare solutions and shape the professionals of tomorrow through cutting-edge research and education.

In the context of REALM, these institutions actively contribute by developing and evaluating AI models for healthcare. REALM enhances their ability to analyse model behaviour through XAI tools, fairness, and performance assessments. It also provides a structured framework for investigating AI decision-making, fostering high-quality academic research in digital health innovation.

5.1.4 Governments / Regional – Authorities

Governments and regional authorities are responsible for overseeing healthcare systems, setting public health standards, financing programs, and ensuring equitable access to services. Their policies shape the ethical, legal, and operational landscape of medical technologies.

With the REALM platform, these authorities can assess whether or not AI-based MDSW complies with existing legal and regulatory standards, without requiring deep technical expertise. REALM's transparency and XAI capabilities support evidence-based policymaking by providing insights into the safety, fairness, and effectiveness of AI tools and helps inform the development of adaptive regulations that remain aligned with evolving technological advancements.

5.1.5 Oversight / Regulatory / Notified Bodies

Regulatory, oversight, and notified bodies are tasked with instituting safety, performance and ethical standards for medical practice. These institutions ensure that healthcare technologies, including AI-based systems, meet stringent validation requirements before being approved for clinical use.

REALM facilitates independent evaluation by these authorities through its robust model assessment tools and transparent explainability features. This allows regulators to assess whether AI models meet safety and compliance standards, even in complex clinical scenarios. REALM also streamlines conformity evaluations, allowing seamless and harmonized regulatory approval of AI-based MDSW.

5.1.6 Patient Groups / Healthcare Consumer Groups

Patient groups and healthcare consumer groups play a vital role in advocating for the rights, safety, and well-being of individuals, often focusing on those with specific health conditions or care needs. Their role is central to promoting patient-centred care and shaping health policy through an ethical and social lens.

By accessing the REALM platform, these stakeholders gain visibility into how AI models impact patient outcomes. The platform's explainability features help make AI decision-making more transparent and understandable to non-technical audiences, enabling patient advocates to push for fairness, accountability, and transparency in the development and deployment of AI-based medical technologies.

5.1.7 Non-profit Groups / NGOs

NGOs, non-profit organisations, and patient organisations play a critical role in addressing healthcare inequalities, supporting vulnerable and underserved populations, and advocating for ethical, inclusive, and transparent health systems. Their activities span advocacy, education, research, and collaboration with public institutions, regulators, and healthcare providers.

Patient organisations, as a specific type of non-profit entity, are formally structured groups mandated to represent the collective views and interests of patients with particular diseases or health conditions. They engage in policy dialogue, awareness-raising, and systemic advocacy to ensure that patient perspectives are integrated into healthcare decision-making, research, and innovation processes.

REALM enables these stakeholders to assess whether AI models used in healthcare are fair, inclusive, and free from harmful bias. By offering transparent, privacy-preserving evaluations, the platform empowers NGOs to advocate for equitable AI deployment and to raise awareness or take action when algorithmic biases or ethical concerns are identified.

5.1.8 Health Technology Assessment (HTA) Agencies

HTA agencies conduct evidence-based evaluations of medical technologies, assessing their clinical effectiveness, economic value, and broader societal impact. Their assessments inform decisions on the adoption, funding, and use of health innovations within public and private healthcare systems.

REALM supports HTA agencies by providing access to transparent analyses of AI models, including evaluations based on real-world data. Its XAI features enhance understanding of model behaviour, enabling agencies to assess safety, efficacy, and population-level impact. Overall, this contributes to more informed, efficient decisions around health policy, reimbursement, and the integration of AI technologies into care delivery.

5.1.9 Health Professional Societies

Health professional societies bring together clinicians, researchers, and experts to advance medical research, education, and standards of care. Societies play a critical role in developing clinical guidelines and shaping healthcare policy to ensure high-quality, patient-centred care.

REALM supports these societies by providing reliable, transparent evaluations of AI tools, including performance metrics, interpretability insights, and alignment with clinical standards. These outputs help professionals assess the readiness and appropriateness of AI systems for clinical integration, fostering informed recommendations and building trust in AI-assisted healthcare.

5.1.10 Healthcare Networks

Healthcare networks connect providers, facilities, and services to collaborate in improving the quality and efficiency of care delivery. These networks often operate across institutions and regions, sharing resources and clinical practices.

PEALM is perfectly applicable in such settings, offering robust data privacy protections and support for multi-node evaluations that align with federated data governance principles. Networks such as DARWIN EU, EHDEN, and PIONEER can leverage REALM to assess AI model performance across diverse clinical settings through REALM's ability to provide consistent, privacy-preserving, and scalable real-world testing of AI systems, driving improvements in both model development and clinical applicability.

5.1.11 Professional Consortia

Professional consortia bring together experts from across healthcare, such as clinicians, researchers, technologists, to collaboratively advance medical knowledge and promote responsible innovation. These groups play a key role in ensuring that new healthcare interventions are effective, ethical, and aligned with professional standards.

The REALM platform supports these consortia by providing transparent, explainable evaluations of AI models, including tools such as XAI and synthetic data generation to help illuminate how decisions are made. With access to these insights, consortia can assess whether AI systems meet scientific, clinical, and ethical benchmarks and help guide their safe and trustworthy integration into healthcare practice.

5.1.12 Insurance Companies

Insurance companies play a pivotal role in the healthcare ecosystem by managing financial risk, controlling healthcare expenditures, and shaping access to care through coverage policies.

REALM supports these stakeholders by providing insights into the clinical effectiveness and economic value of AI-based medical technologies. Through access to transparent evaluation results, such as model performance and real-world outcomes, insurers can make informed, data-driven decisions about reimbursement strategies and policy coverage. This helps ensure that AI-enabled healthcare solutions deliver both cost-efficiency and improved patient outcomes.

5.2 Actors in the Medical Domain

In this section, we focus on the actors expected to interact with the REALM platform and provide a description of each. Figure 4 illustrates the actors identified using the methodology outlined in Section 2.3. These actors are anticipated to engage with the REALM platform either in general or as part of its use cases and pilot implementations. The identified actors include: (a) Clinicians / Carers, (b) Hospital Managers / Executives, (c) Policy Makers / Public Decision-Makers / Policy Advisors, (d) Notified Bodies, (e) Healthcare Providers, (f) Product Makers / Application Developers, (g) Principal Investigators / Researchers, (h) Patient Advocates, (i) HTA Patient and Public Involvement Coordinators, (j) Appraisal Committees, and (k) Entrepreneurs. Since an actor is defined as an external entity that interacts with a system to achieve a specific goal, it is important not only to describe these actors broadly but also to contextualize their objectives within the REALM platform. The following subsections provide a description of each actor along with the goals they aim to achieve through their interaction with REALM.

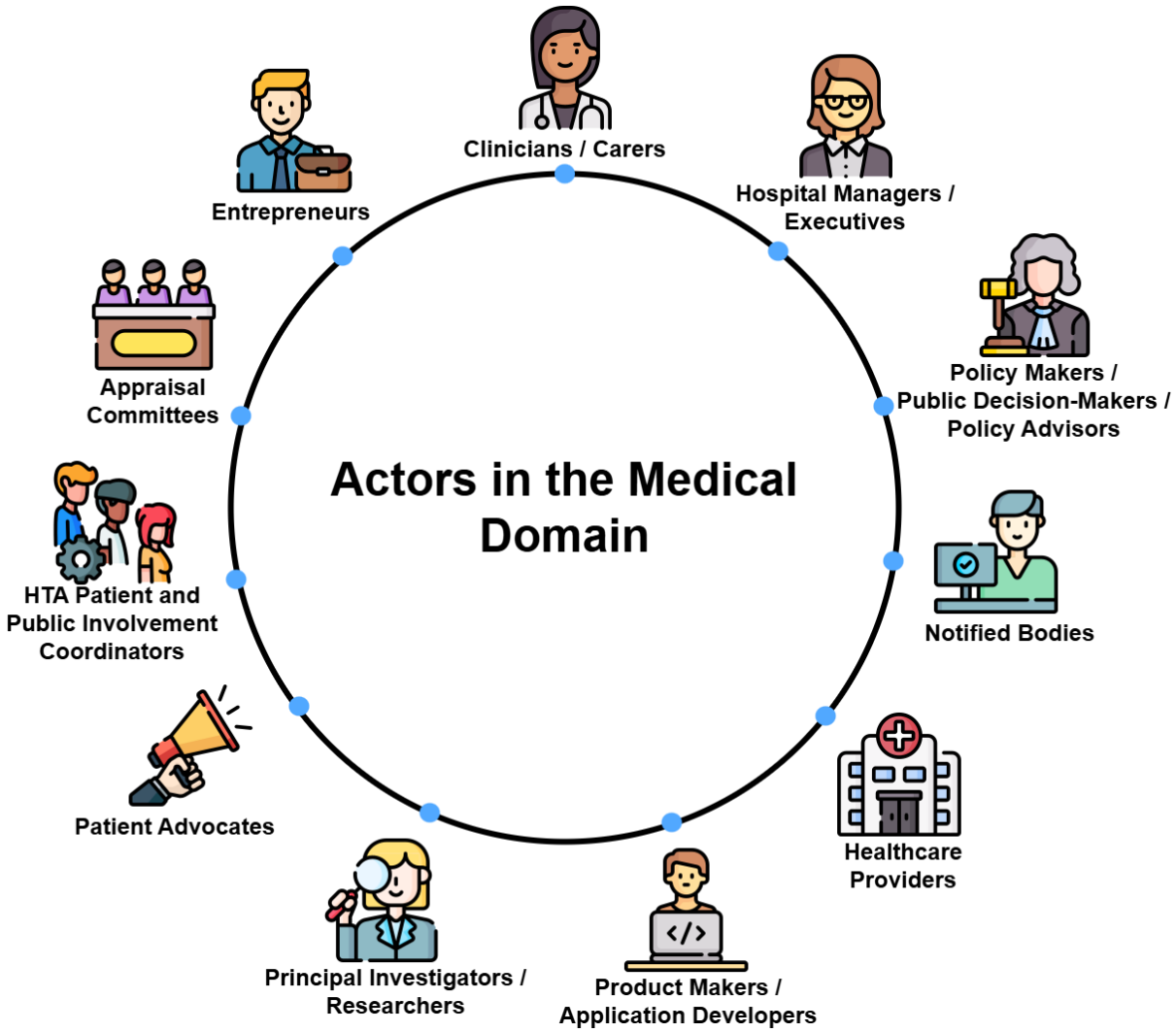


Figure 4: Actors in the Medical Domain

5.2.1 Clinicians / Carers

Clinicians and carers are individuals involved in supporting patient health and well-being. Clinicians are healthcare professionals responsible for diagnosing, treating, and managing medical conditions, while carers are non-professionals such as family members, friends, or volunteers who assist patients in daily life and provide emotional or practical support.

REALM supports both clinicians and carers by providing access to AI tools that have been rigorously evaluated for safety, fairness, and clinical relevance using privacy-preserving real-world data. The platform's XAI capabilities enhance transparency, helping clinicians understand the rationale behind model decisions. This fosters trust in AI-assisted recommendations and supports the responsible integration of AI into clinical workflows to improve patient care.

5.2.2 Hospital Managers / Executives

Hospital managers and executives oversee the strategic and operational functions of healthcare facilities, ensuring efficient service delivery, regulatory compliance, and high standards of patient care.

REALM supports these actors by providing transparent, regulation-informed evaluation results on AI technologies. By accessing evidence on model safety, efficacy, and compliance with healthcare standards, hospital executives can make informed decisions about adopting AI systems. This enables

them to safeguard patient and staff wellbeing while advancing the integration of trustworthy AI solutions in hospital settings.

5.2.3 Policy Makers / Public Decision Makers / Policy Advisors

Policymakers and public decision makers develop and implement healthcare policy to optimize system efficiency, accessibility and enhance patient outcomes.

With REALM, these actors have access to transparent, evidence-based evaluations of AI technologies, facilitating the creation of informed and effective policies. The platform's XAI features also promote ethical decision-making by clarifying how AI models operate, ensuring that patient safety, fairness, and equity remain central considerations in healthcare policy formulation.

5.2.4 Notified Bodies

Notified bodies are independent third-party entities that assess whether medical devices meet regulatory standards before they are approved for use.

REALM supports notified bodies by providing detailed, privacy-preserving assessment reports of AI models. Its XAI tools help clarify model decisions, enabling these bodies to efficiently verify that AI systems comply with safety, performance, and ethical requirements throughout the certification process.

5.2.5 Healthcare Providers

Healthcare providers, such as hospitals, clinics and medical practices, deliver direct medical care to patients and manage clinical services.

Through the REALM platform, providers can evaluate the real-world performance of AI models while maintaining data privacy and security. The platform enables them to assess the reliability, fairness, and clinical readiness of AI tools, supporting their safe integration into healthcare workflows to improve patient outcomes and operational efficiency.

5.2.6 Product Makers / Application Developers

Product makers and application developers design and create healthcare technologies, such as software and medical devices, designed to address clinical needs and improve patient care.

With REALM, these actors can evaluate AI models using privacy-preserving, decentralized data without compromising patient confidentiality. By leveraging performance metrics and XAI insights from the platform, developers can optimize their products for accuracy, reliability, and compliance enabling the creation of trusted, market-ready AI solutions aligned with regulatory and clinical standards.

5.2.7 Principal Investigators / Researchers

Principal investigators and researchers lead and conduct research that advances healthcare technology and information. They provide scientific integrity and analysis of results.

REALM supports these users by enabling the evaluation and refinement of AI models using privacy-preserving real-world data. Researchers can leverage tools such as XAI and synthetic data generation to explore model behaviour, assess performance, and ensure transparency. This enhances the scientific integrity of their work and contributes to impactful, trustworthy medical research.

5.2.8 Patient Advocates

Patient advocates are individuals with the insight and experience to support a broader population of patients living with a specific disease or health condition. They may or may not be affiliated with a formal organisation, but their work focuses on representing the interests of patient communities, particularly in ensuring that healthcare systems and innovations reflect patients' real needs and concerns.

REALM empowers patient advocates by providing insight into how AI models are evaluated, with a focus on fairness, safety, and transparency. Through the platform's XAI capabilities, advocates can better understand and communicate how AI tools impact patient care, ensuring that innovation remains aligned with patient interests and ethical standards.

5.2.9 HTA Patient and Public Involvement Coordinators

Patient and public involvement coordinators ensure that the voices of patients and the broader public are meaningfully integrated into HTAs. Their work helps align healthcare innovation with real-world needs, values, and concerns.

REALM supports them by providing clear, accessible evaluation results of AI technologies. With its explainability and transparency features, the platform facilitates inclusive and understandable assessments, helping to build public trust and enable meaningful engagement in healthcare decision-making.

5.2.10 Appraisal Committees

Appraisal committees assess the clinical and cost-effectiveness of healthcare technologies, playing a vital role in determining which innovations should be adopted and funded within health systems.

REALM provides such committees with transparent, evidence-based evaluations of AI models, including metrics on safety, fairness, and performance. With the platform's XAI features, committee members can better understand how AI systems reach decisions, enabling ethically grounded, outcome-focused judgments on technology adoption.

5.2.11 Entrepreneurs

Healthcare entrepreneurs are at the forefront of innovation, developing AI-driven solutions to enhance care delivery and improve patient outcomes.

The REALM platform supports them by offering robust tools for testing and refining AI products in a privacy-preserving environment. With access to XAI, synthetic data generation, and transparent performance evaluations, entrepreneurs can optimize their models, ensure regulatory readiness, and bring reliable, ethically aligned products to market more efficiently.

6 Standard Data Quality Framework

During the course of the REALM project, we incorporated insights from the EU-funded project QUANTUM[4], which aims to develop a common labelling system across Europe for assessing and communicating the quality and utility of datasets. QUANTUM consortium published a comprehensive set of Data Quality and Utility Dimensions, which we adopted and operationalized in the REALM project. These dimensions were used to assess the data quality across the five demonstrators within REALM. This led to the development of a generic data quality evaluation interface, intended to be used in use cases beyond the scope of REALM.

6.1 Evaluation Dimension

This section outlines the full set of 24 data quality dimensions adopted from QUANTUM [6], categorized into four major groups. In Table 5, for each dimension, we provide a description, its corresponding category, a mapping to the Standard Model Quality Framework (SMQF) of REALM, and whether it is evaluated through quantitative or qualitative methods. Of these, 11 dimensions were assessed using quantitative metrics, while 13 were evaluated qualitatively. The quantitative dimensions are the ones that can be assessed automatically, while the qualitative dimensions are evaluated by a user questionnaire. Details about quantitative evaluations are discussed in Section 6.1.1 and qualitative evaluations are described in Section 6.1.2.

To ensure consistency and facilitate interoperability between the data and model evaluation processes, we established explicit relation between each data quality dimension and relevant aspects of the SMEF, developed in WP3. This cross-mapping allows us to create a full-cycle evaluation, from data acquisition, curation, etc. to model development and its validation. For example, a dataset with limited accessibility or poor documentation on data access processes, negatively impacts *Data Governance* and *Transparency* of the model. Similarly, datasets with insufficient Population *Representativity* may introduce bias and compromise the *Fairness* and *Technical Performance* of models trained on such data.Through such mapping process, we identified how specific data quality dimensions may affect model evaluation criteria such as:

- **Technical Performance**: Influenced by 10 SDQF dimensions including Accuracy, Precision, and Data Completeness.
- **Data Governance**: Linked to 8 dimensions, including Accessibility, Metadata Granularity, and Reliability. While these dimensions contribute indirectly to model evaluation, their alignment is more strongly associated with the FAIR Data Principles to ensure that data is Findable, Accessible, Interoperable, and Reusable, which in turn supports AI model evaluation.
- **Transparency** and **Accountability**: Supported by dimensions like Availability, Trustworthiness, and Compliance.
- **Fairness**: Directly connected to Population Coverage and Population Representativity.
- **Interoperability** and **Robustness**: Informed by Semantic Coherence and Temporal Comparability.

This mapping highlights that data quality is not an isolated concern, but a foundational element that shapes model fairness, interpretability, and performance. By aligning SDQF and SMQF at the dimension level, the REALM project ensures that weaknesses or risks in data quality may be directly traced to

[4]QUANTUM: An EU-funded project in the context of EHDS that aims to create a common label system for Europe that guarantees the quality and utility of datasets for scientific and health innovation purposes - https://quantumproject.eu/about-us/.

potential model-level impacts, enabling a full-cycle quality assurance and continuous improvement process.

Dimensions	Category	Relation to SMEF	Quantitative or Qualitative	Description
Accessibility	C1: Access and provision	Data Governance, Transparency	Qualitative	The degree to which data is easily obtainable, clearly presented in a way that can be understood and available in a suitable format
User permissiveness	C1: Access and provision	Data Governance	Qualitative	The degree of permissiveness that licences and requirements for ethical and data governance approval grant to a user for the intended use.
Population Coverage	C2: Coverage	Fairness, Technical performance	Quantitative	Coverage rate of the population in question.
Population representativity	C2: Coverage	Fairness, Technical performance	Quantitative	The degree to which the data adequately represent the population in question.
Metadata granularity	C3: Data Documentation	Data Governance	Quantitative	Availability, comprehensiveness and level of detail of metadata that help users understand the data being used.
Availability	C3: Data Documentation	Data Governance; Transparency; Accountability	Qualitative	The degree to which data is present, obtainable and ready for use.
Compliance	C3: Data Documentation	Accountability	Qualitative	The degree to which data has attributes that adhere to standards, conventions or regulations in force and similar rules relating to data quality in a specific context of use.
Data origin provenance	C3: Data Documentation	Data Governance; Transparency	Qualitative	a description of the source of the original or raw data prior to any subsequent processing or transformation, including context, purpose, method and technology of data generation.

Trustworthiness	C3: Data Documentation	Data Governance; Transparency	Qualitative	The degree to which context information fosters trust in the data, e.g. by documenting agents involved in the provenance of data, data validation routines, the provenance of available provenance information etc.
Accuracy	C4: Technical quality	Technical performance	Quantitative	The degree to which data correctly describes what it was designed to measure.
Coherence	C4: Technical quality	Technical performance	Quantitative	The degree to which aspects relevant for analysability are used consistently throughout a dataset or across different datasets or versions of one dataset.
Format coherence	C4: Technical quality	N/A	Quantitative	The degree to which formats are used consistently throughout a dataset or across different datasets or versions of one dataset, improving analysability.
Semantic coherence	C4: Technical quality	Interoperability; System robustness	Quantitative	The degree to which the same value means the same throughout a dataset or across different datasets or versions of one dataset, improving analysability
Comparability	C4: Technical quality	N/A	Qualitative	The consistent use of definitions, standards and methods facilitates comparison of data.
Temporal comparability	C4: Technical quality	Interoperability	Qualitative	How the consistent use of definitions, standards and methods facilitates comparison of data over time.
Completeness	C4: Technical quality	Transparency; Accountability	Quantitative	The degree to which all required information is present in a particular dataset.
Data completeness	C4: Technical quality	Technical performance	Quantitative	The degree of data attributes being present in a dataset without reference to specific data values.
Consistency	C4: Technical quality	Technical performance	Qualitative	The degree to which data has attributes that are free

				from contradiction and are coherent with other data in a specific context of use. It can be either or both among data regarding one entity and across similar data for comparable entities.
Relational validity	C4: Technical quality	Technical performance	Qualitative	The degree to which a dataset conforms to the data model.
Syntactic validity	C4: Technical quality	Technical performance	Qualitative	The degree to which data conforms to the syntax (e.g. format, type, range) of its definition.
Reliability	C4: Technical quality	Data Governance	Qualitative	Reliability refers to how closely the data reflect what it was designed to measure and is this consistent over time.
Data dictionary granularity	C4: Technical quality	Data Governance	Qualitative	Availability, comprehensiveness and level of detail of the data dictionary
Relational consistency	C4: Technical quality	Technical performance	Quantitative	The degree to which data has attributes that are free from relational contradiction, i.e. each entity shall be represented by at most one identifiable data unit, or by multiple but consistent identifiable units.
Precision	C4: Technical quality	Technical performance	Quantitative	The degree of approximation by which data can represent reality (e.g. numerical resolution or the number of categories).

Table 5: List of data quality dimensions with their categories, as adopted from QUANTUM [6].

The Table provides their relation to the dimensions presented in the REALM Standard Medical Device Software Evaluation Framework. N/A indicates the absence of explicit relation between the dimension of data quality framework and those of software evaluation framework

6.1.1 Quantitative Dimensions

A key consideration in assessing the suitability of medical data for evaluating AI-based MDSW is the extent to which the evaluation can be automated. To facilitate such automation, we focus on evaluation criteria and dimensions that are sufficiently general and broadly applicable across diverse datasets. In this context, “automated” refers to the use of programmatically implemented quantification methodology that takes a given dataset as input and evaluates it against a specific characteristic, or “dimension”, as defined within the data quality framework.

It is important to note that medical datasets can vary significantly based on the modality, whereby they could include images, time series, tabular data, or text, such as those within the Electronic Health Records (EHR), or combinations thereof. Due to inherent differences between these modalities, it is often neither obvious nor feasible to define a single automated evaluation method for a specific dimension that can be uniformly applied across all of them.

To maintain generalizability without compromising practicality, we adopt a balanced approach. While we aim for automated methods that are broadly applicable, we also recognize the need for trade-offs to ensure the framework remains realistic, usable, and understandable, especially for medical domain experts.

Accordingly, we focus on three commonly encountered modalities in medical datasets: images, time series, and tabular data. This selection aligns with the use cases piloted under the REALM project.

Table 6 presents the quantitative dimensions included in the proposed SDQF framework. which are automatically applied to the examined datasets using custom-developed scripts. In addition to the name and definition of each dimension, the table also outlines how these dimensions translate into specific checks that can be automatically performed on datasets across the three targeted modalities.

Dimension	Description	Image Data	Tabular Data	Time Series Data
Population Representativity	The degree to which the data adequately represent the population in question.	Check each class has a similar number of samples.	Check each class has a similar number of samples.	N/A
Metadata Granularity	Availability, comprehensiveness, and level of detail of metadata that help users understand the data being used.	Check if there are available metadata for each patient.	Check if there are available metadata for each patient.	Check if there are available metadata for each patient.
Accuracy	The degree to which data correctly describes what it was designed to measure (the “real world” entity)	CT-scan slices are of the same dimension.	Common features (age, height) are within expected ranges.	Common features (age, height) are within expected ranges.
Coherence	The degree to which aspects relevant for analyzability are used consistently throughout a dataset or across different datasets or versions of one dataset.	Check if all images have the same number of channels.	Check that for each feature all samples adhere to the same data type.	Check that for each feature all samples adhere to the same data type.
Semantic Coherence	The degree to which the same value means the same thing throughout a dataset or across different datasets or versions of one dataset,	Check for duplicate slices/images.	Check for columns with the same name but different values.	Check for columns with the same name but different values.

	improving analysability.			
Completeness	The degree to which all required information is present in a particular dataset.	Check for missing pixels.	Check the percentage of missing values.	Check the percentage of missing values.
Relational Consistency	The degree to which data has attributes that are free from relational contradiction, i.e., each entity shall be represented by at most one identifiable data unit, or by multiple but consistent identifiable units.	N/A	Check for duplicate rows.	Check for duplicate rows.

Table 6: SDQF Quantitative Dimensions with their implementations for specific modalities.

Based on the information presented in Table 6, several key observations can be made. Among the seven quantitative dimensions, there are two dimensions (*population representativity, relational consistency*) for which no quantification methodology can be applied, for a specific data modality. For the *population representativity* dimension, no implementation is available for time series data. This is primarily because it is not straightforward to define discrete classes within a time series, particularly when attempting to extend the methodology originally developed for images and tabular data. Similarly, for the *relational consistency* dimension, there is no quantification methodology for image data, as identifying duplicates within images cannot be objectively defined in a way that is both practical and meaningful.

Despite these exceptions, three of the quantitative dimensions share a similar quantification methodology across all modalities. Furthermore, six of the dimensions use the same methodology for both tabular and time series data, which reflects the close relationship between these two data types. In contrast, four dimensions exhibit methodological differences between image data and the other two modalities. Such distinctions underscore the fundamentally different nature of image data and the need for adapting evaluation metrics to best match their respective unique characteristics.

Finally, it is important to note that the definitions of the quantitative dimensions in the SDQF framework are intentionally kept flexible. Rather than prescribing strict implementation details, the framework allows for a variety of methodological approaches that can achieve the intended evaluation goals. In practice, we have chosen a few straightforward methods to limit complexity. This decision helps ensure that the results remain accessible and interpretable, particularly for users with limited or no background in data science, such as many clinicians and other healthcare professionals.

6.1.2 Qualitative Dimensions

The dimensions listed in Table 7 are evaluated using qualitative assessment methods, as they involve characteristics that are often subjective, context-dependent, or not easily reducible to numerical metrics. For instance, unlike quantitative indicators such as *Population Representativity* or *Completeness*, the dimensions such as *Accessibility*, *Compliance*, *Trustworthiness*, and *Data Origin Provenance* require assessment based on subjective interpretation of the underlying documentation, availability of metadata, licensing conditions, or the presence of procedural information. To support consistent evaluation, we drafted a structured list of guiding questions and defined ordinal rating scale

(from 1 to 5), with each level anchored by a clear criteria. While the resulting scores are ordinal, they remain interpretive rather than derived from direct measurement, which justifies their classification as qualitative.

Accessibility	Questions	Rating
Accessibility	To what degree is the data easily obtainable, clearly presented, understandable, and available in a suitable format?	1. Data cannot be located or retrieved. 2. Data found only after substantial effort. 3. Data located with moderate effort; format occasionally unclear. 4. Data easily located; format mostly clear. 5. Data easily accessible; format crystal-clear and user-friendly.
Use permissiveness	To what degree are licenses and governance requirements permissive for ethical and approved use of the data?	1. Use prohibited or severely restricted. 2. Multiple heavy constraints; licenses vague. 3. Some permissions granted but with non-trivial hoops. 4. Minor restrictions; licenses clear and largely permissive. 5. Fully open use; licenses explicitly encourage broad reuse.
Availability	To what degree is the data present, obtainable, and ready for use?	1. Data unavailable or offline. 2. Downloadable link is provided but download fails or broken links. 3. Occasional access issues without clear instruction or with formats issues. 4. Mostly stable and clear downloadable links with common formats. 5. Hosted on persistent, reliable repository with open, standard formats.
Compliance	To what degree does the data adhere to relevant standards, conventions, and regulations In force and similar rules relating to data quality in a specific context of use.	1. No adherence to any standards or regulations. 2. Rough or partial compliance with many gaps. 3. Met with core standards with some edge cases non-compliant. 4. Satisfy all main regulations with minor deviations. 5. Fully compliant with all relevant standards/laws.
Data origin provenance	To what degree is the source, context, purpose, method, and technology of data generation documented?	1. No source or collection details. 2. Only source name is provided with no methods or context. 3. Basic method description is provided but dates, operators, ogranizations, and other key components are missing 4. Methods, purpose, dates, and other key components are provided but missing minor context. 5. Complete provenance is provided with detailed descriptions of method, system, dates, agents, data processing process.
Trustworthiness	To what degree does documentation of agents, validation routines, and	1. No information about data origin, agents, or validation. 2. Only some provenance or agent names mentioned, but no details on processes.

	provenance foster trust in the dataset?	3. Key agents and data-validation steps are named, but provenance chains are incomplete. 4. Clear documentation of most agents, validation routines, and where provenance logs exist. 5. Comprehensive records of all agents, end-to-end validation processes, and detailed provenance metadata.
Comparability	To what degree do definitions, standards, and methods facilitate comparison with other datasets?	1. Cannot be compared with any other dataset. 2. Use few shared standards and definitions; limited comparability. 3. Use some common standards and definitions; partial comparison possible in a limited community 4. Use most possible common definitions and standards to facilitate easy comparison with other datasets in a broader community 5. Fully aligned with the common definitions and standards and possible to compare with any other standard data in and across community
Temporal comparability	To what degree do definitions, standards, and methods remain consistent over time for longitudinal comparison?	1. Methods and protocols change every period without any documentation 2. Frequent changes in methods and protocol with limited versioning 3. Occasional but necessary methods and protocol changes minor versioning. 4. Stable methods and protocol with clear versioning. 5. Fully stable in methods and protocol over time.
Consistency	To what degree is the data free from internal contradictions and logically coherent?	1. Logical contradictions pervasive. 2. Frequent logical errors in data attributes (age>200 yrs old, male with pregnancy label) 3. Occasional inconsistencies in data attributes 4. Rare inconsistencies. 5. Fully consistent throughout.
Relational validity	To what degree do the data's internal, external, and relational aspects conform to their intended definitions?	1. Schema ignored; data free-form. 2. Many deviations from intended data model. 3. Mostly conforms to intended data model with a few mismatches. 4. Schema largely respected. 5. Strict and systematic adherence to data/model design.
Syntactic validity	To what degree does the dataset conform to its intended relational/data model?	1. Formats and types frequently invalid. 2. Many syntactic errors with data format and types 3. Some syntactic errors with data format and types 4. Only a few invalid entries or syntactic errors 5. All entries parse correctly with correct syntax
Reliability	To what degree does the data conform to syntax requirements (format, type, allowable range)?	1. Data fluctuate wildly; repeated measures under identical conditions give very different results. 2. Noticeable drifts or inconsistencies over time; occasional repeats mismatch substantially. 3. Generally consistent but with some time-based noise or small unexplained shifts.

		4. Measurements are stable over time with only rare, minor deviations. 5. Data perfectly reproduce intended measures across repeated collections; no temporal variation.
Data dictionary granularity	To what degree does the data consistently reflect what it was designed to measure over time?	1. No dictionary or definitions. 2. Field names only; no details. 3. Basic definitions; missing examples/units. 4. Detailed definitions; minor gaps. 5. Comprehensive dictionary with examples, statistics, and usage notes.

Table 7: SDQF Qualitative Dimensions as defined within REALM, with description of their respective ordinal rating scales.

6.2 Indicative Results

To better demonstrate the practical applicability of the proposed SDQF framework, this subsection presents the implementation of SDQF and its resulting outcomes as applied to a real-world medical dataset. Specifically, we use a subset of the dataset associated with REALM's Use Case 4, which focuses on employing AI models for patient risk stratification related to the medical condition of Chronic Obstructive Pulmonary Disease (COPD) and asthma. The dataset is structured in tabular form. Moreover, this dataset is representative of use case that is potentially suitable for evaluating AI-based MDSW within the broader REALM platform.

To facilitate the practical use of the proposed SDQF framework – a standalone tool - and to more effectively demonstrate its applicability in real-world scenarios, a demo application has been developed using Streamlit. Figure 5 shows the application's home page, where users can select from a list of REALM use cases relevant to their application and upload their data along with the associated metadata.

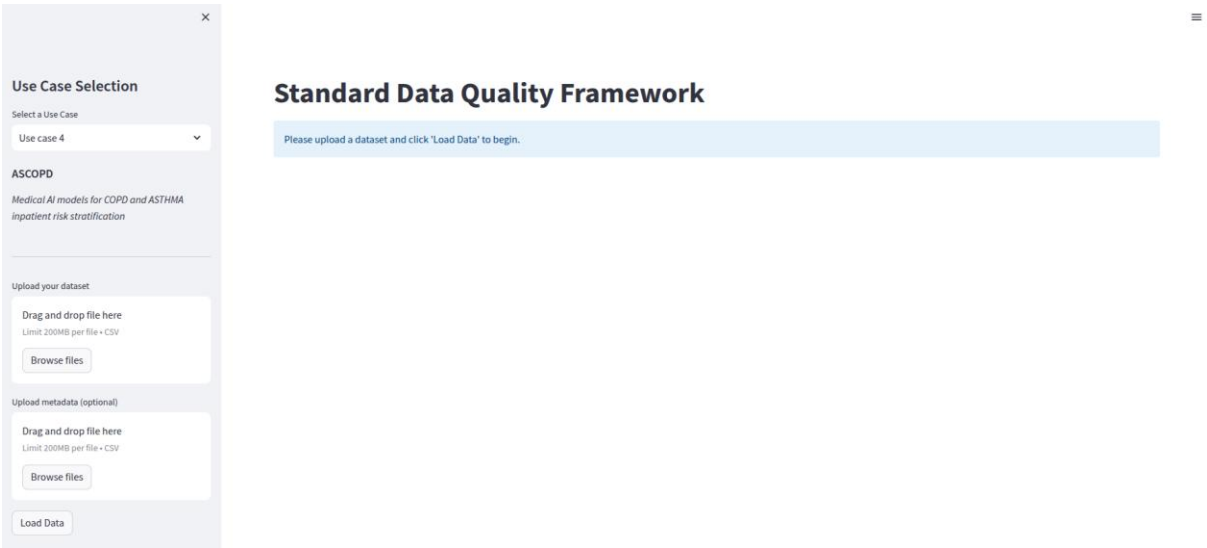
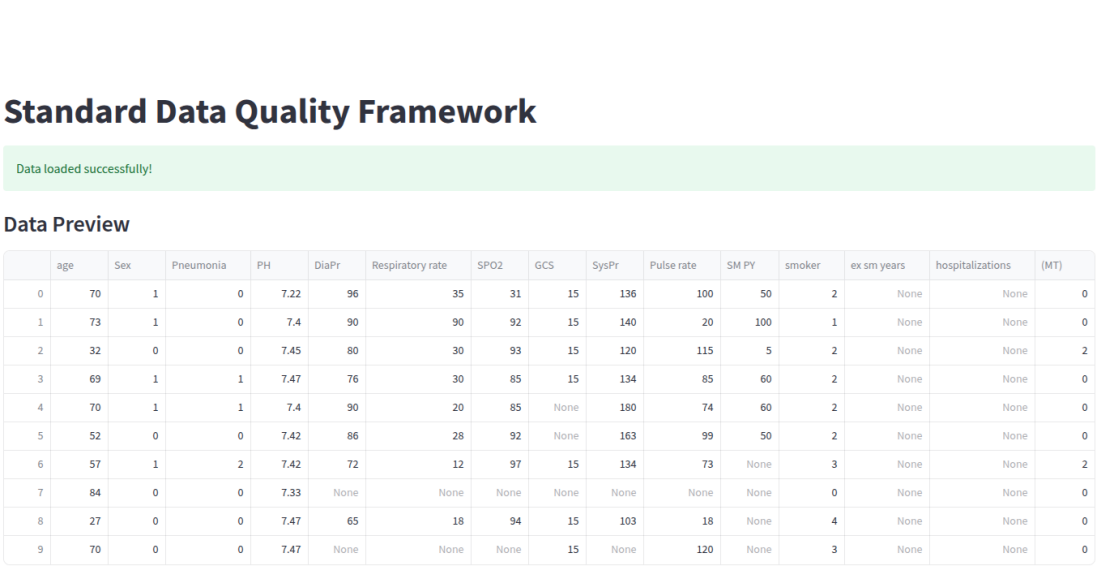


Figure 5: Homepage of the SDQF user interface

After the data is uploaded, an initial preview of the dataset is displayed for visual inspection, as shown in Figure 6.



	age	Sex	Pneumonia	PH	DiaPr	Respiratory rate	SPO2	GCS	SysPr	Pulse rate	SM PY	smoker	ex sm years	hospitalizations	(MT)
0	70	1	0	7.22	96	35	31	15	136	100	50	2	None	None	0
1	73	1	0	7.4	90	90	92	15	140	20	100	1	None	None	0
2	32	0	0	7.45	80	30	93	15	120	115	5	2	None	None	2
3	69	1	1	7.47	76	30	85	15	134	85	60	2	None	None	0
4	70	1	1	7.4	90	20	85	None	180	74	60	2	None	None	0
5	52	0	0	7.42	86	28	92	None	163	99	50	2	None	None	0
6	57	1	2	7.42	72	12	97	15	134	73	None	3	None	None	2
7	84	0	0	7.33	None	None	None	None	None	None	None	0	None	None	0
8	27	0	0	7.47	65	18	94	15	103	18	None	4	None	None	0
9	70	0	0	7.47	None	None	None	15	None	120	None	3	None	None	0

Figure 6: Dataset preview in the SDQF application

Next, the application prompts users to provide their inputs related to the qualitative dimensions. These responses must be manually entered by the user, as they cannot be automatically extracted from the dataset. As described in Section 6.1.2, users are required to complete the questionnaire, which includes definitions for each qualitative dimension, along with a set of predefined set of options for users to choose from. To enhance user experience, the demo application offers two methods for completing the questionnaire:

1) The questionnaire is embedded within the demo application, allowing users to complete it directly in the application's user interface. The full list of questions pertaining to qualitative dimensions can be found in the Annex: SDQF Qualitative Dimensions Questionnaire.
2) Alternatively, users can download the questionnaire as a JSON template, complete it locally, and then upload their responses back into the application. Figure 7 shows the interface for performing this action, while Figure 8 displays the structure of the JSON template where users can enter their responses related to the qualitative dimensions.

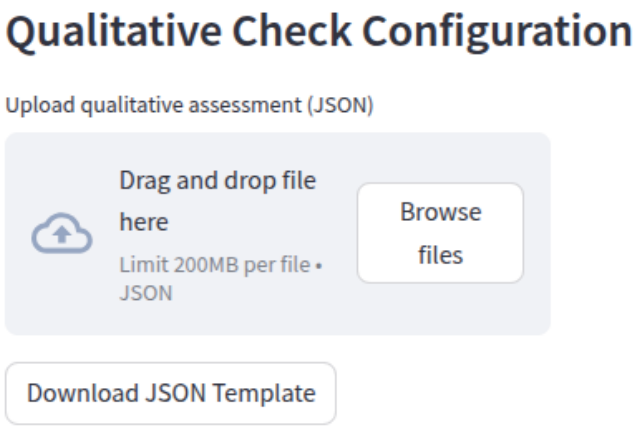


Figure 7: Interface for downloading/uploading the qualitative dimensions questionnaire

```
{
  "qualitative_assessment": {
    "accessibility": 2,
    "use_permissiveness": 3,
    "availability": 1,
    "compliance": 1,
    "provenance": 4,
    "trustworthiness": 4,
    "consistency": 5
  },
  "instructions": "Replace 0 with your score (1-5) for each dimension"
}
```


Figure 8: Filled JSON template for the qualitative dimensions

After collecting the responses for the qualitative dimensions, the next step involves automatically deriving the results for the quantitative dimensions. As outlined in Table 6, for tabular datasets, such as the one used in this example use case of COPD, the user must first specify the target column, as well as indicate whether the dataset includes features for age and height. This information is required because, to compute the population representativity metric, the number of samples per class must be known, which depends on correctly identifying the target feature. Additionally, the dimension for measuring accuracy, assesses whether common features like age and height, fall within expected value ranges. Therefore, the user must indicate the whether these features are relevant in their dataset, in order to enable this assessment.

Once the pre-requisites of specific columns are defined, the evaluation of the quantitative dimensions is performed. The final results for both the quantitative and qualitative dimensions are then presented to the user. Figure 9 shows the visualizations generated to provide a clear overview of the results.

Specifically, two radar charts are produced, one for the quantitative dimensions and one for the qualitative dimensions. The results are mapped to scores ranging from 1 to 5, with higher values indicating better dataset quality. In addition, an aggregated overall score is provided separately for the quantitative and qualitative dimensions.

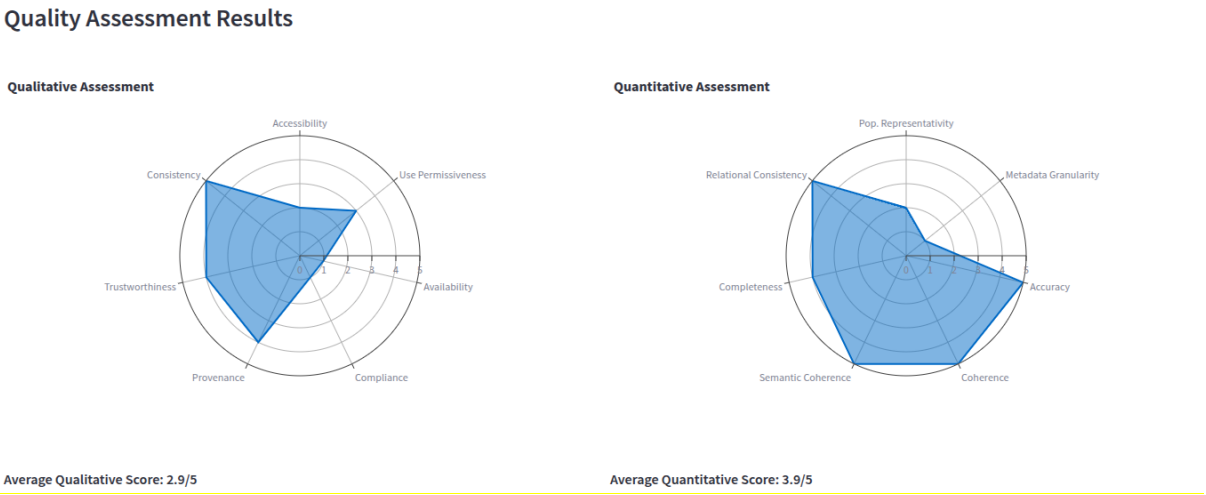


Figure 9: Radar diagrams illustrating the data quality assessment based on the SDQF

Finally, the detailed scores for each individual evaluation dimension, both quantitative and qualitative, are also presented in Figure 10 and Figure 11, respectively.

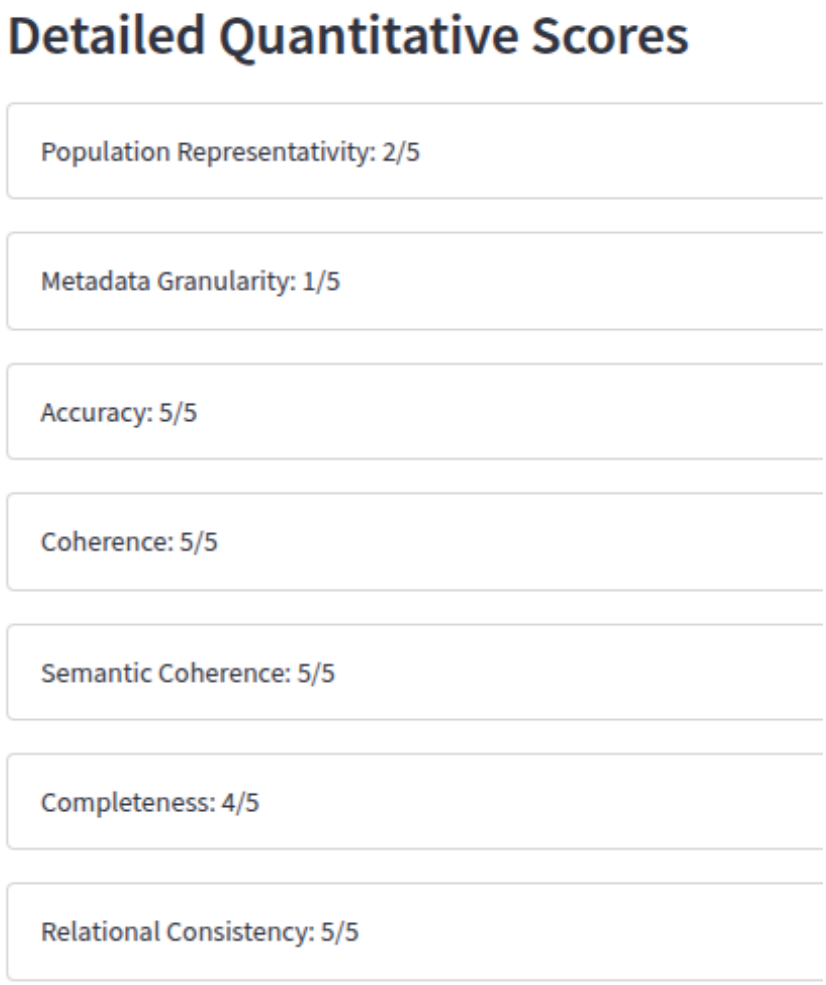


Figure 10: Overview of the obtained quantitative scores

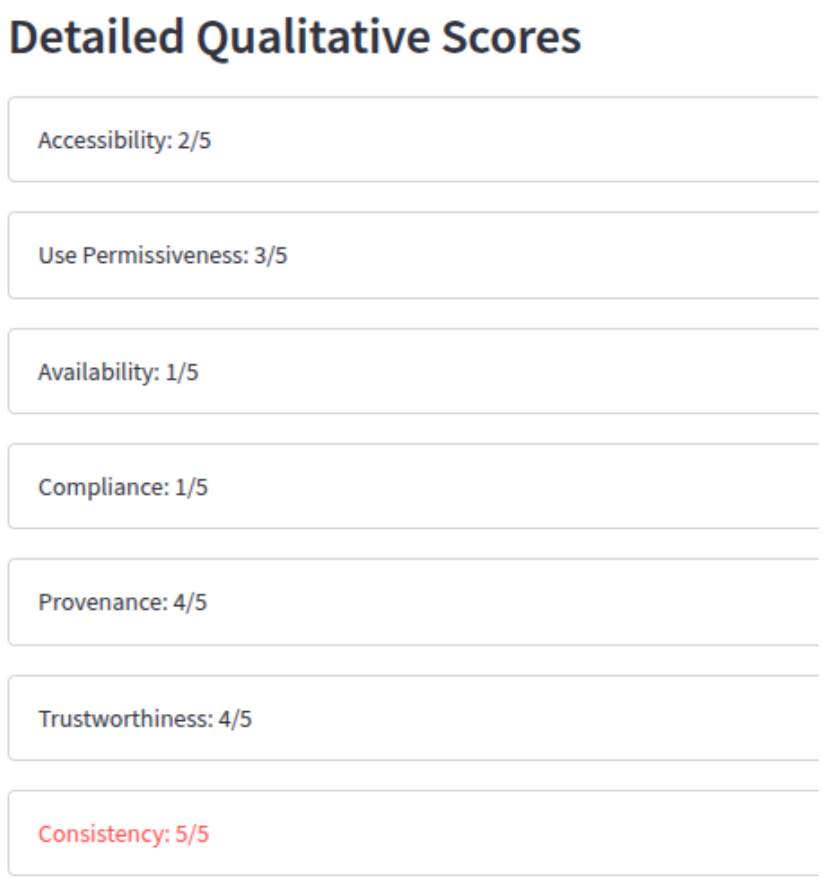


Figure 11: Overview of the obtained qualitative scores

Overall, the proposed SDQF framework, when combined with an interactive interface, demonstrates potential for practical use in real-world scenarios. It offers a straightforward and user-friendly approach for conducting a comprehensive evaluation of the provided dataset. The application's design is guided by the principles of usability and explainability, aiming to improve ease of use and enhance the interpretability of the results.

For example, the results for the quantitative dimensions clearly indicate that the dataset suffers from significant class imbalance, as reflected by the low score in the population representativity dimension. Similarly, the low score in the metadata granularity dimension highlights the absence of associated metadata for the dataset which is consistent with the fact that no metadata were uploaded by the user.

7 Conclusion

The development of the SDQF represents a significant milestone in formalizing and supporting the overall advancement of the REALM platform. It lays the foundation for establishing REALM as a pioneering and effective solution for the evaluation of AI-based MDSW. The work presented in this deliverable has successfully defined the key requirements that must be met both during development and post-launch. Additionally, it provides a deeper understanding of the stakeholders and user groups expected to interact with the platform, enabling a design that is better aligned with their specific needs.

This deliverable presents several key achievements, including the **elicitation of REALM's user requirements across three major categories**: functional user requirements, security and privacy requirements, and ethical, privacy, and data protection requirements. In addition, **system requirements were clearly defined based on the needs of each component within the overall REALM architecture.** This has supported efficient development while minimizing unforeseen risks related to resource planning within the project.

Furthermore, a comprehensive literature review, combined with insights gathered through the dissemination of questionnaires, has contributed to a deeper understanding and more accurate mapping of the stakeholders and actors expected to engage with the REALM platform. This has been instrumental in designing and developing the platform to more effectively meet the needs of its intended users.

Moreover, this deliverable introduced a SDQF framework for evaluating medical datasets intended for use in the assessment of AI-based MDSW. The framework builds upon a pioneering work in the community and **incorporates a range of evaluation methodologies that enable a more holistic and comprehensive analysis of dataset quality**. In doing so, REALM not only facilitates the evaluation of AI-based MDSW but also enhances the credibility of those evaluations by first assessing the quality of the underlying data.

Overall, the elicitation of user and system requirements, the identification of relevant stakeholders and actors, and the introduction of the SDQF framework together provide a strong foundation for defining the REALM architecture. This foundation ensures that the platform aligns with user needs and delivers credible results, while also considering its position within the broader ecosystem of AI applications in the medical sector.

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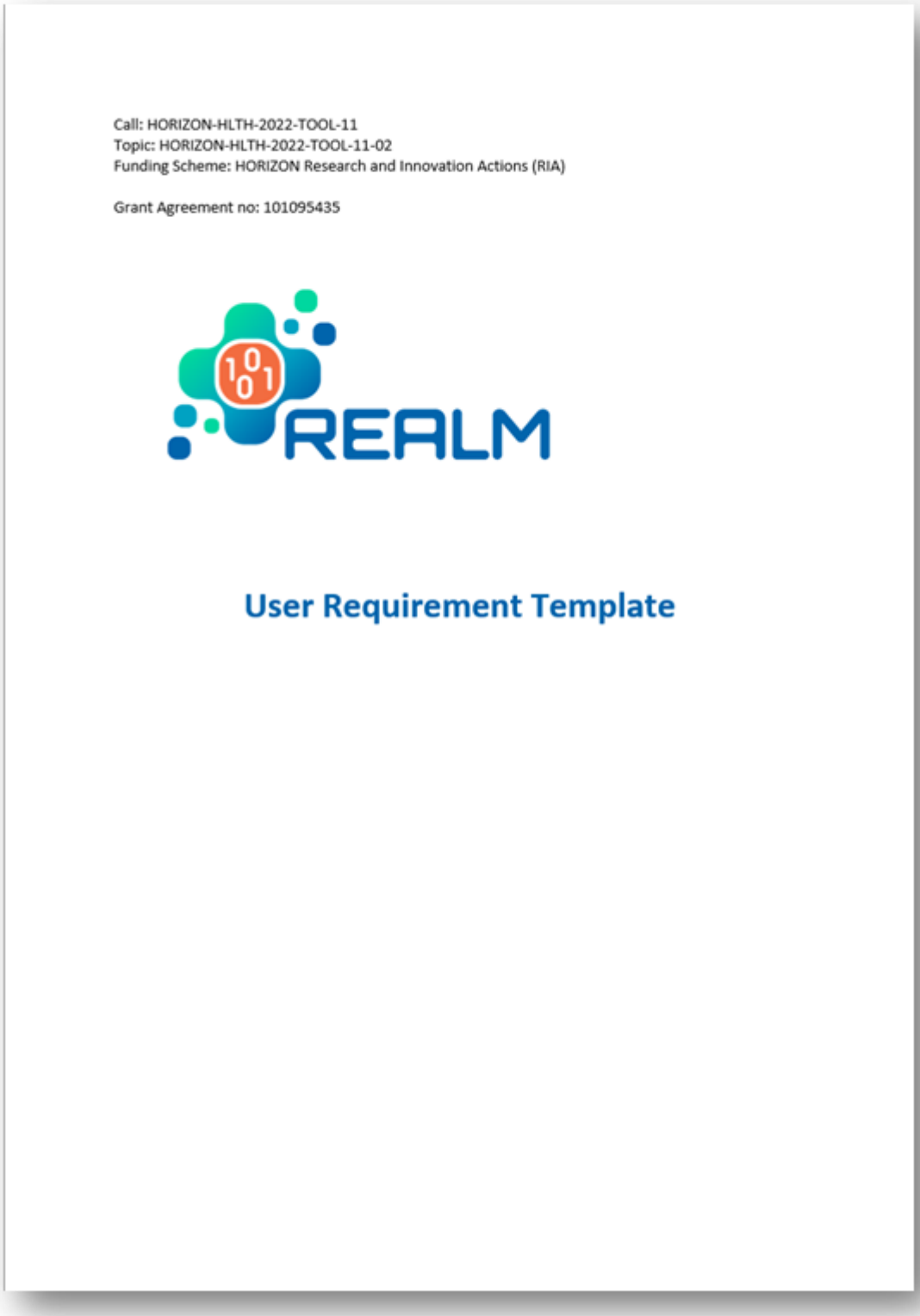
9 Annex: REALM User Requirements Template



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REALM

User Requirement Template

Table of Contents

List of Abbreviations and definitions

The abbreviations and definitions used in the deliverable are based on the AIDAVA Glossary [ref].

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Executive Summary

This document is a template designed to elicit information about the user requirement. In particular, this document receives information about the User, Security & Privacy and Ethical requirements, for both the REALM platform and the data that it handles. These requirements are going to be translated to Functional and Non-Functional Requirements for the platform.

1 Example

1.1 User Requirements

User Requirement ID	User Requirement Title	Description	Type	Priority
REALM_UR_UC1_01	Presenting results	The REALM system must be able to provide, present and visualise the results of processes to the RIANA Dashboard.	Functional	High
REALM_UR_ UC1_02	Ask for approval	The REALM system must ask for the approval of the administrator, when necessary, before proceeding to interventions on the infrastructure.	Functional	High

1.2 Security & Privacy Requirements

User Requirement ID	User Requirement Title	Description	Type	Priority
REALM_SPR_UC1_01	Database security	All databases where personal data are stored in the REALM System must be encrypted, access to them must be restricted and authentication required to access such data.	Functional	High
REALM_SPR_UC1_02	Minimum Systems Configuration	The REALM System shall install only updates and functionalities which are essential for the functioning and security of the system.	Non-Functional	High

1.3 Ethical Requirements

User Requirement ID	User Requirement Title	Description	Type	Priority
REALM_ER_UC1_01	Unbiased Database	All databases in REALM must be evaluated, ensuring these is no unwanted bias in the data	Non-Functional	High

2 User Requirements

User Requirement ID	User Requirement Title	Description	Type	Priority
<Please provide an identifier based on the following format [*UR_UCX_XX where X denotes the number of the use case/pilot, while XX denotes a sequence number*]>	<Please provide a short title [*text*]>	<Please provide a description of the requirement [*text*]>	<Functional, or Non-Functional>	<Low, Medium, High>

3 Security & Privacy Requirements

User Requirement ID	User Requirement Title	Description	Type	Priority
<Please provide an identifier based on the following format [*UR_UCX_XX where X denotes the number of the use case/pilot, while XX denotes a sequence number*]>	<Please provide a short title [*text*]>	<Please provide a description of the requirement [*text*]>	<Functional, or Non-Functional>	<Low, Medium, High>

4 Ethical Requirements

User Requirement ID	User Requirement Title	Description	Type	Priority
<Please provide an identifier based on the following format [*UR_UCX_XX where X denotes the number of the use case/pilot, while XX denotes a sequence number*]>	<Please provide a short title [*text*]>	<Please provide a description of the requirement [*text*]>	<Functional, or Non-Functional>	<Low, Medium, High>

Funded by the European Union

10 Annex: REALM System Requirements Template

Call: HORIZON-HLTH-2022-TOOL-11
Topic: HORIZON-HLTH-2022-TOOL-11-02
Funding Scheme: HORIZON Research and Innovation Actions (RIA)

Grant Agreement no: 101095435

System Requirement Template

Contractual Submission Date: dd/mm/yyyy

Actual Submission Date: dd/mm/yyyy

Responsible partner: Px: xxx (partner name)

Grant agreement no.	101095435
Project full title	REALM - Real-world-data Enabled Assessment for health regulatory decision-Making

Deliverable number	Dx.x
Deliverable title	xxx
Type[1]	xx
Dissemination level[2]	xx
Work package number	xx
Work package leader	Px-xx
Author(s)	Name (partner name) [e.g. Gabrijela Radić (EURICE)] xxx xxx
Keywords	

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency (HaDEA).

Neither the European Union nor the granting authority can be held responsible for them.

Document History

Version	Date	Description
Vx		
Vx		
Vx		

[1] **Type**: Use one of the following codes (in consistence with the Description of the Action):
R: Document, report (excluding the periodic and final reports)
DEM: Demonstrator, pilot, prototype, plan designs
DEC: Websites, patents filing, press & media actions, videos, etc.

[2] **Dissemination level**: Use one of the following codes (in consistence with the Description of the Action)
PU: Public, fully open, e.g. web
SEN: Sensitive, limited under conditions of the Grant Agreement

Table of Contents

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Executive Summary

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1 Example

1.1 System Requirements

The system Requirements identify general needs of the software, hardware and components from the REALM platform.

Requirement ID	Component	Requirement Title	Description	Functional	Non-Functional	Priority
REALM_SR _01	XAI Framework	Computation intensive Task	The REALM system must support the execution and orchestration of computation intensive task	√		High

1.2 Storage Requirements

Here we define the storage requirements of the respective REALM subsystem.

Requirement ID	Component	Requirement Title	Description	Functional	Non-Functional	Priority
REALM_STR_01	XAI Framework	SQL Database Support	The REALM platform must support SQL database for metadata persistence.	√		High
REALM_STR_02	XAI Framework	Image Persistence	The REALM System must support the persistence of image files	√		High
REALM_STR_02	XAI Framework	Model Persistence	The REALM System must support the persistence models/binary files that will be produced from the XAI component.	√		High

1.3 Visualisation Requirements

The Visualisation Requirements identify the needs of the respecting component in respect to visualization that need to be projected in a dashboard/interface.

6

Requirement ID	Component	Requirement Title	Description	Functional	Non-Functional	Priority
REALM_VR_01	XAI Framework	Dashboard Visualisation Support	REALM must support the utilisation and visualisation of the output of the XAI Framework	√		High
REALM_VR_02	XAI Framework	SHAP Visualisation Support	The REALM dashboard should be able to visualise SHAP data using the following plots: • Bar Plot • Beeswarm Plot • Waterfall Plot • Box Plot • Force Plot • Image Plot	√		High

1.4 Deployment Requirements

The Deployment Requirements identify the deployment needs of a respective component in respect to both the capabilities of the deployment system (software/hardware/optimization) but also the location, e.g., cloud, local, etc.

Requirement ID	Component	Requirement Title	Description	Functional	Non-Functional	Priority
REALM_ER_01	XAI Framework	Docker Deployment	The REALM system must support the execution and orchestration of Docker containers	√		High
REALM_ER_01	XAI Framework	GPU Optimisation	The REALM system must support the execution of intensive workflows	√		High

7

1.5 System Requirements

The system Requirements identify general needs of the software, hardware and components from the REALM platform.

Requirement ID	Component	Requirement Title	Description	Functional	Non-Functional	Priority

1.6 Storage Requirements

Here we define the storage requirements of the respective REALM subsystem.

Requirement ID	Component	Requirement Title	Description	Functional	Non-Functional	Priority

1.7 Visualisation Requirements

The Visualisation Requirements identify the needs of the respecting component in respect to visualization that need to be projected in a dashboard/interface.

Requirement ID	Component	Requirement Title	Description	Functional	Non-Functional	Priority

1.8 Deployment Requirements

The Deployment Requirements identify the deployment needs of a respective component in respect to both the capabilities of the deployment system (software/hardware/optimization) but also the location, e.g., cloud, local, etc.

Requirement ID	Component	Requirement Title	Description	Functional	Non-Functional	Priority

8

11 Annex: REALM Stakeholder & Actor Questionnaire

REALM

[Anonymous] Stakeholder Analysis Feedback Form for the REALM project

The REALM project is dedicated to advancing healthcare solutions by fostering innovation and collaboration. It brings together diverse stakeholders including regulatory authorities, software developers, healthcare professionals, and policy makers.

The project aims to create a decentralized, secure evaluation and certification framework for medical software using state-of-the-art technologies. REALM emphasises on developing AI powered tools to assess algorithms for bias, privacy, accuracy, legal accountability, and ethics, enhancing data driven decision making.

In our efforts to shape the REALM project, we've drawn up a preliminary list of potential stakeholders and actors, mainly derived from literature review findings. Your insights, expertise and perspectives are of great importance, and this questionnaire is tailored to capture that knowledge. While it's designed to gather your feedback on the comprehensiveness, relevance, prioritization, and historical context of the stakeholders, we also encourage you to share it further - to your partners and interested parties - based on your knowledge and experience.

It will take only 10 minutes to complete, yet your feedback will be invaluable.

Section 1

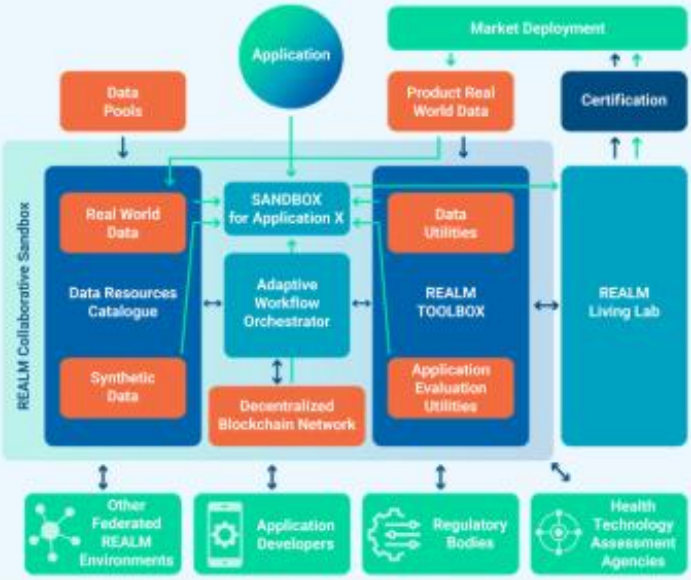
The REALM Project

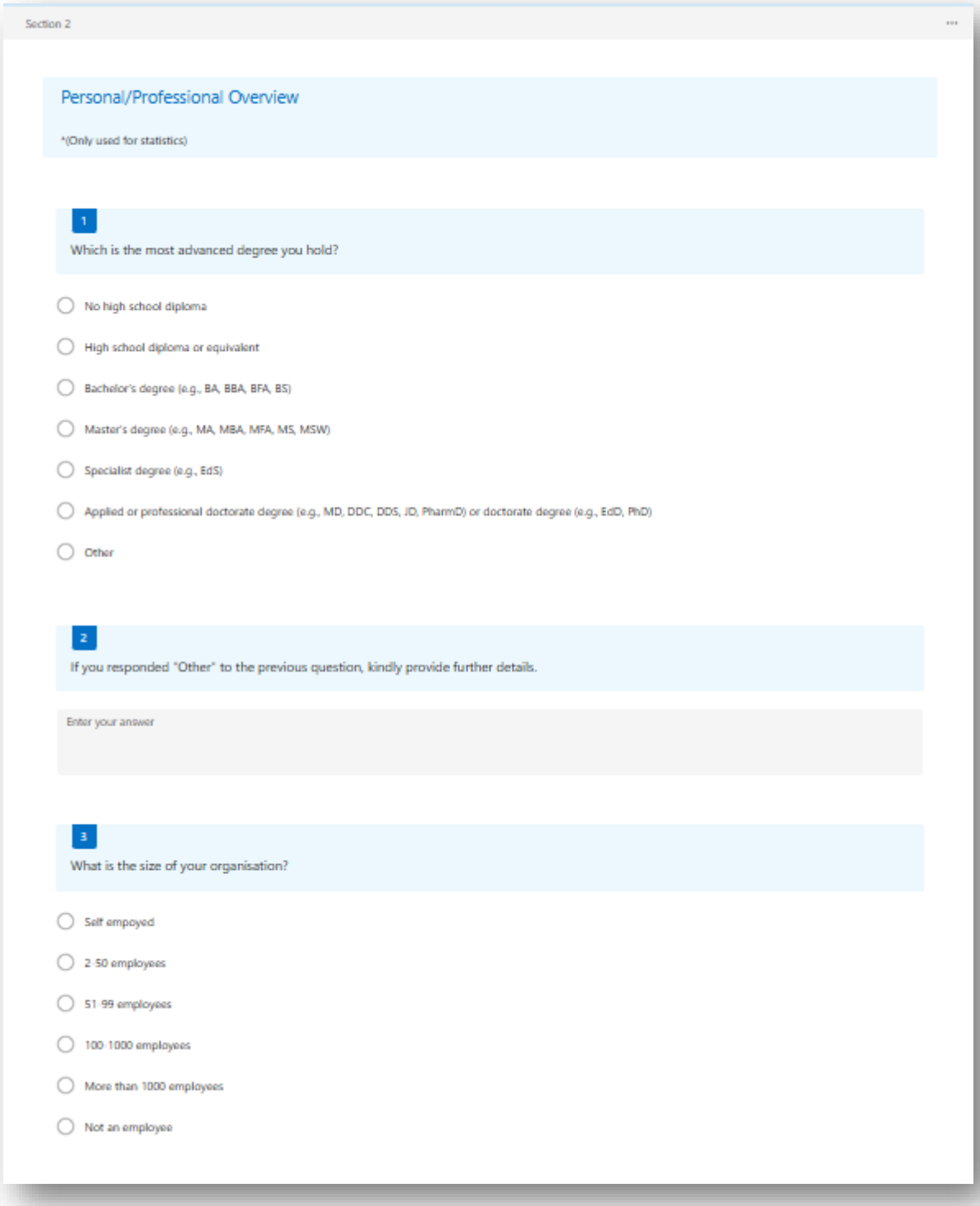
The REALM platform is dedicated to providing a comprehensive and easily accessible source of essential medical data for various applications. It adheres to the principles established by DARWIN and aims to simplify the challenging task of locating medical data for innovative solutions and research activities. The platform operates under a multi procedural framework, offering user friendly support for developing and implementing applications for post market utilisation. It utilises cutting edge practices and technologies for acquiring, storing, processing, and securing medical information, while also providing end users with limited access medical data to evaluate their algorithms.

Objectives:

1. Create guidelines to enhance clinical software assessment with diverse, multimodal health data.
2. Build a decentralized, GDPR compliant health innovation certification framework using Blockchain for transparency and traceability.
3. Implement tools for processing Electronic Health Records, using NLP and machine learning for better health data analysis.
4. Develop AI tools for health data analysis, focusing on bias, privacy, and ethics evaluation in an optimized workflow.
5. Establish explainable AI methods to increase transparency and address bias, promoting machine learning adoption.
6. Use synthetic data and digital twins for realistic medical algorithm training and decision making in rare disease scenarios.
7. Adopt and innovate health data sharing standards and assessment protocols for medical innovations.
8. Optimize real world data parameter selection for efficient post market medical software surveillance.
9. Share best practices and tools among EU regulatory bodies for medical software evaluation using real world data.

*You can find more info on https://realm-ai.eu/





Section 2

Personal/Professional Overview

*(Only used for statistics)

1

Which is the most advanced degree you hold?

- No high school diploma
- High school diploma or equivalent
- Bachelor's degree (e.g., BA, BBA, BFA, BS)
- Master's degree (e.g., MA, MBA, MFA, MS, MSW)
- Specialist degree (e.g., EdS)
- Applied or professional doctorate degree (e.g., MD, DDC, DDS, JD, PharmD) or doctorate degree (e.g., EdD, PhD)
- Other

2

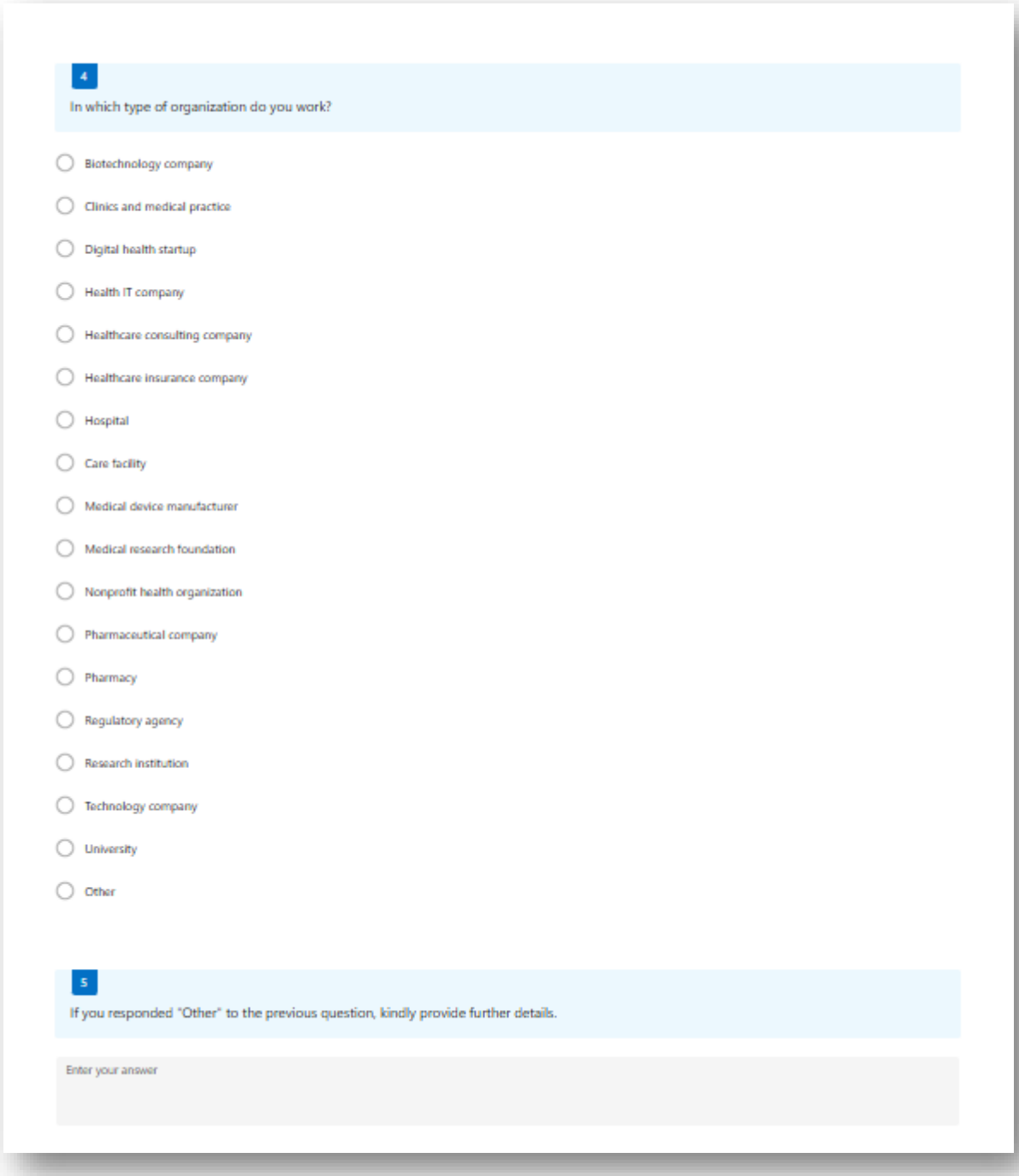
If you responded "Other" to the previous question, kindly provide further details.

Enter your answer

3

What is the size of your organisation?

- Self empoyed
- 2-50 employees
- 51-99 employees
- 100-1000 employees
- More than 1000 employees
- Not an employee



4

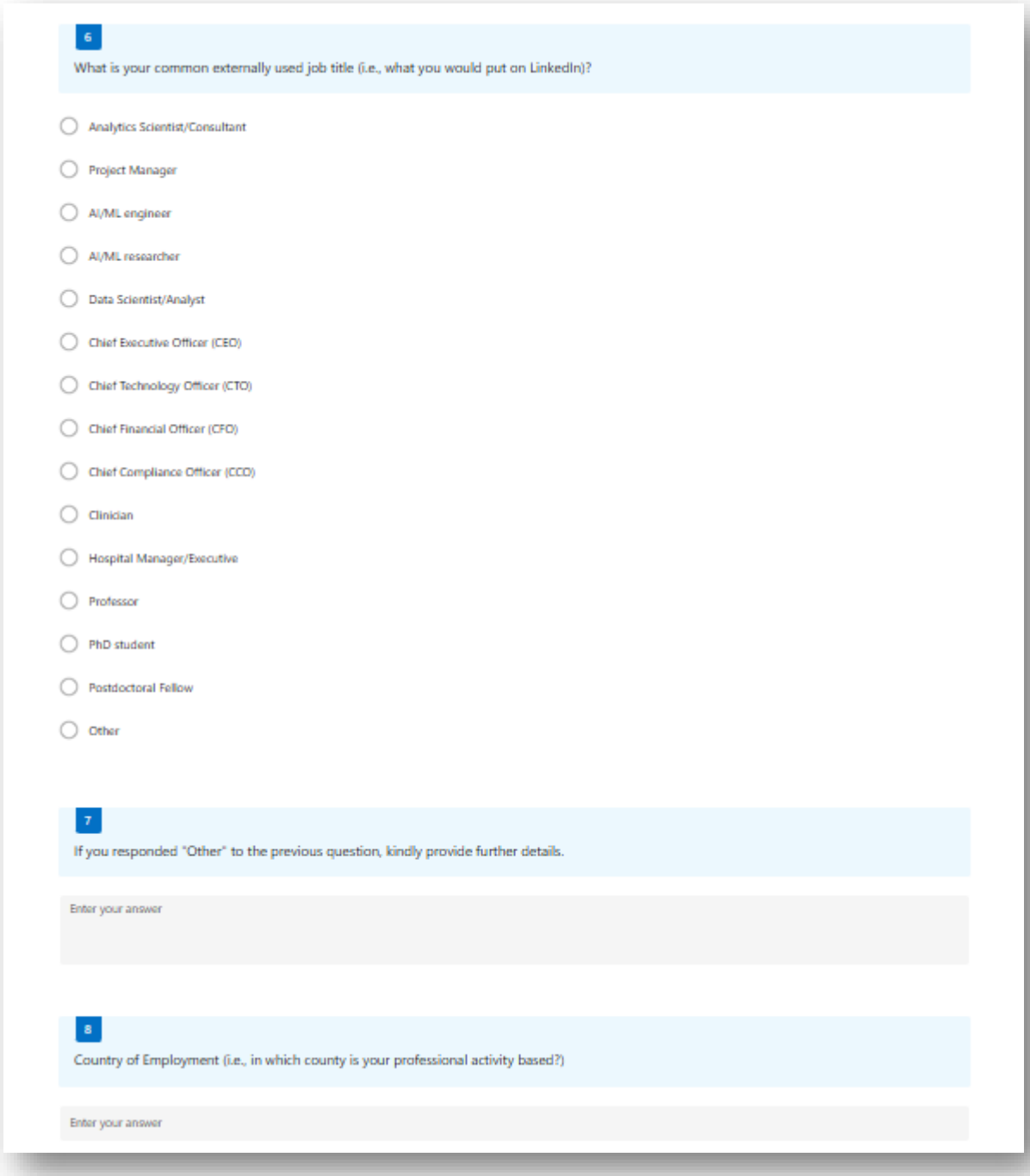
In which type of organization do you work?

- Biotechnology company
- Clinics and medical practice
- Digital health startup
- Health IT company
- Healthcare consulting company
- Healthcare insurance company
- Hospital
- Care facility
- Medical device manufacturer
- Medical research foundation
- Nonprofit health organization
- Pharmaceutical company
- Pharmacy
- Regulatory agency
- Research institution
- Technology company
- University
- Other

5

If you responded "Other" to the previous question, kindly provide further details.

Enter your answer



6

What is your common externally used job title (i.e., what you would put on LinkedIn)?

- Analytics Scientist/Consultant
- Project Manager
- AI/ML engineer
- AI/ML researcher
- Data Scientist/Analyst
- Chief Executive Officer (CEO)
- Chief Technology Officer (CTO)
- Chief Financial Officer (CFO)
- Chief Compliance Officer (CCO)
- Clinician
- Hospital Manager/Executive
- Professor
- PhD student
- Postdoctoral Fellow
- Other

7

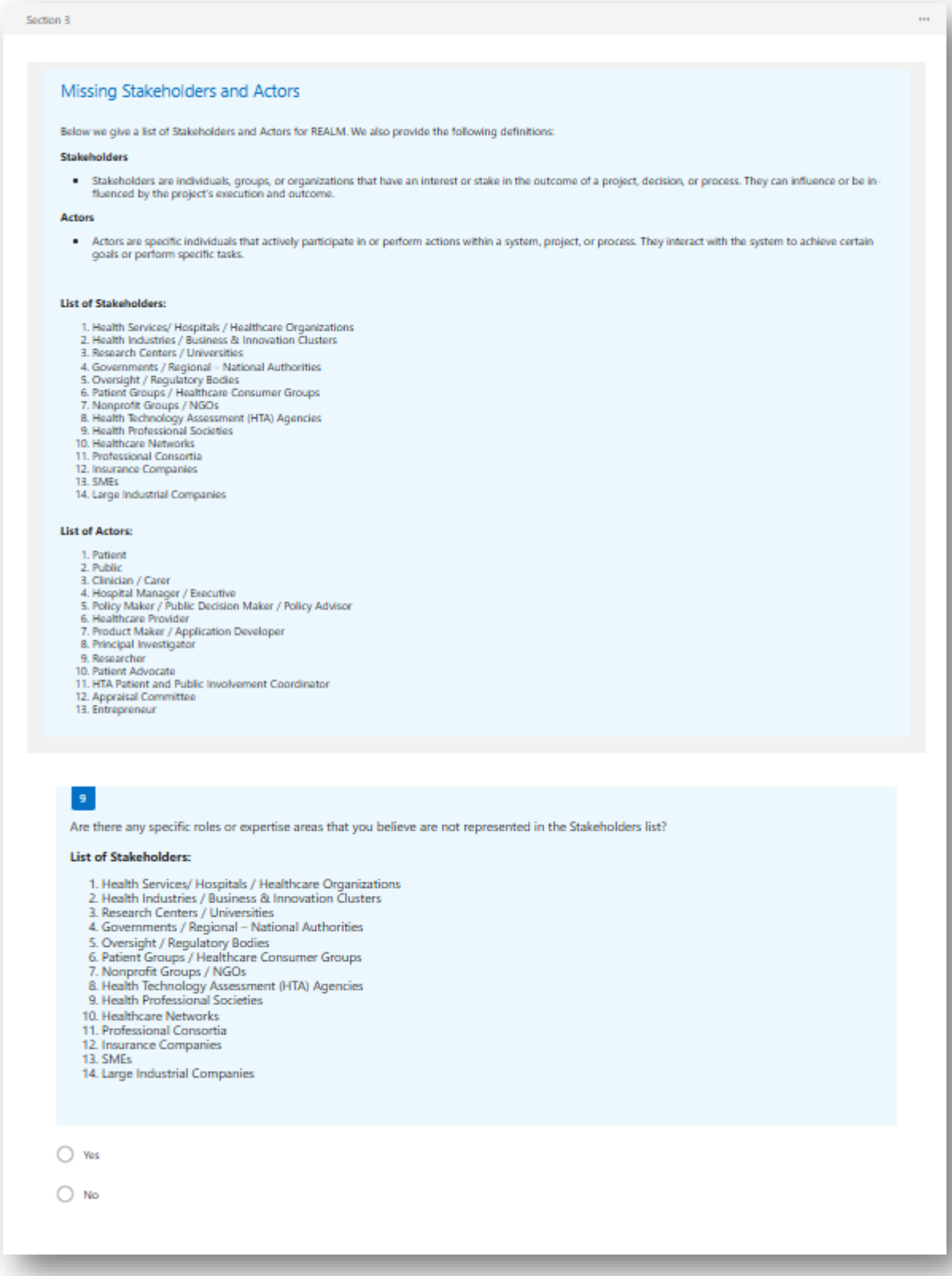
If you responded "Other" to the previous question, kindly provide further details.

Enter your answer

8

Country of Employment (i.e., in which county is your professional activity based?)

Enter your answer



Section 3

Missing Stakeholders and Actors

Below we give a list of Stakeholders and Actors for REALM. We also provide the following definitions:

Stakeholders

- Stakeholders are individuals, groups, or organizations that have an interest or stake in the outcome of a project, decision, or process. They can influence or be influenced by the project's execution and outcome.

Actors

- Actors are specific individuals that actively participate in or perform actions within a system, project, or process. They interact with the system to achieve certain goals or perform specific tasks.

List of Stakeholders:

1. Health Services/ Hospitals / Healthcare Organizations
2. Health Industries / Business & Innovation Clusters
3. Research Centers / Universities
4. Governments / Regional – National Authorities
5. Oversight / Regulatory Bodies
6. Patient Groups / Healthcare Consumer Groups
7. Nonprofit Groups / NGOs
8. Health Technology Assessment (HTA) Agencies
9. Health Professional Societies
10. Healthcare Networks
11. Professional Consortia
12. Insurance Companies
13. SMEs
14. Large Industrial Companies

List of Actors:

1. Patient
2. Public
3. Clinician / Carer
4. Hospital Manager / Executive
5. Policy Maker / Public Decision Maker / Policy Advisor
6. Healthcare Provider
7. Product Maker / Application Developer
8. Principal Investigator
9. Researcher
10. Patient Advocate
11. HTA Patient and Public Involvement Coordinator
12. Appraisal Committee
13. Entrepreneur

9

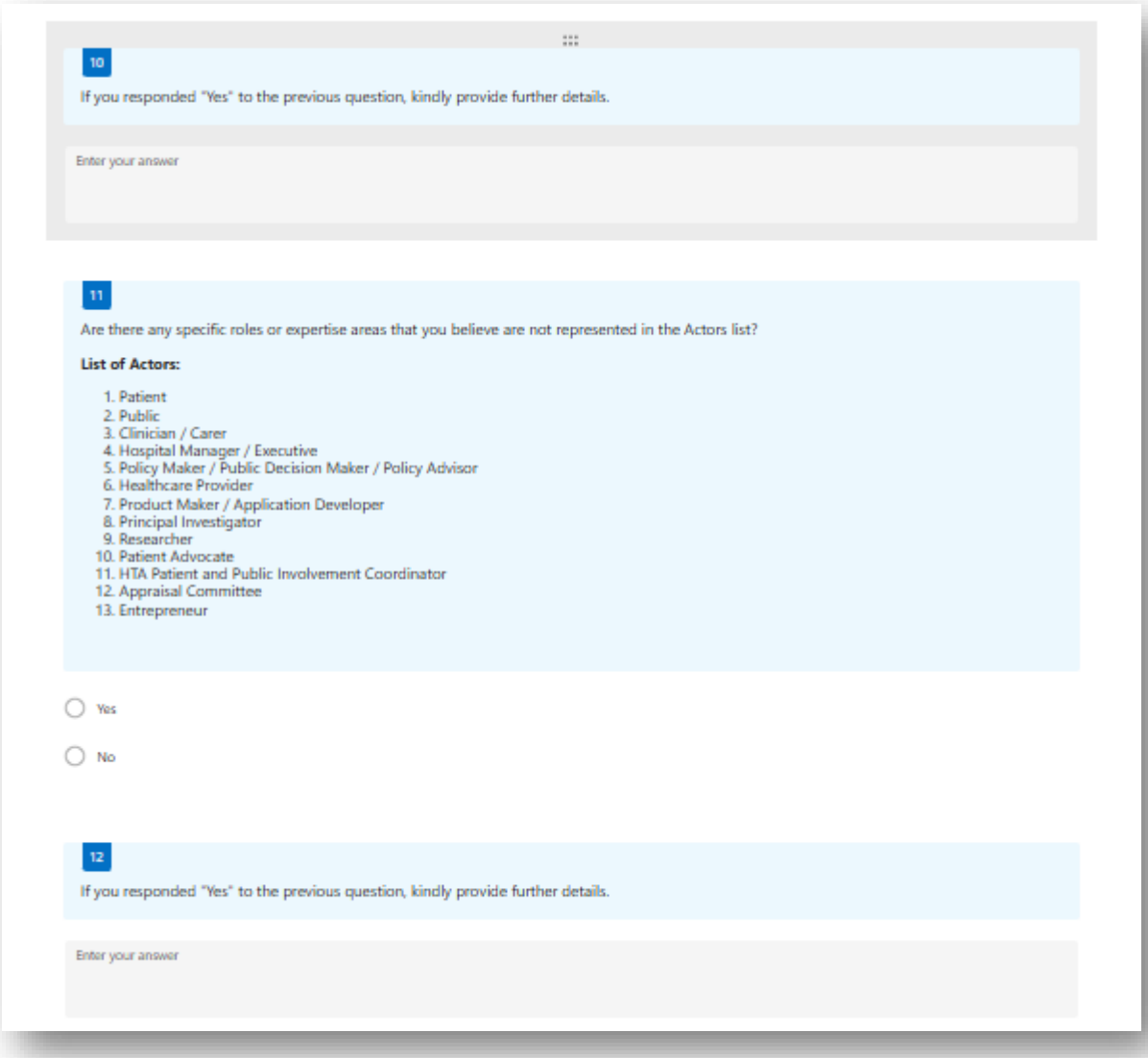
Are there any specific roles or expertise areas that you believe are not represented in the Stakeholders list?

List of Stakeholders:

1. Health Services/ Hospitals / Healthcare Organizations
2. Health Industries / Business & Innovation Clusters
3. Research Centers / Universities
4. Governments / Regional – National Authorities
5. Oversight / Regulatory Bodies
6. Patient Groups / Healthcare Consumer Groups
7. Nonprofit Groups / NGOs
8. Health Technology Assessment (HTA) Agencies
9. Health Professional Societies
10. Healthcare Networks
11. Professional Consortia
12. Insurance Companies
13. SMEs
14. Large Industrial Companies

○ Yes

○ No



10

If you responded "Yes" to the previous question, kindly provide further details.

Enter your answer

11

Are there any specific roles or expertise areas that you believe are not represented in the Actors list?

List of Actors:

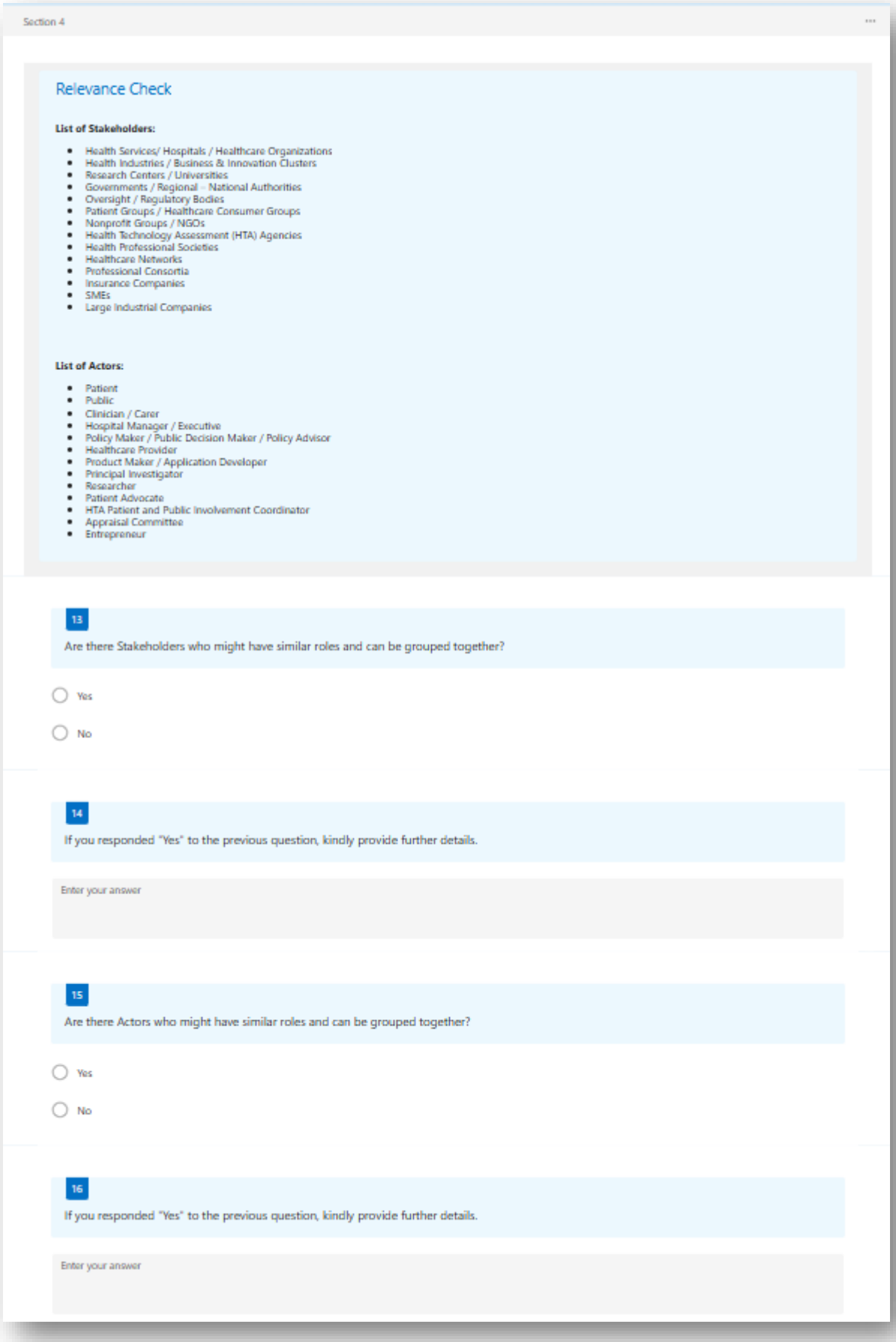
1. Patient
2. Public
3. Clinician / Carer
4. Hospital Manager / Executive
5. Policy Maker / Public Decision Maker / Policy Advisor
6. Healthcare Provider
7. Product Maker / Application Developer
8. Principal Investigator
9. Researcher
10. Patient Advocate
11. HTA Patient and Public Involvement Coordinator
12. Appraisal Committee
13. Entrepreneur

- ○ Yes
- ○ No

12

If you responded "Yes" to the previous question, kindly provide further details.

Enter your answer



Section 4

Relevance Check

List of Stakeholders:

- Health Services/ Hospitals / Healthcare Organizations
- Health Industries / Business & Innovation Clusters
- Research Centers / Universities
- Governments / Regional - National Authorities
- Oversight / Regulatory Bodies
- Patient Groups / Healthcare Consumer Groups
- Nonprofit Groups / NGOs
- Health Technology Assessment (HTA) Agencies
- Health Professional Societies
- Healthcare Networks
- Professional Consortia
- Insurance Companies
- SMEs
- Large Industrial Companies

List of Actors:

- Patient
- Public
- Clinician / Carer
- Hospital Manager / Executive
- Policy Maker / Public Decision Maker / Policy Advisor
- Healthcare Provider
- Product Maker / Application Developer
- Principal Investigator
- Researcher
- Patient Advocate
- HTA Patient and Public Involvement Coordinator
- Appraisal Committee
- Entrepreneur

13

Are there Stakeholders who might have similar roles and can be grouped together?

- Yes
- No

14

If you responded "Yes" to the previous question, kindly provide further details.

Enter your answer

15

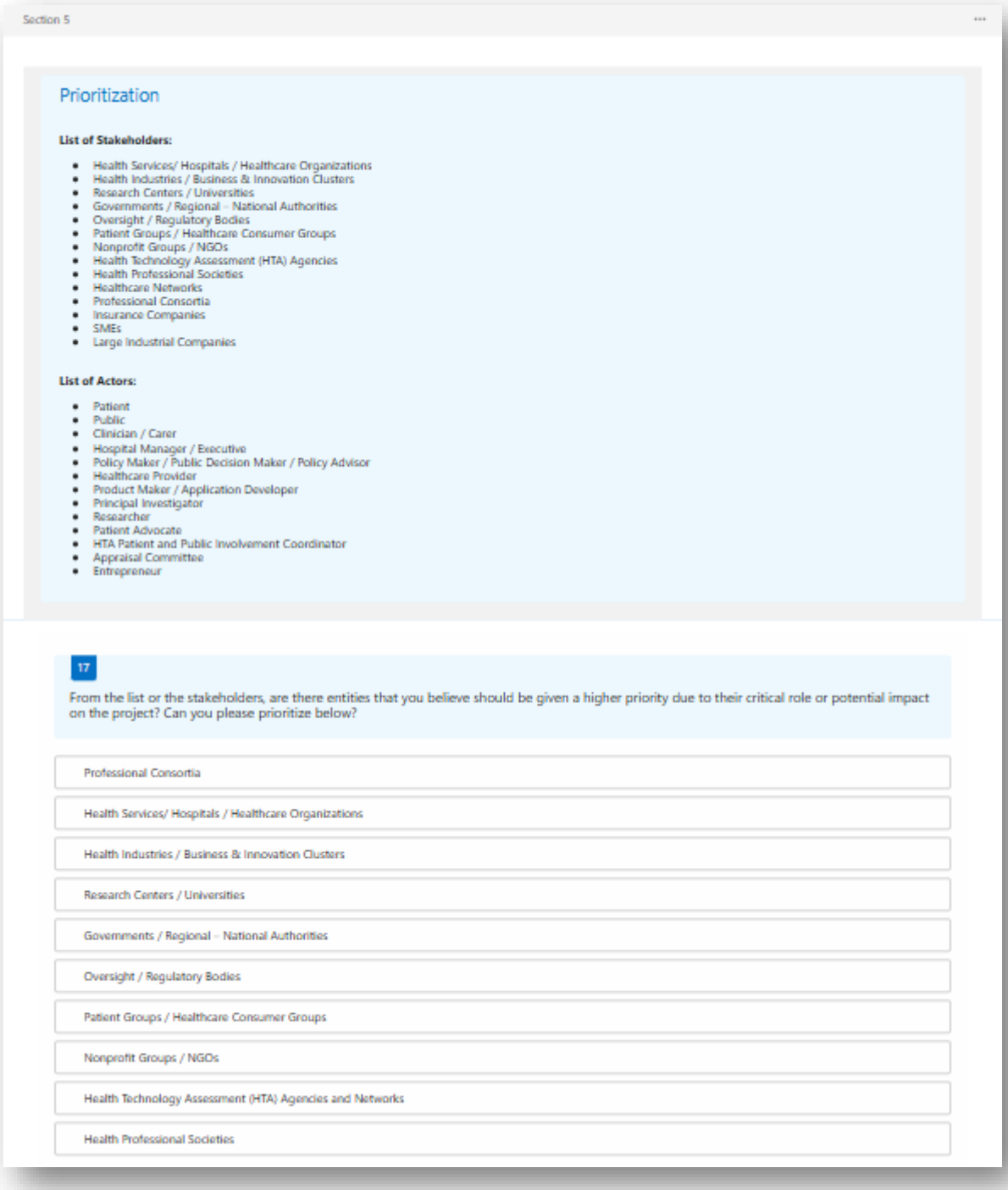
Are there Actors who might have similar roles and can be grouped together?

- Yes
- No

16

If you responded "Yes" to the previous question, kindly provide further details.

Enter your answer



Section 5

Prioritization

List of Stakeholders:

- Health Services/ Hospitals / Healthcare Organizations
- Health Industries / Business & Innovation Clusters
- Research Centers / Universities
- Governments / Regional – National Authorities
- Oversight / Regulatory Bodies
- Patient Groups / Healthcare Consumer Groups
- Nonprofit Groups / NGOs
- Health Technology Assessment (HTA) Agencies
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- Healthcare Networks
- Professional Consortia
- Insurance Companies
- SMEs
- Large Industrial Companies

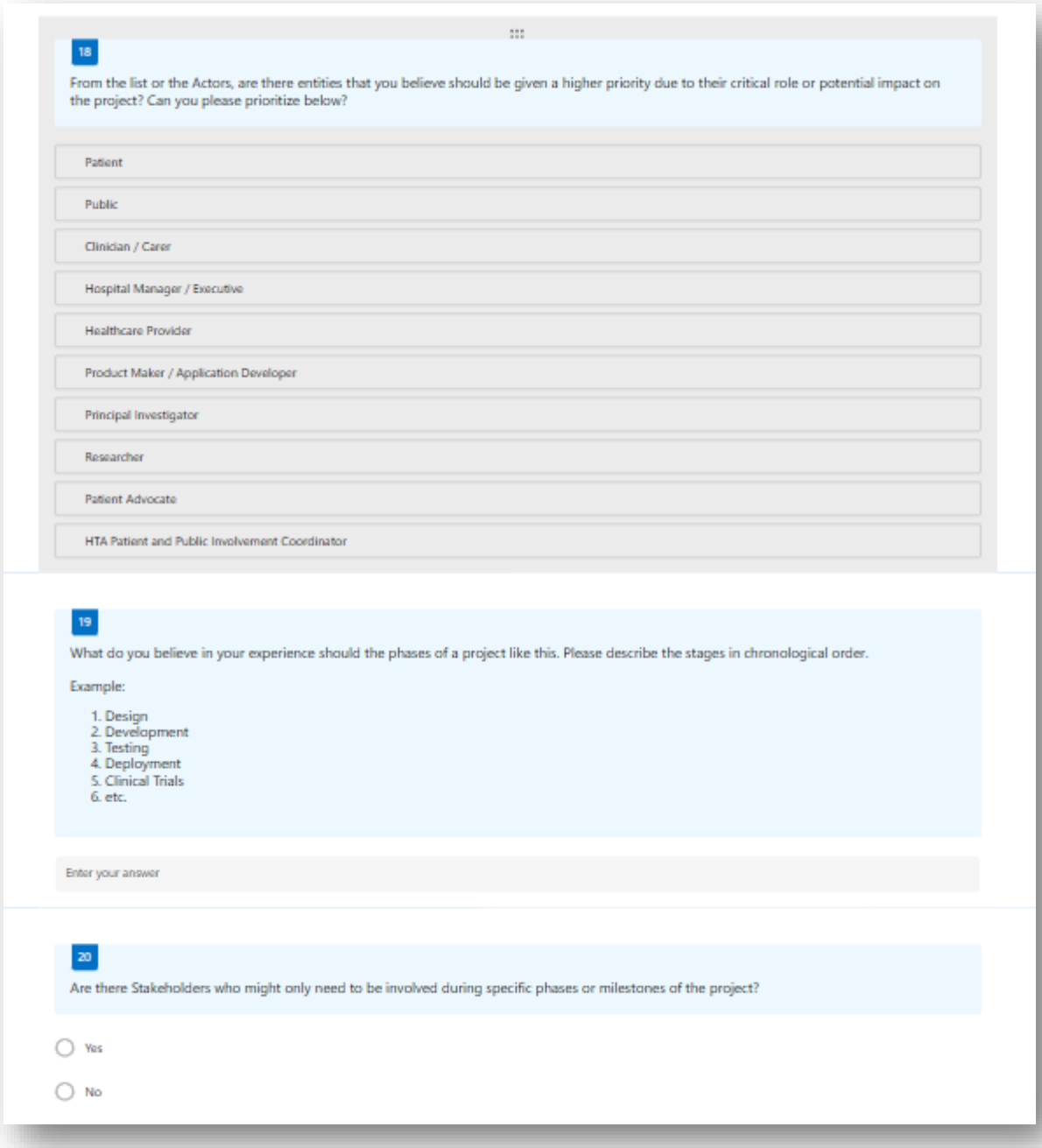
List of Actors:

- Patient
- Public
- Clinician / Carer
- Hospital Manager / Executive
- Policy Maker / Public Decision Maker / Policy Advisor
- Healthcare Provider
- Product Maker / Application Developer
- Principal Investigator
- Researcher
- Patient Advocate
- HTA Patient and Public Involvement Coordinator
- Appraisal Committee
- Entrepreneur

17

From the list or the stakeholders, are there entities that you believe should be given a higher priority due to their critical role or potential impact on the project? Can you please prioritize below?

- Professional Consortia
- Health Services/ Hospitals / Healthcare Organizations
- Health Industries / Business & Innovation Clusters
- Research Centers / Universities
- Governments / Regional – National Authorities
- Oversight / Regulatory Bodies
- Patient Groups / Healthcare Consumer Groups
- Nonprofit Groups / NGOs
- Health Technology Assessment (HTA) Agencies and Networks
- Health Professional Societies



18

From the list or the Actors, are there entities that you believe should be given a higher priority due to their critical role or potential impact on the project? Can you please prioritize below?

- Patient
- Public
- Clinician / Carer
- Hospital Manager / Executive
- Healthcare Provider
- Product Maker / Application Developer
- Principal Investigator
- Researcher
- Patient Advocate
- HTA Patient and Public Involvement Coordinator

19

What do you believe in your experience should the phases of a project like this. Please describe the stages in chronological order.

Example:

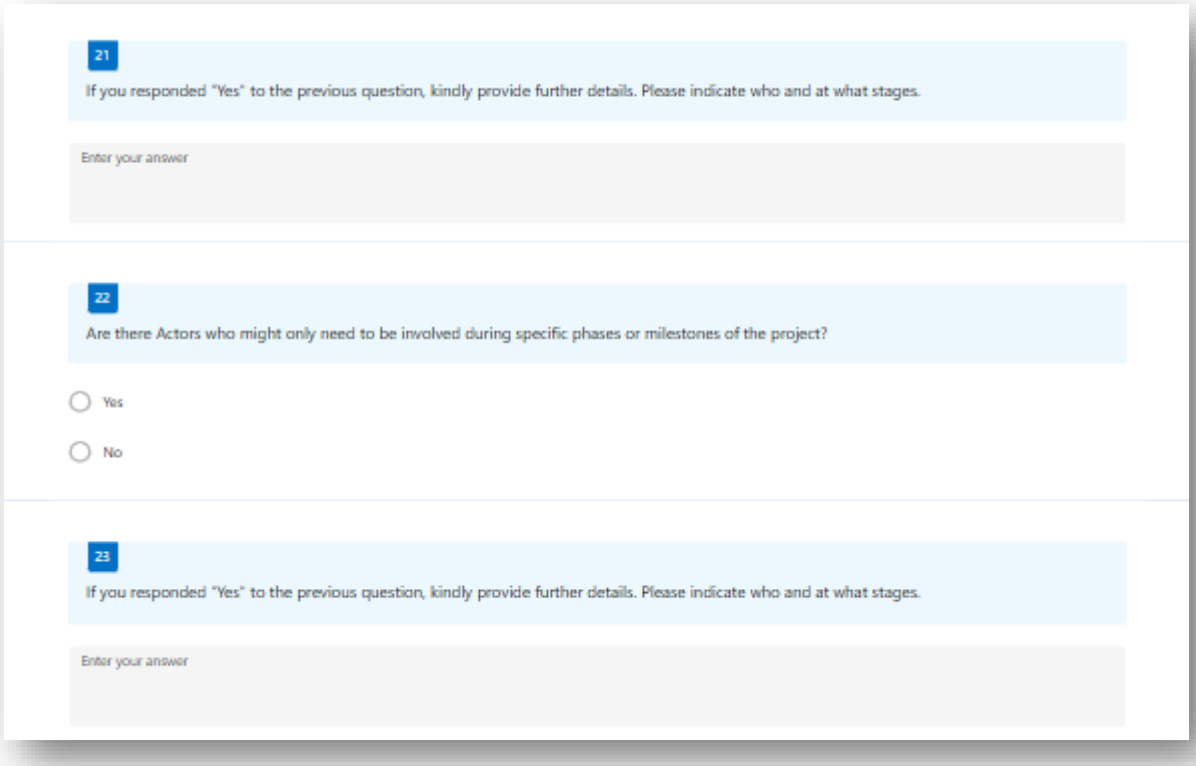
1. Design
2. Development
3. Testing
4. Deployment
5. Clinical Trials
6. etc.

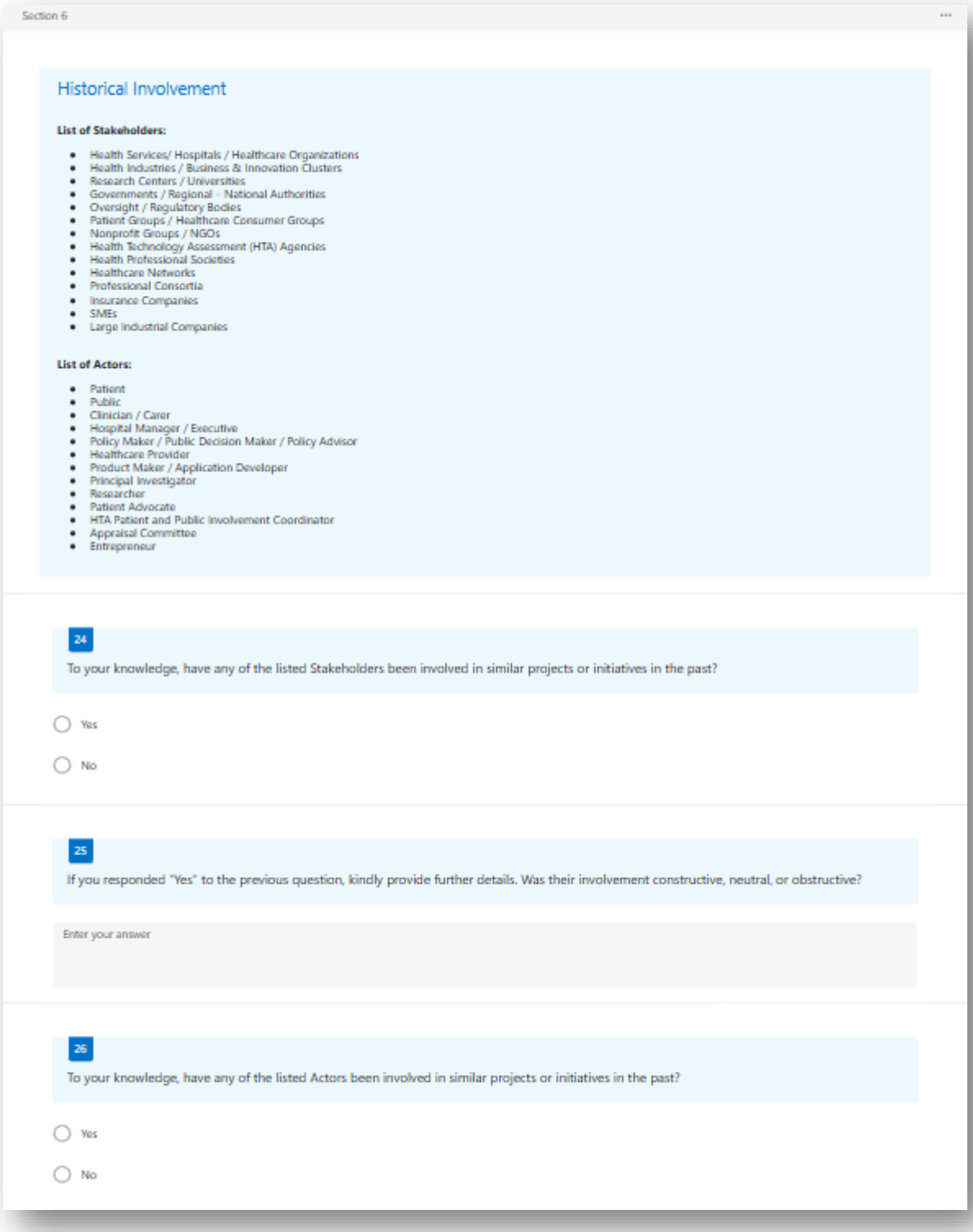
Enter your answer

20

Are there Stakeholders who might only need to be involved during specific phases or milestones of the project?

- Yes
- No


21
If you responded "Yes" to the previous question, kindly provide further details. Please indicate who and at what stages.
Enter your answer
22
Are there Actors who might only need to be involved during specific phases or milestones of the project?
Yes
No
23
If you responded "Yes" to the previous question, kindly provide further details. Please indicate who and at what stages.
Enter your answer



Section 6

Historical Involvement

List of Stakeholders:

- Health Services/ Hospitals / Healthcare Organizations
- Health Industries / Business & Innovation Clusters
- Research Centers / Universities
- Governments / Regional – National Authorities
- Oversight / Regulatory Bodies
- Patient Groups / Healthcare Consumer Groups
- Nonprofit Groups / NGOs
- Health Technology Assessment (HTA) Agencies
- Health Professional Societies
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- Large Industrial Companies

List of Actors:

- Patient
- Public
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- Hospital Manager / Executive
- Policy Maker / Public Decision Maker / Policy Advisor
- Healthcare Provider
- Product Maker / Application Developer
- Principal Investigator
- Researcher
- Patient Advocate
- HTA Patient and Public Involvement Coordinator
- Appraisal Committee
- Entrepreneur

24

To your knowledge, have any of the listed Stakeholders been involved in similar projects or initiatives in the past?

- ○ Yes
- ○ No

25

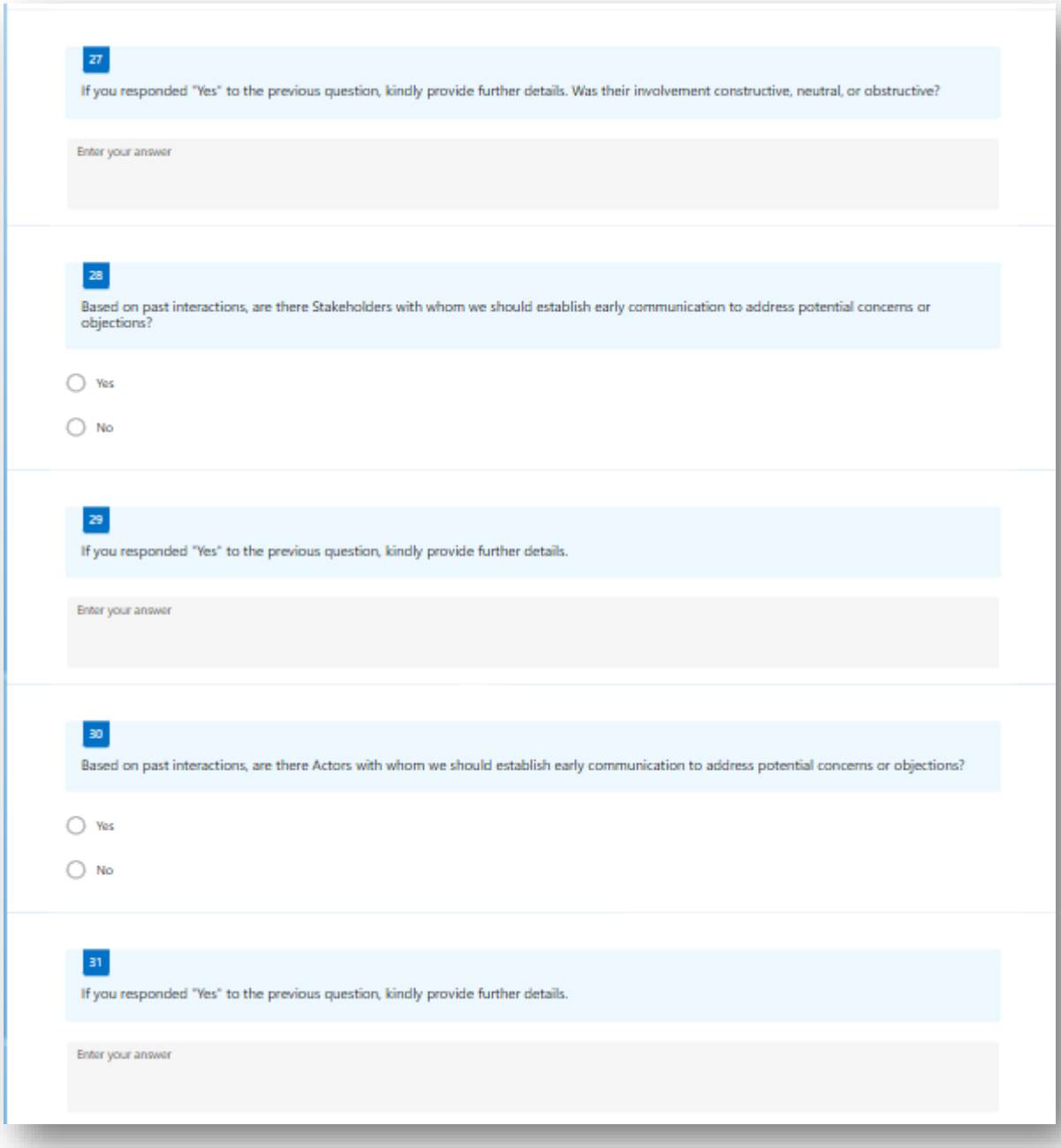
If you responded "Yes" to the previous question, kindly provide further details. Was their involvement constructive, neutral, or obstructive?

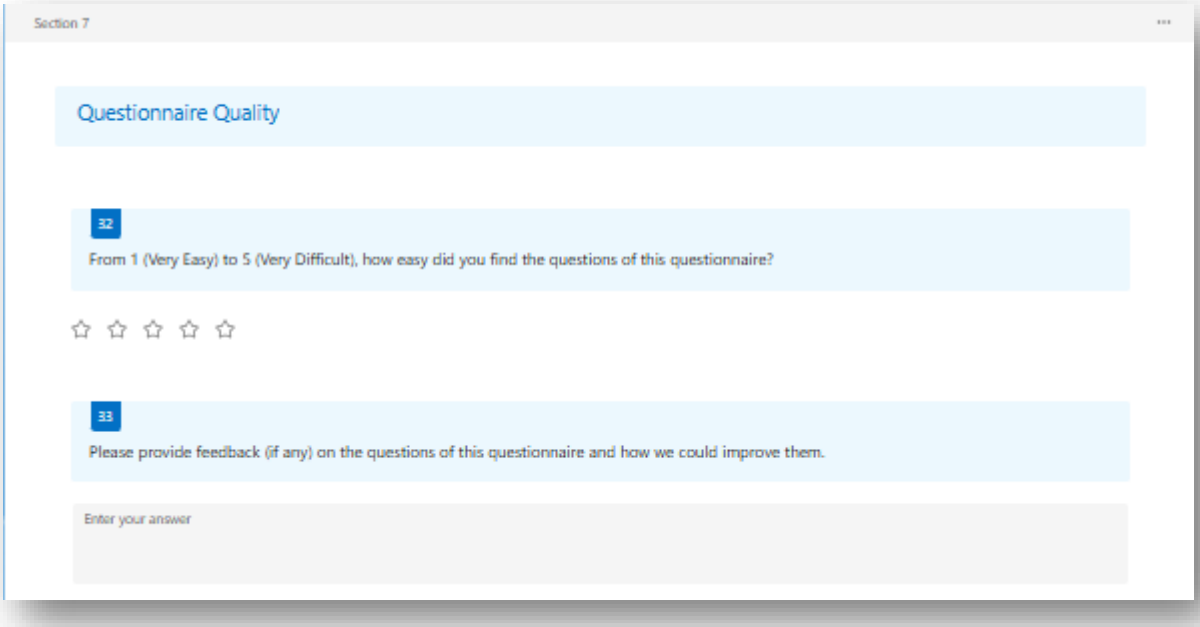
Enter your answer

26

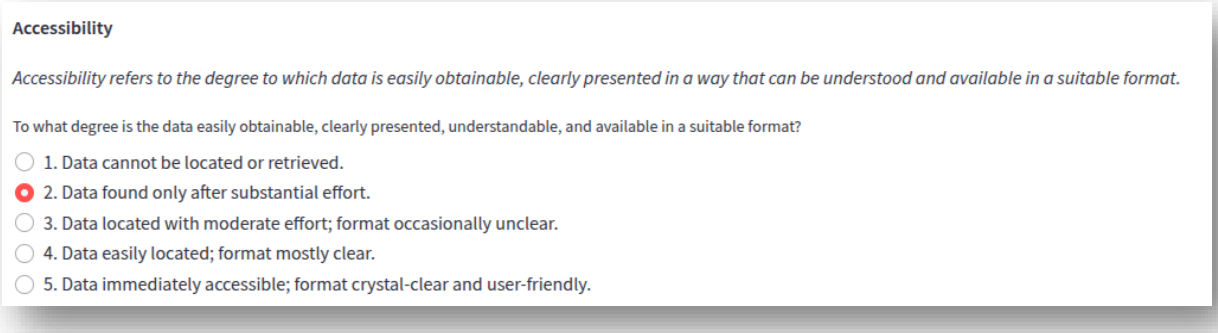
To your knowledge, have any of the listed Actors been involved in similar projects or initiatives in the past?

- ○ Yes
- ○ No


27
If you responded "Yes" to the previous question, kindly provide further details. Was their involvement constructive, neutral, or obstructive?
Enter your answer
28
Based on past interactions, are there Stakeholders with whom we should establish early communication to address potential concerns or objections?
Yes
No
29
If you responded "Yes" to the previous question, kindly provide further details.
Enter your answer
30
Based on past interactions, are there Actors with whom we should establish early communication to address potential concerns or objections?
Yes
No
31
If you responded "Yes" to the previous question, kindly provide further details.
Enter your answer


Section 7
Questionnaire Quality
32
From 1 (Very Easy) to 5 (Very Difficult), how easy did you find the questions of this questionnaire?
33
Please provide feedback (if any) on the questions of this questionnaire and how we could improve them.
Enter your answer

12 Annex: SDQF Qualitative Dimensions Questionnaire

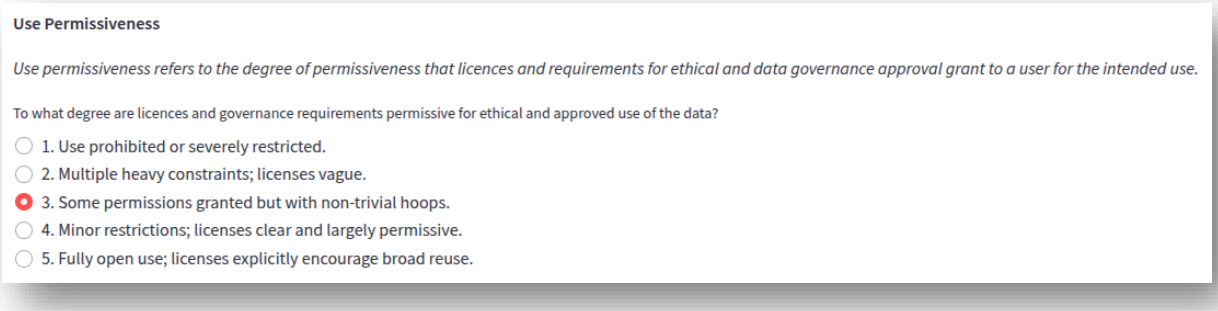


Accessibility

Accessibility refers to the degree to which data is easily obtainable, clearly presented in a way that can be understood and available in a suitable format.

To what degree is the data easily obtainable, clearly presented, understandable, and available in a suitable format?

- ○ 1. Data cannot be located or retrieved.
- ◉ 2. Data found only after substantial effort.
- ○ 3. Data located with moderate effort; format occasionally unclear.
- ○ 4. Data easily located; format mostly clear.
- ○ 5. Data immediately accessible; format crystal-clear and user-friendly.

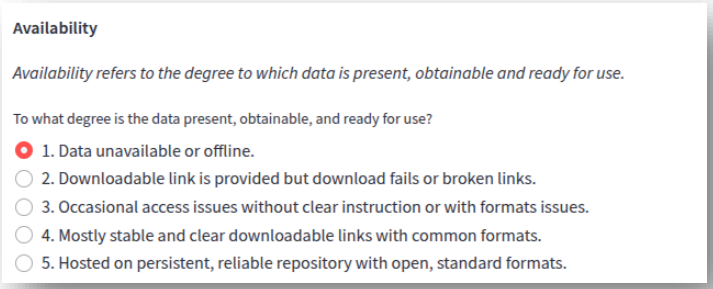


Use Permissiveness

Use permissiveness refers to the degree of permissiveness that licences and requirements for ethical and data governance approval grant to a user for the intended use.

To what degree are licences and governance requirements permissive for ethical and approved use of the data?

- ○ 1. Use prohibited or severely restricted.
- ○ 2. Multiple heavy constraints; licenses vague.
- ◉ 3. Some permissions granted but with non-trivial hoops.
- ○ 4. Minor restrictions; licenses clear and largely permissive.
- ○ 5. Fully open use; licenses explicitly encourage broad reuse.

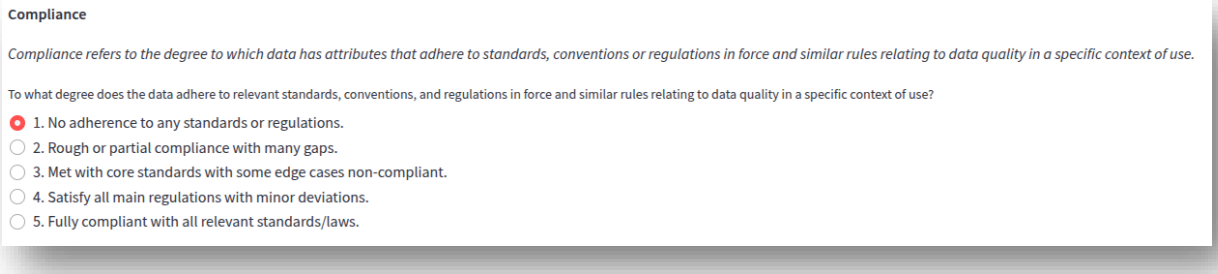


Availability

Availability refers to the degree to which data is present, obtainable and ready for use.

To what degree is the data present, obtainable, and ready for use?

- ◉ 1. Data unavailable or offline.
- ○ 2. Downloadable link is provided but download fails or broken links.
- ○ 3. Occasional access issues without clear instruction or with formats issues.
- ○ 4. Mostly stable and clear downloadable links with common formats.
- ○ 5. Hosted on persistent, reliable repository with open, standard formats.



Compliance

Compliance refers to the degree to which data has attributes that adhere to standards, conventions or regulations in force and similar rules relating to data quality in a specific context of use.

To what degree does the data adhere to relevant standards, conventions, and regulations in force and similar rules relating to data quality in a specific context of use?

- ◉ 1. No adherence to any standards or regulations.
- ○ 2. Rough or partial compliance with many gaps.
- ○ 3. Met with core standards with some edge cases non-compliant.
- ○ 4. Satisfy all main regulations with minor deviations.
- ○ 5. Fully compliant with all relevant standards/laws.

Provenance

Provenance means a description of the source of the original or raw data prior to any subsequent processing or transformation, including context, purpose, method and technology of data generation.

To what degree is the source, context, purpose, method, and technology of data generation documented?

- ○ 1. No source or collection details.
- ○ 2. Only source name is provided with no methods or context.
- ○ 3. Basic method description is provided but dates, operators, organizations, and other key components are missing.
- ◉ 4. Methods, purpose, dates, and other key components are provided but missing minor context.
- ○ 5. Complete provenance is provided with detailed descriptions of method, system, dates, agents, data processing process.

Trustworthiness

Trustworthiness refers to the degree to which context information fosters trust in the data, e.g. by documenting agents involved in the provenance of data, data validation routines, the provenance of available provenance information etc.

To what degree does documentation of agents, validation routines, and provenance foster trust in the dataset?

- ○ 1. No information about data origin, agents, or validation.
- ○ 2. Only some provenance or agent names mentioned, but no details on processes.
- ○ 3. Key agents and data-validation steps are named, but provenance chains are incomplete.
- ◉ 4. Clear documentation of most agents, validation routines, and where provenance logs exist.
- ○ 5. Comprehensive records of all agents, end-to-end validation processes, and detailed provenance metadata.

Consistency

Consistency refers to the degree to which data has attributes that are free from contradiction and are coherent with other data in a specific context of use. It can be either or both among data regarding one entity and across similar data for comparable entities.

To what degree is the data free from internal contradictions and logically coherent?

- ○ 1. Logical contradictions pervasive.
- ○ 2. Frequent logical errors in data attributes (age>200 yrs old, male with pregnancy label).
- ○ 3. Occasional inconsistencies in data attributes.
- ○ 4. Rare inconsistencies.
- ◉ 5. Fully consistent throughout.