TREAT

Transforming Healthcare Through Semantic Interoperability and Self-Efficacy

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D4.1 – White Paper – Stakeholder Needs

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	PP	Restricted to other programme participants	
	RE	Restricted to a group specified by the consortium	
	CO	Confidential, only for members of the consortium	**X**

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Table of Contents

Glossary

Abbreviation / acronym	Description
TREAT	Transforming Healthcare Through Semantic Interoperability & Patient Self-Efficacy
OA	OsteoArthritis
DM	Diabetes Mellitus
NCD	Non-Communicable Disease
AI	Artificial Intelligence
SaaS	Software as a Service

1. Executive Summary

The purpose of this deliverable is to identify and document the specific needs and expectations of key stakeholders across all six national use cases, with a focus on dashboarding, user interface (UI), and data visualization requirements. Additionally, it captures the types of data each use case plans to collect as part of its implementation.

Understanding the needs of users—ranging from clinicians and patients to IT administrators and policy makers—is essential to ensure that the system components developed in subsequent tasks are usable, relevant, and aligned with the local context of each use case. This deliverable serves as a foundation for future tasks and deliverables within this work packages and other work packages.

Each country will provide the following input:

- The stakeholders or stakeholder groups involved in their use case.
- The specific needs of each stakeholder regarding dashboard functionality, interface preferences, and data visualizations.
- The types of data that will be collected in the context of the use case.

Based on the input of each country a cross-use case comparison will be done, highlighting common themes and unique local requirements.

2. General Introduction

This document collects input from each national use case in the TREAT project to identify the key stakeholders involved and their specific needs regarding dashboards, user interfaces, and data visualization. It also outlines the types of data each use case plans to capture. The TREAT project consists of 6 use cases.

The stakeholder needs identified in this deliverable (D4.1) form an important complement to the technical work on demonstrators described in Deliverable D1.3. While D1.3 provides the preliminary status of integrated demonstrators across the six use cases, D4.1 focuses on capturing the specific expectations of stakeholders with respect to dashboards, user interfaces, and data visualization. Together, these deliverables ensure that both technical development and stakeholder perspectives are aligned throughout the project.

- **UC1: Patient-centric digital ecosystem**

  This use case concentrates on the development of a patient-centric digital ecosystem to improve self-efficacy for patients to manage cardiac metabolic diseases, specifically type 2 diabetes at home and the hospital. Further, the development of a wearable device that supports interoperability and can provide real-time decision-making data to both clinicians and patients at an institutional level. This use case supports TREATs goal to increase patient self-efficacy in managing non-communicable diseases (such as type 2 diabetes) by developing a patient centered platform that addresses interoperability between health institutions, decreases the reliance on healthcare providers, and increases patient adherence

- **UC2: Integrated System for Osteoarthritis Patients**

  The goal of the use case is to realize an integrated system for osteoarthritis (OA) patients which can be used by physical therapists and lifestyle coaches to administer and remotely monitor interventions/training programs, supported by automated personalized coaching. This use case supports TREAT's overall goals of improving individualized clinical care, specifically focusing on long-term adherence of individuals with diabetes mellitus (DM) and OA to norms of healthy physical activity. This process will be optimized through remote physical monitoring, progress reports to coaches, semantic interoperability and the use of AI for personalized recommendations. Each partner of the consortium will provide their expertise to work on this common goal.

- **UC3: Recommender SaaS Platform**

  This use case considers the integration of data from various sources (diet, pharmacological treatment, out-of-hospital monitoring, care pathways) into a platform which is able to provide personalized recommendations and improve the effectiveness of treatment for patients with chronic non-communicable diseases. (NCDs). This will include collaboration between health professionals, pharmacists and advanced artificial intelligence (AI) technologies. The platform will be provided through an API, which will allow us to offer it as a Software as a Service (SaaS) solution, allowing its use by other entities and facilitating its integration into various health platforms.

- **UC4: Diabetes monitoring**

  This use case will focus on a diabetes-specific solution aimed at enhancing self-efficacy and improving clinical workflows. The solution will provide a multi-layered framework, including collecting data from patients using two types of wearable devices, measuring the glucose level in

the blood and record the electrical signals in the heart, which will be processed using AI on the platform for semantic operability.

- **UC5: Distributed Diagnoses and Home Healthcare**

  This use case pertains to distributed diagnoses and home healthcare, aiming to develop economically efficient methods for user-centered and home-based systems. These systems focus on monitoring health-related quality of life, particularly for patients with chronic diseases. In this context, the integration of personal devices (such as smartphones and wearables) with hospital information systems allows for remote patient monitoring. The system collects data from sensors, patients, families, and primary care professionals, integrating it with information from the hospital's individual personal care system. This integration enables the development of various services, including information dissemination, coaching, analysis, and alarming.

- **UC6: Enhancing Patient Self-Efficacy and NCD Management through AI-Powered Remote Monitoring**

  The Well@Home platform will integrate AI assistance to streamline patient management for healthcare professionals. This will be achieved in three phases: 1) Enhancing data visualization and obtaining the required dataset, 2) Implementing a predictive AI assistant for patient diagnosis, and 3) Adding a prescriptive AI assistant to optimize content labeling and delivery timing. The goal is to improve the patient's self-efficacy, treatment adherence and decrease healthcare costs by reducing the reliance on healthcare professionals.

3. UC1: Patient-centric digital ecosystem

3.1 Use Case Summary

Main goal:

- Develop a patient-centric digital ecosystem that improves self-efficacy for patients managing type 2 diabetes through 4 key components: collection of data from various sources, including lifestyle, wearable, EHR, and personal information; interoperability of various sources for AI analysis; AI recommendations regarding lifestyle habits; and engaging conversational interfaces.
- Create a device server that collects, transforms, and transmits wearable device and lifestyle data to Electronic Health Records (EHRs) using the FHIR protocol.

Primary actors and participants:

- Patients with type 2 diabetes
- Clinicians (doctors, nurses, diabetes educators, dietitians)
- Healthcare institutions with EHR systems
- Technical staff managing the device server
- My Viva Inc's platform My Viva Plan and accountability avatar, Yaro.
- Wearable device manufacturers (Maastricht Instruments BV makers of the Hospital Fit and MISS Activity Tracker devices)

Expected outcomes or benefits:

- Seamless integration of wearable device data and lifestyle data (i.e. from daily patient journals) into clinical workflows
- Increased patient adherence through engaging interfaces
- Increased patient self-efficacy through the ability to understand their own lifestyle, activity and health data, with the help of AI
- Improved clinical decision-making based on continuous patient monitoring
- Enhanced interoperability between wearable devices and healthcare systems
- More effective patient-provider communication based on shared data

3.2 Stakeholders

1. Patients with type 2 diabetes

- **Role**: Primary users who use platforms, wear monitoring devices and access their own health data
- **Level of involvement:** Daily users, data generators
- **Dashboard/UI needs:**
  - Simple visualization of activity data (steps, movement patterns)
  - Physical activity monitoring data insights from MISS Activity MOX device
  - Access permissions limited to their own data
  - Patients only interact with activity, lifestyle, and movement data associated with their lifestyle journaling and wearable devices.
  - The ability to integrate with My Viva Plan and Yaro, as patient interfaces for collecting journaling data while delivering lifestyle guidance/support.
  - Live conversations with Health Coaches (if possible, text chat is sufficient)

2. Clinicians (doctors, nurses, diabetes educators, dietitians, mental health therapists)

- **Role:** Medical professionals who interpret patient data and adjust care plans
- **Level of involvement:** Regular reviewers during patient care
- **Dashboard/UI needs:**
  - Integrated view of all patient data
  - Ability to set custom thresholds for alerts
  - Permission to view all data for patients under their care

3. Healthcare IT administrators

- **Role:** Configure and maintain the integration between device server and EHR
- **Level of involvement:** Initial setup, occasional updates
- **Dashboard/UI needs:**
  - System status dashboard showing active integrations, including AI recommendation system monitoring and performance
  - Patient-device and patient-app association management
  - Data flow monitoring and error reporting
  - Administrative access for troubleshooting
  - Ensure seamless flow of EHR data to Well@Home system

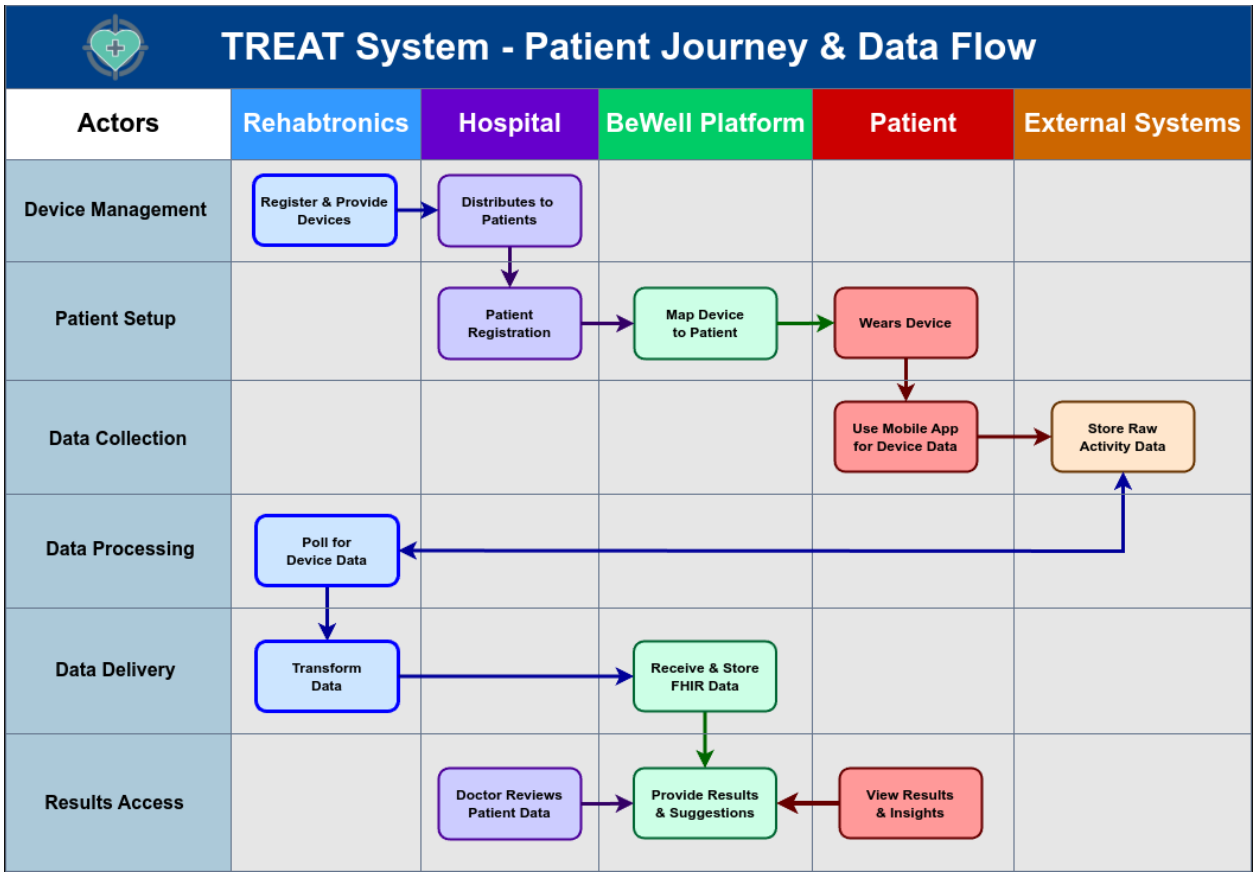
4. Device server operators

- **Role:** Ensure proper functioning of the device server system
- **Level of involvement:** Regular monitoring, maintenance
- **Dashboard/UI needs:**
  - Monitoring interface for data collection processes
  - Device connectivity status
  - Data transformation logs
  - FHIR transmission success/failure metrics

5. Research team operators

- **Role:** Ensure proper running of the study and monitor participant adherence
- **Level of involvement:** Regular monitoring, contact with participants and clinicians
- **Dashboard/UI needs:**
  - Monitoring interface for data collection processes
  - Device connectivity status
  - Input text data from back-and-forth coaching conversations with patients (not necessary if live chat interface exists, otherwise, will use other platforms for coaching conversations).

High Level – Actors and Data Flow



3.3 Data Collection and Availability

Data points collected:

- BMI, HbA1c, questionnaires: Quality of Life (SF-12), and Self-Efficacy for Diabetes (DSES)
- Lifestyle metrics, mental health and lifestyle habits assessments, daily reflection, journal entries, fitness schedule from My Viva Plan and Yaro
- Semi-formal interviews and health coaching interactions
- Heart rate, blood pressure, sleep intervals, stress levels from additional wearable devices, as available
- Physical activity metrics (steps, dynamic activity, standing time, sedentary time) from the MISS Activity Tracker
- Configuration settings for EHR integration
- FHIR transmission logs

Responsible for data entry/collection:

- Research team to ensure effective data collection, including from health coaching conversations
- Automated collection from platforms including wearable devices, My Viva Plan, and Yaro
- Device server for retrieving data from Maastricht University servers
- IT administrators for initial configuration of EHR integration parameters
- System-generated logs for data transmission

Frequency of data collection:

- Scheduled polling of university servers based on configuration (currently nightly)
- Data transmitted from device server to EHR based on configuration (currently nightly)
- Real-time transfer of My Viva Plan and Yaro data, if possible (daily if not).
- Weekly collection of health coaching conversational data.
- Weekly collection and transfer of EHR data to Well@Home system

Data storage:

- Temporary storage in device server during processing
- Persistent storage in EHR system
- Original storage on Maastricht University servers
- Original storage on My Viva servers

Standardized formats:

- FHIR for data transmission to EHRs
- Proprietary formats from wearable devices transformed to FHIR
- Proprietary formats from My Viva Plan and Yaro transformed to FHIR (or common TREAT-wide standard)
- Proprietary format for health coaching conversational data.
- (Basic Auth, OAuth 2.0?) for authentication with EHR systems
- Standard logging formats for system monitoring

Additional Privacy Clarifications:

- The Device Server collects device telemetry data only, without capturing patient identifiers.
- MVPlan data and Yaro data will only be transmitted to BeWell platform without patient identifiers. However, Yaro data may unintentionally include identifiable information due to the open nature of conversation.
- Mapping of device data, MVPlan data, and Yaro data to individual patient records is managed exclusively within the BeWell platform.
- The Device Server transmits activity data using FHIR resources. No patient references are embedded. If required to maintain FHIR schema validity, a dummy or placeholder value may be used. The Device Server does not manage, store, or receive patient identifiers.

3.4 Constraints and Open Questions

Technical or legal constraints:

- Patient data privacy compliance across multiple systems (no PII)
- EHR implementation requires custom FHIR mappings of device to patient
- Standardization of wearable device data formats alongside journaling data and conversational data formats
- Security requirements for healthcare data transmission

Challenges regarding stakeholder needs:

- Determining optimal visualization formats for different user types
- Establishing appropriate thresholds for activity-based alerts
- Integrating with existing clinical workflows
- Determining the exact needs of patients and clinicians

Needs under discussion or dependent on external factors:

- Final specifications for data visualization requirements by user type
- Device-to-patient association must be managed securely within the target EHR platform. The Rehabtronics Device Server does not manage, store, or transmit patient identifiers to maintain compliance with privacy and security requirements.
- Clarification is needed on whether the BeWell platform supports dynamic ingestion of Device FHIR resources submitted by external systems, or if pre-registration of wearable devices is required prior to mapping devices to patients.
- The common TREAT-wide interoperability standard defined and followed by all. This could be based on FHIR but needs to be defined for My Viva to integrate datasets into (i.e. My Viva Plan, Yaro, health coaching conversations).

4. UC2: Integrated System for Osteoarthritis Patients

4.1 Use Case Summary

Brief Description

UC2 focuses on developing an integrated digital health system for osteoarthritis (OA) patients, particularly those that also have diabetes type 2. The goal is to support physical therapists and lifestyle coaches in administering and remotely monitoring individualized intervention programs, utilizing wearable sensors, AI-driven feedback mechanisms, and semantic interoperability to enhance adherence to healthy physical activity norms.

Main Goal

To improve long-term adherence to physical activity regimes among osteoarthritis patients through personalized coaching, remote monitoring, and interfacing with workflows, thereby enhancing self-efficacy and overall health outcomes.

Primary Actors and Participants

- Osteoarthritis patients (with/without type 2 diabetes)
- Physical therapists
- Lifestyle/movement coaches
- General practitioners
- Healthcare administrators/policy stakeholders/municipality officials (e.g. Beweeghuis)
-

Secondary actors, for development phase

- Healthcare IT developers
- Researchers and technology developers

Expected Outcomes or Benefits

- Increased patient self-efficacy and adherence to physical coaching plan
- Reduced need for in-person sessions
- Enhanced integration of home-based data into clinical decision-making
- Improved personalization of interventions
- Secure, semantically interoperable system that ensures data privacy and utility

4.2 Stakeholders

1. Patients (Individuals with Osteoarthritis and Diabetes)

- **Role:** Primary beneficiaries of the intervention; provide activity and biometric data, receive coaching feedback—high daily involvement;
- **Level of involvement:** Daily. Patients actively participate in exercises and coaching sessions, wear monitoring devices, and interact with the digital platform
- **User needs**
  - **Dashboard/UI:**
  - User-initiated receiving of feedback on physical activity (e.g., steps taken, distance walked, heart rate, session completion).

- Progress tracking against personal movement goals.
- Motivational feedback and reminders via a chatbot or notification system from coach or therapist, on initiation of user.
- Simple visualizations that reflect trends in performance and progress.
- Accessible interface via a mobile app or web-client, designed for users with limited health literacy.
- Role-based access to ensure patients can only view their own data, with privacy controls in place.
- **System:**
- the obtrusion of the monitoring device should be minimal
-

2. Physical therapists and general practitioners

- **Role:** Clinical supervisors who design and monitor physical training plans and evaluate patient progress
- **Level of involvement:** Weekly to monthly. Engage with the dashboard during initial assessment, follow-ups, and for evaluating sensor data
- **Dashboard/UI needs:**
  - Overview of individual patient progress (e.g., improvements in walking distance, average heart rate).
  - Access to real-time and historical sensor data, showing the patient internal and external load.
  - Alerts and red flags for non-adherence or regression.
  - Recommendation tools for adapting physical programs and patient movement goals based on AI feedback.
  - Accessible via desktop-client or tablet in clinical settings.
  - Requires privileged access to specific patient data, with editing rights for updating plans.

3. Movement/lifestyle coaches

- **Role:** Guide patients through their physical activity journey, provide weekly check-ins, and support adherence to movement goals
- **Level of involvement:** similar to physical therapists.
- **Dashboard/UI needs:**
  - Goal setting interface and tracking tools.
  - Patient communication module for motivational messaging.
  - Summary views of progress across all assigned patients.
  - Trend dashboards showing progression or stagnation.
  - Access via destktop-client or tablet; requires user-level permissions with editing capability for patient goals and notes.

4. Researchers and evaluation experts

- **Role:** Analyse the collected data to assess intervention effectiveness, inform future development, and validate algorithms
- **Level of involvement:** Periodic. Focused on evaluation phases and data extraction
- **Dashboard/UI needs:**
  - Access to anonymized, aggregated data across patient cohorts.
  - Export functions for statistical analysis.
  - Visualization of outcome metrics (e.g., adherence trends, engagement rates).
  - Access via desktop analytics portal to activity data, with read-only permissions. To develop and assess interventions and possibly setup the motivational messaging.

5. Healthcare IT developers

- **Role:** Develop, integrate, and maintain the software platform, wearable sensor systems, and ensure interoperability with health data standards

- **Level of involvement:** Continuous, during platform development, integration, and support
- **Dashboard/UI needs:**
  - System monitoring tools for performance and data flow integrity.
  - Access logs, error tracking, and device integration statuses.
  - Interoperability testing interfaces to ensure HL7 FHIR and semantic mappings function correctly.
  - Accessible via internal development environment, with administrative-level access.

6. Healthcare administrators/policy stakeholders/municipality officials

- **Role:** Ensure integration into public health services, assess scalability, compliance, and cost-effectiveness of the solution
- **Level of involvement:** Low to moderate. Typically strategic checkpoints and adoption decisions
- **Dashboard/UI needs:**
  - KPIs on patient engagement and program outcomes.
  - Adoption **statistics**, dropout rates, and cost-benefit indicators.
  - High-level analytics dashboards with cohort-level overviews.
  - Restricted or anonymized access via read-only web-client with limited data granularity.

4.3 Data Collection and Availability

Data collected

The UC2 system will collect a variety of structured and semi-structured data to enable monitoring, feedback, personalization, and evaluation of intervention effectiveness. These include:

Physiological and Biometric Data:

- Physical activity patterns (e.g.: sitting, walking, standing, lying) via GNSS and accelerometers
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- Heart rate and heart rate recovery (real-time monitoring)
- 1-lead ECG signals (0.1–100 Hz range)

Garment and Wearable Sensor Data:

- Sensor signal quality and stability during use
- Usability and comfort feedback (e.g., pressure points, ease of donning/doffing, cleaning, skin irritations)
- Torso dimensions and, if required and permitted, photos of fitting details for garment fit verification
- Skin impressions after prolonged wear

Patient data:

- Electronic Health Records (EHRs), if available and permitted, including:
  - Diagnoses (e.g., osteoarthritis locations, diabetes type)
  - Contraindications (e.g., movement limitations)
  -
- Patient reports, if available and premitted
  - Condition report
  - Prescribed activity plans (e.g., intensity, frequency, target heart rate)

Behavioral and Psychosocial Data:

- Patient-reported preferences and motivations (e.g., interest in hiking or swimming)
- Progress on movement goals via validated questionnaires
- Feedback on personalized coaching messages
- User engagement with chatbot support

Responsible Parties

A number of pilots is performed to collect data, where the first pilot collects data to develop the integrated digital health system for UC2 and one of the last pilots will be to validate this developed system. The pilots will be organized and managed via one of the UC2 members, where the following responsibilities can be identified:

- Patients (via wearables, apps)
- Coaches/therapists (manual input, supervision)
- System (automated processing)

Collection Frequency

- Real-time (wearable sensors)
- Weekly/monthly (goal tracking, feedback)

Data Storage

- Integrated eHealth platform development
    - Compliant with GDPR and national healthcare privacy laws

Standardized Formats

- HL7 FHIR for health data
- APIs for device interoperability
- Potential semantic layers mapped through reinforced learning NLP models

4.4 Constraints and Open Questions

Known limitations

- Varying levels of health literacy among patients
- Limited existing technology use in current practice (e.g., no standard smart device integration yet)
- Ensuring sustained motivation beyond initial 12-week supervised phase

Technical Constraints

- Need for high-accuracy HR sensors and data interpretation
- Ensuring semantic interoperability across heterogeneous data sources
- Power efficiency and unobtrusiveness of wearables

Legal/Regulatory

- Full compliance with GDPR and Dutch health data regulations required
- Consent protocols for data sharing and AI feedback

Uncertainties

- Final user acceptance of new technology still to be validated
- Optimal communication styles for behavior change remain under experimentation

5. UC3: Recommender SaaS Platform

5.1 Use Case Summary

Main goal:

The main objective of Use Case 3 (UC3) is to develop an intelligent recommendation platform following a Software as a Service (SaaS) model. It integrates clinical, pharmacological, nutritional, and contextual data to provide personalized recommendations aimed at improving care for patients with non-communicable chronic diseases (NCDs).

Primary actors and participants:

- Healthcare professionals (doctors, clinical staff)
- Pharmacists
- Patients
- Technological partners within the TREAT ecosystem (GLINTT, DEXTRO)

Expected outcomes or benefits:

- Improved treatment adherence and patient self-efficacy
- Clinical decision support through AI-generated recommendations
- Seamless integration with healthcare platforms via API
- Reduced clinical variability and enhanced continuity of care

5.2 Stakeholders

Key stakeholder groups:

- **Patients:** Indirect users benefiting from tailored care recommendations
- **Healthcare professionals:** End users who receive contextualized clinical recommendations
- **Pharmacists:** Support treatment adherence and promote patient empowerment
- **IT staff / integrators:** Responsible for implementing and maintaining the API
- **Healthcare administrators:** Assess system impact on care delivery efficiency

Role and level of involvement:

- Patients: Indirect beneficiaries, low interaction with the system
- Healthcare professionals and pharmacists: Frequent users, high level of interaction
- IT staff: Integration and support, moderate involvement
- Administrators: Decision-makers and evaluators, moderate to low interaction

Dashboard/UI needs per stakeholder:

- **Healthcare professionals:** Access to patient-specific recommendations, current and historical data, alerts, and comparison tools
- **Pharmacists:** Follow-up recommendations, adherence indicators, actionable insights
- **IT staff:** API integration and system configuration tools
- **Interaction modes:** Primarily via web client or desktop client; potential mobile access for consultation
- **Access control:** Role-based permissions (read, write, admin)

5.3 Data Collection and Availability

Data types collected:

- Clinical parameters: diagnoses, treatment history, adherence data
- Pharmacological data: prescribed medication, interactions
- Dietary information: general nutritional patterns
- Care pathway data and clinical context
- Patient-reported experience and self-efficacy metrics (e.g., PREMs)

Who collects it:

- Healthcare professionals and pharmacists during routine consultations
- Integrated systems (e.g., FarmaTools, electronic medical records)

Collection frequency:

- Semi-automated data input triggered by healthcare events (consultations, prescriptions)
- Near real-time data update

Storage location:

- Secure cloud infrastructure compliant with GDPR
- Structured and indexed databases supporting traceability

Standardized formats:

- HL7/FHIR for semantic interoperability
- JSON for API integration

5.4 Constraints and Open Questions

Technical and legal constraints:

- Mandatory compliance with data protection laws (e.g., GDPR, national legislation)
- Assurance of data anonymization in real clinical environments

Challenges or uncertainties regarding stakeholders:

- Varying levels of digital maturity across pharmacies and healthcare centers
- Need for targeted training in digital tools among healthcare staff

Open questions or external dependencies:

- Degree of integration with regional healthcare systems
- Long-term clinical impact still under evaluation
- Sustainability and scalability mechanisms beyond the project timeline

6. UC4: Diabetes Monitoring

6.1 Use Case Summary

This use case focuses on developing an intelligent diabetes monitoring system that enables continuous collection and analysis of biometric data through wearable technology and digital health tools. The system will collect vital signs such as ECG, blood glucose, blood pressure, body temperature, and oxygen saturation, and uses AI to provide personalized, explainable health insights to both patients and healthcare providers. The ECG signal will be collected using a small ECG device and an integrated T-shirt, both of which will be developed as part of the project. Achieving this relies on robust data quality assurance processes, encompassing data accuracy and reliability analysis, comprehensive checks for missing data and consistency, and stringent data format controls. Furthermore, a significant effort will be dedicated to designing user-centric dashboards tailored to different user profiles (personas) to ensure these insights are delivered effectively and intuitively.

Main goal:
To support proactive diabetes management by combining real-time biosignal monitoring with AI-based decision support and accessible visual dashboards.

Primary actors and participants:

- Individuals living with or at risk of diabetes
- Medical professionals involved in monitoring and treatment
- Technical staff maintaining digital health infrastructure
- Public health authorities utilizing aggregated insights

Expected outcomes or benefits:

- Early detection of health deterioration or comorbidities
- Enhanced treatment adherence through patient empowerment
- Time-efficient clinical decision-making
- Improved health outcomes and reduced burden on healthcare systems

6.2 Stakeholders

Key stakeholder groups:

- **Patients:**
  - Role: Daily users of wearable devices and the mobile application
  - Needs:
    - Easy-to-understand, real-time feedback; progress monitoring; lifestyle guidance
    - Clear progress monitoring tools and personalized lifestyle guidance.
    - Intuitive visualizations of health data, designed to promote self-efficacy and understanding.
    - Assurance of high data quality for reliable personal health insights.
  - Access: Mobile-based UI; personal data only; options to export/share with clinicians

- **Clinicians (GPs, endocrinologists, cardiologists):**
  - Role: Medical decision-makers using AI-enhanced dashboards
  - Needs:

        - Risk scores (e.g., CHA_2DS_2-VASc), trend analysis, anomaly detection, explainable AI outputs
        - Access to risk scores (e.g., CHA2DS2-VASc), trend analysis, and anomaly detection features through web/desktop dashboards.
        - Explainable AI outputs to support clinical judgment.
        - Statistical analysis, predictive insights, and planning functionalities to optimize patient care.
    - Access: Web/desktop dashboard; individual and group-level data; notification alerts

- **Healthcare administrators and policymakers:**
    - Role: Oversee public health metrics, strategic planning
    - Needs:
        - Aggregated insights, comparative KPIs (e.g., control rate, readmission risk), time-based trends
        - Dashboards providing aggregated insights and comparative Key Performance Indicators (KPIs) (e.g., control rate, readmission risk).
        - Clearly defined KPIs, developed through thorough business analysis, to support strategic decision-making.
    - Access: Secure web portal with layered visualization (e.g., by region, age group, risk tier)

- **IT and data science teams:**
    - Role: System integration, AI development, data pipeline maintenance
    - Needs:
        - Monitoring tools for data quality, model explainability, error logs
        - Robust data pipelines supported by comprehensive data quality analysis, missing data management strategies, and data format controls to ensure reliable inputs for AI development.
    - Access: Admin interfaces, sandbox dashboards, real-time and batch logs

Interaction with the system:

- Patients interact through a mobile app with push notifications, insights, and optional survey input
- Clinicians use a desktop or tablet-based clinical dashboard integrated into care routines Public health users interact via web portals offering high-level visualizations
- Role-based access control ensures secure, compliant data interaction with GDPR and national regulations

6.3 Data Collection and Availability

The use case relies on a range of data sources, including wearable sensors, mobile applications, and external health databases. Collected parameters include:

Data Category	Examples	Key Quality Assurance Activities	Data Collection Method/Source	Collection Frequency	Data Storage	Interoperability Standards
Biometric Signals & Vital Signs	ECG (heart rate, rhythm), Blood Glucose, Blood	Accuracy & reliability analysis, missing data identification &	Wearable sensors, Mobile applications	Continuous or regular intervals	Structured, interoperable formats	HL7/FHIR targeted

	Pressure, Body Temperature, Oxygen Saturation	consistency checks, data format control.				
Derived Health Indicators	Health scores, AI-generated risk indicators	Validation of input data quality, consistency checks for derived outputs.	System-generated (AI processing)	As processed	Structured, interoperable formats	HL7/FHIR targeted
System & Platform Data	Data flow logs, error reports, user interaction data	Completeness checks, format validation, anomaly detection in logs.	Platform	Real-time and batch	Secure logs, analytics databases	Standard logging formats
Historical patient health records	Patient information forms, epicrisis notes, test results	Accuracy & reliability analysis, missing data identification & consistency checks, data format control.	Scanned documents and database entries from integrated hospitals	Continuous or regular intervals	Database	HL7/FHIR targeted

Data flow and management:

- Data is collected continuously or at regular intervals, depending on the signal type
- Real-time transmission is used for time-sensitive indicators
- Data is processed and stored in structured, interoperable formats
- Interoperability standards such as HL7/FHIR are targeted for system integration
- Aggregated data is used for public health dashboards and policy analysis

6.4 Constraints and Open Questions

Known limitations include:

- Legal and regulatory requirements for handling sensitive medical data
- The need for seamless anonymization and secure data access control
- Technical challenges in wireless data transmission and device calibration

Open questions under discussion:

- How to ensure inclusive engagement for users with limited digital literacy
- Final system configuration for clinical integration and scalability
- Long-term sustainability, funding, and maintenance models
- Strategies for incorporating new data sources or AI features over time

7. UC5: Distributed Diagnoses and Home Healthcare

7.1 Use Case Summary

This case study focuses on the application of innovative digital solutions to optimize the management of chronic conditions, namely childhood obesity, diabetes, and cardiac rehabilitation in patients who have previously experienced a cardiac event. The intervention is implemented in home and community settings, aiming to expand access to healthcare services in a personalized, efficient, and continuous manner beyond the hospital environment.

By integrating emerging technologies such as wearable devices and remote monitoring systems, this project seeks to facilitate home-based diagnostics, enable real-time follow-up, and strengthen patients' and families' capacity for self-management. At the same time, it aims to reduce the need for hospital visits, enhance the quality of clinical data available, and support medical decision-making with timely and updated information.

Key stakeholders in the management of childhood obesity and diabetes include pediatricians, nutritionists, psychologists, and nurses. In the context of cardiac rehabilitation, the clinical team comprises cardiologists, physiatrists, physiotherapists, and nurses, who work in close coordination to ensure an integrated and patient-centered approach. These multidisciplinary teams are responsible for monitoring clinical progress, adapting therapeutic plans, and implementing early interventions whenever necessary.

The expected benefits of this use case include improved quality of care through more personalized clinical follow-up, increased adherence to treatment plans, and early detection of health deterioration. Additionally, the system fosters patient autonomy, encourages active engagement in the therapeutic process, facilitates communication with healthcare professionals, and contributes to more efficient management of clinical resources.

7.2 Stakeholders

	Stakeholder	Primary Function	Usage Pattern	Application Requirements	Permissions
Cardiac Rehabilitation	**Patients**	They participate in the training sessions (phases I and II) of the program, complete questionnaires, and collaborate with the clinical team.	Daily use via mobile app.	- Simplified view of their progress (vital parameters, perceived effort, training progress). - Alerts for appointments, sessions, exams, and changes in clinical status.	Access only to their own data.

				- Ability to log symptoms and health status. - Access to videos and educational recommendations.	
	Nurses	They monitor the patients, plan and conduct the sessions, and collect and record clinical data.	Frequent use (on consultation and training days) via desktop or tablet.	- Access to real-time and historical clinical data. - Interface for quick recording of vital signs and observations. - Automatic generation of alerts in case of clinical anomalies. - Decision support tools for adjusting the training plan.	Full access to the data of patients under monitoring.
	Physiotherapist	They lead warm-up, training, and stretching sessions; collaborate in recording vital parameters.	Frequent use (on training days) via desktop or tablet.	- Visualization of personalized training plans and respective adjustments. - Recording of effort and progress per session. - Trends in clinical data (e.g., heart rate, Borg scale).	Access to clinical data relevant to training.
	Doctors (Cardiologist and Physiatrist)	They assess the eligibility to join the program, supervise the therapeutic plan, and issue medical discharge.	They use it during clinical consultations before, during, and after the program via desktop.	- Access to clinical history and session records. - Visualization of progress through clinical and functional indicators. - Ability to issue exams, referrals, and transportation credentials.	Full access to all clinical data
	Administrative staff	Scheduling of appointments and admissions.	Frequent use.	- Interface for managing schedules, rescheduling, and absences.	Restricted access to administrative data.
Childhood	**Patients (Children)**	They participate in multidisciplinary consultations, undergo exams,	Frequent use (in the case of childhood obesity), daily use (in the	- Visualization of their progress (BMI, blood glucose, lifestyle habits).	Restricted access and supervised by caregivers.

		and collaborate with the clinical team.	case of diabetes) via app.	- Access to educational content (nutrition, activity, monitoring). - Logging of behaviors, diet, and symptoms.	
	Caregivers of the patients	They accompany the child, implement therapeutic plans at home, record data, and communicate with the professionals.	Frequent use (especially in diabetes).	- Access to relevant clinical records (blood glucose, weight, dietary plan). - Personalized alerts (appointments, clinical changes, monitoring reminders). - Logging and viewing of dietary and behavioral data.	Full access to the child's data.
	Nurses	They collect clinical parameters and fill out structured forms.	Use on consultation days (every 3 months) via desktop.	- Recording and viewing of data (BP, weight, blood glucose). - Integration with other clinical records from different specialties.	Partial access.
	Nutritionist	They assess nutritional status, eating habits, and prescribe a dietary plan	Frequent use, primarily on consultation days (every 3 months) via desktop.	- Recording of anthropometric data, percentile and Z-score calculations. - Comparative charts and personalized dietary plan.	Full access.
	Psychologist	They assess the child's emotional state and the family context.	Frequent use, primarily on consultation days (every 3 months) via desktop.	- Application and analysis of psychological forms. - Emotional and behavioral history. - Contextual alerts (e.g., abrupt clinical changes).	Full access.
	Pediatrician	They coordinate clinical care, prescribe exams,	Frequent use, primarily on consultation days (every 3	- Full access to the clinical history and records from other specialties. - Issuance of	Full access.

		and define the therapeutic plan.	months) via desktop.	diagnostic test requests and referral reports (e.g., for adult care at age 18).	
	Administrative staff	Scheduling and recording of appointment admissions (with and without prior scheduling).	Frequent use.	Management of appointments for various specialties on the same day.	Restricted access to administrative data.

7.3 Data Collection and Availability

In this use case, various types of data will be collected with the aim of supporting clinical monitoring, personalizing interventions, and ensuring the ongoing management of patients in cardiac rehabilitation, childhood obesity, and type 1 diabetes programs.

Below is a table summarizing the main types of data to be collected, specifying who is responsible for their collection, the frequency of collection, storage locations, and the standards adopted to ensure interoperability between the systems involved.

Collected data type	**Who collects/enters the data**	**Data collection frequency**	**Data storage location**	**Interoperability standards**
Personal Data: - Date of birth; - Age; - Place of residence; - Education level; - …	Data integrated through SONHO.	Once.	DB EHR	HL7 ADT
Anthropometric Data: - Weight; - Height; - BMI (Body Mass Index); -Waist circumference; - Z-score; ...	Collected using monitoring devices or by healthcare professionals.	During appointments and/or daily.	DB EHR and PIIC	HL7 / FHIR

Vital Signs: - Heart rate; - Oxygen saturation; - Blood pressure; - Blood glucose levels; - ...	Collected via monitoring devices or through healthcare professionals.	During training sessions, in the case of cardiac rehabilitation, during consultations, or daily in the specific case of blood glucose monitoring in diabetes.	DB EHR and PIIC	HL7 / FHIR
Training / Physical Activity Data: - Training duration; - Borg scale; - ...	Collected via wearable monitoring devices or through healthcare professionals.	During training sessions.	DB EHR and PIIC	HL7 / FHIR
Nutritional Data: -Carbohydrate count; - Calorie intake.	Collected by nutritionists and by patients (or their caregivers, in the case of children).	Collected daily, as well as during consultations.	DB EHR and PIIC	HL7 / FHIR

7.4 Constraints and Open Questions

No constraints.

8. UC6: Enhancing Patient Self-Efficacy and NCD Management through AI-Powered Remote Monitoring

8.1 Use Case Summary

BeWell Innovations is enhancing its Well@Home digital health platform through the integration of advanced AI capabilities to support the remote monitoring and management of patients with Non-Communicable Diseases (NCDs). The use case focuses on combining real-time physiological and behavioral data with intelligent alerting and prediction mechanisms to enable timely, personalized, and preventive care.

Primary Actors and Participants:

- **Healthcare Professionals (HCPs):** Use the Clinical Command Center (CCC) and Alerts Dashboard to monitor, triage, and intervene based on real-time and AI-predicted patient signals.
- **Patients:** Use the mobile Well@Home app to input measurements, complete questionnaires, and receive personalized educational content.
- **BeWell Engineers & Researchers:** Responsible for developing the AI models, integrating backend/frontend functionality, ensuring security and compliance, and coordinating partner feedback.
- **Clinical and Research Partners:** Contribute medical knowledge, validate AI functionality, and assess usability and outcomes.

Expected Outcomes / Benefits:

- **For Care Teams:**
  - Early warning of health deterioration via vital trends and outlier detection.
  - More targeted and relevant alerts reduce overload and improve clinical response.
  - Reduced workload through automation of routine monitoring and prioritization.
- **For Patients:**
  - Increased understanding of their health status through tailored educational content.
  - Empowerment through clear feedback loops and visibility into care progress.
  - Stronger sense of connection to their care team, even remotely.
- **For the Platform:**
  - Scalable architecture supporting AI integrations with explainable, ethical decision support.
  - Strong alignment with medical device regulations and information security frameworks.
  - Reinforcement of BeWell's leadership in responsible and clinically integrated digital health AI.

8.2 Stakeholders

1. Patients

Role:
Patients are the primary data providers and beneficiaries of the platform. They input daily health data (measurements, questionnaire answers), consume personalized educational content, and receive feedback through alerts or messages.

Level of Involvement:
Daily users of the mobile application. They contribute real-time data and interact with educational content and care instructions.

UI Needs:

- **Features Needed:**
  - Easy-to-understand reminders.
  - Trend visualization of key vital signs.
  - Access to tailored educational articles.
- **Interaction Mode:**
  - Mobile application (primary).
  - Optional use of browser-based platform.
- **Access/Permissions:**
  - Can only view their own data.
  - Strong authentication enforced (e.g., 2FA, app lock screen).
  - Cannot modify care protocols but can provide feedback on AI suggestions and their experience.

2. Healthcare Professionals (HCPs)

Role:
Primary users of the Clinical Command Center and Alerts Dashboard. They monitor patients, interpret alerts (including AI-generated ones), take action (follow-up, triage, interventions), and document patient progress.

Level of Involvement:
Daily or weekly users depending on clinical workflow. Key decision-makers and interpreters of patient signals.

Dashboard/UI Needs:

- **Data Type:** Both real-time and historical data.
- **Features Needed:**
  - Patient overview dashboards with alert summaries.
  - Trend analysis over time for vital signs and diary responses.
  - Visualization of AI-predicted risks.
  - Smart filtering, triaging tools, and audit logs.
- **Interaction Mode:**
  - Web-based platform on secure hospital workstations.
  - Optionally mobile devices or tabelets (e.g., during home visits).
- **Access/Permissions:**
  - View/edit patient data only within their assigned cohort.
  - Action permissions depend on role (e.g., nurse vs physician).
  - All access is logged for traceability.

3. Clinical Administrators / Coordinators

Role:
Supervise operations, assign tasks to HCPs, and ensure patients are enrolled in appropriate care pathways. They manage alert rules, care protocol configurations, and data quality checks.

Level of Involvement:
Weekly or monthly users. Operational decision-makers.

Dashboard/UI Needs:

- **Data Type:** Aggregated and historical data.
- **Features Needed:**
  - Carepath configuration interface.
  - Alert rule editor.
- **Interaction Mode:**
  - Web-based platform (desktop).
- **Access/Permissions:**
  - Full access to configuration settings.
  - Cannot view clinical notes unless also licensed as HCP.

4. IT & Technical Staff (Hospital and BeWell)

Role:
Deploy, maintain, and monitor the infrastructure supporting the Well@Home platform. This includes hosting, data integration, authentication, backups, and audit compliance.

Level of Involvement:
Occasional users. Responsible for system integrity, uptime, and security.

Dashboard/UI Needs:

- **Data Type:** System logs, status dashboards, API monitoring.
- **Features Needed:**
  - User access management tools.
  - System health checks and logs.
  - Data export/audit trail functionality.
- **Interaction Mode:**
  - Admin web portal or backend interface.
- **Access/Permissions:**
  - No access to patient-identifiable health data.
  - Admin access to infrastructure and metadata only.

5. Researchers and Data Scientists

Role:
Analyze anonymized or pseudonymized data from the platform to assess care outcomes, train and validate AI models, and support continuous improvement of prediction algorithms.

Level of Involvement:
Periodic users depending on research timeline. External evaluators or internal team members.

Dashboard/UI Needs:

- **Data Type:** Historical, structured datasets (measurements, alerts, interventions, outcomes).
- **Features Needed:**

    - Access to de-identified exports.
    - Interfaces for feedback loop collection.
- **Interaction Mode:**
    - Data portals or secure dashboards.
- **Access/Permissions:**
    - No access to identifiable patient data.
    - Must meet strict data governance and ethics criteria.

8.3 Data Collection and Availability

Core variables

variable sources

The core variables can come from the following sources:

- If available for the patient set, the preferred source is the the BeWell platform database, from the patient-recorded and wearable-device recorded data.
- If no historical data is available, then the data can come from the hospital EHR/DWH/OMOP:
    - demographic data: patient attributes
    - height/weight if available, else use BMI
    - resting heart rate, spo2, o2 supplemental, temperature, respiration rate, blood pressure: these are typically measured as part of the NEWS protocol.
    - activity level and sleep quality are likely not available in hospital data

variable details

The table below specifies the definitions of each core variable. For each variable, expect gender and date of birth, we require the time of the measurement of the variable (not the time it was entered in the system). Data will use the OMOP-CDM standard.

Variable	Unit/type	Notes	Min	OMOP-CDM
date of birth	date	Minimum required is year of birth. Needed to calculate age at time of prediction.	1	person.year_of_birth, person.month_of_birth, person.day_of_birth
gender assigned at birth	categorical: (F, M, U)		1	person.gender_concept_id
weight	kg	We do not distinguish between dressed/undressed weight in the initial dataset	1	measurement.measurement_datetime, measurement.value_as_number from omopcdm.measurement where measurement_concept_id in (4099154) and unit_concept_id in (9529)

height	cm	This variable is expected to be measured less frequently and will be interpolated as needed	1	measurement.measurement_datetime, measurement.value_as_number from omopcdm.measurement where measurement_concept_id in (607590) and unit_concept_id in (8582)
resting heart rate	bpm	Should be taken at rest	5	measurement.measurement_datetime, measurement.value_as_number from omopcdm.measurement where measurement_concept_id in (40481601) and unit_concept_id in (8541, 8483)
spO2	%	If 'O2 supplemental' associated boolean is not available: assume patient is not on supplemental oxygen	5	measurement.measurement_datetime, measurement.value_as_number from omopcdm.measurement where measurement_concept_id in (4011919) and unit_concept_id in (8554)
O2 supplemental	boolean	Indicator whether the patient is on supplemental oxygen during the spO2 measurement	5	(condition) condition_occurrence.condition_start_date, 1 from omopcdm.condition_occurrence where condition_concept_id in (42873170)
temperature	C	Initially, do not require specific method (oral, armpit, rectal, etc)	5	measurement.measurement_datetime, measurement.value_as_number from omopcdm.measurement where measurement_concept_id in (4302666) and unit_concept_id in (586323)
respiration rate	bpm		5	measurement.measurement_datetime, measurement.value_as_number from omopcdm.measurement where measurement_concept_id in (4313591) and unit_concept_id in (8541, 8483)
diastolic blood pressure	mmHg	Initially, do not require specific location (arm, leg, etc)	5	measurement.measurement_datetime, measurement.value_as_number from omopcdm.measurement where measurement_concept_id in (4154790) and unit_concept_id in (8876)
systolic blood pressure	mmHg	See above	5	measurement.measurement_datetime, measurement.value_as_number from omopcdm.measurement where measurement_concept_id in (4152194) and unit_concept_id in (8876)
Activity level	categorical: (low,	The activity level can be investigated to understand what other activity metrics	5	Typically not available in hospital data

	medium, high)	can be calculated from the raw data.		
Sleep Quality	categorical: (low, medium, high)		5	Typically not available in hospital data

Outcome variables

variable sources

The outcome variables will come from the hospital EHR/DWH/OMOP. Most likely, this will come directly from ICD10 diagnosis.

variable details

The outcome that we aim to predict is the diagnosis of a NCD, therefore, we need to capture for all patients in our dataset: the date of first diagnosis of the NCD. Below is the initial list of NCD diagnoses with the relevant ICD10 and SNOMED codes.

Variable	**unit/type**	**ICD10**
First date of diabetes type 2	date	E11, 11.0, 11.1, 11.2, 11.3, 11.4, 11.5, 11.6, 11.7, 11.8, 11.9
First date of essential hypertensive disorder diagnosis	date	I10
First date of chronic kidney disease diagnosis	date	N18, N18.1, N18.2, N18.3, N18.4, N18.5, N18.9
First date of Alzheimer diagnosis	date	G30, G30.0, G30.1, G30.8, G30.9
First date of COPD diagnosis	date	J44.0, J44.1, J44.8, J44.9
First date of asthma diagnosis (exclude allergy-only asthma)	date	J45.1, J45.8, J45.9
First date of depression diagnosis	date	F32, F32.0, F32.1, F32.2, F32.3, F32.8, F32.9, F33,

		F33.1, F33.2, F33.2, F33.3, F33.4, F33.8, F33.9
…	date	

8.4 Constraints and Open Questions

Technical and Legal Constraints:

- **Integration with hospital EHR systems:** While the OMOP-CDM standard is used for structuring the dataset, integration with live hospital systems in Belgium may require tailored data pipelines and alignment with each hospital's internal architecture and policies.
- **GDPR compliance:** All data collected and processed through the Well@Home platform must fully comply with Belgian and European data protection laws. Special care must be taken to ensure pseudonymization, access control, and secure handling of sensitive health data across institutions.
- **Medical Device Regulation (MDR):** The AI modules providing clinical support may fall under EU MDR classification, necessitating additional validation, documentation, and CE marking. This affects project timelines and the scope of permitted functionalities in pilot settings.
- **Explainability of AI models:** Given the clinical impact of AI-generated alerts and recommendations, explainability is essential to build clinician trust and meet legal requirements under GDPR (right to explanation).

Challenges Regarding Stakeholder Needs:

- **Alert fatigue for clinicians:** A key challenge is finding the right balance in AI-generated alerts to ensure they are meaningful and reduce cognitive load instead of increasing it. Continuous refinement of alert thresholds and prioritization algorithms is needed.
- **Stakeholder alignment:** Hospital IT staff, data governance bodies, and clinical users must be aligned around interoperability and data-sharing responsibilities. This coordination remains a logistical and administrative challenge.

Open Questions and External Dependencies:

- **Common interoperability standard:** While OMOP-CDM and HL7 FHIR are targeted, a unified TREAT-wide semantic model still needs to be finalized to ensure consistency across all data inputs and partners.
- **Clinical acceptance of predictive AI in triage:** The extent to which Belgian clinicians are comfortable relying on predictive AI for patient triage or alert prioritization is still under evaluation. Training and usability studies are needed during the pilots.

9. Cross-Use Case Analysis

A comparative analysis of the six national use cases reveals both shared priorities and distinct approaches in the types of data collected to support their respective goals. While all use cases aim to improve patient outcomes through personalized care and digital health integration, the nature and scope of the data collected vary according to the targeted condition, stakeholder roles, and technological maturity of each setting.

9.1 Common Data Types and Standards

Several core data types emerge across the majority of use cases:

Vital signs and biometric data—such as heart rate, blood pressure, oxygen saturation (SpO_2), and body temperature—are collected in nearly all use cases, reflecting a shared emphasis on continuous health monitoring. Clinical parameters and EHR data, including diagnoses, treatment plans, and historical medical records, are also widely used. Integration with hospital systems is typically implemented using standardized formats, most notably HL7 FHIR.

Patient-reported outcomes and questionnaire-based inputs (e.g., SF-12, DSES, PREMs) are collected in UC1, UC2, and UC3 to assess engagement, self-efficacy, and intervention effectiveness. Behavioral and lifestyle data—such as journaling, activity levels, nutrition, and sleep quality—are collected in UC1, UC2, UC5, and UC6 to provide a more comprehensive view of the patient's context and support personalized feedback mechanisms.

All use cases demonstrate a strong commitment to semantic interoperability, often using open APIs and structured data models to support integration across platforms, providers, and care settings.

9.2 Differentiators and Advanced Use Case Characteristics

Despite these commonalities, each use case highlights specific priorities and innovations in how data is collected and used:

UC1 (Patient-centric digital ecosystem) integrates lifestyle journaling, wearable data, and conversational coaching inputs through external platforms such as My Viva Plan and Yaro. The combination of structured health data with semi-structured journaling and chatbot interaction emphasizes patient empowerment and engagement.

UC2 (Integrated system for osteoarthritis patients) focuses on physical rehabilitation, collecting detailed movement and posture data through wearables, along with patient feedback on sensor garment usability. The use of behavioral metrics and motivational feedback via digital coaches supports sustained adherence to activity plans.

UC3 (Recommender SaaS platform) aggregates structured clinical, pharmacological, nutritional, and contextual data to generate personalized recommendations for NCD management. Though it does not

prioritize real-time biosignal acquisition, its strength lies in data integration and the semantic depth of its recommendation logic.

UC4 (Diabetes monitoring) collects biometric signals—including ECG, glucose, and blood pressure—through custom wearable technology. The data is processed through a robust quality assurance pipeline and used to generate AI-enhanced insights for both patients and clinicians, with particular attention to explainability and usability.

UC5 (Distributed home healthcare) supports a diverse patient population, including individuals undergoing cardiac rehabilitation and children with obesity or type 1 diabetes. It includes anthropometric, nutritional, psychological, and caregiver-entered data, with a strong emphasis on multidisciplinary collaboration. Integration with regional systems like SONHO and PIIC supports broader healthcare coordination.

UC6 (AI-powered remote monitoring via Well@Home) is characterized by its structured and clearly defined data model. It combines real-time physiological and behavioral data collection with AI-based risk prediction and outcome tracking. The use case implements standardized variable definitions, OMOP-CDM mappings, and ICD10/SNOMED-coded events, offering a high level of alignment with clinical workflows, interoperability frameworks, and regulatory compliance.

9.3 Implications for Future Work

The diversity of data types across the use cases underscores the need for a harmonized yet flexible approach to interoperability. While HL7/FHIR is widely adopted and provides a strong foundation, additional effort will be required to ensure that semi-structured formats—such as free-text journaling, conversational coaching data, and device-specific outputs—can be effectively mapped to a common standard.

As several use cases aim to expand the use of AI-based personalization and decision support, maintaining high data quality and robust metadata definitions becomes critical. This includes clear traceability of data sources, timestamping of measurements, and validation protocols that ensure input data meets clinical standards.

Data governance and compliance with ethical and legal requirements—particularly in relation to patient consent, caregiver-mediated input, and data anonymization—remain essential. This is particularly relevant for use cases involving minors, mental health data, or conversational agents.

9.4 Proposal for Improved Interoperability via Standardized API

To support better interoperability across the TREAT ecosystem, a standardized API endpoint is proposed for integration within the Well@Home platform. This endpoint will allow authorized third-party systems—such as wearable device platforms, research systems, or national health databases—to transmit structured measurement data using HL7 FHIR-compliant payloads.

The API will initially support a defined set of vital parameters that are both clinically relevant and already supported within the Well@Home platform. These include blood pressure, oximetry (SpO_2), sleep score, temperature, weight, spirometry, heart rate, respiration rate, and Early Warning Scores (e.g., NEWS). Each

of these has a well-defined FHIR resource representation, which will be adopted to the extent possible to ensure semantic consistency and ease of integration.

To ensure technical clarity and data integrity, the behavior of the API and the supported payloads will be described in detailed developer documentation. This documentation will be made available to authorized parties, including members of the ITEA4 TREAT consortium, and will include authentication requirements, data formats, and usage guidelines.

As part of Work Package 4, BeWell Innovations will develop a detailed implementation proposal for this API. The proposal will include governance considerations, security requirements, and a suggested data flow model. It will be presented to the consortium for review and refinement. The overarching goal is to provide a reusable and extensible interface that facilitates secure, standards-based data exchange across use cases and partner platforms, thereby accelerating technical integration and maximizing clinical value.

