PROLEPSIS

D2.5 / Updated report on user research and co-creation process

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List of abbreviations

dBM	Digital biomarker
DHT	Digital Health Technology
EHR	Electronic Health Record
GR	Greece
HCP	Healthcare Professional
KPI	Key Performance Indicator
NL	The Netherlands
NPS	Net Promoter Score
PRP	Patient Research Partner
PsA	Psoriatic Arthritis
PsO	Psoriasis
PT	Portugal
SEQ	Single Ease Question
SUS	System Usability Score
UI	User Interface
UK	The United Kingdom
UR	User Requirement
UX	User Experience
xAI	Explainable AI

Executive summary

This deliverable, D2.5 “Updated report on user research and co-creation process,” summarises how patients, healthcare professionals, and researchers have jointly shaped the development of the iPROLEPSIS Digital Care Ecosystem. The report presents the progress of user research and co-creation activities conducted within Work Package 2, which aimed to ensure that all digital health technologies developed for psoriatic arthritis are meaningful, acceptable, and usable in real-life clinical settings.

Building on the empathic insights of Deliverable D2.1, this report documents the transition from understanding user needs to developing, testing, and refining digital tools through a structured participatory design process. Activities took place between July 2023 and October 2025 across four countries: the Netherlands, the United Kingdom, Portugal, and Greece. More than 780 patients and 30 healthcare professionals participated through focus groups, surveys, co-creation workshops, and usability tests, forming an active iPROLEPSIS community.

The process combined the CAPTAIN Framework with Design Thinking principles, encouraging continuous dialogue between users and developers. Participants were involved not only in testing but in shaping how digital tools should look, function, and support daily life with PsA. Their contributions provided clear guidance on usability, accessibility, and the emotional experience of technology use.

For the miPROLEPSIS app, used to monitor PsA symptoms, participants appreciated the clear visual design but requested improvements in navigation, active tests, and data visibility. These insights led to a redesigned interface with simplified reporting and better self-tracking functions. Usability testing produced a System Usability Scale (SUS) score of 68, indicating acceptable usability with room for further optimisation.

The Lifestyle Recommendation System for personalised nutrition and activity advice was received positively for its clarity and flexibility. Participants asked for stronger consideration of dietary preferences, portion sizes, and translations, leading to updated prototypes offering greater personalisation and cultural relevance.

The biAURA app, supporting sleep and relaxation, was perceived as calming and visually appealing. Users highlighted the need for clearer visual cues, easier playlist navigation, and improved onboarding. These adjustments were incorporated into the next version of the app.

Regarding the iPROLEPSIS Games, the sessions revealed that successful game design for PsA hinges on user-centred, adaptive, and clinically relevant features. Participants prioritised engaging gameplay that combines education and entertainment, with personalised content, emotional support, and accessibility. Clear instructions, appealing visuals, and motivational elements were valued, while feedback also identified areas for refinement such as tutorial clarity, device compatibility, and physical comfort. These insights now guide the development of more responsive and meaningful serious games.

The iPROLEPSIS Dashboard for healthcare professionals was valued for its clarity and potential to integrate digital biomarkers into clinical decision-making. Clinicians appreciated the flare-risk score and the interpretability of explainable AI outputs but requested simpler visualisation and better integration with existing electronic health records.

Across all activities, participants emphasised that successful digital care depends on usability, trust, and the preservation of human connection. The co-creation process has already resulted in concrete design improvements and has strengthened collaboration between patients, clinicians, and developers.

Deliverable D2.5 demonstrates that meaningful innovation in digital health arises from long-term engagement with its users. The insights gained will guide further refinement, multilingual testing, and clinical validation within the ongoing iPROLEPSIS studies, bringing the ecosystem closer to real-world implementation and to a future of more connected, personalised, and empathetic PsA care.

1 Introduction

The development of effective and sustainable digital health technologies (DHTs) requires a deep understanding of the contexts, expectations, and needs of their intended users. Digital health interventions do not operate in isolation but within a broader care ecosystem, where patients, healthcare professionals (HCPs), and other stakeholders interact with digital tools in complex and often dynamic ways. Ensuring that such solutions are relevant, acceptable, and usable demands a systematic process of user research and co-creation, which grounds technological innovation in lived experience and practical clinical realities.

Deliverable D2.1 documented the *Empathise phase* of the iPROLEPSIS design process. Through a combination of literature review, context analysis, focus groups and survey research conducted in the four participating countries. D2.1 captured the perspectives of psoriatic arthritis (PsA) patients and highlighted the challenges and opportunities for introducing digital biomarkers (dBMs) and DHTs. The findings underscored four central themes:

- **Complexity:** Healthcare systems across the participating countries vary considerably in their organisation and accessibility. This heterogeneity creates both opportunities and challenges for the integration of digital innovations, requiring solutions to be carefully aligned with existing structures and care touchpoints.
- **Heterogeneity:** PsA itself is a diverse and fluctuating condition, affecting different age groups and life stages in variable ways. Personas were therefore developed to represent this diversity and guide the design of the iPROLEPSIS DHTs.
- **Trial and Error:** Living with PsA involves navigating cycles of uncertainty, adaptation, and grief, as patients learn through trial and error how to manage their symptoms. Supporting patients through this process was identified as a central purpose of the iPROLEPSIS Digital Care Ecosystem, visualised in a patient experience map.
- **Preference Differences:** Patients expressed diverse expectations and requirements for DHTs, particularly in relation to features such as visual design, notifications, and daily monitoring. These differences highlight the need for clear explanations, iterative testing, and consensus-building during co-creation and development.

Together, these insights provided a detailed foundation of user needs and system-level considerations, which were translated into initial user requirements for each iPROLEPSIS DHT. Deliverable D2.5 builds directly on this foundation and continues to place users at the centre of the development process of the iPROLEPSIS Digital Care Ecosystem.

1.1 Document scope

Deliverable 2.5. is the updated report of D2.1. As part of WP2, the deliverable provides an update on the user research and co-creation activities executed within Task T2.2 of the iPROLEPSIS project since July 2023. Activities performed under T2.2. have contributed to the development of the iPROLEPSIS Digital Care Ecosystem reported in the WP4 deliverables. Furthermore, Usability Assessments implemented in the PDPID, IDBV and PPIDC study of WP5 are part of T2.2.

1.2 Document structure

D2.5 provides an overview of the methods and outputs of the conducted user research and co-creation. It is a standalone document that continues the work reported in D2.1. Apart from this **introductory Section 1**, the document is structured in additional sections as follows:

- **Section 2: User Research & Co-Creation Method** – The section summarizes user identification, a description of the iPROLEPSIS Digital Care Ecosystem components, the user-research and co-creation methodology and an overview of the key activities with Key Performance Indicators (KPIs) updates;
- **Section 3: User scenarios** – Describes the user scenarios of the iPROLEPSIS DHTs from the various user perspectives;
- **Section 4: User Requirements** – Provides the updated set of user requirements per DHT deducted from the literature, focus groups, surveys and co-creations;
- **Section 5: Usability Assessment Plans** – Outlines the usability evaluations implemented in the PDPID, IDBV and PPIDC study, along with preliminary results if available.

2 User Research & Co-Creation Method

2.1 Intended users

Psoriatic arthritis (PsA) is a chronic inflammatory disease of the joints and spine that severely impacts patients' quality of life. The iPROLEPSIS Digital Care Ecosystem is designed to empower both PsA patients and individuals with psoriasis (PsO), who are at risk of progression, offering tools for early detection, prevention, and personalised disease management. The iPROLEPSIS Digital Health Tools (DHTs) are intended to empower these patient populations to actively manage their health.

Simultaneously, healthcare professionals (HCPs) should use the ecosystem to monitor disease progression, support decision-making, and provide timely interventions for their patients. Their involvement and clinical expertise ensure that the system directly improves care pathways.

The effective use of iPROLEPSIS Digital Health Ecosystem, depends on reliable system governance and maintenance. Administrators and developers will guarantee that the ecosystem is implemented and maintained effectively across different care settings. Administrators are responsible for managing accounts and ensuring secure, efficient integration into healthcare organisations, while developers provide continuous technical updates and improvements. Together, these stakeholders, indicated in **Table 1**, form the backbone of the iPROLEPSIS Digital Care Ecosystem, enabling its successful deployment and long-term sustainability.

Table 1 Intended Users of the iPROLEPSIS Digital Care Ecosystem

Role	Description
Developers	iPROLEPSIS development team, responsible for continuous upgrades to the iPROLEPSIS Digital Care Ecosystem and the individual DHTs.
Administrators	One dedicated person within the Hospital or study coordinating team that takes on the responsibility of managing and implementing the iPROLEPSIS Digital Care Ecosystem. • *iPROLEPSIS Administrator;* one person per country that can oversee all accounts of their country. • *Hospital Administrator;* one person per hospital that can oversee all accounts within the hospital rheumatology department.
Healthcare Professionals	Rheumatologist and rheumatology nurses that are responsible for the care of the PsA patients who want to utilize the iPROLEPSIS Digital Care Ecosystem offered by their hospital.
PsA Patients	Patients diagnosed with PsA whose rheumatologist offers use of the IPROLEPSIS Digital Care Ecosystem
PsO Patients	Any patient with PsO that wants to make use of the iPROLEPSIS Digital Care Ecosystem
Tech Assistant	Support hospital personnel with the dedicated responsibility for data monitoring and technical explanations to patients and HCPs.

2.2 Description of the iPROLEPSIS Digital Care Ecosystem

The iPROLEPSIS Digital Care Ecosystem is a comprehensive, patient-centred digital health solution designed to support early detection, personalised risk assessment, and targeted intervention in PsA. The ecosystem integrates multi-source data, including clinical, lifestyle, genetic, microbiome, and dBMs, to power explainable AI (xAI) models that predict inflammation risk, disease progression, and support preventive strategies. **Table 2** outlines the various DHTs comprising the iPROLEPSIS Digital Care Ecosystem. Each component of the system is further described in the WP4 Deliverables (D4.1 – 4.4).

Table 2 A list of the DHTs in the iPROLEPSIS Digital Care Ecosystem

DHT	Description
miPROLEPSIS app	Mobile application targeting PsA patients for symptom monitoring with dBMs. The app also provides educational material and incorporates the Lifestyle Recommendation System (personalised dietary and physical activity recommendations).
miPROLEPSIS Lite app	Stand-alone mobile application developed targeting PsO patients. The app can be used to monitor the development of any PsA symptoms.
miPROLEPSIS Joint Landmarker app	Mobile application that supports the active video tests in the miPROLEPSIS app. The app needs to be installed on the users' phone, but does not require any further user interaction.
iPROLEPSIS Games app	The Serious Gaming Suite is a mobile application targeting PsA patients. The serious games are designed to promote wellness and prevent health decline. Fourteen serious games are planned to be included in the gaming suite.
miPROLEPSIS biAURA app	Mobile application targeting PsA patients for symptom management. biAURA offers binaural beat tracks for various use cases, i.e. sleep and relaxation.
iPROLEPSIS Dashboard	Web-Application Dashboard targeting HCPs involved in PsA care to monitor patient data, assess risk, and support decision-making. The dashboard shows outcomes of the iPROLEPSIS digital monitoring, prediction models and interventions.
iPROLEPSIS Interventions	The mobile applications and features that support PsA patients with symptom management; the personalised dietary and physical activity recommendations; biAURA; and the serious games.
iPROLEPSIS Digital Care Ecosystem	The full Digital Health Ecosystem comprising all DHTs described above.

2.3 Recap of the methodology

Within iPROLEPSIS the Captain Framework (Tessarolo et al., 2022) is followed with an increased emphasis on Design Thinking (Gibbons, 2016). The approach is outlined in **Figure 1**. Basically, the process is divided in an *Empathising phase* to develop knowledge about what our users do, say, think, and feel; a *Development phase* that applies co-creation with all stakeholders in sprints; and finally, *User Testing* to ensure that in native languages the DHTs are properly understood and easy to use.

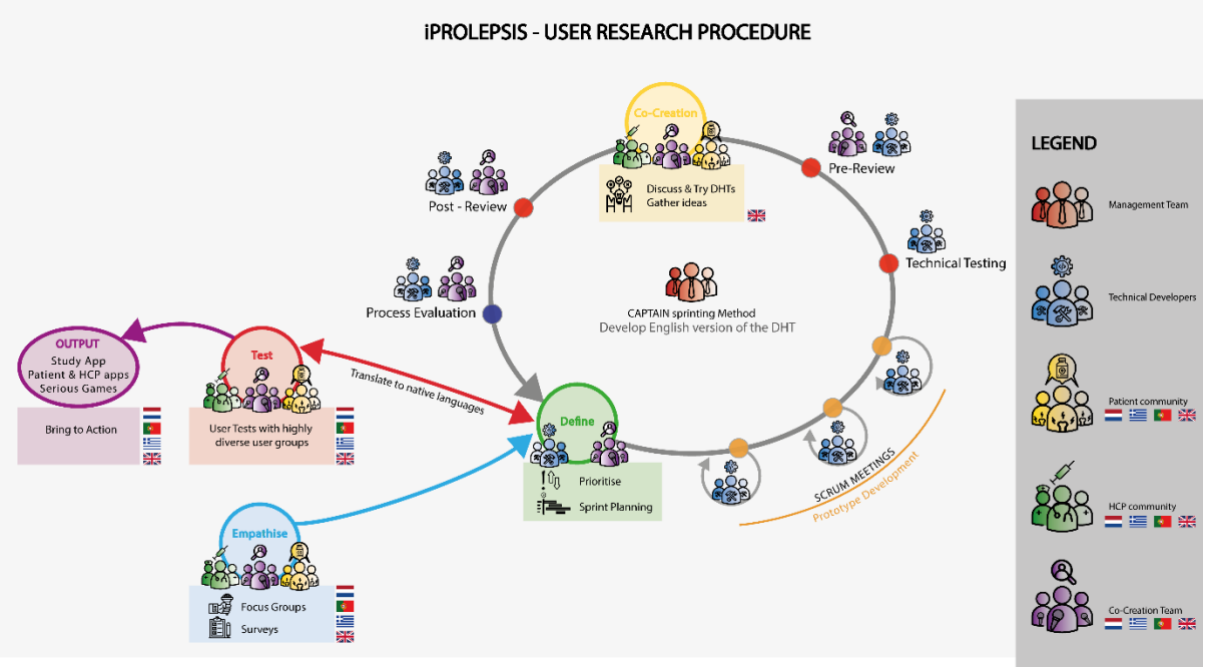

Figure 1 iPROLEPSIS User Research & Co-Creation approach, based on Design Thinking & The CAPTAIN Framework.

Phase 1 – Empathise was previously described in D2.2. Focus group and survey findings were used to create a Patient Experience Map and five different Personas. An additional focus group with HCPs is reported on in Section 2.5.5.

Phase 2 – Development is divided into Design Sprints. These sprints were conducted separately for the various iPROLEPSIS components to be developed. Co-creation sessions within each sprint were conducted with Patient Research Partners (PRPs) and/or HCPs. PRPs are individuals living with a health condition who 'provide input to research, through active collaboration as equal partners with researchers' (Aouad et al., 2024). The sessions were conducted in English with participants from the Netherlands (NL), The United Kingdom (UK), Portugal (PT) and Greece (GR).

GATE 1: Design sprints until satisfaction about the DHT is achieved.

Phase 3 – User Testing is conducted after translating the DHTs from English to Greek, Portuguese and Dutch. User Tests are set up to make sure that the DHTs will be understandable to the test participants, thus participants outside the co-creation group. So far, task-based user tests have been performed for the study version of miPROLEPSIS app (used in PDPID study). The resulting SUS score of 68/100 meets the SUS benchmark, but leaves space for further improvements and updates during the duration of the PDPID study.

GATE 2: User Test results in native languages should be satisfactory before starting implementation of the DHTs in the iPROLEPSIS Studies

After implementation of the DTH study versions (used in the PDPID, IDBV and PPIDC studies), users' satisfaction and acceptability will be assessed as part of the study outcomes (and reported in the corresponding deliverables of WP5) and can be used to further improve the iPROLEPSIS Digital Care Ecosystem. The Usability Assessments are outlined in Section 5.

Benchmarks (stemming from the KPIs defined under O6 and O7 in the Grant Agreement): Average SUS score >70 (per tool and end-user group). Users' satisfaction and acceptability of the personalised interventions (>90%).

2.4 Overview of activities + KPI status

The objective of T2.2 is to define the needs of relevant stakeholders and actively engage them in research aimed at understanding the transition from health to PsA. This includes the development of xAI-driven tools to support personalised healthcare delivery for PsA treatment, inflammation risk assessment, and prognosis, as outlined in WP2.

KPIs stemming from O2 in the Grant Agreement and to be addressed in WP2 are:

- 1 round of focus groups/surveys
- 3 rounds of co-creation workshops
- ≥3 design sprints
- iPROLEPSIS community of ≥500 persons with/at risk of PsA and ≥50 HCPs from ≥4 countries involved.

T2.2 was carried out from Month 1 to Month 34 during which clinical and technical partners collaborated with individuals living with or at risk of PsA and HCPs. This collaboration forms the iPROLEPSIS community, built on a culture of dialogue and openness. Various activities supported the ideation and development of the iPROLEPSIS DHTs, including the miPROLEPSIS app, biAURA app, iPROLEPSIS Games, and the iPROLEPSIS Dashboard. The various interactions and the current size of the iPROLEPSIS community are listed in **Table 3** and **Table 4**.

Table 3 User Research and Co-Creation activities.

Type	**# Interactions**
Focus Groups	12
Surveys	2
Co-Creations • miPROLEPSIS app • biAURA • iPROLEPSIS Games • iPROLEPSIS Dashboard	 10 2 7 5
Usability Testing	18
Total # Interactions	56

Table 4 Stakeholder Involvement Status.

	Patients	**Healthcare Professionals**

Focus Groups	39	5
Survey	398	-
Co-Creations	16	27
Usability Testing	18	0 / 5*
PDPID Study Participants	321 / 600*	-
IDBV Study Participants	0 / 3458*	-
PPIDC Study Participants	0 / 72*	0 / 16*
Total # Stakeholders • Current • Incl. Expected	 792 / 500 4601 / 500	 32/ 50 51 / 50

* Expected number of stakeholders

2.5 Key Insights

2.5.1 miPROLEPSIS App

Interactions #1-8 (Sept. – Jan, 2023): Between the introduction of the PDPID version of the miPROLEPSIS app and its early development phase, a total of 8 structured interactions with PRPs were conducted. These interactions formed a continuous co-creation process, starting with 2 introductory sessions to build rapport, followed by a formal co-creation workshop, and then a series of bi-weekly meetings to iteratively refine and test the app.

The first co-creation session for the PDPID version of the miPROLEPSIS app was held with 5 PRPs online on October 3, 2023. The purpose of this session was to explore the preliminary design of the app, focusing on the overall look and feel of the user interface (UI) and identifying ways to improve its usability for patients with PsA. Overall, the session was evaluated positively. Facilitators and observers noted that rapport was built successfully and that patients contributed openly.

PsA patients generally approved of the visual design and appreciated the opportunity to give feedback in an open, respectful environment. They highlighted, however, several areas where improvements were needed. A central theme that emerged was the importance of being able to review their own data within the app. Participants stressed that this was not only a key motivator for their continued use but also a condition for participation in the PDPID study. Without personal access to data, the effort of contributing information felt one-sided.

Specific feedback included requests for clearer visual cues about when activities should be performed and which pages are accessible. Certain design elements, such as the large central button and avatar at the top of the screen, were seen as distracting or unnecessary, while the use of “smiley faces” to represent pain levels was rejected as childish and demotivating. Patients also asked for simpler ways to report their status, such as colour-coded buttons or comparisons to the previous day, instead of being required to fill in detailed daily questionnaires. Missing features were also noted, including medication tracking, fatigue and pain measures on the home screen, and the ability to keep notes or a diary.

Building on these insights, five bi-weekly meetings were held to address specific design and functionality areas in an iterative manner. These meetings covered in-app questionnaires, the photo & video tasks (instructions), and the added ‘MyJourney section’ that provides a historic overview of dBM measurements, filled questionnaires and reported flares. It also includes a note-taking function, enabling users to record medication use, including missed doses, and other external factors they consider relevant to their symptoms, thereby supporting more

reflective and personalised health tracking. In each meeting, PRPs were asked to reflect on new iterations of the app and provide targeted feedback. The iterative process has provided developers with concrete direction and created a foundation of trust and collaboration with PRPs, which will be critical for the ongoing development of the miPROLEPSIS app.

PDPID App User Testing (June, 2024): The usability testing of the miPROLEPSIS–PDPID app was conducted with 18 PsA patients across NL, UK, PT, and GR. Participants represented a diverse demographic in age (27–78), education (from lower secondary to Master's level), and digital literacy (basic to expert). Most had no prior contact with the application. The study set-up included one-to-one task-based sessions using a think-aloud protocol, during which facilitators observed errors, difficulties, and user strategies. After completing tasks, participants filled in a usability questionnaire to capture their perceptions of the app.

Overall, participants appreciated the app's clean visual design, but reported substantial usability barriers. Sign-in was straightforward, although font size was noted as small. Major issues included difficulty locating language settings, poor comprehension of the "My Journey" section, and misinterpretation of quadrant metrics as manual inputs rather than smartwatch data. Users frequently struggled to distinguish clickable from non-clickable items, and cancellation functions caused unintended data loss.

Specific tasks highlighted critical problems. Questionnaires were hindered by imprecise sliders, confusion with mannequin orientation, and poor recognition of review and skipped-question functions. The photo test was difficult to perform, particularly during flares; images could not be retaken, cropping obscured quality, and uploads often failed. The video test presented the greatest challenge: movements were painful or unsafe during flares, phone positioning was problematic, instructions unclear, and gestures easily misinterpreted. While skeletal tracking was positively received, participants required substantial observer support.

Quantitative findings corroborated these issues. The SUS score was 68/100, indicating marginal but suboptimal usability. The Net Promoter Score (NPS) was +6, reflecting mixed views: some participants valued the app's potential, while others were hindered by usability difficulties.

Thus, although the app's design was well regarded, serious usability concerns were to be addressed before clinical deployment. The most pressing issues concerned the questionnaire interface, video task feasibility and safety, and overall navigation clarity, which risked compromising data quality, user engagement, and study retention.

2.5.2 miPROLEPSIS Lifestyle Recommendations

Regarding the Lifestyle AI-based Recommendation System, two co-creation sessions have been performed to gather user feedback and refine the user interface and features. The key insights gathered during these co-creation sessions are:

Interaction #1 (October 25, 2024): During a virtual meeting, the developers of the recommendation system presented the functionalities of the system and the way the nutrition and physical activity recommendations will be presented to users. PRPs engaged actively in discussions about the initial mock-ups to identify elements that users liked, gather insights from user experiences, highlight needs and gaps, and capture user preferences, desires, and aspirations. Overall, participants expressed a great level of satisfaction with this co-creation session, describing it as a collaborative and engaging experience. The users valued the clear presentation and simplicity of the nutrition and physical activity recommendations, as well as the inclusion of intensity levels next to the proposed physical activity exercises. The users noted the complexity involved in crafting appropriate nutrition and physical activity recommendations for accommodating the needs of users with varying backgrounds and

knowledge levels. Finally, the users asked for clearer definition of portion sizes, guidance on specific meal timings, the ability to choose alternative meal options and the accommodation of diverse dietary preferences (e.g., vegetarian, gluten-free, lactose-free, etc.).

Interaction #2 (February 11, 2025): During a virtual meeting, the developers of the recommendation system made a live demonstration of the nutrition recommendation system, along with the updates performed to the system given the user feedback collected during the co-creation session #1. In terms of positive reactions, the PRPs highly valued the refinements in the recommendation engine that were performed based on the user feedback from the first co-creation session. In particular, the users liked the addition of a new functionality that enables users to change their daily meal plans (selection from 3 options), thus giving them more power over the nutrition recommendations, as well as the inclusion of meal timings in the recommendations. Finally, the participants requested more clarity on the way the general nutritional advice is constructed and highlighted the need for the recommendation system to consider different dietary preferences, intolerances and allergies and to have translations of the meals and ingredients in different languages to accommodate all 4 population groups (UK, NL, PT, & GR).

2.5.3 miPROLEPSIS biAURA App

Interaction #1 (September 20th, 2024): The first biAURA co-creation session was organised with the research team. Users engaged with the biAURA prototype by performing tasks and recording feedback in Microsoft Forms, followed by group discussions on the app screens and a proposed diary feature. This approach combined hands-on experience with guided discussion to gather both practical and conceptual user insights. Overall, participants responded positively to the biAURA user interface and core functionalities. However, the co-creation session revealed several areas for improvement. Usability could be enhanced by adopting a more readable colour scheme and providing clearer indicators of active modes. Navigation and onboarding would benefit from preloaded sounds, a guide for new users, and a tutorial explaining app features. Device compatibility issues include inconsistent button placement and a lack of standardization for frequently used controls. The playlist feature required refinement to address bugs and to better distinguish between adding and selecting sounds. Additional suggestions included usage tracking, visual indicators of sleep patterns, and preset sounds and guidance modelled on established sleep apps.

Interaction #2 (June 30th, 2025): The second co-creation session with PRPs aimed to identify potential UI/UX issues in the biAURA app from the PsA patient perspective, focusing on both general impressions and specific functionalities such as sleep and relax mode, playback, the diary, the sounds page, and the tour feature. Prior to the 45-minute session, PRPs explored the app independently, and during the session a live demo showcased each page and functionality, with feedback collected interactively. PsA patients provided input on usability, design, and navigation, discussing issues directly with developers or facilitators as needed. Participants found the Diary feature difficult to interpret, particularly the meaning of diagram colours and the indication of the days. The Sleep Mode setup was viewed as unintuitive, with the alarm clock interface considered cumbersome. In Relax Mode, users requested enhancements such as a clearer playlist display and an option to repeat tracks. The app's tour function was also judged insufficiently intuitive. Finally, several bugs were reported in the iOS version.

2.5.4 iPROLEPSIS Games

Interaction #1 (June 21, 2023): The first co-creation session of the iPROLEPSIS Serious Games brought together 32 participants, including Clinical Partners, PRPs, researchers, and technical experts. Organised into four multidisciplinary teams, the session fostered a rich

exchange of perspectives aimed at designing serious games tailored for individuals with PsA. Guided by experts from FMH-ULisboa, the session employed the Crazy 8s technique to stimulate rapid ideation, resulting in the creation of 32 game scenarios (see **Figure 2**). Participants used sketching, dot voting, and timed exercises to collaboratively develop and evaluate game concepts, highlighting the importance of user-centered design and interdisciplinary input.

Key outcomes of this session included the generation of diverse and innovative game ideas, strong engagement with the ideation process, and recognition of the challenges in balancing clinical relevance with engaging gameplay. In addition, the activities proved highly effective, particularly the use of the Crazy8s method (Knapp et al., 2016), though participants suggested more structured time for discussion could enhance future sessions. The insights gathered provided valuable guidance for the next stages of game development, reinforcing the importance of user preferences and collaborative input in shaping a more responsive and user-centred design process. Moreover, this session highlighted the value of stakeholder involvement in creating meaningful and impactful serious games.

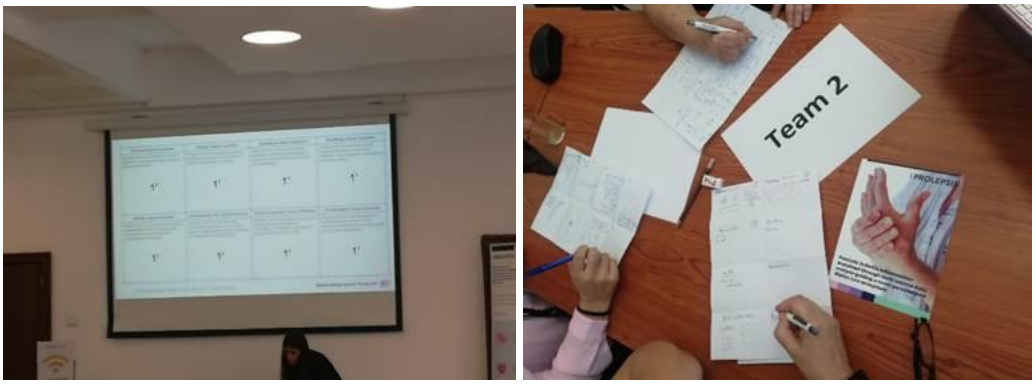

Figure 2 Games Interaction#1 using Crazy 8s ideation method.

Interaction #2 (October, 2023): The second co-creation sessions of the iPROLEPSIS Serious Games (one with HCPs (October 2, 2023) and one with patients (October 16, 2023)) played a crucial role in refining game design through collaborative feedback. The first session involved 14 participants who evaluated four game categories using storyboard techniques, offering insights on clinical relevance, personalization, and therapeutic potential (see **Figure 3**-left). Emphasis was placed on adaptive gameplay, integration of occupational therapy, and the use of AI to tailor difficulty levels. HCPs also highlighted the value of serious games as dBMs and emotional support tools, recommending usability improvements for patients with motor limitations.

In parallel, the patient-focused session engaged 11 participants to assess Exercise, Dietary, and Emotional games (see **Figure 3**-right). PsA patients provided feedback on gesture-based mechanics and expressed a strong preference for games that blend entertainment with education. They emphasized the need for personalized content, accurate nutritional guidance, and emotional support features. "The Spy" exergame stood out for its full-body engagement, while time constraints in "Mr. Blue Sky" were seen as stressful.

To sum up, both co-creation sessions reinforced the importance of co-design in developing meaningful, user-centered serious games that address the diverse needs of PsA patients.

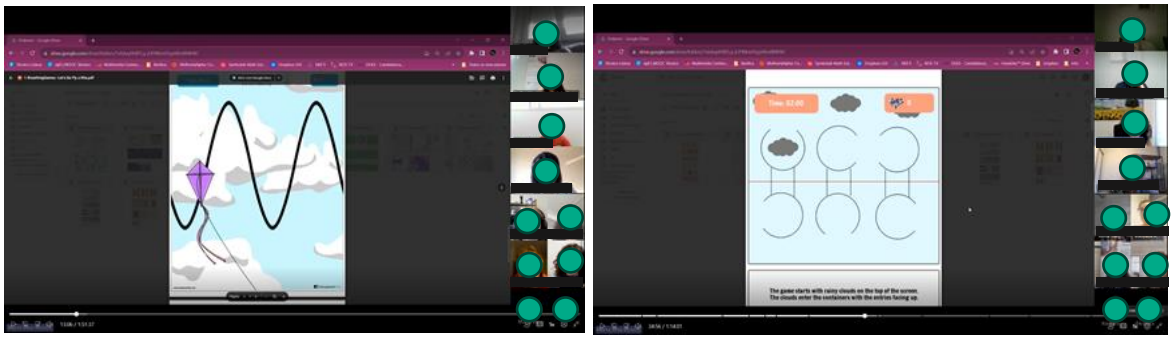

Figure 3 Games Interaction#2 including the presentation of Breathing games to HCPs (left) and presentation of Exergames to PsA patients (right), with participants actively engaging with storyboards.

Interaction #3 (December 12, 2023): The third co-creation session engaged 29 participants, including PRPs from EMC, clinical partners, researchers, and developers. Using the 4Ls method (Liked, Lacked, Learned, Longed For), the session focused on refining "The Kite" Breathing game prototype (see **Figure 4**). Participants were divided into four multidisciplinary teams to ensure a broad exchange of perspectives. The session highlighted the value of clear instructions, engaging graphics, and feedback mechanisms, while also identifying areas for improvement such as screen clutter, tutorial simplicity, and customization options.

Key insights emphasised the therapeutic potential of breathing exercises, particularly in stress reduction and immune system support. Participants appreciated the combination of relaxation and enjoyment, and suggested enhancements like audio/haptic cues and a cleaner visual design. They expressed a desire for deeper scientific grounding, personalized features, and motivational elements, including autonomy in selecting breathing patterns and a more positive approach to failure. These findings played an important role in guiding the next phase of development, helping to ensure that the Breathing Games category continues to be user-centered, clinically meaningful, and emotionally engaging for individuals living with PsA.

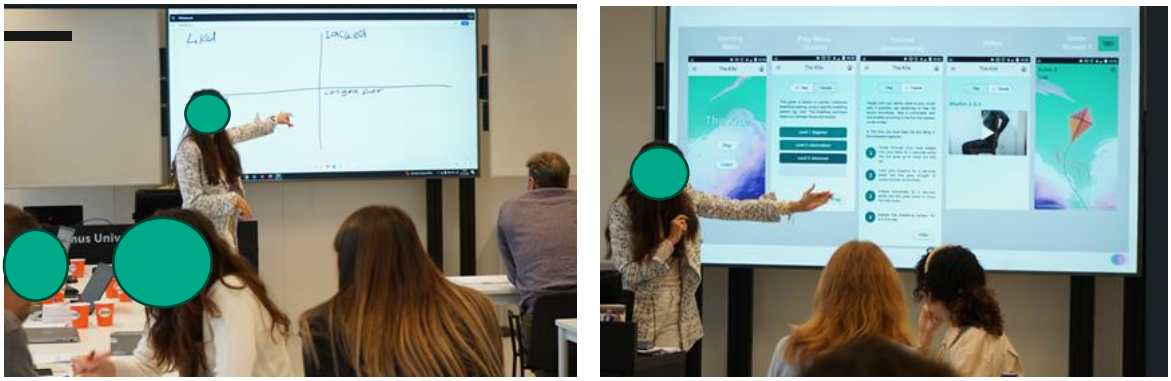

Figure 4 Games Interaction#3 using 4Ls method (left) and presentation of the mock-ups and initial prototype of "The Kite" Breathing Game (right).

Interaction #4 (July 2, 2024): The fourth co-creation session was held during the fourth plenary meeting, bringing together 47 participants, including patients, researchers, HCPs, and technical experts. The session focused on gathering feedback on the mobile app, two Breathing games, and one Exergame, using video demonstrations and structured discussions (see **Figure 5**). Key features under review included "More Info," "Warning Pop-up Messages," "Tutorial Instructions," "Practice Session," and "Calibration." Facilitators guided the session with targeted questions, while observers documented insights to inform future iterations of the games.

Participants responded positively to several features, appreciating the clarity of instructions, intuitive calibration, and the informative “More Info” section. Warning pop-ups were appreciated for enhancing user control, and the rotation movement in the Exergame was seen as beneficial for accessibility. However, areas for improvement were identified, such as refining the scoring system, simplifying tutorials, and addressing physical discomfort during gameplay. Feedback from PRPs, especially regarding usability and personalization, played a crucial role in shaping the game development phase, ensuring the games remain engaging, effective, and tailored to the needs of PsA patients.

Figure 5 Games Interaction#4 including the presentation of the iPROLEPSIS Serious Games app (left) and Exergame features (right).

Interaction #5 (May 9, 2025): The fifth co-creation session of the iPROLEPSIS Serious Games was held online, bringing together 17 participants (including PRPs, HCPs, and technical experts) to evaluate and refine the NoPain Games category (see **Figure 6**). Led by design experts from FMH-ULisboa, the session focused on validating key game features such as “Characterizing Goals,” “More Info,” “Tutorial Instructions,” “Practice Session,” “Navigation,” and “Stats/Scores.” Participants tested the “Space Oddity” game and reviewed a prototype of “Four Seasons,” providing feedback on gameplay mechanics, visual design, and user experience. Particular attention was given to insights from PRPs, ensuring the games align with the needs of PsA patients.

Key findings highlighted the engaging nature of Space Oddity, especially its zoom-in/zoom-out feature and self-assessment scoring system, though iOS compatibility issues were noted. The SUS score of 76.6 reflected generally positive user experiences. The Four Seasons prototype was appreciated for its seasonal mechanics and gentle movements, which enhance accessibility and stress reduction. Participants also appreciated the bonus level and discussed the potential of smartwatch integration for tracking stress. Suggestions for future improvements included adaptive AI for difficulty levels, enhanced 3D rendering, and broader device compatibility, guiding the next phase of development toward more personalized and therapeutic gameplay.

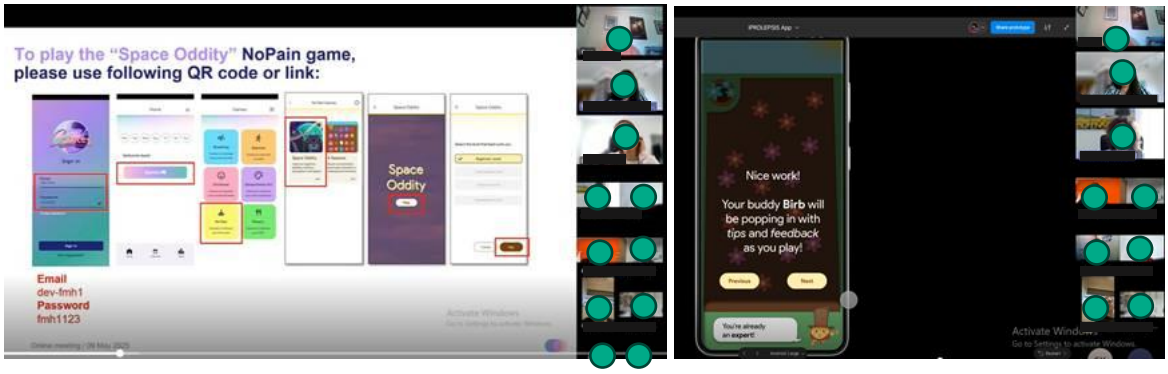

Figure 6 Games Interaction#5 showcasing the presentation of NoPain games: "Space Oddity" (left) and "4 Seasons" (right).

2.5.5 iPROLEPSIS Dashboard

HCP Focus Group (February 11th, 2025): Five rheumatologists engaged in a structured focus group discussion on the future of rheumatology care and the potential role of dBMs. The discussion covered a range of topics, including expectations for their profession over the next decade and the role of remote monitoring and wearable technologies in PsA care.

The integration of dBMs into rheumatological care presents both promising opportunities and complex challenges. Insights from a recent focus group with practising rheumatologists reveal a nuanced understanding of the prerequisites for successful implementation, as well as the reservations that must be addressed to ensure clinical utility and patient-centred care.

A primary concern among participants was the lack of validated, evidence-based dBMs capable of reliably indicating disease activity. While technologies such as wearables and remote monitoring devices offer the potential for continuous data collection, clinicians emphasised that without robust sensitivity, specificity, and predictive value, such tools remain insufficient for guiding therapeutic decisions. The absence of standardised disease activity metrics for remote use was repeatedly cited as a critical bottleneck.

Equally important is the interpretability and actionability of data. Participants expressed scepticism regarding the clinical relevance of patient-reported outcomes and sensor-derived metrics, particularly when these do not translate into clear diagnostic or therapeutic pathways. The need for biomarkers that can predict flares, distinguish between inflammatory and non-inflammatory conditions, and support triage decisions was underscored.

The integration of dBMs into existing clinical workflows emerged as a logistical challenge. Current electronic health record (EHR) systems were described as fragmented and poorly interoperable, impeding the seamless exchange of patient data across institutions. A universal digital infrastructure, enabling consistent access to patient histories, laboratory results, and monitoring data, was identified as a desirable goal, albeit one fraught with technical and regulatory complexities.

From a patient perspective, accessibility and acceptability of digital tools were highlighted as essential considerations. Not all patients possess or wish to use devices such as smartwatches, and attitudes towards data sharing and surveillance vary. Thus, dBMs must be designed with inclusivity, privacy, and patient autonomy in mind.

Despite these concerns, HCPs acknowledged the potential of dBMs to enhance efficiency and triage. Technologies such as xAI-driven dashboards and novel sensing methods (e.g., electronic noses for detecting inflammation) were viewed as innovative avenues that could

reduce unnecessary consultations and enable more targeted interventions. However, the reliability of such methods remains to be established.

The discussion also touched on the preservation of the human element in care. Several clinicians expressed concern that increased reliance on remote monitoring could erode the doctor-patient relationship and diminish the quality of patient interactions. Subtle cues observed during in-person consultations, such as gait, demeanour, and non-verbal communication, were deemed vital to accurate diagnosis and empathetic care.

Finally, the evolving digital landscape necessitates clarity in professional roles and multidisciplinary collaboration. Rheumatologists emphasised their expertise in pattern recognition and differential diagnosis, suggesting that while remote tools may assist in monitoring, the interpretive and integrative functions of the clinician remain indispensable.

In summary, while HCPs are cautiously optimistic about the role of dBMs in rheumatology, their successful development and implementation will require rigorous validation, thoughtful integration into clinical practice, and a steadfast commitment to preserving the human dimension of care. When developing the HCP dashboard, the dashboard should clearly distinguish actionable insights, such as predicted flares or deviations in disease activity, from background data, and be grounded in validated metrics with known sensitivity and specificity. Future integration with existing electronic health record systems is crucial to avoid duplication and administrative burden, while ensuring seamless access to patient histories and monitoring trends. Lastly, the UI must support rapid triage and decision-making without compromising the human element of care, allowing clinicians to maintain a holistic view of the patient.

Interaction #1 (February 13th, 2025): The first co-creation session for the iPROLEPSIS Dashboard was held online with the technical developers and two rheumatologists participating as co-designers. The session was structured around reviewing various example dashboards **Figure 7** and gathering feedback to inform the design of a user-centered UI. Facilitators and observers reported general satisfaction with the session, noting that the activities were productive and the feedback valuable. Participants appreciated the opportunity to influence the dashboard design.

Participants in the session explored various dashboard concepts to inform the design of the iPROLEPSIS UI, focusing on usability and relevance for clinical workflows. They emphasized the importance of intuitive patient search functionality, clear demographic details, and appointment information. Filters for daily visits and alerts were seen as valuable for streamlining daily practice. Feedback highlighted the need to avoid information overload and to ensure that clinical indicators, such as severity scores and flare risks, are presented with clear definitions, reference ranges, and data sources. Participants also stressed the importance of separating alerts from general patient overviews to maintain clarity, suggesting either a dedicated tab or filter option. In reviewing patient-specific views, they underscored the necessity of timestamping measurements to support clinical decision-making. Additionally, rheumatologists expressed interest in monitoring patient engagement with recommendations and interventions, not for prescribing but to support and motivate behavioural change. A note-taking feature was requested to allow documentation of individual appointments, reinforcing the need for integrated clinical tools within the dashboard.

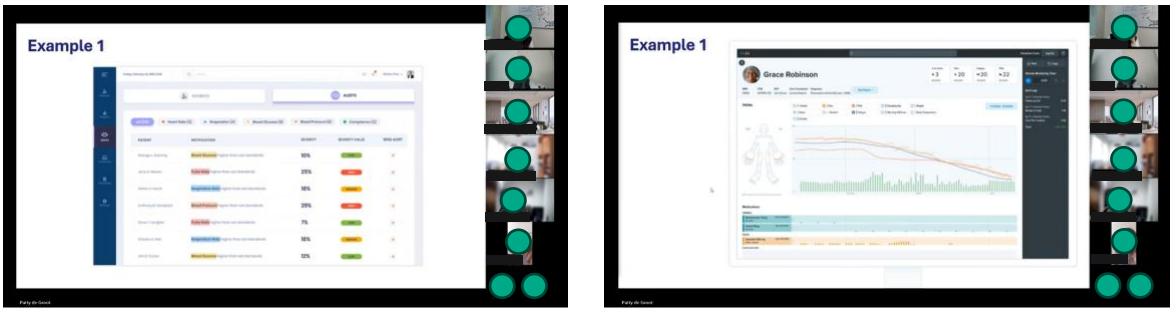

Figure 7 Examples of the dashboards discussed during HCP Dashboard Interaction #1

Interaction round #2 (October, 2025): The aim of this session was to gather early feedback from HCPs on the prototype of the iPROLEPSIS Dashboard, which is being developed to present dBMs for PsA in a clinical research context. Input was collected through one group feedback session and five individual task-based walkthroughs with rheumatologists. Prior to the sessions, participants were given access to the interactive mock-up to explore independently (see **Figure 8**). During the discussions, they were guided through key dashboard functionalities including patient overview, patient specific data and intervention sections while being prompted with open-ended questions to surface strengths, weaknesses and opportunities for improvement in usability, clarity and clinical relevance. In total, 14 HCPs (rheumatologists, rheumatology nurses and research coordinators) from NL, GR and UK contributed feedback. The key findings and insights that emerged from this session are:

Strong perceived value of the flare risk score. Clinicians consistently highlighted the flare risk score as the most clinically relevant feature, with the accompanying SHAP explanations seen as particularly helpful for understanding why a patient may be at risk. Many felt this feature alone could support decision-making within the time constraints of outpatient consultations.

Need for clarity, simplicity, and alignment with clinical workflow. While the dashboard was praised for being easy to navigate and visually appealing, concerns were raised about interpretability. Several graphs and metrics lacked clear labelling or clinical thresholds, and some abbreviations (e.g. MVPA, UEI, ROM) were not understood. Clinicians stressed that limited consultation time (15–30 minutes) requires streamlined overviews, with minimal duplication of EHR functions and patient identification linked to names rather than study IDs.

Positive reception of timelines, but with requests for refinement. Timelines and longitudinal views were valued for providing insight beyond the single clinic visit. However, participants requested clearer indicators (e.g. “today”, new medications, flare types), consistent colour schemes, and standardisation so that scores always reflect directionality in the same way (e.g. higher always better or worse).

Lifestyle interventions are seen as valuable for patients, but less practical for HCPs. Dietary advice, physical activity recommendations, and serious games were recognised as potentially empowering for patients, yet most clinicians said they would not have time to review them in detail. Instead, they preferred concise summaries indicating whether patients adhered to recommendations and whether these interventions led to measurable outcomes (e.g. BMI reduction, activity improvement), leaving detailed content for patient self-management.

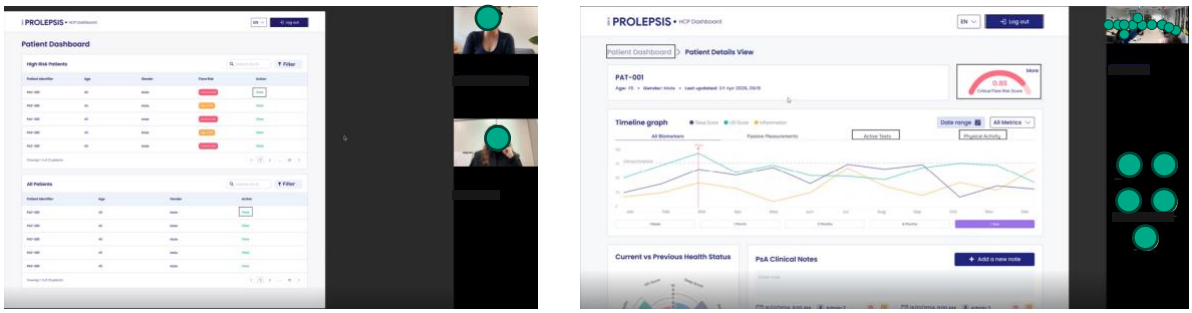

Figure 8 Examples of the dashboards discussed during HCP Dashboard Interaction #2.

3 User scenarios

This section describes the user scenarios of the iPROLEPSIS Digital Care Ecosystem from the perspective of the three core stakeholders: the PsO patient, the PsA patient and HCPs. The section is written to describe the use of the aspired iPROLEPSIS Digital Care Ecosystem and will contribute to the identification and prioritisation of User Requirements (URs).

3.1 The Psoriasis Patient

Three years ago, the PsO patient was diagnosed with psoriasis. Since then, the PsO patient learned that PsA runs in their family and about 30% of the psoriasis patients develop this disease. This information has caused the PsO patient to feel anxious about missing the early signs of PsA.

Recently, the PsO patient read an article in one of the Patient Association Magazines about an app that can help monitor the development of PsA complaints. After discussing with a fellow PsO patient, who had good experiences, the patient decides to give the app a try.

3.1.1 miPROLEPSIS Lite Onboarding

The PsO patient owns an Android phone and navigates to the Google Play Store. However, they heard it is also available for iOS in the Apple app store. They search for the miPROLEPSIS Lite app and successfully installed the app on their device. A free account can be created through the miPROLEPSIS Lite app.

During the sign-up process, the PsO patient needs to fill in some details that are necessary for their user account. After creating their user account, the PsO patient receives a pop-up that informs them that if they own a smartwatch, this could improve the accuracy of the PsA early symptom monitoring. The PsO patient happens to have one and follows the instructions to establish connection.

3.1.2 miPROLEPSIS Lite Usage

After installation, the miPROLEPSIS Lite app tracks the dBMs of the PsO patient unobtrusively. At the end of every month, the app gives a pop-up to verify that the PsO patient has not noticed any joint discomfort.

For another 3 years, the PsO patient is not experiencing any signs of PsA. On a regular basis, the PsO patient reviews their dBM data in the app to see if there are any behavioural changes. Additionally, the PsO patient reports any moment of joint discomfort through the home screen. On occasion, the PsO patient wonders if one of their joints is inflamed. When in doubt, they decide to perform the active tests in the miPROLEPSIS Lite app. After performing the photo and video tests that indicate no sign of swelling or restricted range of motion, they feel at ease

again. In the myJourney section of the app, the PsO patient sometimes places a comment about their health, or certain triggers that may have caused an exacerbation of their psoriasis.

Then slowly over time the PsO patient has developed PsA complaints and behavioural changes are detected by the miPROLEPSIS Lite app. The PsO patient again performs the active tests, which this time confirm the presence of joint swelling, and receives a notification that advises them to arrange a visit with their general practitioner, dermatologist or a rheumatologist.

The PsO patient is nervous about their visit and therefore wants to prepare for the consultation. From the hospital, the PsO patient has received a Medical History questionnaire. The PsO patient has trouble recalling the start of their complaints and if they have experienced mild or singular moments of complaints before. Luckily, in the miPROLEPSIS Lite app they made comments, kept track of joint discomfort, and they can review the dBM data to reduce this uncertainty. The PsO patient arrives at their rheumatology appointment well-prepared, which is appreciated by the clinician. This gives a head-start to their doctor-patient relationship.

3.1.3 Opt-Out

Unfortunately, after the diagnostic process, the rheumatologist confirms the PsO patient has indeed developed PsA. Since the hospital is part of the iPROLEPSIS community, they offer health services through the iPROLEPSIS Digital Care Ecosystem. After the consultation with the rheumatologist, the PsO patient visits the rheumatology desk, and the tech-assistant transfers their miPROLEPSIS Lite account to the miPROLEPSIS App. The PsO patient can then safely uninstall the miPROLEPSIS Lite app from their phone.

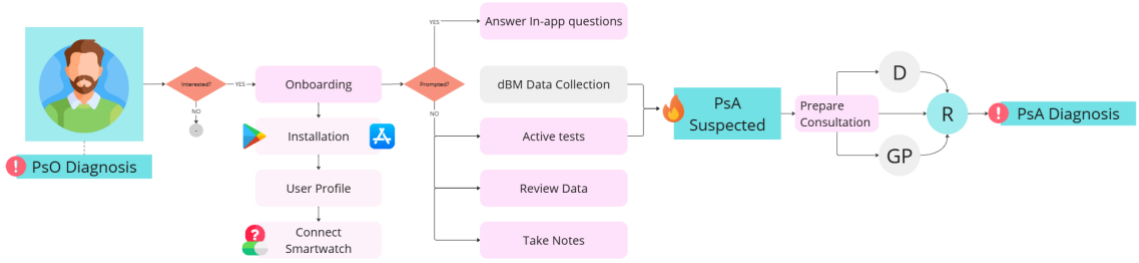

Figure 9 The PsO patient's user scenario. D = touchpoint Dermatologist; GP = touchpoint General Practitioner; R = touchpoint Rheumatologist.

3.2 The Psoriatic Arthritis Patient

After being diagnosed with PsA, the PsA patient feels overwhelmed by the complexity of managing a chronic condition. They are concerned about tracking symptoms, understanding triggers, and maintaining their quality of life. During their consultation, the rheumatologist proposes to them; the miPROLEPSIS app, part of the iPROLEPSIS Digital Care Ecosystem, which is designed to support PsA patients in monitoring and managing their condition. In shared-decision with their rheumatologist the PsA patient agrees to become part of the iPROLEPSIS community. After their consultation, the PsO patient visits the rheumatology desk and the clinic assistant schedules an iPROLEPSIS onboarding appointment the following week. **Figure 10** illustrates the user scenario of the PsA patient when using the iPROLEPSIS Digital Care Ecosystem.

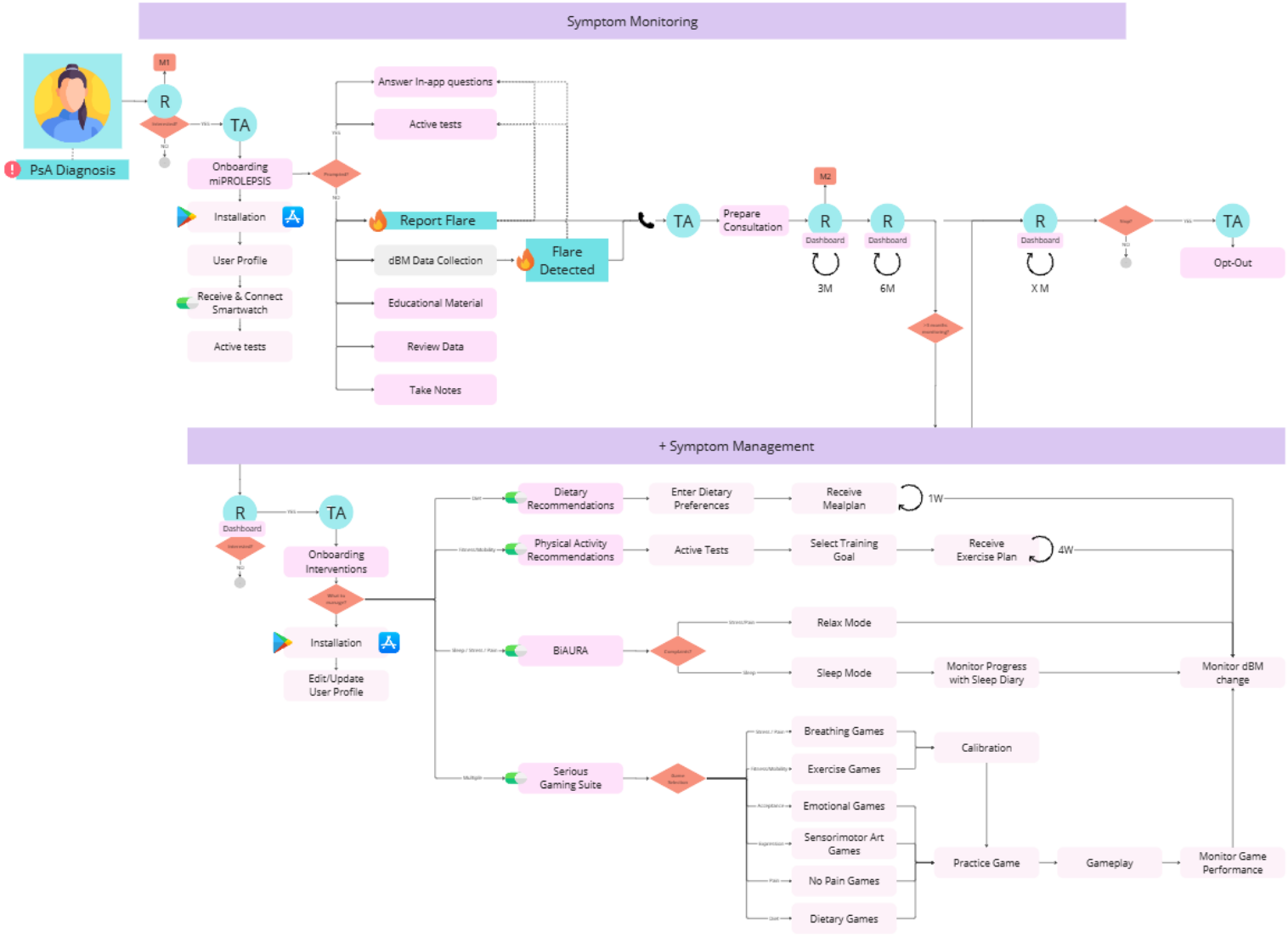

Figure 10 Overview of the iPROLEPSIS Digital Care Ecosystem for PsA Patients. R = touchpoint Rheumatologist and TA = touchpoint Tech-assistant.

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3.2.1 Onboarding

The PsA patient arrives for the onboarding appointment with one of the tech-assistants. Together, they create a miPROLEPSIS account and the PsA patient receives their credentials in their e-mail. Since the PsA patient was already a miPROLEPSIS Lite user, their accounts can be synced, and no medical history is lost.

During the creation of the account, the PsA patient is asked to install the iPROLEPSIS apps required for health tracking (miPROLEPSIS app and the Joint Landmarker App) from the Google Play or Apple App store. During the installation, the PsA patient receives various requests to provide permissions and settings that are required to be accepted when the application is installed. The assistant explains that 3 months of monitoring are required before the user can start to use any of the iPROLEPSIS health interventions.

After installation, the PsA patient can sign in with their secure account and is asked to fill in the required personal health details. The PsA patient is prompted to enable the Research Keyboard and then the set-up process continues automatically with the active photo and video tests, where the assistant shows the patient how to perform the tests as intended. Following the initialization of the app, the PsA the patient receives the Smartwatch and together with the assistant they make sure the watch is connected to the iPROLEPSIS Digital Care Ecosystem. Then, the assistant guides the PsA patient through the app's features and how it supports symptom tracking and lifestyle management.

The patient feels a little overwhelmed by the number of instructions received, but from looking at the miPROLEPSIS app, they trust that the app is easy to use, and everything will be fine.

3.2.2 Symptom Monitoring with the miPROLEPSIS App

From what the PsA patient understood, the miPROLEPSIS app has a couple of core functionalities. The miPROLEPSIS app unobtrusively tracks dBMs of disease activity through their smartphone and the received smartwatch. The app further requires some active input from the PsA patient, specifically answering in-app questions and performing the active tests every now and then and in case a flare is detected. The app shares its data with the hospital and during their next consultation the collected data can be discussed with the rheumatologist.

3.2.2.1 Educational Material

On a quiet evening in the first month after diagnosis, the PsA patient browses through the app's educational library. They find short articles explaining flares, medications, lifestyle adjustments and the dBMs. Some of the content feels directly relevant to their recent experiences, so they bookmark it for future reference.

Reading this material gives the patient a sense of empowerment. Instead of searching randomly on the internet, they know the information comes from trusted medical sources within iPROLEPSIS.

3.2.2.2 Unobtrusive Disease Activity Monitoring

Over the next months, the PsA patient begins to get familiar with the app. The PsA patient tries to wear the smartwatch day and night, only removing it when showering or charging. Initially, the patient worried that the smartwatch wristband would cause skin irritation, but the provided nylon strap and regular cleaning prevented this issue. Occasionally, they forget to wear it, but data collection resumes automatically when the watch is put back on.

The PsA patient notices how much the miPROLEPSIS system works quietly in the background; recording steps, sleep, and stress levels through the watch and the phone. Every month they receive a summary of the data collected. In addition, when curious, the PsA patient

checks their daily stats. On the home screen, they review how many steps they walked, how long they slept, and how stressed they were. In the My Journey calendar, they see icons marking previous flare days and days with personal comments. Clicking on one of those days, they compare their dBM metrics during that period and check the comments they have added to the MyJourney section. These small moments of interaction make the patient feel more connected to their own health data. They begin to see patterns that otherwise would have been lost.

3.2.2.3 Disease Exacerbation

Flare Reported: One morning, the PsA patient wakes up with swollen fingers and joint stiffness and immediately knows it is a flare. They open the miPROLEPSIS home screen, press the flare button, and are guided through a 12-item questionnaire. The app then asks them to perform the active tests, if possible. Although the flare is unpleasant, the PsA patient feels reassured that the app is capturing what is happening in real time. They call the rheumatology department to be seen on their emergency outpatient clinic.

Flare Detected: One afternoon, the PsA patient receives a notification from the miPROLEPSIS app: "*We've noticed some changes in your activity and stress levels. This may indicate a flare. Please confirm how you are feeling*." Surprised, the PsA patient opens the app and sees a short summary of recent metrics: fewer steps, disrupted sleep, and elevated stress. The app asks them to answer a few quick questions and to perform the active tests. The patient realizes that, indeed, their joints have been stiffer than usual the past days, even though they hadn't considered it a flare yet. This early detection makes them feel reassured: the app is picking up signals they might have overlooked, giving them the chance to act earlier and discuss these findings with their rheumatologist if they get worse.

3.2.2.4 Active Tests

Every few weeks, the app prompts the PsA patient to perform the active tests. The notifications can be used to guide the PsA patient to the active tests directly. In case they forget, gentle reminders appear the next day. Although the tests take a bit of effort, the PsA patient appreciates that they only need to do them occasionally. At times when the PsA patient feels unsure about the presence of swelling in their fingers, they take additional pictures within the miPROLEPSIS app to verify if any joints are affected.

3.2.3 Symptom Management with the iPROLEPSIS Interventions

After 3-4 months of steady use, the PsA patient arrives for their usual visit with their rheumatologist. From the miPROLEPSIS dBMs they have noticed that the medication provided has already started to have an effect. The PsA patient feels ready to start working on their lifestyle habits and is interested in the use of the serious games and biaural sounds to help them cope with some residual complaints. Thus, after the appointment, the PsA patient visits the tech-assistant, who helps them enable the personalized interventions within the miPROLEPSIS app and with downloading the iPROLEPSIS Serious Gaming Suite and iPROLEPSIS biAURA apps. Together they discuss the usage and purpose of the various DHTs in managing PsA related symptoms and lifestyle.

Now when they open the app, there is an additional page that navigates them to the tailored interventions. The PsA patient feels empowered, now that they can explore different options and try what feels right for them. The journey with the iPROLEPSIS Digital Care Ecosystem becomes a cycle of awareness, action, and support where the miPROLEPSIS app supports them day-to-day, while the doctor helps them make sense of the bigger picture.

3.2.3.1 biAURA sleep and relaxation

biAURA's sleep mode: After enabling the personalised interventions, the PsA patient decides to try the biAURA sleep mode, as poor sleep has remained one of their most

frustrating residual complaints. The PsA patient is curious to see whether the binaural sounds can help them relax and achieve more restorative rest.

That evening, the PsA patient puts on the smartwatch and sleep ear-/headphones, then opens the biAURA app. They read some of the sound descriptions and which audio stimulates which brain function, then from the list of available tracks, the PsA patient selects one that feels calming, sets the wake-up alarm, and chooses a gentle alarm sound.

As the track begins to play, the PsA patient feels their body gradually unwind. The app quietly monitors sleep signals from the smartwatch and, once it detects that the PsA patient has fallen asleep, the sounds fade away. Throughout the night, biAURA adapts the experience in the background, supporting a deeper, more continuous sleep without requiring any extra effort. By morning, the alarm wakes the PsA patient at the right time, leaving them feeling rested and supported.

Over time, the patient monitors their progress in the Sleep Diary section, where a record of their sleep sessions and weekly summaries is displayed. Seeing their progress visualised provides reassurance and motivates the PsA patient to continue experimenting with the available sounds on the Sounds page. In the Sounds page, they gradually start to create and edit their personal sleep play lists. This way, the experience of using the biAURA sleep mode gives the PsA patient a sense of calm control over their nights.

biAURA's relax mode: The PsA patient has been regularly using the sleep mode of the biAURA app when a flare occurs. From the miPROLEPSIS educational materials, they know that stress can worsen symptoms, yet the pain and frustration of a flare make it difficult to stay calm. Seeking relief, the patient decides to switch from sleep mode to the biAURA relax mode to help manage stress and ease discomfort.

They open the app and browse through the available tracks, curious to see which sounds might help ease their tension. The PsA patient selects a few calming options to create a personalised Relax playlist, then settles in to listen.

With the familiar music player controls, the PsA patient can skip to the next or previous track, repeat favourites, or simply let the playlist run. As the sounds play through their headphones, the PsA patient notices their breathing slow and their shoulders drop. The gentle tones provide a sense of calm, helping to quiet the racing thoughts that often accompany their pain and fatigue.

3.2.3.2 Dietary recommendations

Another option in the miPROLEPSIS app are dietary recommendations. The PsA patient has been overweight for most of their life. With their recent diagnosis, they feel an additional motivation to take an action, recognising that excess body fat contributes both to increased mechanical stress on their joints and to elevated levels of inflammation throughout the body. The miPROLEPSIS dietary recommendations offer guidance to help the PsA patient adjust their nutrition and maintain consistent healthy eating habits.

In the miPROLEPSIS app, the PsA patient enables the Dietary Recommendations feature. Some personal details, such as gender, age and co-morbidities are already prefilled in the user profile. They just need to fill some additional information about their dietary preferences.

Using this information, the system generates a biweekly personalised meal plan. Every two weeks, the patient receives a notification that the plan has been updated with meals for two

weeks after. At the start of each week, the PsA patient takes time to browse the plan and create a grocery list. The meals are organised by week or by day and each day includes breakfast, morning snack, lunch, afternoon snack, dinner, and supper. All meals are clearly presented with ingredients and quantities. This level of detail reassures the PsA patient that they can prepare each meal correctly and confidently.

From time to time, a meal may not appeal to the PsA patient. If this happens, they swap an entire day's meals for one of three alternative options, providing flexibility without disrupting the overall plan. This ability to customise daily meals makes it easier for the PsA patient to adhere to the plan. As the PsA patient engages with the meal plan consistently, they strengthen their dietary habits and feel improvement in their pain, energy levels and overall health.

3.2.3.3 Physical activity recommendations

Since following the miPROLEPSIS dietary recommendations, the PsA patient has lost some weight and notices a boost in energy. This early success not only enhances physical capacity but also motivates them to engage in other health behaviours. Feeling lighter and energised, the PsA patient realises that physical activity may now feel more achievable and less daunting. Encouraged by this, they decide to explore the physical activity recommendations within the miPROLEPSIS app.

When enabling the feature, the PsA patient selects a goal that aligns with their current priorities, such as improving mobility, strength, balance, cardio, flexibility, or general health. To ensure the system has the latest information on their capabilities, the PsA patient performs the Active Video Test. This data, combined with their profile information, daily step counts and flare status, is used to generate a personalised four-week physical activity plan. Every four weeks, a notification prompts them to generate their new exercises.

Performing the exercises is straightforward, as each activity includes instructions on sets, repetitions, rest intervals, and intensity, along with instructional videos and text guides to ensure proper execution. As the PsA patient follows the plan, they notice gradual improvements in strength and mobility, which provide a sense of progression and accomplishment.

When a flare occurs, whether detected by the system or reported by the patient, the intensity of the exercises is automatically reduced. This adjustment prevents frustration about what the PsA patient is temporarily unable to do, while helping them focus on what remains achievable. It reinforces the understanding that it is normal for disease activity to limit performance, while still encouraging continued movement and engagement in manageable activities during periods of exacerbation.

3.2.3.4 iPROLEPSIS Games

During their appointment with the tech assistant, the PsA patient also installed the iPROLEPSIS Games app on their mobile device. Together, they discussed which serious games could be most beneficial for the patient's specific needs, considering areas such as pain management, mobility, and stress reduction.

Onboarding: The PsA patient signs in using their personal miPROLEPSIS credentials, and their user profile data, as well as relevant dBMs, are automatically synchronised. A guided tour of the app introduces the PsA patient to the various game categories and shows how to engage with the games in a structured way.

The PsA patient browses the available categories and selects one that aligns with their current condition and personal goals. To understand the overarching aim of the chosen category, they

tap the 'More Info' button, which provides additional context and guidance. Curious about the individual games within the category, the PsA patient reads the detailed descriptions, explaining the purpose of each game, its expected benefits, and the skills it targets along with their scientific background.

Game Selection: After reviewing the options, the PsA patient chooses one of the 14 game categories that fits the current state of their disease experience.

The PsA patient begins by browsing *the Breathing category*, particularly drawn to one game after a stressful morning. The calming visuals and guided breath exercises have a meditative effect and help with stress reduction, which is confirmed by the tracked stress levels.

In *the Exercise category*, the PsA patient explores The Spy immersive game, which combines full-body movements with fun, action-oriented challenges. The engaging nature of the game makes physical activity enjoyable, reinforcing motivation to stay active alongside their personalised physical activity plan. Similarly, the games in *the Dietary category* motivate the patient to reinforce healthy eating habits in an interactive, rewarding way. This boosts their dedication to the dietary meal plans and helps them understand more about their contents.

On more difficult days, when pain levels are higher and emotions are more intense, he PsA patient discovers *the Emotional Games category*, which helps them regulate emotions by combining cognitive engagement with relaxation. Additionally, *the No Pain game category* offer a welcome distraction, allowing them to focus on gameplay rather than discomfort. *The Sensorimotor Art category* provides opportunities for creative self-expression. The PsA patient experiments with patterns, colours, and gestures, finding these playful exercises both therapeutic and enjoyable.

Gameplay: When trying a game for the first time, the PsA patient begins by selecting either a standard difficulty level or a personalised level tailored to their abilities. A step-by-step tutorial guides them through the mechanics, offering options to read, listen to, watch, or skip the instructions, depending on their preferred learning style.

Before starting, the PsA patient can practice the game. For games that involve breathing or movement, calibration features ensure the system accurately measures performance. Once ready, the PsA patient plays the game, knowing they can pause or exit at any time if needed.

After completing the session, the PsA patient reviews their score and progress, which provides insight into their performance and improvements. They can then choose to play again, either to reinforce skills or to enjoy the game for fun. In returning gameplay, familiar games can be launched quickly, with or without repeating the tutorial, allowing the patient to focus on improvement, engagement, or relaxation.

By regularly exploring these games, the PsA patient experiences tangible benefits: reduced stress, distraction from pain, enhanced mobility and coordination, emotional regulation, creative expression, and reinforcement of healthy dietary habits. The playful, adaptive design of the iPROLEPSIS Games app keeps the patient motivated, making self-management a rewarding and integral part of their daily routine.

3.2.4 iPROLEPSIS Dashboard

During each consultation, the PsA patient is shown their iPROLEPSIS Dashboard. By the time they sit down, the HCP has already reviewed the data, so they can dive straight into a meaningful discussion. Together they go over the graphs and trends, with the HCP pointing out the most relevant patterns. The PsA patient feels genuinely seen and heard because the

dBMs make it easier to explain what life has been like between visits, and there is space to finally address the questions they have been carrying for weeks.

Looking at the dashboard, they can see that the PsA patient's disease activity has been stable for a considerable period. Encouraged by this, the rheumatologist raises the possibility of tapering medication. The PsA patient listens carefully. On the one hand, they long to manage with as little medication as possible; on the other, the memory of the early days with unbearable pain and crushing fatigue makes them fearful of a flare. They leave the consultation promising to think it over.

Over the following week, the PsA patient reflects on the conversation. They decide they are open to trying tapering, but only if they feel fully prepared. To build confidence, they commit to logging any lingering symptoms in the My Journey section of the miPROLEPSIS app and to engaging more actively with the miPROLEPSIS interventions. By strengthening their daily routines and tracking habits, they hope to maintain a sense of control. With this approach, the idea of tapering no longer feels like a risk, it feels like a careful step forward, taken in partnership with both their rheumatologist and the support of the iPROLEPSIS Digital Care Ecosystem.

3.2.5 Opt-Out

Years later, the PsA patient feels they have gained enough experience to recognize their complaints early and have built healthy coping strategies into their daily life. Their disease has been in complete remission for some time, and they no longer feel the same need for continuous support from the iPROLEPSIS Digital Care Ecosystem. Around this time, news stories about data privacy spark reflection. Although the PsA patient still trusts iPROLEPSIS, they decide it is time to reduce their digital footprint and close accounts that no longer feel essential.

At their next consultation, the PsA patient explains their thoughts to the rheumatologist and expresses the wish to stop iPROLEPSIS monitoring. Together they discuss the implications, and an appointment is scheduled with the tech-assistant. During this session, the PsA patient and the assistant carefully go through the process of deactivating the account. The PsA patient leaves feeling in control of their decision, reassured that if they ever wish to return to the iPROLEPSIS Digital Care Ecosystem, the option will remain open.

3.3 The Healthcare Professional

Hospitals and rheumatology departments face increasing pressure to deliver high-quality, patient-centred care amidst a shortage of healthcare professionals, growing patient volumes, and rising healthcare costs. For conditions such as PsA, timely detection, accurate risk assessment, and proactive disease management are essential to prevent irreversible joint damage and improve patient quality of life. Through a strategic decision to strengthen PsA care and modernise clinical workflows, the rheumatology department has recently acquired the iPROLEPSIS Digital Care Ecosystem. The system is introduced as a dedicated web-based platform that supports HCPs in monitoring and managing their PsA patients. The system is introduced to the rheumatologists one-by-one and the HCP is curious to be next in line.

3.3.1 Onboarding

The tech assistant has created an account for the HCP and they receive their credentials by e-mail. Furthermore, the HCP received training covering navigation of the dashboard, interpretation of patient-generated data, and understanding the outputs of the xAI models. Following this onboarding, the HCP can access the iPROLEPSIS Dashboard through a secure login on their workstation. The tech assistant helps them to familiarise with key features,

including patient overviews, dBMs, predictive risk indicators and the miPROLEPSIS interventions. Supplementary resources, such as user manuals, video tutorials, and helpdesk support, are provided to ensure a smooth introduction.

3.3.2 iPROLEPSIS Dashboard

The dashboard provides an organised overview of patient-reported outcomes, sensor data, and model-generated risk assessments, supporting clinical decision-making without disrupting existing workflows.

3.3.2.1 Preparation of next day's clinic

Before starting the next day's consultations, the HCP reviews the iPROLEPSIS Dashboard to prepare for each patient visit. The homepage provides an overview of all patients using the miPROLEPSIS app, allowing the HCP to quickly see the status of their caseload.

Noticing an empty slot in the schedule, the HCP feels slightly frustrated, as the waitlist for appointments is continuously growing. Fortunately, the dashboard includes a section that highlights patients who may require urgent attention due to elevated inflammation risk, worsening symptoms, or deviations from their usual behavioural patterns. The HCP asks their clinic assistant to contact these patients and see if any can fill the open slot.

The HCP then reviews the scheduled patients one by one, searching by the hospital patient ID or by last name and date of birth. On each patient's page, the dashboard presents a structured overview of status, previous visits, and trends over the intervening period, including graphs of dBM readings, symptom reports, and risk predictions. By examining these trends, the HCP can anticipate potential complications, prioritise patients, and plan discussion points or interventions in advance.

For example, the HCP notices that patient B has a high flare risk score. By reviewing the SHAP values, they can understand the contributing factors behind this prediction. The HCP then adds a comment in the dashboard with suggested talking points for the upcoming consultation. This preparation ensures that consultations are focused, efficient, and tailored to each patient's individual needs, while making full use of insights from patient-generated data in clinical decision-making.

3.3.2.2 During consultation

Just before each patient arrives, the HCP quickly reviews the iPROLEPSIS Dashboard to refresh their memory. Once the PsA patient enters the room, the HCP sets the dashboard aside and listens first. Giving the patient full attention is a core professional value, so the consultation begins with an open conversation rather than technology.

For some PsA patients, the dashboard already suggests that disease activity is stable. When the patient confirms they are doing well, the dashboard remains in the background, and the consultation focuses on broader health, lifestyle, and patient concerns.

For others, there is a mismatch between how the PsA patient feels and what the dashboard indicates. A patient might describe little improvement, even though the data shows reduced inflammation. Together, the HCP and the PsA patient explore the dashboard to uncover where this discrepancy arises. Are there particular disease domains, such as fatigue or skin involvement, that explain the higher perceived burden? In this case, the PsA patient recently switched medication. While inflammation is under control, residual complaints remain. The HCP suggests exploring iPROLEPSIS interventions and, in shared decision-making, they agree to adjust the patient's training goals and trial the biAURA and iPROLEPSIS games to support stress, pain, and sleep management.

For the next consultation, the dashboard shows a clear worsening of dBMs since the last visit. Yet, the PsA patient indicates they are doing fine. The HCP knows this patient well and is aware of their tendency to underreport complaints. To explore further, the HCP reviews the worsening dBMs together with the patient. The discussion reveals that the patient has recently taken on responsibilities as an informal caregiver for their partner, which has added stress and physical strain. Acknowledging this, the HCP offers a referral to the rheumatology nurse for additional support and guidance on where to seek external help.

The last PsA patient on today's schedule is one whose disease activity remains difficult to control. Despite several treatment adjustments, inflammation levels fluctuate, and the PsA patient often struggles to follow their medication regimen consistently. The HCP senses that part of the difficulty lies in understanding the full extent of the disease and in developing good coping mechanisms.

The HCP is glad that the iPROLEPSIS Dashboard helps them to gain a clearer picture of the patient's day-to-day reality between visits. By visualising patterns of dBMs and highlighting the impact of medication adherence on disease activity, the HCP can make the condition more tangible and easier to grasp for the PsA patient. In the hope to strengthen the patient's understanding, the HCP reminds the patient that they can review the educational materials within the miPROLEPSIS app for accessible, bite-sized information about PsA and its treatments.

At the end of a full day of consultations, with the earlier gap in the schedule filled through the dashboard's prioritisation feature, the HCP closes the day with a sense of efficiency and satisfaction that their outpatient clinic has run smoothly and productively. The dashboard helped make certain conversations more concrete, for example by visualising patterns of activity or highlighting subtle changes in disease activity that might otherwise have gone unnoticed. These moments did not replace clinical expertise, but they enriched it, allowing the HCP to guide patients with more personalised and targeted advice. The HCP values that the dashboard quietly supported their workflow without demanding extra time or effort; instead of adding complexity, it provided reassurance that decisions were backed by both professional judgment and continuous patient data.

3.3.3 Opt-out

After many years of practice, the HCP decides to retire. The tech assistant manages the closure of their iPROLEPSIS Dashboard account. The tech assistant ensures that the HCP's access to the iPROLEPSIS Digital Care Ecosystem is securely deactivated, while all patient data and records remain unaffected and accessible to the rest of the clinical team. This process allows the HCP to exit the system smoothly, with user management handled centrally and without disruption to ongoing patient care **Figure 11** provides an overview of the HCPs user scenario.

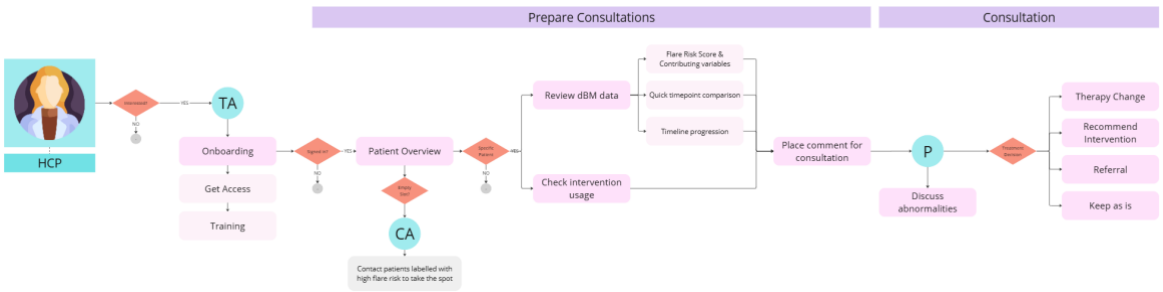

Figure 11 The HCP's user scenario. TA = touchpoint Tech-assistant; CA = touchpoint Clinic Assistant; P = touchpoint Patient consultation.

3.4 The Tech-Assistant

After the implementation of the iPROLEPSIS Digital Care Ecosystem, hospitals will need to establish a dedicated tech-assistant role. These tech-assistants will act as a bridge between technology and care, providing both technical and clinical support to PsA patients and HCPs. Their responsibilities will include system management, patient data monitoring, and direct patient support.

The tech-assistant role can be an expanded responsibility of some clinic assistants; however, it differs from their current administrative duties such as answering phones, scheduling appointments, and handling routine patient logistics. Instead, the tech-assistant will take on a more specialized function focused on the operation and integration of digital health tools within the clinical workflow.

Since the iPROLEPSIS Digital Care Ecosystem is designed to reduce the workload of HCPs, it is essential that these new responsibilities are delegated to designated support staff within this newly defined role, rather than added to the existing tasks of clinicians.

4 User Requirements

This section lists all User Requirements (URs) identified. The iPROLEPSIS DHTs take as starting point the DoA, which reflects the consortium's expertise and long-term experience with PsA and is supported by literature. Other sources of URs at this stage are the focus groups; surveys; and stakeholder interactions.

The MoSCoW approach (Chandrasekaran et al., 2025) was applied for prioritisation, in order to primarily comply with the DoA requirements and fulfil as many as possible user aspirations that were not initially foreseen. The MoSCoW approach is a rather simple one, prioritizing the requirements using the words "must have", "should have", "could have", "won't have at this time". The "must have" requirements are obligatory and absolutely necessary. The "should have" requirements are high priority, but not obligatory. The "could have" requirements are considered desirable (nice-to-have) but not necessary. The "won't have at this time" or "would like to have" requirements are considered as out-of-scope for this project and can be considered as future requirements (accomplishable after the end of the project). Keeping balance in the features list size is crucial, that will lead to a realistic planning of the developments and integration activities of the project while ensuring that the user requirements are sufficiently covered.

Table 5 through **Table 9** provide the URs, providing the requirement ID, a description, priority and the status of implementation for each DHT.

4.1 miPROLEPSIS App Lite

Table 5 miPROLEPSIS Lite User Requirements.

UR.mL.#	Description	Priority	Status
UR.mL.01	Data stored in the smartphone will be sandboxed, ensuring that no information will be shared with other apps.	Must	Done
UR.mL.02	Patient should be able to install the miPROLEPSIS Lite app and the Joint Landmarker app from the apple store / play store	Must	Done
UR.mL.03	The apps can be installed on IOS (version 17+) as well as Android (version 12-14)	Must	Done
UR.mL.04	The patient needs to be able to use all functionalities of iPROLEPSIS with only 2 apps. miPROLEPSIS + Joint Landmarker App.	Must	Done
UR.mL.05	Patient needs to agree with the terms of the application before entering app	Must	To do
UR.mL.06	The app needs to adjust to various phone screen sizes	Must	Done
UR.mL.07	Patient should be able to log in to the application	Must	Done
UR.mL.08	Upon initial first login to the app, the user needs to fill a form of initial user profiling	Won't	-
UR.mL.09	Upon initial first login to the app, the user can upload an user avatar (optional)	Won't	-
UR.mL.10	Patient needs to be able to manage their account: • Change or reset their password • Delete their account	Must	Done
UR.mL.11	Patient needs to be able to edit his/her user profile / account	Won't	-

UR.mL.12	Patient needs to be able to delete his/her account	Must	To do
UR.mL.13	Patient needs to be able to review the privacy terms of the miPROLEPSIS app	Must	Done
UR.mL.14	Patient needs to be able to retrieve his/her historical data	Must	To do
UR.mL.15	The patient should be able to select the preferred language for the app [NL, GR, EN, PT]	Must	Done
UR.mL.16	The app should be controllable by patients with sore hands, inflamed fingers and reduced dexterity	Must	Done
UR.mL.17	The app will not present any recommendations to the patient that will affect decision-making related to their health conditions.	Must	Done
UR.mL.18	The app collects keyboard data and screen time data	Must	To do
UR.mL.19	The app collects accelerometer and gyroscope data from the smartphone accelerometer sensor	Must	Done
UR.mL.20	The app includes optional photo tests of the hands and feet	Must	Done
UR.mL.21	The app includes optional video tests	Must	Done
UR.mL.22	The user has the option to connect a suggested wearable to the app (Apple health, Google Fit, Fitbit, Withings, Polar, Oura, Samsung (Android only), Suunto, Garmin)	Should	To do
UR.mL.23	The patient can report the presence of joint pain	Must	Done
UR.mL.24	When the joint symptom button is selected in the app, participants will be presented with a joint map to indicate which joints are causing discomfort - daily joint pain until turned off.	Must	To do
UR.mL.25	Patient needs to be able to review reported joint complaints states	Should	Done
UR.mL.26	The app provides a monthly pop-up to check that they haven't had any symptoms, if the joints/tendons symptom button was not pressed.	Should	To do
UR.mL.27	Patients should be allowed to log and track other external factors that they think might influence their symptoms	Should	Done
UR.mL.28	Patients must be alerted when something is wrong with their data collection	Must	To do
UR.mL.29	Patient needs to be able to review historical measurements of the smartphone and wearable	Must	To do
UR.mL.30	Patient needs to be notified that joint complaints that are detected by the AI model	Should	To do
UR.mL.31	Patient needs to be able to confirm joint complaints that are detected by the AI model	Should	To do

4.2 miPROLEPSIS App

In **Table 6**, the identified URs for the miPROLEPSIS app (UR.mP.#) are tabulated. Requirements for the recommendations section are indicated with UR.RS.#.

Table 6 miPROLEPSIS app User Requirements.

UR.mP.# / UR.RS.#	Description	Priority	Status
UR.mP.01	Patient should be able to log in to the application	Must	Done
UR.mP.02	Patient needs to be able to edit his/her user profile / account	Must	Done
UR.mP.03	Patient needs to be able to delete his/her data	Must	Done (with an external mechanism)
UR.mP.04	Patient needs to be able to delete his/her account	Must	In progress
UR.mP.05	Patient needs to agree with the terms of the application before entering the application	Must	Done
UR.mP.06	Patient needs to be able to review the privacy terms of the miPROLEPSIS app. There should be transparency on an app's developer, funding source, content validation process, version updates and data ownership.	Must	Done
UR.mP.07	Patient needs to be able to (re)connect his/her wearable	Must	Done
UR.mP.08a	Patient needs to be able to review the current daily measurements monitored through the smartphone and wearable	Must	Done
UR.mP.09a	Patients should be allowed to log and track medication [chronic & painkillers] intake	Could	Done – through notes
UR.mP.09b	Patients should be allowed to log and track other external factors that they think might influence their symptoms	Must	Done – through notes
UR.mP.09c	Patient should be able to indicate when they forgot to take their chronic medications	Won't	Done – through notes
UR.mP.10a	Patient needs to receive notifications about wearable connections (Wearable connected or disconnected)	Must	Done
UR.mP.10b	Patient needs to receive notifications that request them to fill out in-app questions	Must	Done
UR.mP.10c	Patient needs to receive notifications that request them to perform active tests	Must	Done
UR.mP.10d	Patient needs to receive notifications that new recommendations are available/generated when the recommendation system	Must	To do
UR.mP.10e	Patient needs to be notified that a flare was detected by the AI model (optional)	Must	To do
UR.mP.10f	Patients must be alerted when something is wrong with their data collection	Could	-
UR.mP.10g	Patients should receive a notification when updates to the app are required or a newer version is available.	Must	Done

UR.mP.# / UR.RS.#	Description	Priority	Status
UR.mP.11a	Patient can enable a medication reminder	Could	-
UR.mP.11b	Patients must be able to customize the frequency and timing of reminders and alerts to match their comfort levels	Could	-
UR.mP.12	Patient should get an explanation on why the app collects the information it collects - purpose	Could	-
UR.mP.13	Patient needs to be able to confirm flares that are detected by the AI model	Won't	-
UR.mP.14a	Patient needs to be able to answer in-app questions	Must	Done
UR.mP.14b	Patient needs to be able to perform photo tests of hands and feet	Must	Done
UR.mP.14c	Patient needs to be able to perform video tests	Must	Done
UR.mP.14d	Patient needs to be able to report a flare up	Must	Done
UR.mP.15	Patients need to be able to receive nutrition and physical activity recommendations	Must	To do
UR.mP.16	Patient needs to be able to retrieve statistics on the wellness activities / recommendations performed in a selected period	Must	To do
UR.mP.21	Patient needs to be able to install the miPROLEPSIS app on Android and IOS	Must	Done
UR.mP.22	The patient should be able to select the preferred language for the app [NL, GR, EN, PT]	Must	Done
UR.mP.23a	The information content in self-management apps should be up-to-date, scientifically justifiable, user acceptable and evidence based where applicable.	Must	In progress
UR.mP.23b	A patient needs to have access to a knowledge base	Must	In progress
UR.mP.24a	A patient should be able to review trends of basic metrics retrieved from the DHTs	Must	In progress
UR.mP.24b	Patient needs to be able to review reported flare ups	Must	Done
UR.mP.24c	Patient needs to be able to review answered questionnaires	Must	In progress
UR.mP.24d	Patient needs to be able to review historical measurements of the smartphone and wearable	Must	In progress
UR.mP.25	The patient needs to be able to use all functionalities of iPROLEPSIS with only 4 apps. miPROLEPSIS + Joint Landmarker + BiAURA + PGS	Must	In progress
UR.mP.26	Patients shouldn't have to change any screen settings in order to use the miPROLEPSIS app, despite their screen size	Must	Done
UR.mP.27	Patients should be able to use their phone with normal battery capacity when the miPROLEPSIS app is installed	Must	Done

UR.mP.# / UR.RS.#	Description	Priority	Status
UR.mP.28	PsA patients should be able to intuitively use the miPROLEPSIS app	Must	Done
UR.mP.29	The PsA patient should be able to easily control the app with sore hands, inflammed fingers and reduced hand dexterity	Must	Done
UR.mP.30	Both elderly patients and younger patients should be able to easily use the miPROLEPSIS app. Onset PsA is 30-50 years of age and chronic.	Must	In progress
UR.mP.31	Both patients with low as well as high levels of digital literacy / skills should be able to use the core functionalities of the miPROLEPSIS app	Must	In progress
UR.mP.32	Both patients with low as well as high reading skills should be able to safely use the miPROLEPSIS app	Must	Done
UR.mP.33	Both patients with low health literacy and high health literacy should be able to safely use the miPROLEPSIS app.	Must	Done
UR.mP.34	Patient should be able to install the miPROLEPSIS app from the apple store / play store	Must	Done
UR.mP.35	Patient needs to be able to retrieve his/her historical data	Must	Done (with an external mechanism)
UR.mP.36	Patient should be able to use the Garmin Smartwatch functionalities, such as paying, receiving text messages, etc.	Could	-
UR.mP.37	Patients should be able to navigate from the miPROLEPSIS app to the miPROLEPSIS Games app.	Should	To do
UR.mP.38	Patients should be able to navigate from the miPROLEPSIS app to the biAURA app	Should	To do
UR.mP.39	Patient needs to change or reset his/her password	Must	Done
UR.mP.40	Patient needs te able to access the educational materials about their disease and healthy coping mechanisms on the iPROLEPSIS Website through the miPROLEPSIS app	Could	In progress
UR.RS.#			
UR.RS.01	The recommendations should be integrated in the miPROLEPSIS app.	Must	To do
UR.RS.02	The user can enable and disable the [Nutrition / PA] recommendations in the miPROLEPSIS app.	Must	To do
UR.RS.03	The user must be able to choose the language [EN, NL, GR, PT] in which they want to receive the recommendations.	Must	In progress
UR.RS.04	The user must be able to provide & update information regarding their age, body height, weight and physical activity levels to the AI	Must	Done

UR.mP.# / UR.RS.#	Description	Priority	Status
	recommendation system for improved dietary advice.		
UR.RS.06	The user should be able to provide their dietary restrictions (e.g., type of diet, food intolerances, etc.) to the AI recommendation system.	Should	In progress
UR.RS.07	The user must receive personalized daily and weekly meal plans from the AI recommendation system for the next 2 weeks.	Must	Done
UR.RS.08	The user must receive clear instructions about the meal plan, regarding day of the week, timings, dishes, ingredients and portions.	Must	Done
UR.RS.10	The user should be able to get alternative meal choices from the recommendation system	Should	Done
UR.RS.11	The user should be able to select the country [UK, NL, PT, GR] in which they reside and receive meals which are commonly prepared in this country.	Should	Done
UR.RS.12	The user should get information on the calories and nutrients of the meals generated by the AI recommendation system.	Should	In progress
UR.RS.13	The physical activity recommendations provided must correspond with the patients' physical activity level.	Must	Done
UR.RS.14	The physical activity recommendations provided must correspond with the patients' disease activity status.	Must	Done
UR.RS.15	The patient must receive monthly personalized physical activity suggestions from the AI recommendation system.	Must	Done
UR.RS.16	The patient must be able to set a target for their personalized exercise plan.	Must	Done
UR.RS.17	The patient must be able to perform the exercises at home without any costs.	Must	Done
UR.RS.18	The patient must be able to understand the recommended exercises and perform them without any additional guidance.	Must	Done
UR.RS.20	The system should collect data on usage of the system (e.g., views of the recommendation screens).	Should	To do

4.3 biAURA

Table 7 miPROLEPSIS biAURA User Requirements.

UR.BA.#	Description	Priority	Status
UR.BA.01	The biAURA app must allow the users to start the binaural beat sound.	Must	Done
UR.BA.02	The biAURA app must provide a sleep diary to users.	Must	Done
UR.BA.03	The biAURA app should provide an alarm to users.	Should	Done
UR.BA.04	The biAURA app should block notifications from other apps during playing the binaural beat sounds	Could	To do
UR.BA.05	The battery consumption of the biAURA app should be optimized.	Should	To do
UR.BA.06	The biAURA functionalities must be integrated in the miPROLEPSIS app	Must	In progress
UR.BA.07	The user must access the biAURA section of the miPROLEPSIS app at any given time.	Must	To do
UR.BA.08	The user must be able to select the preferred language [NL, EN, PT, GR]	Must	In progress
UR.BA.09	The biAURA app contains a Relaxation mode that helps with managing symptoms of stress and pain	Must	In progress
UR.BA.10	The biAURA app contains a Sleep mode that can be used during sleep.	Must	Done
UR.BA.11	The biAURA app must adapt the sounds during sleep mode according to sleep status.	Must	In progress
UR.BA.12	The biAURA must display the available soundtracks (both for sleep and relax aid) with a descriptive manner.	Must	Done
UR.BA.13	The biAURA must provide guidance to the user.	Must	Done
UR.BA.13a	The user is informed that the biaural sounds only work when wearing headphones / in-earphones	Must	To do
UR.BA.14	The user must be informed about the scientifically proven benefits of biAURA sounds and how they work.	Should	In progress
UR.BA.15	The user can like sounds of choice	Could	To do
UR.BA.16	The user can create and edit personalised playlists	Must	Done
UR.BA.17	The user must be able to enable repeat mode while listening to music tracks in relaxation mode.	Must	Done
UR.BA.18	The user must be able to choose between 24-hour digital and 12-hour analog clock formats when setting the sleep alarm	Must	Done

4.4 iPROLEPSIS Games

Table 8 iPROLEPSIS Serious Games User Requirements.

UR.SG.#	Description	Priority	Status
UR.SG.01	A patient must be able to register and sign in in the Serious Gaming Suite. (User sign in)	Must	Done
UR.SG.02	A patient must be able to choose from a variety of games targeting different health aspects. (Game selection)	Must	Done
UR.SG.03	A patient should be able to actively participate in the games through physical movements, gestures, or other inputs. (Gameplay interaction)	Should	In progress
UR.SG.04	The system must provide feedback to patients based on their gameplay performance. (Gameplay feedback)	Must	Planned
UR.SG.05	The system should track and record patient progress within the games for evaluation and analysis. (Progress Tracking)	Should	Planned
UR.SG.06	The system should offer personalized game scenarios and adapt gameplay and levels of difficulty based on individual patient profile and goals. (Personalization and adaptation)	Should	In progress
UR.SG.07	The games could be accessible on various devices such as smartphones, and tablets (Multi-platform support)	Could	In progress
UR.SG.08	Patient progress and preferences could be synchronized across devices to ensure a seamless gaming experience. (Data synchronization)	Could	Planned
UR.SG.09	The system could allow clinicians to monitor patient progress, provide recommendations, and adjust game interventions if needed. (Clinician interaction from HCP Dashboard)	Could	Planned
UR.SG.10	The system could support regular updates, to add new features, and improvements to the suite. (Game updates)	Could	In progress
UR.SG.11	The system should provide patients with clear explanations of how AI-adaptive algorithms influence game scenarios, difficulty levels, and personalized recommendations. (Transparency and Explainability)	Should	In progress
UR.SG.12	The AI adaptation algorithm must ensure equitable access to game benefits across diverse patient profiles, avoiding biases related to age, gender, or physical ability. (Fairness)	Must	In progress
UR.SG.13	The system must implement privacy-preserving techniques in AI algorithms, ensuring that patient data used for personalization is anonymized and securely processed. (Privacy and data protection)	Must	In progress
UR.SG.14	The AI adaptation algorithm should undergo regular evaluations to identify and mitigate biases, improve personalization, and ensure alignment with evolving health guidelines. (continuous improvement)	Should	In progress

4.5 iPROLEPSIS Dashboard

Table 9 iPROLEPSIS Dashboard Requirements.

UR.mH.#	Description	Priority	Status
UR.mH.01	HCP should be able to sign in to the web-based iPROLEPSIS Dashboard	Must	Planned
UR.mH.02	HCP need to be able to manage their accounts: • Edit their account detail • Delete their data • Change or reset their password	Must	Planned
UR.mH.03	Tech-assistant needs to be able to manage patient accounts: • Add new patients to the system • Edit the patients' account details	Must	Planned
UR.mH.07	HCP should be able to select the preferred language for the dashboard[NL, GR, EN, PT]	Must	Planned
UR.mH.08	The HCP needs to be able to view the data in different screen sizes	Must	Planned
UR.mH.10	Should present the patients coming in for an appointment per day	Could	On Hold
UR.mH.11	Should present the date and time of the patient's next appointment	Could	On Hold
UR.mH.12	The patient profile should contain ID, sex and age.	Must	Planned
UR.mH.13	HCPs should be able to search for patients by means of ID.	Must	Planned
UR.mH.14	HCPs/Tech-assistants should be able to filter out patients with detected flares or a high risk of flares in the general overview or in a separate alert tab.	Must	Planned
UR.mH.15	The patient overview should present only core information of the patient profile. Other data should be in a patient-specific page.	Must	Planned
UR.mH.16	The HCP needs to be able to insert clinical observations / scores relevant to the flare prediction / detection model.	Must	On Hold
UR.mH.17	HCPs should be able to review data patient by patient.	Must	Planned
UR.mH.18	The patient details overview show the patient ID, age and sex(must), first and last name (should)	Must	Planned
UR.mH.19	When presenting a flare-risk score, it should be clear which data was used to calculate this score.	Must	Planned
UR.mH.20	The patient details overview needs a dedicated section where the HCP can make notes about any specifics of the PsA diagnosis, such as core complaints, joints usually involved, etc.	Should	Planned
UR.mH.21	The patient details overview should show the data of how a patient is doing at a given point in time. e.g. last appointment, currently.	Must	Planned
UR.mH.22	All data presented should have a clear indication of when the measurement was taken.	Must	Planned

UR.mH.#	Description	Priority	Status
UR.mH.23a	HCPs need to be able to compare current dBM values to the previous timepoints and see if they have improved or worsened.	Must	Planned
UR.mH.23b	HCPs want to be able to compare current values of PROMs / Disease Activity Measures to the previous measurement and see if they have improved or worsened.	Could	On Hold
UR.mH.24	The dashboard will not show the exact answers to questionnaires, but only total / domain scores.	Won't	-
UR.mH.25	The HCP should have access to a graph/figure that shows how symptoms / measures have evolved over time and filtered in various timeframes.	Must	Planned
UR.mH.26	If a value/feature has defined cut-offs, it should be indicated in the graphs if the values are above or below these cut-offs.	Must	Planned
UR.mH.27	The HCPs should be able to select which time-series data is presented in the graph. Avoid many side by side graphs and group data by domain.	Must	Planned
UR.mH.28	Graphs should indicate the points in time when the patient experienced a flare.	Must	Planned
UR.mH.29	The HCP should be able to review which medications, which precise dose and start date of the medications that are currently used by the patients.	Won't	-
UR.mH.30	The HCP should be able to review the medication history of the patient indicating previous medications taken, which dose and start and end date of the medication.	Won't	-
UR.mH.31	HCPs want to see when patients reported to have forgotten taking their chronic medications.	Won't	-
UR.mH.32	HCPs want the dashboard to make a distinction between reported swollen and painful joints	Could	On Hold
UR.mH.33	It is useful to present SOS medication (painkillers) taken at which point in time and with which precise dose.	Won't	-
UR.mH.34	HCPs need to be presented an indication of the flare risk / detection and an explanation of what data is used for the score.	Must	Planned
UR.mH.35	HCPs need to be able to review the progress of a selected patient as opposed to the last clinic visit.	Could	On Hold
UR.mH.36	When it comes to physical activity, it would be useful to make a distinction between the intensity levels of the activities. E.g. walking vs running	Must	Planned
UR.mH.37	HCPs should be able to view the recommendations the DHT has provided to the patients. So they can check if the recommendations are accurate and fit the patient.	Could	On Hold
UR.mH.38	HCPs would like to see if their patients have followed or tried any of the recommendations or interventions. Without any specifics of when and how.	Should	On Hold
UR.mH.39	HCPs want to be able to make notes about their observations during one specific appointment with the patient.	Could	Planned

5 Usability Assessment Plans

This section presents the usability assessments conducted within each of the iPROLEPSIS clinical studies, outlining how user experience, interaction quality, and system performance were or will be evaluated across different patient and healthcare professional populations. The aim of these assessments is to ensure that the iPROLEPSIS digital health solutions are usable, acceptable, and aligned with the real-world needs and contexts of their intended users. Building on established theoretical frameworks such as the Dix Usability Model (Dix et al., 1993), ISO 9241-11 ((ISO), 2018; Bevan et al., 2015), and the HEART Metrics Model (Rodden et al., 2010), each study employs a structured combination of quantitative and qualitative methods to capture effectiveness, efficiency, satisfaction, learnability, and engagement. Together, these assessments provide critical evidence to inform iterative system refinement and support the user-centred development of the iPROLEPSIS ecosystem.

5.1 PDPID Study

5.1.1 Objective

The objective of this usability assessment is to evaluate the miPROLEPSIS application with respect to effectiveness, efficiency, satisfaction, and learnability among the intended user population over a one-year period. The assessment is designed to capture participants' subjective experiences and perceived ease of use, providing evidence to guide iterative improvements and support user-centred design decisions within the context of the PDPID study.

5.1.2 Theoretical Framework

This usability assessment integrates the interaction-focused principles of the Dix Usability Model (1993) (Dix et al., 1993) with the construct definitions of ISO 9241-11 (1998) ((ISO), 2018; Bevan et al., 2015). Usability, according to these frameworks, is determined not only by users' ability to complete tasks but also by the quality of interaction, ease of learning, and overall experience within a specific context of use (Hornbæk, 2006).

- **Effectiveness** is defined as the degree to which users achieve their interaction objectives accurately and completely, reflecting both task success and minimisation of errors.
- **Efficiency** refers to the ease with which users can perform tasks once familiar with the system, encompassing both resource expenditure (ISO) and cognitive ease of interaction (Dix).
- **Satisfaction** reflects the extent to which the application is perceived as engaging, pleasant, and trustworthy, capturing both pragmatic outcomes and hedonic experiences, including comfort, perceived value, and emotional response.
- **Learnability**, explicitly highlighted in the Dix model but not formalised in ISO, represents both the initial ease of learning and the longitudinal development of proficiency, including improved user confidence and fluency over time.

Usability is inherently context-dependent: the same system may be perceived very differently depending on the user population, the tasks being performed, the environment, and prior experience with technology. Within the PDPID study, context encompasses participants' clinical characteristics, daily routines, and technological experiences. Evaluating usability in context ensures that findings reflect real-world experiences, allowing interpretation of difficulties or preferences relative to individual capabilities and environmental constraints.

5.1.3 Usability Constructs and Measurement

Contextual Information is captured to characterise the users interacting with the miPROLEPSIS app. A *Digital Literacy Questionnaire* at baseline assesses familiarity and confidence with relevant devices, while *demographic data* such as age, gender, disease activity, physical activity, and cultural background provide additional context. Data from dBMs (dBM) may further help identify previously unrecognised patient subgroups. This information supports interpretation of usability findings relative to participants' prior experience and characteristics.

Effectiveness is assessed through participants' self-reported experiences of completing in-app tasks, using the *System Usability Scale (SUS) (Sauro & Lewis, 2016)* and *open-ended feedback* to identify perceived difficulties, errors, or barriers. While objective task completion metrics are not collected, these instruments provide a valid proxy for assessing perceived accuracy and completeness in task performance.

Efficiency is evaluated via the *Single Ease Question (SEQ) (Sauro & Lewis, 2016)*, which captures participants' perceived ease of performing key app tasks, including completing questionnaires, undertaking photo and video tasks, and interacting with the miPROLEPSIS keyboard. This approach operationalises Dix's emphasis on cognitive ease and minimisation of effort, alongside ISO's conceptualisation of resource expenditure.

Satisfaction encompasses both hedonic and pragmatic aspects of user experience. Assessment is conducted using SUS, *Net Promoter Score (NPS) (Sauro & Lewis, 2016)*, and open-ended qualitative questions, capturing comfort, engagement, trust, and perceived value. This aligns with Dix's emphasis on the emotional and experiential quality of interaction, in addition to ISO's definition of satisfaction.

Learnability is evaluated longitudinally. Initial learnability is inferred from Month 3 self-report measures, while proficiency over time is assessed by comparing SUS and SEQ scores between Month 6 and Month 12. This approach reflects Dix's focus on learning curves and interaction proficiency, while maintaining alignment with the ISO constructs of effectiveness and efficiency.

5.1.4 Data Collection Instruments and Timeline

Table 10 Overview of the usability assessment within the PDIPD study.

Questionnaire / Instrument	Purpose / Construct Assessed	Timepoint
Demographics	Participant characteristics, such as age, sex, time since diagnosis and digital literacy.	T0
Technology Experience Questionnaire	Baseline familiarity and confidence with technology; contextualises usability findings	T0
System Usability Scale (SUS)	Overall perceived usability; effectiveness, satisfaction	T6 & T12
Single Ease Question (SEQ)	Perceived ease of performing key tasks; efficiency	T6 & T12
Open-ended questions	Problems encountered and suggestions; effectiveness, satisfaction	T6 & T12
Net Promoter Score (NPS)	Likelihood to recommend the app; satisfaction	T6 & T12

5.1.5 Preliminary Results

These findings represent interim usability results based on the first 53/600 respondents from NL (N=21) and GR (N=32) for the T6 questionnaire. Table [X][ref] indicates our findings. Data collection is ongoing, and the final analysis will be conducted once all responses are received.

Table 11 PDPID interim T6 Usability results.

	NL N = 21	**GR** N= 32	**Total** N= 53
Age, (years), mean (SD)	53.5 (9.6)	51.0 (12.7)	51.9 (11.5)
Sex, (% Female)	47.6	37.5	41.5
Confidence with* (scale 1 to 5),, mean (SD) • Smartphone • Smartwatch	 4.1 (1.3) 3.0 (1.7)	 4.1 (1.2) 3.6 (1.7)	 4.1 (1.2) 3.4 (1.6)
System Usability Score (SUS), mean (SD)	45.4 (12.4)	46.8 (7.0)	46.2 (9.5)
Single Ease Question (SEQ) (scale 0-6), mean (SD) • Answering in-app questions • Photo task • Video Task • Using iPROLEPSIS keyboard	 5.2 (1.1) 3.5 (2.0) 2.5 (1.7) 3.1 (2.2)	 5.7 (0.7) 3.5 (2.0) 2.8 (1.6) 4.6 (1.8)	 5.5 (0.9) 3.5 (1.7) 2.7 (1.6) 4.0 (2.1)
Net Promoter Score (scale –100 to100): • Promoters (%) • Passives (%) • Detractors (%)	-71.4 4.8 19.0 76.2	-31.3 15.6 37.5 46.9	-47.2 11.3 30.2 58.5

The mean age of the sample was 51.9 years (SD = 11.5), and 41.5% were female. Overall, the participants reported relatively high confidence in using smartphones (M = 4.1, SD = 1.2 on a scale from 1 to 5), whereas confidence with smartwatches was more modest (M = 3.4, SD = 1.6).

When comparing the two sites, the usability results were broadly similar. The *overall System Usability Score (SUS)* was 46.2 (SD = 9.5), which lies below our KPI of 70 that is typically considered indicative of acceptable usability. This result therefore points towards substantive limitations in the usability of the system at its current stage of development. At the level of specific tasks by means of *Single Ease Questions (SEQ)*, answering in-app questions was experienced as very easy (M = 5.5, SD = 0.9 on a 0–6 scale), both the iPROLEPSIS keyboard (M = 4.0, SD = 2.1) and the photo task (M = 3.5, SD = 1.7) were regarded as neutral in difficulty, whereas the video task was considered difficult (M = 2.7, SD = 1.6).

The Net Promoter Score (NPS) for the system was negative (-47.2), with only 11.3% of participants classified as promoters. This finding reinforces the impression that participants are not satisfied with the app and thus are not inclined to recommend the system in its present form. The Dutch participants reported a markedly lower NPS (-71.4), while the Greek participants, although still negative, expressed comparatively higher levels of acceptance (NPS = -31.3).

The observed significant discrepancy in NPS between Dutch and Greek participants, despite comparable usability metrics such as SUS scores and task-level ease ratings, can be attributed to well-documented cross-cultural differences in response styles and rating behavior. NPS, which classifies only scores of 9 or 10 as “promoters,” is particularly sensitive to cultural tendencies in scale usage. Northern European respondents, including those from the Netherlands, are known to adopt a more conservative and critical stance when rating products or services. They tend to avoid extreme positive ratings unless their expectations are clearly exceeded (Qualtrics XM Institute, 2021). In contrast, Southern European cultures, such as Greece, are more likely to use mid-to-high ratings to express moderate satisfaction, even when their experience is similar (MeasuringU, 2016).

This cultural response bias is further amplified by how individuals interpret the concept of “recommendation.” Dutch participants may associate recommending a system with personal endorsement and reputational risk, leading to lower scores unless the system is perceived as highly reliable and polished. Greek participants, on the other hand, may interpret recommendation more relationally or contextually, especially in health-related domains where community benefit and shared experience play a role (Livingstone, 2020). These divergent interpretations affect NPS more than standard usability metrics, which are typically framed around task performance and interface clarity.

Moreover, NPS has been criticized as a measurement artifact when used across cultures without calibration. Studies have shown that countries with similar satisfaction levels can yield vastly different NPS results due to linguistic framing and cultural calibration issues (SurveyMonkey, 2018). In this case, the Dutch participants’ markedly lower NPS may reflect stricter evaluative norms rather than genuine dissatisfaction. Conversely, the relatively higher NPS among Greek participants, though still negative, may indicate a more flexible or socially attuned rating behavior.

In light of these findings, it is essential to interpret NPS within its cultural context and supplement it with qualitative feedback or normalized satisfaction measures. For cross-national usability studies, relying solely on NPS may obscure meaningful insights and lead to misinterpretation of user sentiment.

Analysis of the open-ended responses provided further insight into the quantitative findings. From the UX-Design perspective, participants expressed some uncertainty regarding the interpretation of ‘Flare-up’ and recommended adjustable font sizes and the inclusion of more open-ended questions. However, the majority of reported difficulties were technical in nature rather than stemming from UI or design flaws. Participants reported problems with connectivity and synchronisation, noting that the smartwatch disconnected easily or that values such as steps, sleep, or heart rate variability were either missing or displayed incorrectly. Technical instability also emerged as a concern, including the application freezing when uploading photographs or videos, videos failing to play, and unexpected log-outs. Further issues were noted about notification delivery, with some participants not receiving alerts when new tasks were available, while others found the routine synchronisation notifications intrusive.

Taken together, these findings suggest that, although the system was generally adequate for completing simple in-app questionnaires, users encountered substantial barriers related to connectivity, system stability, and the handling of multimedia tasks. It should be noted that these responses were obtained from the first patients participating in the PDPID study, and that continuous updates have been implemented throughout the study to address technical issues as they were identified. Nevertheless, the low SUS scores and markedly negative NPS highlight the need for ongoing refinement before the system can be considered acceptable for broader implementation.

5.2 IDBV Study

The objective of the usability assessment is to evaluate the miPROLEPSIS Lite application in terms of effectiveness, efficiency, and user satisfaction among PsO patients over a one-year period. The assessment is designed to capture both participants' experiences and their perceived ease of use within the framework of the IDBV in HPOS study. The outcomes will provide evidence to guide improvements and inform user-centred design decisions for the miPROLEPSIS Lite app.

As the miPROLEPSIS Lite app addresses a different target population from the main miPROLEPSIS app, its usability requires dedicated evaluation. User experience is shaped by multiple factors, including whom the users are, the tasks they perform, the environment of use, and their prior familiarity with technology. In the context of the HPOS study, the assessment will therefore also consider participants' clinical characteristics, demographics, and lifestyle factors. This broader approach enables usability findings to be interpreted in relation to individual capabilities and environmental conditions, providing a more nuanced understanding of user difficulties and preferences.

5.2.1 Usability and Measurement

Contextual Information is captured on demographics and digital literacy, like in the PDPID study, to characterise the users interacting with the miPROLEPSIS Lite app.

Efficiency will be evaluated via the Single Ease Question (SEQ), which will capture participants perceived ease of performing key app tasks, such as undertaking optional photo and video tests.

Effectiveness, User satisfaction & Learnability will be captured at month 6 and 12, with SUS, NPS and some open-ended questions as is done in the PDPID study.

5.2.2 Data Collection Instruments and Timeline.

Table 12 Overview of the usability assessment within the IDBV study.

Questionnaire / Instrument	Purpose / Construct Assessed	Timepoint
Demographics	Participant characteristics, such as age, sex, time since diagnosis and digital literacy.	T0
Digital literacy	Experience with technology	T0
SUS	Overall perceived usability; effectiveness, satisfaction	T6 & T12
Single Ease Question (SEQ)	Perceived ease of performing key tasks; efficiency	T6 & T12
Open-ended questions	Problems encountered and suggestions; effectiveness, satisfaction	T6 & T12
Net Promoter Score (NPS)	Likelihood to recommend the app; satisfaction Net Promoter Score (NPS)	T12

5.3 PPIDC Study

In Task 5.5, we are undertaking a study entitled "Prevention of Psoriatic Arthritis Inflammation Through Digital Care: A Feasibility Mixed-Methos Study." The overarching aim is to evaluate the feasibility of the iPROLEPSIS Digital Health Promotion Programme for individuals living with PsA within a real-world clinical context. To this end, we are conducting a mixed-methods feasibility evaluation, integrating both quantitative and qualitative methodologies.

The primary objective is to assess the usability of the iPROLEPSIS Digital Health Promotion programme from the perspectives of both PsA patients and HCPs. Usability is defined as "the extent to which specified users can use a system, product, or service to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" ((ISO), 2018). This assessment is a critical step in the development of eHealth innovations, as it informs UI improvements and enhances user interaction (Broekhuis & Van Velsen, 2022).

5.3.1 Theoretical Framework

This usability assessment builds upon the foundational principles of the Dix Usability Model (1993) and the construct definitions of ISO 9241-11 (1998). As described in **Section 5.1.2** these together they define usability as a multifaceted construct encompassing effectiveness, efficiency, satisfaction, and learnability within a specific context of use. These models emphasize both the technical and experiential dimensions of user interaction, offering a robust lens for evaluating digital health technologies.

To enrich this framework, we incorporate *the HEART Metrics Model* developed by Google, which introduces a complementary set of user-centred dimensions: *Happiness*, *Engagement*, *Adoption*, *Retention*, and *Task Success* (Rodden et al., 2010). While the Dix and ISO models primarily focus on interaction quality and task performance, HEART extends the evaluative scope to include behavioural indicators that reflect sustained usage patterns in real-world settings.

- **Operational Metrics:** HEART introduces quantifiable behavioural signals that complement self-reported usability scores and provide a richer interpretation of user experience.
- **Engagement:** HEART adds the construct of engagement to our theoretical model. Where engagement is defined as the degree of interaction, involvement, and emotional connection users have with a digital system. It reflects how actively and frequently users interact with the UI, indicating the depth of their relationship and perceived value.
- **Behavioural Continuity**: Whereas Dix and ISO emphasise momentary interaction success, HEART captures longitudinal engagement, retention, and adoption.

5.3.2 Usability Constructs and Measurement

Contextual Information. To characterise the user base interacting with the iPROLEPSIS app, contextual data will be collected from both patients and HCPs. This includes demographic information and digital health literacy, gathered via structured surveys.

Effectiveness/Task Success. Refers to the extent to which users can achieve their intended goals accurately and completely, encompassing both task success and error minimisation. This construct will be assessed using:

- *System Usability Scale (SUS):* Captures perceived ease of use and confidence in task completion.
- HUBBI Domains: Including *Task–Technology Fit*, *Information & Terminology*, and *Guidance & Support*, which evaluate alignment between user goals and system capabilities.
- *Task Completion Rates and Error Rates:* Provide objective behavioural indicators of successful interaction.

Efficiency/Task Success. Denote the time and effort that are needed for task completion. It will be measured through:

- *SUS scores* reflecting perceived ease and speed of use.

- *HUBBI domains:* Basic System Performance, Navigation & Structure, and Interface Design, assessing system responsiveness and intuitive design.
- *Time on Task:* Quantifies user effort and interaction fluidity.

Satisfaction / Happiness. It captures the extent to which users find the system engaging, pleasant, and valuable. It will be evaluated using:

- *SUS* and *HUBBI Satisfaction domain*: Assessing comfort, trust, and overall user sentiment.

Learnability. Refers to the ease with which users acquire proficiency over time. It is inferred from longitudinal changes in usability scores and behavioural patterns:

- *SUS* and *HUBBI scores* compared across T3, T6, and T12 to assess progression.
- *Time on Task and Error Rates over time*: Indicate increased fluency and reduced difficulty.

Engagement. Reflects the frequency and intensity of user interaction with the system. It will be measured through:

- Session Frequency & Duration
- Feature Access Rates & Dwelling Times
- Notification Opening Rates

Adoption & Retention. The uptake and sustained use of optional app features. These indicators reflect users' willingness and ability to integrate the system into their routines. Given the feasibility nature of the study, some features are obligatory while others are optional. Measures include:

- *Analysis of Declined Participation*: Understanding barriers to adoption.
- *Feature Access Rates over time*
- *Notification Opening Rates over time*

Qualitative Enrichment. To contextualise quantitative findings and explore emotional responses, perceived benefits, and suggestions for improvement, qualitative data will be collected via *focus groups*. At study completion, a sample of rheumatologists and participating patients will be invited to separate sessions conducted in English, involving participants from all participating countries. Each session will last up to 90 minutes and follow a semi-structured topic guide with open-ended questions to encourage in-depth discussion. All sessions will be audio or video recorded for subsequent analysis. Sociodemographic data will be collected from clinicians prior to participation.

5.3.3 Data Collection Instruments and Timeline

In this study, usability will be assessed independently for study participants and HCPs at 3 (T3), 6 (T6), and 12 (T12) months after initiating use of the iPROLEPSIS DHTs (**Table 13**).

Table 13 User Reported Usability

Outcome Measure	Measure Description	Timepoints
Systems Usability Scale (SUS)	A validated, standardised, 10-item questionnaire assessing the ease of system use through user agreement with usability statements for electronic systems, web portals, or devices (Brooke, 1996). Responses are given on a 5-point Likert scale (1 = "strongly disagree" to 5 = "strongly agree").	Patients @T3, T6, T12 HCPs @T12

Outcome Measure	Measure Description	Timepoints
	Total SUS scores are converted to a 0-100 scale. A score of ≥68 indicates an above-average usability experience (Brooke, 1996). SUS scores can also be interpreted using the grading scale proposed by Sauro and Lewis, 2016 (Sauro & Lewis, 2016) (e.g., scores between 84.1 to 100 are an "A+"; between 80.8 to 84 are an "A"; between 78.9 to 80.7 are an "A-"; between 77.2 to 78.8 are a "B+"; etc.).	
eHealth UsaBility Benchmarking instrument (HUBBI)	A structured heuristic tool that assesses usability across seven domains: Basic System Performance, Task–Technology Fit, Interface Design, Navigation & Structure, Information & Terminology, Guidance & Support, and Satisfaction (Broekhuis & Van Velsen, 2022). Results are presented as categorical usability ratings (*Good*, *Moderate*, *Insufficient* or *Poor*) and can be visualised using radar charts, as recommended by the instrument's developers (Broekhuis & Van Velsen, 2022).	Patients @T3, T6, T12 HCPs @T12
Patient Focus Groups	Will explore how they experienced the iPROLEPSIS digital health programme, focusing on their comfort with technology, overall impressions, ease of using the apps, and how well the programme fit into their daily lives. It also examines perceived health benefits, challenges faced, and suggestions for improvement.	Patients @T12
HCP Focus Groups	Will focus on their experiences with the iPROLEPSIS Dashboard and study procedures, including usability, clinical relevance, workflow integration, and the role of AI and dBMs. They will also be asked to reflect on patient engagement and offer feedback for improving both the dashboard and procedures.	HCPs @T12

Table 14 Performance and Behavioural Metrics.

Domain	Outcome Measure	Measure Description
Performance	Task Completion Rate	Completed vs. abandoned/incomplete tasks. E.g, abandoned questionnaires, Incomplete video tests, Photo test completed.
	Time on Task	Time it takes for users to complete an initiated task. E.g. see Task Completion Rate.
	Error Rate	Logging of errors encountered when working on a task. E.g. Number of false photo submissions, number of repeated video tests
Behavioural	Session Frequency	Number of discrete user sessions or logins into the miPROLEPSIS, biAURA, iPROLEPSIS Games apps or the HCP dashboard.
	Session Duration	Duration users spend interacting with the iPROLEPSIS apps or HCP Dashboard as a whole.
	Feature Access Rate	Number of discrete user interactions with specific features or modules. E.g. Dietary Recommendations, My Journey, biAURA Diary.
	Feature Dwell Time	Duration users spend interacting with specific features or modules on their own incentives. E.g.

Domain	Outcome Measure	Measure Description
		Relaxation sound player, patient specific data overview, specific serious game.
	User Generated Entries	Frequency and quantity of data input by users, e.g., notes or flare entries

6 Conclusions

Deliverable D2.5 provided an updated report of user research and co-creation activities within Task T2.2, consolidating insights from patients, healthcare professionals, and technical partners to inform the user-centred development of the iPROLEPSIS Digital Care Ecosystem. Through 56 structured interactions, including focus groups, surveys, co-creation workshops and usability tests, >822 diverse stakeholders from the four participating countries actively contributed to the iterative design of all iPROLEPSIS Digital Health Tools (DHTs): miPROLEPSIS, miPROLEPSIS Lite, biAURA, iPROLEPSIS Games, and the iPROLEPSIS Dashboard.

Key Takeaways:

- Stakeholder interactions confirmed the value of patient research partners (PRPs) and healthcare professionals as equal collaborators, ensuring that both clinical validity and lived experience underpin the technological solutions developed.
- Findings demonstrated that while the visual design and conceptual clarity of the tools were well-received, several usability barriers persist, particularly concerning task clarity, navigation, and interaction design, highlighting the importance of continued iteration throughout the project's lifecycle.
- With 3 rounds of focus groups/surveys, a total of 56 stakeholder interactions across ≥13 design sprints, and a growing community size of 792 persons with/at risk of PsA and 32 HCPs from ≥4 countries the KPIs assigned to T2.2 under Objective 1 were partially achieved. As the iPROLEPSIS studies collect feedback from end-users and DHTs are further developed, this community shall grow to meet the final KPI of 50 HCPs in the community.
- The development of user scenarios transformed qualitative insights into concrete, narrative use cases, showing how PsO patients, PsA patients, healthcare professionals, and tech-assistants engage with the iPROLEPSIS Digital Care Ecosystem. Serving as a bridge between research and implementation, the scenarios guide interface design, workflow alignment, and usability evaluation.
- The resulting set of 169 updated user requirements (URs) now provides a solid foundation for technical implementation and evaluation in the forthcoming clinical and usability studies.
- Preliminary usability testing of the miPROLEPSIS app and iPROLEPSIS Games indicates acceptable but improvable usability, demonstrating the feasibility of user-driven refinement ahead of large-scale deployment.

Future steps:

As Task T2.2 concludes, its outputs will directly feed into subsequent work packages:

- *WP4* will further integrate and technically mature the DHTs, addressing the usability and functional requirements identified through the co-creation and testing cycles reported in this deliverable.

- *WP5* will operationalise the planned usability assessments in the iPROLEPSIS studies (PDPID, IDBV and PPIDC), using the frameworks defined here to collect empirical evidence on system effectiveness, efficiency, satisfaction and learnability in real-world contexts.

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