

Exhibit 1

Project Plan

IPARD

Improving Integrated care pathways for Patients with chronic diseases And their Relatives through a Digital solution - focusing on patients with Parkinson's, acquired brain or spinal cord injuries.

Describe the common goal and vision for the project

The vision of the IPARD project is to empower patients with chronic diseases and their relatives to better handle their own health and increase communication across sectors by the use of a digital platform.

The background of the project is that the hospital and caregiving sectors lack a coherent solution to effectively support patients with chronic diseases and their relatives on integrated care pathways. Patients transit hospital clinics, rehabilitation, and municipal care services with the risk of losing important data and knowledge during the transfers in and between the care pathways. The primary challenges are poor organization and inefficiency in communication and coordination between patients, relatives, and healthcare professionals. Consequently, patients and relatives are burdened with the responsibility of managing tasks, sharing knowledge, repeating information, and ensuring coordination.

The objective of the project is to make it possible for three patient groups with chronic diseases and their relatives - together with healthcare professionals - to coordinate, communicate, and work together on care pathways across the hospital and caregiving sectors. Thus, the project will:

1. Facilitate the transition across hospital and caregiving sectors with a digital solution, thus improving the integrated care pathways for three patient groups.
2. Support and enhance relevant and timely actions and assistance from relatives to three patient groups.

The patient groups are patients with Parkinson's disease, acquired brain injury and spinal cord injury.

The success criteria are to:

1. Carry out patient journey analyses in Q3 2024 to generate knowledge on needed improvements and how the platform specifically can support users.
2. Further develop a digital solution from *app to nursing homes to a digital platform to both caregiving and hospital sectors* and launch it for test in Q3 2025
3. test and adjust the digital solution across three patient groups across hospital and caregiving sectors during 2025 - 2026.
4. Produce data from patients and relatives' input and present this in dashboard views for professionals to use as research component and predictive analysis from Q3 2026.
5. Promote four waves of questionnaires and focus groups interviews to validate the use and value of the digital solution from Q3 2025 to Q1 2027.
6. Carry out analyses to generate data insights on impact and improvements on patient journeys from Q1 2027.

The project creates value in several ways:

Enhanced efficiency, process optimization, and cost savings:

The project will help streamline work processes, automate administrative tasks, provide tools to support patients and relatives in their daily lives with the diagnoses and improve communication between the involved parties across patient pathways.

For professional healthcare workers, the digital solution will reduce paperwork and manual processes, minimize misunderstandings/errors, alleviate repeating the same tasks due to lack of control and information, and reduce time spent on coordination and communication about patient history.

Previous research from the nursing home sector indicates that the overall efficiency of the administrative work can be improved by at least 25% through digitization and automation – whilst also improving on the perceived quality of the coordination and communication.

Preventive care and disease management:

The project will empower people to take better charge of their health and manage their chronic conditions. By promoting preventive care and disease management through assisting individuals in their daily routines, the project helps to manage chronic conditions more effectively supported by relatives as it integrates preventive care and disease management by offering personalized health tracking, reminders for appointments and medication adherence, possible educational resources on healthy living, and access to telemedicine services for consultations and monitoring. Through data analytics and AI, the app can provide tailored recommendations and early intervention alerts based on users' health profiles and behaviours, empowering individuals to take proactive steps towards better health outcomes. Moreover, by fostering collaboration between healthcare providers and the target groups the app can facilitate seamless coordination of care and support across various sectors.

Reduced inequalities in health:

The digital solution provides people with chronic diagnoses with a tool that can continuously follow and empower them to take charge of their own health, and relatives with a tool that supports them in their role as relative in the care pathway. This will help balance out the differences in treatment in the long term and increase the Quality of Life of chronic patients and their relatives. However, it is important to identify the individuals who need a more in-depth education and supervision regarding the app features, connection, and digital competencies. This is why WP 7, which is led by researchers at University of Copenhagen, concentrates its focus on inequality in health when implementing new digital solutions.

Moreover, up to 80 pct. of informal caregivers are middle-aged women. The project will from the beginning set focus on and help reduce both gender and generation gaps. It will make the invisible tasks and burdens visible, and reach out to digital natives, who from 2028 will be people under the age of 50. Thus, by empowering individuals with knowledge, support, and resources to manage their health effectively, regardless of their socio-economic status or geographic location, the app

can contribute to narrowing the gap in health outcomes and promoting health equity across diverse populations.

Data-driven decision making and research:

The project will generate large amounts of data from that can be analyzed to extract valuable insights. By leveraging big data analytics and machine learning (ML) algorithms, the project outcome can help identify patterns, enrich healthcare profiles of chronic diseases, and optimize treatment plans across patient pathways. This data-driven approach enables healthcare providers to make informed decisions and tailor healthcare interventions.

A digital app across sectors can enhance data-driven decision making and research by collecting and analyzing vast amounts of anonymized user data. By leveraging machine learning algorithms and predictive analytics, the app can identify patterns, trends, and correlations in health-related data, enabling researchers to gain insights into disease prevalence, risk factors, and treatment outcomes. Moreover, through user consent, the app can facilitate the sharing of anonymized data for research purposes, supporting population health studies, clinical trials, and epidemiological research. By serving as a platform for real-time data collection and analysis, the app can accelerate the pace of scientific investigation leading to improved healthcare delivery.

Economic growth and job creation: The project is expected to prove and validate the relevance of Kintella's digital solution and foster further commercialization. Potential customers are public and private hospital clinics with patients with chronic diseases, municipalities (rehabilitation, home care, and nursing homes) as well as private individuals willing to pay for a solution to better support their life with chronic diseases. Customers are not limited to DK, but also international as the solution will not be dependent on municipal healthcare IT systems. Patient and relatives' organizations, insurance companies and pharmaceutical industry could also be interested in knowledge and meta data about the health, wellbeing, and healthcare profiles of patients and relatives - naturally in respect of consent to the sharing of data. Kintella is expected to increase the number of employees during the project period, supporting overall economic growth. IPARD can be used as an example to show and support the Danish position of strength within international health and welfare technologies stimulating economic growth and job creation. It drives innovation, attracts investments, and fosters entrepreneurship.

The value for the users (Value Proposition) will, in short, be as follows:

- Quality of Life improvement via self-management; symptoms tracking, lifestyle management, predictive care suggestions (patients & relatives).
- Decrease in length of stay and healthcare utilization via decision support (patients).

- Personalized health management via tracking of health metrics (patients)
- Enhanced health literacy through access to knowledge and educational resources (patients and relatives)
- Clinical decision support: Insights into health status and symptoms development (professionals).
- Improved efficiency by workflows optimization, tasks automation, and patient history access (professionals).
- Enhanced collaboration through digital communication and information sharing (all).

Strategic capabilities of the project parties regarding fulfilling the vision of the project are as follows:

- Technological Infrastructure such as smartphones and web access.
- Citizens and healthcare professionals who understand technology and can manage working with and in an app.
- IT professionals with knowledge within data science, software development, and data management.
- User engagement and ability to understand and translate user needs and preferences to IT requirements.
- Regulatory compliance and knowledge of General Data Protection Regulation - GDPR and health information security.
- Collaboration among different stakeholders, transparent cross sector governance, and public relation capabilities.
- Change management including stakeholder engagement, communication, training, and addressing resistance to change. Leadership commitment to digital transformation for driving the implementation process.

The exit strategy of the project includes the following elements:

Meeting project completion criteria:

- Achieving the objective and success criteria of the project
- Meeting the deliverables about six research-based articles and publishing relevant data in peer reviewed international journals
- Obtaining approval from steering committee.

Transferring knowledge and responsibilities:

- Providing training material and manual for working procedures and processes including cross sector collaboration

- Conducting knowledge transfer meetings among project partners
- Clarifying how data will be stored, secured, and transferred to ensure compliance with data protection and privacy regulations.

Providing relevant documentation and reporting:

- Steering committee approving final report about project results and plan for further collaboration.
- Drawing up customer and supplier contract and data processing agreement for further collaboration
- Handing over updated system documentation and continuity plan
- Archiving project-related documents, data, and artifacts for future reference.

Stakeholder communication and Public Relations:

- Informing about conclusion and findings to identified Danish and international stakeholders (regions, municipalities, patient- and relatives organizations, research communities at universities and hospitals)
- Communicating at SoMe
- Participating at conferences to share findings.

Resource reallocation:

- Detailing how project resources, including human resources and software licenses, will be re-allocated and released.

Contractual and legal considerations:

- Performing contract closure and post-project obligations with partners and Innovation Fund Denmark: outstanding bills, payments, and financial accounting.
- Drawing up possible contract for further collaboration and implementation

Post-project review and evaluation:

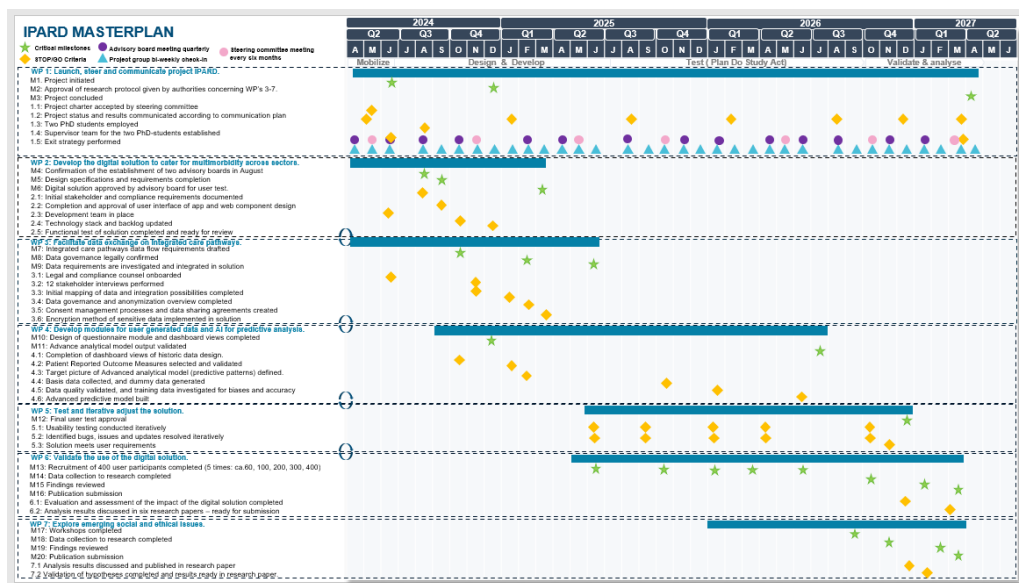
- Conducting a post-project review to evaluate the overall success of the project. Identify lessons learned, areas for improvement, and strategies for future projects.
- Scheduling a follow-up evaluation after the project's closure to assess the long-term impact, client satisfaction, and any unforeseen.
- Scaling of the results and solution to other patient groups national and internationally

Celebrating achievement and collaboration:

- Identifying ongoing collaboration in new international project setting.
- Celebrating contributions of project team and advisory board members to recognize efforts and foster further collaboration.

Master plan for the whole project

The IPARD masterplan depicted below and attached to this document outlines the master plan of the project including the critical milestones and stop/go criteria in a Gantt chart.



The plan includes critical milestones and success criteria distributed into horizontal phases and vertical work packages (WP). The phases are Mobilization, Design & Develop, Test (Plan, Do, Study, Act), Validate & Analyze. The Milestones and success criteria are as follows:

WP 1: Launch, steer and communicate project IPARD.

The milestones are:

- M1: Project initiated in June 2024
- M2: Approval of research protocol concerning WP's 3-7 given by authorities December 2024.
- M3: Project concluded in April 2027

The success criteria are:

- 1.1: Project charter accepted by steering committee on May 2024

1.2: Project status and results communicated according to communication plan starting in April 2024 and ending in March 2027

1.3: Two PhD students employed in May with start in August 2024.

1.4: Supervisor team for the two PhD-students depending on research focus and target group established in June

1.5: Exit strategy performed in March 2027.

WP 2: Develop the digital solution to cater for multimorbidity across sectors

The milestones are:

M4: Confirmation of the establishment of two advisory boards in August 2024 – one with political/health care economists stakeholders and one with patients and caregivers representing the three disease groups

M5: Design specifications and requirements completion in September 2024

M6: Digital solution approved by advisory board for user test in February 2025

The success criteria are:

2.1: Initial stakeholder and compliance requirements documented August 2024

2.2: Completion and approval of user interface of component design August 2024

2.3: Development team in place in June 2024

2.4: Technology stack and backlog updated in October 2024

2.5: Functional test of solution completed and ready for review January 2025

WP 3: Facilitate data exchange on integrated care pathways.

The milestones are:

M7: Integrated care pathways designs with data flow completed in October 2024.

M8: Data governance legally confirmed in February 2025

M9: Data requirements are investigated and integrated in solution in June 2025

The success criteria are:

3.1: One legal and compliance counsel onboarded in June 2024

3.2: 12 stakeholder interviews performed by November 2024.

3.3: Initial mapping of data, workflows, systems and integration possibilities completed in November 2024.

3.4: Data governance and anonymization overview completed in February 2025

3.5: Consent management processes and data sharing agreements created in solution in February 2025

3.6: Encryption method of sensitive data implemented in solution in March 2025

WP 4: Develop modules for user generated data and for predictive analysis

The milestones are:

M10: Draft design of questionnaire module and dashboard views completion in December 2024.

M11: Advanced analytical model output validated in July 2026.

The success criteria are:

4.1: Completion of dashboard views of historic data design in October 2024.

4.2: Patient Reported Outcome Measures (PROMs) selected and validated January 2025.

4.3: Target picture of advanced statistical modelling (predictive patterns) defined in February 2025.

4.4: Basis data collected, and dummy data generated in October 2025.

4.5: Data quality validated, and training data investigated for biases and accuracy in January 2026.

4.6: Advanced predictive model built using e.g. PCA and ML/AI in June 2026.

WP 5: Test and iterative adjust the solution.

The milestone is:

M11: Final user test approval in December 2026

To test the feasibility of the digital solution in a pilot study

The success criteria are:

5.1: Usability testing conducted iteratively until October 2026

5.2: Identified bugs, issues and updates resolved iteratively until October 2026

5.3: Solution meets user requirements in November 2026.

WP 6: Validate the use of the digital solution

The critical milestones are:

M12: Recruitment of 400 user participants completed (5 times: ca.60, 100, 200, 300, 400) in March 2026

M13: Data collection to research completed November 2026

M14 Findings reviewed in January 2027

M15: Publication submission in March 2027

The success criteria are:

6.1: Evaluation and assessment of the impact of the digital solution completed in December 2026.

This includes more specifically:

Evaluation of improvements in clinical outcomes

- Including disease management, medication adherence, and patient health indicators, facilitated by the use of the digital solution.

Assessment of the impact of the digital solution on healthcare provider efficiency

- Including time saved, improved decision-making, and streamlined workflows.

Measurement of the reduction in adverse events or medical errors

- resulting from enhanced data access, sharing, and communication through the digital solution.

Evaluation of the level of patient engagement and participation in own care

- considering the factors appointment adherence, self-monitoring, and utilization of educational resources provided through the digital solution.

Tracking of preventive care uptake and screenings

- facilitated by the digital solution, leading to early detection and intervention.

Measurement of the effectiveness of the digital solution in supporting the management of chronic diseases through remote monitoring, data sharing, and timely interventions.

Assessment of the impact on healthcare resource utilization, such as reduced visits or hospital admissions due to improved communication and coordination.

6.2: Analysis results discussed and published in six research papers

WP 7: Explore emerging social and ethical issues.

The critical milestones are:

M16: Workshops completed in September 2026

M17: Data collection to research completed November 2026

M18: Findings reviewed in February 2027

M19: Publication submission in March 2027

The success criteria are:

7.1 Analysis results discussed and published in research paper in December 2026

7.2 Validation of hypotheses completed and results ready in research paper in January 2027

Project structure

The project will run over a period from 1 April 2024 to 31 March 2027. The project is composed of overall four phases (Mobilize, Design & Develop, Test, and Validate & Analyze) and structured into seven work packages (WP) that run through the phases. The WP's are as follows:

WP 1. Launch, steer and communicate project IPARD

WP 2. Develop the digital solution to cater for multimorbidity across sectors.

WP 3. Facilitate data exchange on integrated care pathways.

WP 4. Develop modules for user generated data and for predictive analysis.

WP 5. Test and iterative adjust the solution.

WP 6. Validate the use of the digital solution.

WP 7. Explore emerging social and ethical issues.

WP 1. Launch, steer and communicate project IPARD

Description

WP 1 focuses on the activities required to launch, subsequently effectively manage, and conclude the entire IPARD project. It involves establishing the project team and governance structure, refining the communication plan, preparation of collaboration agreements and data processing agreements, employment and engaging PhD students and technical resources, activating stakeholders, and setting up the necessary tools for project management throughout the project's timeline.

The schedule of the WP is April 2024 through to March 2027.

The critical milestones of WP1 are:

M1: Project initiated in June 2024

M2: Approval of research protocol concerning WP's 3-7 given by authorities December 2024.

M3: Project concluded in April 2027

The success criteria are:

1.1: Project charter accepted by steering committee on May 2024

1.2: Project status and results communicated according to communication plan starting in April 2024 and ending in March 2027

1.3: Two PhD students employed in May with start in August 2024.

1.4: Supervisor team for the two PhD-students depending on research focus and target group established in June

1.5: Exit strategy performed in March 2027.

The tasks of WP1 are outlined in the Gantt chart and includes:

- Establishing governance structure and project team according to the chosen agile governance model
- Activating and engaging stakeholders. To begin with we invite:
 - the steering committee to meetings every 6 months

- the advisory board to meetings once every three months at the Movement Disorder clinic or Bodil Eskesen Centre in Glostrup or digital meetings.
- the project team to bi-weekly digital meetings
- the project team to quarterly retrospectives to reflect on progress and identify areas for improvement.
- five cross-functional teams to introduction and training sessions
- recruit participants (patients and relatives) to project together with patient and relatives' organizations starting up through membership magazines and homepages.
- Communicating the project charter outlining project purpose, deliverables, timeline, and resources. This includes to:
 - Create a simple one pager to introduce stakeholders to project
 - Set up LinkedIn profile of project where we communicate activities and milestones of project.
 - Create a simple template to communicate about status, progress, and risks to the steering committee.
- Continuously refining the communication plan based on progress, feedback from stakeholder and surrounding (political) environment.
- Setting up backlog management and sprint board to prioritize risk handling and development and visually show upcoming development and project activities.

The agile project tools, backlog and sprint boards will be set up in Microsoft DevOps within two weeks after project start. Together with the masterplan and Gantt chart, it will be ready to be used at the first project team meeting.
- Steering the exit strategy with the following activities:
 - Transferring knowledge and responsibilities
 - Providing relevant documentation and reporting
 - Resource reallocation
 - Contractual and legal considerations
 - Post-implementation review and evaluation
 - Celebrating achievement and collaboration

Roles and resources

The project leaders (Trine Hørmann Thomsen and Tilda Van Het Erve) have the overall responsibility for the project plan, and they will together ensure that all activities are carried out.

Two PhD students will be hired to run the daily activities during the whole project.

PhD-student 1: Masters degree within health science. Health care profile (medical doctor, physiotherapist, occupational therapist etc)

PhD-student 2: Masters degree within Health technology, data science or Informatics.

Trine Hørmann Thomsen and Christian Gunge Riberholt will together with other scientists at the area supervise the PhD students, who will be responsible for planning, carrying out and following up on activities during the project. Each of the PhD-students will have separate supervisor teams with one consistent supervisor in both groups. They coordinate team members, manage risks, resources, and communicate with stakeholders at each stage of the value chain. They will involve all contributing partners in the project in due time - for example involve the patient and relative organizations in the activities about the recruitment of patients and relatives, and involve healthcare professionals and citizens of the relevant municipalities (for example Glostrup, Hvidovre, Rødovre, and Ballerup) in activities about test and validation of the solution.

The resources of this WP are outlined in the Gantt chart and are as follows for each party (FTEs):

TOTAL FTE for WP: 1,59

Movement Disorder Clinic (Rigshospitalet): 0,77 FTE

Bodil Eskesen Center (Department of Brain and Spinal Cord Injury at Rigshospitalet): 0,30 FTE

Kintella: 0,39 FTE

University of Copenhagen (BAT CAG): 0,04 FTE

Legal: 0,0 FTE

Parkinson's Association: 0,03 FTE

Hjernesagen: 0,03 FTE

RYK: 0,03 FTE

Risk assessment and mitigation

The risk assessment and mitigation of this work package concerns the overall management of the project:

Scope creep:

Consequence: Changes in project scope that may lead to delays and increased costs.

Likelihood: Moderate due to different background and career.

Mitigation: Clearly define and document project scope. Change of project scope requires formal approval by the steering committee.

Resource constraints:

Consequence: Insufficient resources (human, financial, or equipment) may lead to delays and not meeting project milestones.

Likelihood: Moderate due to general lack of resources in hospital and primary sector to test solution as well as general difficulties in finding software coding resources.

Mitigation: Regularly monitor resource allocation. Have contingency plan for resource shortages. Cross-train team members for flexibility. Further risk mitigation sought by opening up for inviting in several municipalities rather than being limited to one municipality.

Communication breakdown:

Consequence: Ineffective communication leading to misunderstandings and misalignment.

Likelihood: Low to moderate

Mitigation: Establish clear communication channels. Conduct regular team meetings and status updates bi-weekly. Use project management tools to facilitate communication e.g. introduce Teams chat among project group members.

Budget overruns:

Consequence: Project costs exceeding the allocated budget.

Likelihood: Low to moderate

Mitigation: Conduct thorough cost estimation and budgeting. Monitor expenses regularly and implement cost controls.

Timeline delays:

Consequence: Unforeseen events causing delays in project completion.

Likelihood: Low to moderate

Mitigation: Develop a realistic project schedule. Identify critical path activities and allocate resources accordingly. Include buffer time in the schedule for potential delays.

Expected results, including their integration with the overall vision of the project.

This work package orchestrates the many stakeholders who are participating in the project and steer the overall coordination of the other work packages of the project. The WP thus supports the entire project to reach the overall vision of the project. The expected results of the WP are as follows:

- Project deliverables: Completion of all project milestones and deliverables as outlined in the project plan.

- Budget compliance: Adherence to the approved budget and prevention of any budget overruns as well as accurate financial reporting and tracking of expenses (together with Administrator).
- Timeline achievement: On-time completion of project work packages and the overall project.
- Stakeholder satisfaction: Positive feedback from key stakeholders and effective communication and collaboration with stakeholders throughout the work package.
- Risk mitigation: Successful identification and mitigation of potential risks as well as proactive handling of issues to prevent disruptions.
- Team collaboration and development: Effective teamwork and collaboration among project team members.
- Stakeholder communication and Public Relations: Successful visibility of project learnings and findings to identified Danish and international stakeholders.
- Post-project plan: Completion of strategy plan for future projects and scaling of solution as well as successful knowledge transfer to relevant stakeholders of lessons learned of public and private partnerships and developing and testing of tech solution.

WP 2. Develop the digital solution to cater for multimorbidity across sectors

Description

WP 2 includes the steps of the development process about designing an interactive prototype, adjusting user flows through back-end development, creating customized front-end interfaces, and preparing solution for intersectoral integrations. Advisory board reviews are conducted, incorporating feedback to enhance performance and user experience.

To accommodate customers' different uses of the digital platform, we develop and code a flexible group association structure. This means that users can have different roles and customized ways of showing their profile for their respective group association. A user can for example be both a patient with one or more chronic diseases, but at the same time be a relative to someone else.

Moreover, we integrate interoperability standards and protocols to facilitate seamless data exchange between different parties and across sectors. The digital solution will be compatible with other systems so the link between hospital and home care sectors can be made.

The schedule of the WP2 is April 2024 to February 2025

The critical milestones of WP2 are:

M4: Confirmation of the establishment of two advisory boards in August 2024 – one with political/health care economists stakeholders and one with patients and caregivers representing the three disease groups

M5: Design specifications and requirements completion in August 2024

M6: Digital solution approved by advisory board for user test in February 2025

.

The success criteria are:

2.1: Initial stakeholder and compliance requirements documented August 2024

2.2: Completion and approval of user interface of component design September 2024

2.3: Development team in place in June 2024

2.4: Technology stack and backlog updated in October 2024

2.5: Functional test of solution completed and ready for review January 2025

The tasks of this WP are outlined in the Gantt chart and includes:

- Defining and agreeing on design principles of digital solution. The principles shall set the direction and guide the design of the solution and what users it shall cater to in the project and post-project.
- Creating design specifications for interactive prototype. This includes preparing, showcasing and face validating design specifications to advisory board. It also includes user interface, user experience, navigation flows and visual elements described and visualized in flowcharts and documented in user stories.
- Developing back-end platform functionalities. This activity includes creating servers, tables, migration scripts and database calls. System architecture and technical specifications will be described and documented.
- Setting up sandbox environment. This involves setting up a dedicated sandbox environment for development and testing purposes. It includes configuring the necessary infrastructure and tools.
- Developing front-end with customized, responsive user interfaces. View is available on computer, tablet, and mobile phone. Focus is on developing the customized user interface layout, interactive elements, forms, and user interaction functionalities for seamless user experience across use of devices.
- Defining and building API (Application Programming Interface) to support potential intersectoral data communications. This involves the possibility to integrating the stand-alone digital solution with defined municipal systems (SSO and Cura) facilitating exchange of data through API.

- Making one demonstration and two reviews with advisory board. This includes receiving feedback and making corrections, so the digital solution is ready to test.

The following functional and non-functional requirements are set up for the solution:

Functional requirements

The platform shall:

- Create profiles for private (patients and relatives), professional and business users.
- Create and manage roles and consent for sharing of data
- Edit logbook with history.
- Send, save, and delete documents.
- Create photo and video gallery with history.
- Communicate securely via chat and video calls.
- Set reminders for exercise, diet and medication intake.
- Create and edit a module on chronic diagnoses including symptoms and treatment.
- Set automatic generated jobs and reminders for nudging to use solution.
- Create and edit templates and automatic generated jobs.
- Exhibit knowledge and offers from collaboration partners such as patient organizations.

Non-functional requirements concerning performance, capacity, scalability, availability, and security.

The platform shall be:

- fast – preferably under 2 seconds.
- secure in accordance with current legislation.
- scalable and without problem have 1 million users.
- usable by all modern browsers.
- compliance according to rules about Web availability.
- able to integrate into MitID, KOMBIT, the municipal health care systems.

Roles and resources

Kintella (Toke Andersson) will be responsible for the activities in WP 2. The PhD-students (PhD student 1 and 2) have shared responsibility for driving the day-to-day activities. A UX designer from Kintella will participate in this WP to create drafts of user interfaces and both front- and back-end software developers from Kintella will work in this WP.

Resources have competences within agile project management, user experience design, and software development.

Contributing partners will be advisory boards and project team members as well as selected users, patients, relatives, and healthcare professionals that have signed up for participation and communicated that they are available for interviews on ongoing basis during the project period.

The resources of this WP are outlined in the Gantt chart and are as follows for each party (FTEs):

TOTAL FTE for WP: 1,93

Movement Disorder Clinic (Rigshospitalet): 0,16 FTE

Bodil Eskesen Center (Department of Brain and Spinal Cord Injury at Rigshospitalet): 0,16 FTE

Kintella: 1,6 FTE

University of Copenhagen (BAT CAG): 0

Legal: 0

Parkinson's Association: 0

Hjernesagen: 0

RYK: 0

Risk assessment and mitigation

The risk assessment and mitigation of this work package are:

User Experience (UX) issues:

Consequence: Poor user interface leading to low user adoption.

Likelihood: Low to moderate

Mitigation: Iteratively design and test the user interface, involve end-users in the design process, and implement improvements based on feedback.

Quality assurance issues:

Consequence: Poor quality deliverables that may require rework or compromise project success.

Likelihood: Moderate as we may run into difficulties in defining precise requirements to system development. Users may have difficulties in conceptualizing and describing their precise needs.

Mitigation: Conduct regular reviews and face validations. Use testing and validation processes to ensure need and quality standards are met.

Stand-alone and integration challenges:

Consequence: Lack of overview and agreement of what to and not to integrate with existing systems and framework architecture leading to delays in development.

Likelihood: Moderate

Mitigation: Open discussions and manage expectations among parties. Develop standardized APIs and evaluate compatibility with different platforms and databases.

Technology stack risks:

Consequence: Incompatibility or obsolescence of chosen technologies.

Likelihood: Low to moderate

Mitigation: Regularly assess the relevance of the chosen technologies. Use established and supported technologies, plan for regular updates, and have contingency plans for technology changes.

Scalability issues:

Consequence: Inability to handle increased user loads.

Likelihood: Low.

Mitigation: Project potential user growth and assess current infrastructure. Design the architecture for scalability, conduct load testing, and implement scalable cloud solutions.

Expected results, including their integration with the overall vision of the project.

The expected results of this WP are as follows:

- **Minimum Viable Product:** The MVP showcases the core functionality of the solution. This version allows users to interact with and test the solution.
- **Functional modules and features:** The solution is developed with specific functional modules and features according to defined requirements.
- **User Interfaces (UI) and User Experience (UX):** User interfaces are designed to provide a positive and intuitive user experience. This includes the design and implementation of user interfaces for both professionals and end-users (patients and relatives).
- **Scalability and performance optimization:** The solution is designed and optimized for scalability to handle increasing user loads. Performance optimization measures are implemented to ensure quick response times and efficient utilization of resources.
- **Kintella ready for functional test and subsequently user test in hospital clinics and in the municipality with citizens in their own homes.**

This means that we now test the solution internally to make sure that patients with chronic diseases and their relatives have a digital tool that they can try out in their every day. This is the first step in reaching the vision about enabling patients to better handle their own health.

WP 3. Facilitate data exchange on integrated care pathways

Description

This WP3 is very closely interlinked to and overlaps with WPs 2 and 4. Introducing an intersectoral digital solution requires careful investigation and analysis of the data types that need to be exchanged. This includes mapping stakeholders, determining data exchange frequency, and formats. Establishing consent management processes and data sharing agreements is essential to ensure compliance with data privacy regulations and user preferences. To protect sensitive data within the digital solution, robust encryption measures are implemented.

An additional task is to specify needs for sharing data with other systems across sectors, document these requirements in comprehensive process overviews and clarify these with relevant stakeholders (for example IT departments in RegionH and municipalities). Legal documentation of healthcare data remains in other existing systems and is not expected to become part of the digital solution. We apply consent management processes, data sharing agreements, and implement encryption measures to protect sensitive data exchanged within the digital solution.

The schedule of the WP will be April 2024 to June 2025.

The critical milestones of WP3 are:

M7: Integrated care pathways designs with data flow completed in October 2024.

We will follow and describe patients in different stages of their way through the hospital system from early diagnose to late chronic stage.

We will follow two patients in each phase: early start of rehabilitation or diagnosis made (the latter concerns Parkinson's), patients in the transition from rehabilitation to the municipalities and for parkinson's at the start of rehabilitation/training courses, patients who complete a municipal training course or possibly a secondary rehabilitation phase as we see in the brain injury area, and finally patients "on the other side" of the system, characterized by municipal maintenance training or self-purchase/own attendance at a training center.

M8: Data governance legally confirmed in February 2025

M9: Data requirements are investigated and integrated in solution in June 2025

The success criteria:

3.1: One legal and compliance counsel onboarded in June 2024

3.2: 12 stakeholder interviews performed by November 2024.

We will perform interview of patients, relatives, patient organisations, health care providers from

hospitals and municipality, and active researchers within the field. The number of interviews will depend on the different information stakeholders provide, but we expect to perform interviews of at least 12 patients representing the three different diagnoses, and two representatives from each of the other stakeholder categories.

3.3: Initial mapping of data, workflows, systems and integration possibilities completed in November 2024.

3.4: Data governance and anonymization overview completed in February 2025

3.5: Consent management processes and data sharing agreements created in solution in February 2025

3.6: Encryption method of sensitive data implemented in solution in March 2025

The tasks of this WP are outlined in the Gantt chart and includes:

- Investigating the types of data that need to be exchanged.
This includes analyzing the data exchange needs and requirements for integrated care pathways. This involves mapping of the stakeholders involved, the frequency and format of data exchange, and specific standards to be followed.
Furthermore, interview of stakeholders representatives will be held.
- Mapping data elements and formats between different systems to prepare the solution to enable smooth data exchange.
It includes developing data integration layer and mechanisms to ensure compatibility and consistency of data that may be exchanged between the solution and external systems at a later stage.
- Creating and assessing baseline of the time spent for healthcare professionals to access relevant patient information and treatment plans.
- Creating consent management processes and data sharing agreements.
This involves establishing a data governance framework, which includes defining data ownership, consent management processes, data sharing agreements, and ensuring compliance with data privacy regulations and patient/user preferences.
- Implementing robust encryption measures to protect sensitive data exchanged within the digital solution.
This involves selecting and configuring encryption software, key management protocols and secure communication processes.

Roles and resources

Christian Riberholt from Bodil Eskesen Centret will be overall responsible for this WP.

The PhD-students (PhD student 1 and 2) have shared responsibility for driving the day-to-day activities. Trine Hørmann Thomsen and Tilda Huttunen van het Erve will be active participants and help map out patient journeys and process flows. Toke Andersson will participate with his technical viewpoint and ensure that the digital solution includes security and consent measures.

The legal and compliance office of Region H. will be included as experts and advisors GDPR and data consent.

Additional resources have knowledge of secondary and primary sectors and what kind of data that is documented and potentially get lost when patients transit the sectors. Particularly the municipalities will be invited in for sparring and mapping of the patient journeys.

Overall, competences are within project management, process design, software development, and data compliance and security.

Contributing partners will be advisory board and project team members as well as selected users, patients, relatives, and healthcare professionals that have signed up for participation and communicated that they are available for interviews on ongoing basis during the project period.

The resources of this WP are outlined in the Gantt chart and are as follows for each party (FTEs):

TOTAL FTE for WP: 1,67

Movement Disorder Clinic (Rigshospitalet): 0,53 FTE

Bodil Eskesen Center (Department of Brain and Spinal Cord Injury at Rigshospitalet): 0,52 FTE

Kintella: 0,36 FTE

University of Copenhagen (BAT CAG): 0,003 FTE

Legal: 0,22 FTE

Parkinson's Association: 0,01 FTE

Hjernesagen: 0,01 FTE

RYK: 0,01 FTE

Risk assessment and mitigation

The risk assessment and mitigation of this work package are:

Security breach:

Consequence: Unauthorized access to sensitive data with potential legal penalties, project delays, and reputational damage.

Likelihood: Moderate as the project involves handling sensitive data, and this data can be a target for cybercriminals.

Mitigation: Implement encryption protocols, access controls and regular security audits, as well as engage expert for advice.

Regulatory compliance:

Consequence: Failure to comply with regulations (GDPR and AI) with potential legal penalties, project delays, and reputational damage.

Likelihood: Low to moderate (as new regulations about AI can be interpreted differently).

Mitigation: Engage legal expert for compliance checks, consent, encryption, and establish procedures on data privacy.

Expected results, including their integration with the overall vision of the project.

The expected results of this WP are as follows:

- Data collection strategy: Clear guidelines for collecting and inputting data through the care pathways. This includes defining data and validating data.
- Data model and storage: A defined data model that outlines the structure of the database, implementation of robust and scalable data storage architecture that meets the performance and security requirements.
- Data security measures and access controls: Implementation of security measures to protect sensitive data and implementation of role-based access controls to manage who has access to specific types of data. This ensures data confidentiality and compliance with privacy regulations.
- Data backups and recovery procedures: implementation of data backup and recovery procedures to ensure that data can be restored in case of data loss or system failures.
- Input to Minimum Viable Product: The MVP showcases the core functionality of the solution. This version allows users to interact with and test the solution.

The results of this WP give input to WP's 2 and 4 making the solution ready for functional test and subsequently user test in hospital clinics and in the municipality with citizens in their own homes. This means that we know precisely what type of data that the solution shall manage. We can now test the solution to make sure that patients with chronic diseases and their relatives have a digital tool that they can try out in their every day. This is the second step in reaching the vision about enabling patients to better handle their own health.

Furthermore, the expected results of WP 3 are baseline and initial estimation of the time taken for healthcare professionals to access relevant patient information and treatment plans. Moreover, we will have an assessment of the level of coordination (time spent) among multidisciplinary healthcare teams. This is important baseline knowledge that we will use WP 6 when we validate the solution.

WP 4. Develop modules for user generated data and predictive analysis.

Description

This WP4 is very closely interlinked to and overlaps with WPs 2 and 3.

Valuable new insights can be gained by collecting, organizing and structuring data and combining with non-sensitive user data. To empower citizens and healthcare professionals with insights, we apply technologies used in handling big data to identify patterns, trends, and correlations. These include advanced statistical and analytical methods such as Principal Component Analysis and Machine Learning to develop models and algorithms that can be used for prediction and treatment optimization. User insights will include and be presented in dashboard views; patients can see a historic development of their diagnoses, relatives have access to a historic development of their view of the condition and their own well-being, and professionals and researchers will be able at mega-data level to see an overview of the individual disease group and also patterns across chronic diseases. These data can create and enrich healthcare profiles of chronic diseases on societal level.

The schedule of the WP will be August 2024 to June 2026.

The critical milestones of WP4 are:

M10: Draft design of questionnaire module and dashboard views completion in December 2024.

M11: Advanced analytical model output validated in July 2026.

The success criteria:

- 4.1: Completion of dashboard views of historic data design in October 2024.
- 4.2: Patient Reported Outcome Measures (PROMs) selected and validated January 2025.
- 4.3: Target picture of advanced statistical modelling (predictive patterns) defined in February 2025.
- 4.4: Basis data collected, and dummy data generated in October 2025.
- 4.5: Data quality validated, and training data investigated for biases and accuracy in January 2026.
- 4.6: Advanced predictive model built using e.g. PCA and ML/AI in June 2026.

The tasks of this WP are outlined in the Gantt chart and includes:

- Creating a questionnaire generation system
This includes to identify questions to ask patients and relatives, as well as develop a system to create and edit recurring jobs to distribute questions and collect answers. These questionnaires

are tailored based on users' diagnoses and include questions carefully selected by health care professionals. The questions capture information about symptoms experienced by users during a specific period and their overall health status.

- Designing data model and dashboard views to present historic data.
Developing a data model that organizes and structures the data collected, and design user-friendly dashboard views that present the historic data.
- For private users, the dashboard displays personalized visualizations that illustrate the evolution of their responses over time, enabling them to track their everyday life with a chronic disease, including mental well-being, changes in diet, and exercise habits.
- Identifying patterns, trends, and correlations.
Applying data analysis techniques to identify patterns, trends, and correlations within the collected data when combined with user metadata. Utilize statistical methods and data visualization tools to gain insights from the data. At the aggregated level, the solution provides healthcare professionals with visualizations that present data for patients and their relatives living with chronic diseases. The deliverable includes visualizations and instructions for use to facilitate a broader understanding of the collective data, allowing professionals to identify trends, patterns, and insights on a societal level. This also includes making the raw data available to professionals in anonymized form for research purposes.
- Preparing predictive analysis for the solution.
This includes developing and applying machine learning models and algorithms to enable predictive analysis based on the collected data. This means that the solution can identify predictions about future developments of patients' profiles and offer the capability to create and enrich healthcare profiles that can contribute to improved healthcare management and planning.

According to the following functional requirements, the platform shall:

- Generate and distribute questionnaires based on health care professional input
- Track and display reply status and rates.
- Set up recurring jobs to nudge users into answering the questionnaires.
- Provide visual representations of the citizen-generated data at individual and aggregated levels.
- Create encryption of sensitive health data to ensure that information is not disseminated to others without explicit consent.
- Create and enrich healthcare profiles
- Utilize predictions in development in symptoms based on ML developed models and algorithms.
- Create an API for fetching raw anonymized data that professionals can use to get data for use in research.

Roles and resources

Kintella will be responsible for the activities in WP 4 and PhD student 2 (Masters degree within Health technology, data science or Informatics) will run the WP in practise.

Resources from Kintella will primarily have capabilities within agile project management, software development, ML and data analytics, and UX design. Moreover, Trine Hørmann Thomsen and Christian Gunge Riberholt will make sure that Patient Reported Outcome Measures (PROMs) are selected and validated.

Contributing partners will be advisory board and project team members as well as selected users, patients, relatives, and healthcare professionals that have signed up for participation and communicated that they are available for interviews on ongoing basis during the project period. Moreover, we expect to receive legal advice on GDPR, data consent and machine learning.

The resources of this WP are outlined in the Gantt chart and are as follows for each party (FTEs):

TOTAL FTE for WP: 2,15

Movement Disorder Clinic (Rigshospitalet): 0,54 FTE

Bodil Eskesen Center (Department of Brain and Spinal Cord Injury at Rigshospitalet): 0,50 FTE

Kintella: 1,0 FTE

University of Copenhagen (BAT CAG): 0,03 FTE

Legal: 0,05 FTE

Parkinson's Association: 0,01 FTE

Hjernesagen: 0,01 FTE

RYK: 0,01 FTE

Risk assessment and mitigation

The risk assessment and mitigation of this work package are:

Data quality and completeness:

Consequence: Inaccurate predictions due to poor-quality or incomplete data.

Likelihood: Moderate to high

Mitigation: Implement a data cleansing process, validation checks, and data augmentation techniques.

Model complexity:

Consequence: Selection of an overly complex model leading to difficulties in interpretation.

Likelihood: Moderate

Mitigation: Opt for simpler model when interpretability is crucial, use model-agnostic interpretability tools, and provide clear documentation.

Model Drift:

Consequence: Changes in the underlying data distribution over time affecting model performance.

Likelihood: Moderate

Mitigation: Regularly retrain model with updated data, implement monitoring systems, and adapt models to changing conditions.

Data bias:

Consequence: Biased training data leading to biased predictions.

Likelihood: Low to moderate

Mitigation: Analyze the training data for potential biases, identify and implement bias detection tools, and diverse data collection.

Inadequate communication:

Consequence: Misunderstandings or misinterpretations of predictive results.

Likelihood: Low to moderate

Mitigation: Assess stakeholder understanding of predictive analysis outputs, establish clear communication channels, provide documentation, and conduct 5 training sessions for professionals.

Expected results, including their integration with the overall vision of the project.

The expected results of this WP are as follows:

- Successful completion of the Questionnaire generation system's development and deployment, and its functionalities
This includes the capability to create recurring jobs to distribute questionnaires to all users of the app and web platform. These questionnaires are tailored based on users' diagnoses and include questions carefully selected by health care professionals. The questions capture information about symptoms experienced by users during a specific period and their overall health status.
- Selection and validation of Patient Reported Outcome Measures (PROMS).
PROMs measure the patient's health status or health-related quality of life at a single point in time, and are collected through the above-mentioned, self-completed questionnaires.
- Data model and dashboard views to present historic data designed and ready for test.

This includes visualization of citizen-generated data at both individual and aggregated levels. For private users, the dashboard displays personalized visualizations that illustrate the evolution of their responses over time, enabling them to track their everyday life with a chronic disease, including mental well-being, changes in diet, and exercise habits.

- Visualizations of patterns, trends, and correlations created and ready for test.
At the aggregated level, the solution provides healthcare professionals with visualizations that present data for patients and their relatives living with chronic diseases. The deliverable includes visualizations and instructions for use to facilitate a broader understanding of the collective data, allowing professionals to identify trends, patterns, and insights on a societal level.
- Capability of predictive analysis prepared.
This means that we have prepared the solution to identify predictions about future developments of patients' profiles and offer the capability to create and enrich healthcare profiles that can contribute to improved healthcare management and planning.
- Reporting and analytics framework.
Implementation of a reporting and analytics framework that enables users to derive insights from the data.

The results of this WP give input to WP 2 and builds on WP 3 making the solution ready for functional test and subsequently user test in hospital clinics and in the municipality with citizens in their own homes.

This means that we are now ready to collect and produce data from patients and relatives' input and present this in dashboard views for the users at individual level and for professionals at aggregated level. The aim is that when enough data has been collected this can be applied as a research component and predictive analysis.

This is an additional step in reaching the vision about enabling patients to better handle their own health.

WP 5. Test and iterative adjust the solution.

Description

It is crucial that we test, give feedback, evaluate, and adjust the digital solution so we after the project end up with a solution that will generate value for the target groups. Moreover, this part of the project is carried out together with a great number of stakeholders across sectors as it builds the fundament for further implementation after the project ends. It requires a great amount of orchestration and attention to fallbacks that might occur regarding for example available resources and training needed.

By conducting pre-tests, we assess and address discrepancies before the solution is deployed to

the production environment for user tests.

We test the solution in a small user group (20 patients, 20 relatives, and 20 healthcare professionals) to learn, study, and adjust the digital solution to the defined requirements. We then scale the size of the group four times until we reach a national user group of 400 people. We test the solution in various life situations and through transitions; own home, hospital-rehabilitation, rehabilitation-home, home-home care, homecare-nursing home. We compile knowledge and experience and share this through observations, focus groups and individual interviews as well as 15-20 training sessions with healthcare professionals. All tests include training sessions and analogue and digital training materials which are developed and distributed to support competences and capabilities among users.

The schedule of the WP will be June 2025 to November 2026.

The critical milestone of WP 5 is:

M12: Final user test approval in December 2026

The success criteria are:

- 5.1: Usability testing conducted iteratively until October 2026
- 5.2: Identified bugs, issues and updates resolved iteratively until October 2026
- 5.3: Solution meets user requirements in November 2026.

The tasks of this WP are outlined in the Gantt chart and includes:

- Conducting testing of the solution.
- Exploring user-technology interpretations and interactions
- Conducting regular evaluations through focus groups and individual interviews.
- Implementing iterative enhancements and updates based on user feedback.
- Developing and delivering training sessions as well as educational materials.

We conduct tests in a test environment to ensure quality and reliability of the solution:

- Functional test of features and functionalities to ensure they work as intended.
- Performance testing to assess performance under different load conditions, stress testing, and measure response times.
- Security testing to evaluate the solution's security measures to identify potential security risks and vulnerabilities.
- Compatibility testing to verify the solution's compatibility with different devices and browsers

- Compliance testing to validate the solution's compliance with the GDPR and crypto requirements.
- Data validation to ensure accuracy and integrity of data processed and stored by the solution.

Roles and resources

Kintella (Toke Andersson) will be responsible for the first part of WP 5 concerning conducting tests of the digital solution and both PhD students will be included in daily practise and research.

The second and biggest part of the WP about testing the solution through multiple transitions is headed by the project leaders (Trine Hørmann Thomasen and Tilda Huttunen van het Erve). They will ensure that a stakeholder and involvement plan is well-designed so the intervention can be executed by the team with a great amount of user-involvement. The two PhD students will be responsible for planning, carrying out, and following-up on all activities. Patients and relatives as well as healthcare professionals in hospitals and municipalities (rehabilitation, home care, and nursing homes) will participate to test and evaluate the digital solution in the cross-sectoral transitions. Tilda Huttunen van het Erve will be an active part of selected interviews and training sessions, ensuring that change requests to the solution are identified, documented, and applied to the digital solution.

Resources will have competences within agile project management, user experience design, anthropology, software development, testing and stakeholder engagement.

The resources of this WP are outlined in the Gantt chart and are as follows for each party (FTEs):

TOTAL FTE for WP: 3,22

Movement Disorder Clinic (Rigshospitalet): 1,18 FTE

Bodil Eskesen Center (Department of Brain and Spinal Cord Injury at Rigshospitalet): 0,91 FTE

Kintella: 0,82 FTE

University of Copenhagen (BAT CAG): 0,18 FTE

Legal: 0,0 FTE

Parkinson's Association: 0,04 FTE

Hjernesagen: 0,04 FTE

RYK: 0,04 FTE

Risk assessment and mitigation

The risk assessment and mitigation of this work package are:

System performance issues

Consequence: Low performance leading to delays in the project.

Likelihood: Low to moderate

Mitigation: Conduct load testing, stress testing and performance testing.

Limited user adoption:

Consequence: Low participation and utilization rates of solution hindering the achievement of desired outcomes.

Likelihood: Moderate as user resistance or lack of awareness can impact adoption

Mitigation: Involve users in development, test, and feedback process, provide training and ongoing support, emphasize benefits, and point out key-persons responsible for integrating the solution.

Insufficient training and education:

Consequence: Insufficient training leading to user errors.

Likelihood: Moderate

Mitigation: Develop training for users and offer ongoing support and educational resources.

Usability issues:

Consequence: Complicated user interfaces leading to usability challenges.

Likelihood: Low to moderate

Mitigation: Conduct usability testing with representative users. Iterate user interface design based on feedback.

Change management issues:

Consequence: Resistance to change from users leading to delays and hindering the achievement of desired results.

Likelihood: Moderate

Mitigation: develop a change management plan, communicate the benefits, and involve key stakeholders in the decision-making and development processes.

Expected results, including their integration with the overall vision of the project.

The expected results of this WP are as follows:

- Successful pilot of the solution in a real-world production environment documented.
This includes that test cases are created, and testing of solution is completed and documented in report.

- Iterative enhancements and updates based on user feedback implemented. This includes iterative evaluations conducted to assess effectiveness and impact.
Ideas, issues and improvements will be prioritized in backlog and in sprints of six weeks. They will address user needs, improve functionality, and optimize user experience.
- Educational materials, including video materials developed and use of the digital solution documented through system reports. The latter can for example be aggregated data listed in table formats.
- Establishment of a support hotline before validation of the solution in WP6
Analogue and digital educational materials are created to ensure effective user onboarding and usage of the solution, including user guides, manuals, video tutorials, and in app directions to support users in understanding and utilizing the solution.
- Training and adoption success.
Deliverable includes 15-20 training sessions delivered. Professionals are adequately trained to use the solution in their workflows and dialogue with citizens and relatives. Change management success: Successfully organizational change by addressing resistance, communicating effectively with stakeholders, and ensuring a smooth transition to the new solution.
- Kintella user tested and further developed to meet user requirements.
It is now ready to be validated according to the Key Performance Indicators (KPIs) that have been established to reach the vision of the project about empowering patients with chronic diseases and their relatives to better handle their own health and increase communication across sectors.

The user test and KPIs will relate to the following items:

- Patient and relatives satisfaction: Assessing patient satisfaction with the solution in terms of user-friendliness, accessibility, and overall experience with the patient portal.
- Improved Health Outcomes: Assessing improvements in patient health outcomes resulting from better-informed decision-making based on integrated data.
- Improvements tracking in usability over iterative testing phases.
- User engagement: Measuring the level of user engagement with the portal features to ensure that users are actively using the system (Quest)
- Task completion rates: Assessing the success rates of users in completing specific tasks within the portal to gauge the effectiveness of the design and user interface (Quest)
- User feedback and suggestions: Gathering feedback and suggestions from users during each testing iteration to identify areas for improvement and address user concerns (Focus group interviews)

- Accessibility compliance: Ensuring that the solution meets accessibility standards, making it usable for individuals with disabilities, especially cognitive declines, and monitor compliance throughout the development process. (we will use the principles of Webtilgængelighed).
- Error rates: Monitoring and analyzing error rates during user interactions to identify and address areas of the portal that may lead to user mistakes.

WP 6. Validate the use of the digital solution.

Description

Validation of a digital solution is essential to ensure that it meets the intended objectives, functions as intended, and delivers the desired outcomes. It is important that we validate the digital solution in a real-world environment enabling the identification of any issues or adjustments needed before full-scale deployment.

This WP is closely connected to WP 5 as feedback from users and stakeholders collected during WP 5 about testing will be part of the analyses.

The WP includes the use of the validation criteria based on the requirements and objectives of the digital solution that we have established. Evaluation of the digital solution will be carried out based on focus group interviews and questionnaires. It also contains statistical analyses, including visualization of the development in evaluation results as well as feedback from users and stakeholders to identify areas for improvement and as input to further development of solution. Key performance indicators (KPIs) and metrics will be analyzed to measure the success of the project.

More specifically we will carry out three to four questionnaire rounds and focus group interviews with patients and relatives – 10 in total. In addition, we will carry out one focus group interview with a group of managers in the primary sector, and one focus group interview with healthcare professionals. The results are integrated into WP 7 together with the questionnaire the results.

The schedule of the WP will be May 2025 to March 2027.

The critical milestones are:

M13: Recruitment of 400 user participants completed (5 times: ca.60, 100, 200, 300, 400) in March 2026

M14: Data collection to research completed November 2026

M15 Findings reviewed in January 2027

M16: Publication submission in March 2027

The success criteria are:

6.1: Evaluation and assessment of the impact of the digital solution completed in December 2026 - with 60% of the 400 stakeholders participating.

This includes more specifically:

Evaluation of improvements in clinical outcomes

- Including disease management, medication adherence, and patient health indicators, facilitated by the use of the digital solution.

Assessment of the impact of the digital solution on healthcare provider efficiency

- Including time saved, improved decision-making, and streamlined workflows.

Measurement of the reduction in adverse events or medical errors

- resulting from enhanced data access, sharing, and communication through the digital solution.

Evaluation of the level of patient engagement and participation in own care

- considering the factors appointment adherence, self-monitoring, and utilization of educational resources provided through the digital solution.

Tracking of preventive care uptake and screenings

- facilitated by the digital solution, leading to early detection and intervention.

Measurement of the effectiveness of the digital solution in supporting the management of chronic diseases through remote monitoring, data sharing, and timely interventions.

Assessment of the impact on healthcare resource utilization, such as reduced visits or hospital admissions due to improved communication and coordination.

6.2: Analysis results discussed in six research papers - ready for submission in March 2027.

The tasks of this WP are outlined in the Gantt chart and includes:

- Collecting evidence-based knowledge on how digital solutions can be tested.
- Collecting feedback from users and stakeholders to identify areas for improvement.
- Analyzing key performance indicators and metrics to measure the project's success.

Validation of the digital solution will be carried out based on ethnographic observations, focus group interviews and questionnaires (digital and analogue) that are carried and posted in waves of three to four times by the users of the solution after 6, 12, 18, and 24 months. The questions will be posted through the digital solution and will be accessible for views and responds via mobile phones, tablets and computers. We measure Key Performance Indicators (KPIs) that will consider value and relevance of the Kintella solution for relatives and healthcare professionals (throughout the care pathway or in the sector transition).

The score for System Usability Scale is calculated for each participant (relative/patient/healthcare professional/manager) by summing up the scores for each of the 10 questions (score = 1-5). The summary score is multiplied by 2 to reach a scale from 0 to 100. A score which is higher than 68 is considered to be above average. The KPI's on usability considers General satisfaction and Ease of use. Data is collected and documented after 6, 12, 18, and 24 months during the intervention. Based on the data collection, a statistical analysis, including visualization of the development in evaluation results, will be carried out.

Roles and resources

Trine Hørmann Thomsen, Christian Gunge Riberholt and the supervisors will be responsible for this WP.

They will guide the two PhD students who will be responsible for planning, carrying out, and following-up on all activities. Patients and relatives as well as healthcare professionals in hospitals and municipalities (rehabilitation, home care, and nursing homes) will participate in focus groups interviews and answering the questionnaires.

Resources in this WP will partly focus on research activities, which will be carried out by two PhD students.

Resources will primarily have competences within project and stakeholder management, survey design, research, and analyses as well as focus on social and ethical perspectives on the use of digital solutions.

The resources of this WP are outlined in the Gantt chart and are as follows for each party (FTEs):

TOTAL FTE for WP: 2,10

Movement Disorder Clinic (Rigshospitalet): 0,77 FTE

Bodil Eskesen Center (Department of Brain and Spinal Cord Injury at Rigshospitalet): 0,64 FTE

Kintella: 0,18 FTE

University of Copenhagen (BAT CAG): 0,48 FTE

Legal: 0,0 FTE

Parkinson's Association: 0,01 FTE

Hjernesagen: 0,01 FTE

RYK: 0,01 FTE

Risk assessment and mitigation

The risk assessment and mitigation of this work package are:

Ethical dilemmas arising

Consequence: Adding complication to the project leading to delays and hindering the achievement of desired results.

Likelihood: Low to moderate

Mitigation: Involve ethicists in the project (University of Copenhagen) and regularly review ethical considerations throughout the research process.

Intellectual property concerns:

Consequence: Unclear ownership and protection of IP hindering the completion of the project.

Likelihood: Low

Mitigation: Clearly define intellectual property rights, establish agreements among collaborators, and seek legal advice to ensure proper protection. A research lawyer from the Legal department at Rigshospitalet has been connected to the overall project (Nanna Bech Ferguson)

Informed consent challenges:

Consequence: Issues related to obtaining informed consent from participants leading to delays.

Likelihood: Low

Mitigation: Develop clear and understandable consent forms, provide thorough participant education, and maintain transparent communication about the research objectives.

Interdisciplinary collaboration challenges:

Consequence: Difficulties in collaboration among researchers from different disciplines leading to delays.

Likelihood: Low

Mitigation: Encourage interdisciplinary team building and regularly establish meetings to facilitate effective cooperation.

Data quality issues:

Consequence: Inaccuracies or inconsistencies in research data hindering the achievement of desired results.

Likelihood: Moderate to high

Mitigation: Implement robust data validation processes, conduct regular data quality assessments, and establish protocols for data correction and validation.

Expected results, including their integration with the overall vision of the project.

The expected results of this WP are as follows:

- Analysis results, discussion and evaluation carried out and published in research paper. This include the creation of a knowledge base on how digital solutions can be tested. This includes analysis of the qualitative data (ethnographic observation and focus interviews) collected in relation to real-world examples of practical and technical challenges faced throughout the project period. The focus is on utilizing evidence-based approaches to ensure future accuracy, reliability, and quality of testing.
- Validation of hypotheses carried out and ready in research paper. Visualization of the development in evaluation results after 6, 12, 18, and 24 months. The validation includes an analysis and discussion of the collected data about the Key Performance Indicators that have been established end linked to the hypotheses to measure the benefits of the project and the digital solution. They concern 1. improving the overall access to information for relatives in transitions, 2. adding value to collaboration and dialogue with relatives for the health care professionals, 3. User-friendliness for relatives, healthcare professionals, and patients with Parkinson's disease, acquired brain or spinal cord injuries, and 4. Social and ethical sustainability of the solution in a real-world setting.
- Kintella validated according to the Key performance indicators (KPIs) that have been established to reach the vision of the project about empowering patients with chronic diseases and their relatives to better handle their own health and increase communication across sectors.

WP 7. Explore emerging social and ethical issues.

Description

This work package will contribute to the building of ethical capacity throughout IPARD by providing in-depth understanding of the emerging social and ethical issues of designing and applying a digital solution for managing information and self-care needs among patients and relatives. Ethics of building a digitally supported care collective is not merely a matter of ethical impact assessment, but rather a cultivated capacity to understand and interact with the values, concerns, and use-practices of those affected by disease or injury and by the digital interventions made. This entails the building of ethical capacity throughout IPARD by providing in-depth understanding of the emerging social and

ethical issues of designing and using the digital prototype. We explore experiences among stakeholders (patient, relatives, health care professionals, designers) of changing roles and tasks, burden and benefits as well as other emerging social and ethical issues arising from engaging with a digitally supported care pathway. This will help us assess the overall social and ethical sustainability of the solution. We will have a particular focus on issues of trust in technology, transparency of decision-making algorithms, data work and digital inclusion.

The tasks will be:

- 1) to review and summarize existing in-depth knowledge of everyday life of the involved patient groups and of ethical concerns in relation to a digital solution and Advanced analytical models (AI/ML) in chronic care management;
- 2) to communicate and elaborate on these in workshop 1 involving the advisory board and the project group;
- 3) to do an ethnographic study of a subset of patients in WP 6 in the context of their everyday life. The emphasis will be on their experiences with and practices of collecting/receiving/using data collected by and/or feed back to them to support treatment and/or coordination. These will be explored in observations and interviews;
- 4) to support and monitor the embeddedness of ethical considerations in innovation activities;
- 5) to evaluate ethical and social implications of the intervention with reference to AI ethics and equality in accessing health care services;
- 6) report and discuss this in workshop 2 involving the advisory board and the project group.

Primary objectives:

- In-depth understanding of the emerging social and ethical issues
- Ethical capacity building in project.
- Evaluation of ethical and social implications particularly in relation to:
 - User trust in technology and AI
 - Transparency in decision making algorithms.
 - Algorithmic bias
 - Digital health disparity mitigationPatient data work and disruptions of everyday life

The schedule of the WP will primarily be January 2026 to March 2027

The critical milestones are:

M17: Workshops completed in September 2026

M18: Data collection to research completed November 2026

M19: Findings reviewed in February 2027

M20: Publication submission in March 2027

The success criteria are:

7.1 Analysis results discussed and published in research paper in December 2026

7.2 Validation of hypotheses completed and results ready in research paper in January 2027.

Roles and resources

University of Copenhagen (Henriette Langstrup) will be responsible for this WP.

Patients and relatives as well as healthcare professionals in hospitals and municipalities (rehabilitation, home care, and nursing homes) will participate in interviews. Resources in this WP will primarily focus on research activities that will be carried out by one postdoctoral researcher.

Resources will primarily have competences within social science, ethics, research, and analyses.

The resources of this WP are outlined in the Gantt chart and are as follows for each party (FTEs):

TOTAL FTE for WP: 1,23

Movement Disorder Clinic (Rigshospitalet): 0,38 FTE

Bodil Eskesen Center (Department of Brain and Spinal Cord Injury at Rigshospitalet): 0,25 FTE

Kintella: 0,02 FTE

University of Copenhagen (BAT CAG): 0,53 FTE

Legal: 0,0 FTE

Parkinson's Association: 0,02 FTE

Hjernesagen: 0,02 FTE

RYK: 0,02 FTE

Risk assessment and mitigation

The risk assessment and mitigation of this work package are:

Lack of timely recruitment: Inability to recruit post doc with adequate competences in time for task.

Consequence: Postponement of insights and workshops, lack of ethical capacity building

Likelihood: Moderate

Mitigation: Early search for candidate, co-involved in data collection, analysis, and reporting.

Insufficient participant cooperation:

Consequence: Participants not fully cooperating during the process leading to delays in the project.

Likelihood: Moderate

Mitigation: Provide clear instructions to participants, establish rapport and communication channels, and consider incentives to encourage cooperation.

Data quality issues:

Consequence: Inaccuracies or inconsistencies in research data hindering the achievement of desired results.

Likelihood: Moderate

Mitigation: Conduct regular data quality assessments, and establish protocols for data correction and validation.

Interpretation challenges:

Consequence: Difficulty in interpreting validation results leading to delays in the project and hindering the achievement of desired results.

Likelihood: Moderate

Mitigation: Clearly define validation criteria, involve experts in the interpretation process, and document methodologies to facilitate transparent interpretation.

Expected results, including their integration with the overall vision of the project.

The expected results of this WP are as follows:

- Knowledge base (Documented summary) of existing in-depth knowledge of everyday life of the involved patient groups and of ethical concerns in relation to a digital solution and Advanced analytical models (AI/ML) in chronic care management;
- an ethnographic study of patients and relatives in the context of their everyday life. The emphasis will be on their experiences with and practices of collecting/receiving/using data collected by and/or feed back to them to support treatment and/or coordination.
- Embeddedness of ethical considerations in innovation activities;
- Evaluation of ethical and social implications of the intervention with reference to AI ethics and equality in accessing health care services;
- Findings analyzed, and analysis results and discussion carried out and published in research paper.
- The collected knowledge about social and ethical issues of digitally supported care pathways and care collectives is closely linked to the vision of the project.

It adds knowledge to how patients and their relatives can be empowered to better handle their own health and increase communication across sectors by the use of a digital platform.

Plan for data management in the project

In this project involving data exchange on integrated care pathways within a digital app, compliance with the General Data Protection Regulation (GDPR) is essential to protect the privacy and rights of individuals whose data is being processed.

The general plan for managing data is that the project in March 2024 has onboarded a legal and compliance expert from Region Hovedstaden (Nana Bech Ferguson, Forskningsjura, Rigshospitalet) to help and guide throughout the project.

Moreover, the project will use the templates of Region Hovedstaden which are in accordance with the templates of the Danish Data Protection Agency. The plan is that Rigshospitalet, Copenhagen University and Kintella will enter into an agreement about shared data responsibility (Fælles data ansvar). For each work packages the parties will define the following in a table format - by advice from Region Hovedstaden:

- Documentation and Metadata
- Ethics and legal compliance
- Storage, backup and security
- Selection, preservation and sharing
- Responsibilities and Resources

In addition, the project has specifically defined WP 3. Facilitate data exchange on integrated care pathways that will clarify these items as well.

These are the **actions** (steps) that will be taken due to GDPR compliance:

- **Data minimization:** Only necessary patient data is collected and processed within the app, adhering to the principle of data minimization outlined in GDPR. This involves limiting the types and amount of personal data collected to what is strictly required for the intended purpose of facilitating integrated care pathways.
- **Lawful basis for processing:** Explicit informed consent from users will be obtained in terms of the Declaration of Helsinki.
- **Privacy by design:** Implementation of privacy by design principles throughout the development and deployment of the app, integrating data protection measures into the app's architecture and features from the outset to ensure that privacy considerations are addressed at every stage of the project lifecycle.
- **Data security measures:** Robust technical and organizational measures to ensure the security of patient data processed within the app, including encryption, access controls, pseudonymization, and regular security assessments to mitigate the risk of data breaches or unauthorized access will be implemented.

- Transparency and consent management: A clear and concise information to users about how their data will be used, who it will be shared with, and their rights under GDPR, will be an integrated procedure, including the ability for users to withdraw consent at any time.
- Data processing agreements: written agreements within parties of the project group and any third-party service providers or data processors involved in the project, outlining their obligations regarding data protection, and ensuring that they adhere to GDPR requirements, will be made transparent.

Dissemination of knowledge about the project in a societal context

The project group will share knowledge with the target groups regularly during the entire project period. We compile knowledge and experience and share this through the advisory board and focus groups.

The project group will appoint specific employees to lead and be ambassadors of the project in the hospital and municipal entities, for example Parkinson coordinators.

Furthermore, we have already shared the idea with patients and relatives' organizations such as Alzheimer's, Sclerosis, and Ældresagen, associations for employees such as the Union of Public Employees (FOA) and the Danish Nurses' Organization (DSR), Det Nære Sundhedsvæsen, and several municipalities. They are all interested in receiving knowledge and experience from the project.

Moreover, a comprehensive communication plan will be drawn up to ensure that the continuity and sharing of agreed knowledge and experiences from the project are shared with other relevant stakeholders within the fields of healthcare, IT/digitization, social sciences, and politicians, from local municipalities to members of parliament from the beginning of the project. The plan includes writing seven research-based articles and publishing relevant data in peer reviewed international journals as well as writing a national report of results and evaluation of the project and process. Furthermore, an opinion piece with findings from the project will be submitted to at least one nationwide newspaper in order to stimulate public impact.

Further, it is part of the plan to create animation films as learning material and to participate in conferences such as OffDig - Public digitization and the National conference about user involvement (KL, Danske Regioner, Danske Patienter).

Overall, the project group will include the following elements in the plan to disseminate knowledge:

- Develop key messages according to the milestones of the project: Craft key messages that convey the significance of the project, its findings, and potential impacts.

- Create communication materials: Develop communication materials suitable for different channels, for example research summaries and visual representations of key points.
- Utilize social media: Leverage platforms (e.g., X, LinkedIn, Facebook, Instagram) to share project updates and key findings. We create a posting schedule and use relevant hashtags.
- Organize webinars and workshops: Host virtual events to present and discuss project findings. Invite key stakeholders, researchers, and the public to participate.
- Participate in conferences: Present findings and network with researchers, practitioners, and policymakers to increase visibility and foster collaborations.
- Engage with policymakers: Share project insights through targeted briefings, or meetings.
- Document success stories: Collect and share stories or testimonials related to the project's impact on individuals or communities.
- Seek collaborative opportunities: Explore opportunities to collaborate with community organizers who can help share the project's message through their networks.