PASPADOC

A new holistic way to capacitate patients who suffer chronic pain

The Regional Health Service of Murcia (Servicio Murciano de Salud-SMS) provides healthcare to 1.47 million inhabitants (about 3.09% of the whole Spanish population). It integrates 11 hospitals, with 3,651 beds and more than 400 primary care centers. It is noteworthy that the Region of Murcia has been chosen by technological partners as a convenient living lab. Being a single-province region, political and administrative decision-making would be faster, which saves time, money and resources. The Region of Murcia owns the award of Reference site 2 stars in EIP AHA (European Innovation Partnership on Active & Healthy Ageing).

The Murcian Health Service has extensive experience in demand-driven co-creation, associated or not with innovative public procurement. Not in vain, SMS has obtained national and international awards such as the First International Prize in the category of "*Outstanding Innovation Procurement in ICT*" of the Procura+ 2021 awards for the 'InDemand' project or the Technology & Health Foundation Award for the *Best Technological Innovation in Health Driven by an Autonomous Community 2022* to the "InDemand" project.

Challenge description

The current health system has difficulties in carrying out efficient activity in patients with chronic painful pathologies. Due to the system structure, patients with chronic pain find themselves left aside as a result of the lack of accessibility, care and follow-up. On many occasions they create false expectations of healing with tests and referrals that distort the patient's perception, preventing their empowerment and self-care, which decreases quality of life.

Currently, the indicators of first visit and follow-up in hospital care and referrals through consultations from Primary Care are not relevant to evaluate the efficiency of treatments in patients with chronic pain. The patient is seen by a hospital specialist that refers them again to the Primary Care team with a new treatment, which is again ineffective, and the Primary Care doctor once again consults another specialist to look for new solutions. In all referrals, with their waiting times due to the overload of the healthcare system, caused, in turn, by the prevalence of chronic processes, the patient is left in a care limbo, waiting...

The waiting lists for services that deal with musculoskeletal problems (Traumatology, Rehabilitation and Rheumatology) add up to 30% of the total list of waiting times of the Murcian Health Service and they increase year after year, without an efficient staff management to balance activity/demand. Notably, surgical indications for chronic processes occur due to an increase in user demand once it has been considered that the conservative treatments do not achieve the expected benefit and even though it will not be achieved with surgical treatment either. The surgical indication is very striking conditions such as fibromyalgia. The objective would be to treat the processes by indication and not by escalation (RD 605 indicators, surgery, outpatient consultations and evidence).

In this sense, we highlight the following needs for chronic pain patients:

- Longitudinal and comprehensive patient follow-up.
- Holistic treatment.
- Continuous remote assistance, avoiding unnecessary in-person consultations.
- Linkage with the patient that facilitates quality care in their process.

- Empowerment of the patient that allows them to manage their pain using all available tools, both pharmacological and non-pharmacological.
- Unified therapeutic plan that not only focuses on a false promise of healing, but also focuses on achieving your best functional state, making you understand key aspects such as diet, activity, sleep, emotional management and medication with the aim of improving the patient's quality of life.

Challenge main objectives

- A more efficient management of chronic pain from Healthcare Organization point of view.
- Improve accessibility and follow-up of patients with chronic pain.
- Promote self-empowerment among patients with chronic pain.

Solution functional requirements

Compulsory functional requirements

- The solution must offer the patient a quick access route to healthcare.
- User's environment will be a dashboard for professionals (nurses of the call centre, family doctor and hospital healthcare professionals) and a responsive mobile app for patients.
- The solution will be hosted in the cloud and managed by the company with all the guarantees of privacy and security.
- The tool will provide the operator with indicators that are relevant to detect changes in health status that allow them to make changes to the therapeutic plan.
- The solution may request care with other healthcare services depending on the needs detected (Nursing, physiotherapy, doctor, social worker, etc.).
- The operator will be able to modify the indications within the limits of the treatment plan.
- Automation of responses to patients depending on the query.
- The tool will have standardized support health resources (recommendations on healthy habits, emotion management, relaxation, etc.).
- The tool will allow the registration and exploitation of data.
- A ´dashboard´ view for health professionals where they can exploit all the information and ability to manage all patients and detect abnormal situations or suggest changes, being able to configure a system of alerts to avoid them.
- It´s also needed a dashboard for the patient, showing them the path to their empowerment with the strengths and needs, motivating him /her through rewards and gamification of tasks.
- Synchronous and asynchronous contact through chats and video conferencing.
- It will allow the administration of questionnaires and scales that the patient can complete autonomously and generate a tree of automatic recommendations.
- SMS will provide a nursing team that integrates the management of all these needs remotely.

Desirable functional requirements

- Possibility of translation to avoid language barriers.
- The patient will receive information about their follow-up from a professional who knows their situation and it will be reflected in the patient's history.
- Possibility of synchronization with other devices such as a smart watch that reduces the digital divide, with autonomy >5 days, allowing the registration of the agreed physiological parameters and with voice recognition.

- It will allow the monitoring of certain physiological parameters (HR, BP, RR, circadian rhythm, activity, etc.).
- The solution will be able to apply Artificial Intelligence (AI) embedded in the workflow manager to alert of possible problems at the 'process' level not perceived by the actors or nodes.
- We want technology to help in the adherence and sharing with third parties of good practices in chronic pain management, as well as community resources in a sustainable and cost-efficient way for SMS.

Pilot scope

The pilot will be developed in a total period of 12 months, including design, validation, testing and measuring of the impact of the co-created solution.

It will include at least 30 patients, who will test the solution for 6 months.

The healthcare professionals' team will be composed by different profiles and specialities. The main professional actors in the pilot will be nurses, physicians from Primary Care, rehabilitation, and physiotherapists.

Type and number of targeted end-users:

End-user type	Role	Number
Patients	With different skills and conditions	At least 30
Nurses	Close patient´s follow-up, bridging the gap between patients and SMS resources.	5
Rehabilitation physician	Leading the design and compliance of the plan	1
Physiotherapist	Leading the compliance of the plan	1
Primary Care physician	Recruitment and monitoring of the patients	1

Table 1. Targeted users

Language

- The solution must be in Spanish. Other languages would be desirable (English, French, German, Arabian).

Pilot set-up conditions

The pilot set-up conditions are based on three pillars: a data processing contract, the use of standards as HL7 or FHIR, and an agile and short integration with the corporative system during the pilot, focused on validating a Minimum Viable Product (MVP).

Ethical, legal or regulatory

The Entity undertakes to process the personal data to which it has access as a result of the execution of the contract, observing the principles required by the legislation on data protection, in particular those relating to data quality, data security and duty of secrecy, as well as in accordance with the specific instructions received from the data controller, not using the data for any purpose other than the provision of services described in the object of the contract. Likewise, it undertakes to observe professional secrecy, maintaining absolute

confidentiality and confidentiality on any data it may come to know on the occasion of compliance with the contract, in accordance with the level of protection established in the European data protection Regulation (EU 2016/679)of the European Parliament and of the Council, of 27 April 2016, relating to the protection of individuals with regard to the processing of personal data and Organic Law 3/2018 of 5 December, on the Protection of Personal Data and guarantee of digital rights, not communicating to any third party the data provided by the data controller. The data controller will determine whether, at the end of the services provided by the data processor, the personal data should be destroyed, returned to the data controller or handed over, where appropriate, to a new data processor. The destruction of the data shall not proceed when there is a legal provision obliging their conservation, in which case they shall be returned to the data controller, who shall guarantee their conservation for as long as such obligation persists. This obligation will continue even after the end of their relationship with the person in charge. The Entity will ensure and be responsible for its employees and / or collaborators receive the data only to the extent that it is necessary to their knowledge for the provision of the object of the contract. In the event that the Entity uses the data for purposes other than those stipulated, communicates them or uses them in breach of the instructions set out in this contract, it shall be liable for the infringements set out in Articles 70 et seq. of Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the guarantee of digital rights, in which it has incurred.

Technological

The user identification will be then provided through the OAuth standard. The solution may notify SMS systems about certain events and situations. Ideally via ´HL7´ messaging, but web services could also be an option. This information may include registration status, activity, progress and periodic (summarized) clinical information. The IT systems needed for running the solution will be hosted by the solver. If the complexity of the connections is too high or the personal data could be at risk, these systems could be hosted in local servers of the SMS. This will be established in a technical session at the beginning of the project. Anyway, the solver will provide mechanisms to guarantee that the Servicio Murciano de Salud can exploit the data. Data No prior Challenger data is expected to be available, meaning all users will start as new users in the system. The repository of documents and resources to be shared with the end users will be supplied and / or validated by the SMS.

Data access

No initial data will be provided for pre-load. All participants will have to register for free and fill their own data.

Expected impact and KPIs

The expected impact is:

- a decrease in the perception of pain (measured using pain scales),
- a decrease in the need for medications with consequent reduction in side effects,
- increase in self-care,
- improvement in accessibility to the health system,
- reduction in the number of visits (primary care, emergencies, etc.),
- reduction in the number of hospital admissions caused by exacerbation of the disease,
- increase in their quality of life.

KPIs are divided into three categories:

Health

We will measure this aspect with quality-of-life questionnaires administered to the patient both prior to the pilot and afterwards, as well.

- Quality of life before / after valued through the SF12 short questionnaire. Goal: 20% improvement. Satisfaction:

A control cohort could be created to establish differences.

Satisfaction

We will determine the impact on satisfaction through validated satisfaction questionnaires, such as the System Usability Scale (SUS), both in terms of users as well as the professionals who work with the solution.

- Tool satisfaction survey segmented by user roles (patient, neurologist and nurse) using the Customer Satisfaction Score (CSAT).): Goal: CSAT >8 (out of 10) in each user group (role).
- Patient experience through the Net Promoter Score (NPS). Goal: NPS >+50

Usability measured by System Usability Scale (SUS). Goal: SUS >80 Efficiency

Regarding the healthcare impact, we will measure the efficiency of the solution based on the reduction of tests, referrals and in-person consultations, as well as savings on medication pre-registration. We could compare the different variables before and after inclusion in the pilot and even establish a cohort control.

Business opportunity

Market size

In the Region of Murcia chronic pain is responsible for more than 30% of the total waiting list, as the rest of the region in Spain. This new solution could be easily expanded to all the other healthcare systems after a hypothetical success in this pilot, based on demonstrated cost savings achieved.

The challenger group offers their cooperation in the following:

- Advice on business model.
- In case of success of the pilot experience, the SMS undertakes to manage the possible resulting solutions in the volume to be determined, through the appropriate legal means, in particular as provided by the contractual regulations.
- Dissemination of results with the support of clinicians and patient associations, in order to make patient organizations aware of the solution at national and international level.
- Collaboration with a study of cost saving based on the published evidence, as well as with its publication and dissemination.
- Identification and contact with other potential customers.
- Advice on collaboration with the pharmaceutical industry by shortening treatment evaluation times in collaborative clinical trials.

Adoption plans

If the pilot is successful, SMS intends to adopt the solution, by a shared ownership of the solution co-created and procure its maintenance.

Intellectual Property Rights

This section sets the rules for the evaluation, ownership, and exploitation of Intellectual and Industrial Property Rights.

Evaluation and Documentation: Each party shall evaluate and document in the Pilot Action Plan their respective contributions to the new solution. This assessment will consider each party's background knowledge, resources, and tasks undertaken in the co-creation pilot project, determining the ownership and rights of the resulting shared IP&IPR.

Intellectual Property (IP) Rights: The intellectual property rights developed or contributed by SMS are inalienable, reflecting the knowledge and resources provided by SMS, including work time, patient access, and real-world validation. Usage of such intellectual property by other parties shall require a formal licensing agreement with mutually agreed terms.

Industrial Property Rights (IPR): SMS may opt-out of the commercial exploitation of the solution due to its lack of capacity in this area. In such a case, the exploitation rights will defer to the two companies, subject to compensations to SMS. These compensations will be based on SMS relinquishing approximately 20% of royalties to both companies and shall include:

- Reduced overall cost in licensing and maintenance of the solution.
- Allocated hours for corrective and evolutionary maintenance.
- Priority status for SMS in incident handling and new developments.
- Collaboration by SMS in promoting the solution, including identifying customer networks and assisting in presentations.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	INVESTIGACIÓN Y DESARROLLO INFORMÁTICO EIKON S.L. – IDI EIKON
DESCRIPTION OF THE SME	IDI EIKON is a software development Spanish SME operating in European markets and created in 1989. Its e-Health Business Unit provides a wide service portfolio to local, regional, national and European socio-sanitary and healthcare organizations (HCO). To do so, we rely on AdsuM++, IDI EIKON's 100% proprietary development. AdsuM++ operates as a Meta-Platform allowing to design and implement different types of services on top of it. AdsuM++ offers project co-ordination and co-creation roles as well as care protocol designers, IT engineers, AI experts and support profiles. IDI EIKON recurrent R&D activity expands AdsuM++ modules, features and capability along time. Currently, AdsuM++ is being used by HCOs in Primary (as a daily practice tool, TRL9) and Secondary (within Research Studies and Observatories, TRL8-9) use cases in Spain, Italy and United Kingdom. IDI EIKON has wide experience in participating and co-ordinating different European Projects, also focusing in validating different technical proposals. INCA Project included the participation of Servicio Murciano de Salud, partner in HealthChain. In addition, IDI EIKON has already participated in different co-creation processes with private partners and HCOs which resulted in successful commercial products, now being marketed jointly with different stakeholders. IDI EIKON provides extensive expertise in: • Care protocols and individualised care pathways design and implementation (inflammatory diseases, infectious diseases, rare diseases and chronic conditions) • Multi-disciplinary care co-ordination and patient-centric care models • Patient-reported outcomes • New Artificial Intelligence (AI) models supporting clinicians (predictive models) and patients (self-care guidance) • Integration and interoperability with third party systems

WEBSITE URL	http://www.idieikon.com http://www.idieikon.com/adsum

Table 2. Leading SME general information

Solution proposed:

PALDOC: Chronic Pain Liquid Care Platform

IDI EIKON will contribute an AdsuM++ value-based healthcare Meta-Platform licence ("in the market", TRL9) supporting PALDOC to:

- Implement HCO's innovative care protocols and procedures on whatever condition/pathology in the need of providing a "proactively monitored patient journey" along time.

- Ensuring care protocols allow multidisciplinary groups (MDG) active participation, considering not only different clinical profiles but an active patient (and informal caregiver) profile participating from the care process.

- Using those validated instruments that can add value to measure patient's achievements in self-managing chronic pain attending the following areas:
  - Patient's pain intensity (i.e. VAS)
  - Patient's holistic characterization
  - Patient's functional quality of life (i.e. EQ5D)

- Offering easy-to-use interfaces for patients, running in any Internet-connected device and using pictograms to simplify interactions, where possible.

- Focusing on Health Outcomes achievements from multiple perspectives.

- Introducing Data Analysis capabilities based on deterministic business rules and in AI Large Multimodels Models (LMM) that provide counsel and guidance [this component is on a TRL8-9 maturity level, as adaptations and training of the AI model is to be tailored to PASPADOC needs]
  - To clinical providers: detecting patterns that deviate from Care Protocol control goals, "triggering" manual adaptations of care plan.
  - To patients: providing "always on" interfaces to ask for guidance and resources on managing chronic pain.

- Standardizing data collected from third parties, clinical providers records or patient-reported data, in order to ensure powerful data exploitation options afterwards, in primary use cases (detecting how to improve care models) and in secondary use cases (enabling new research studies).

- Providing intermediate Care Pathway Management interfaces, so designed processes can be:
  - Easily modelled
  - Progressive extended
  - Flexibly adapted, when evidence demands so

- Seamlessly integrated with other IT systems
- Independently managed by HCO without dependencies on IDI EIKON

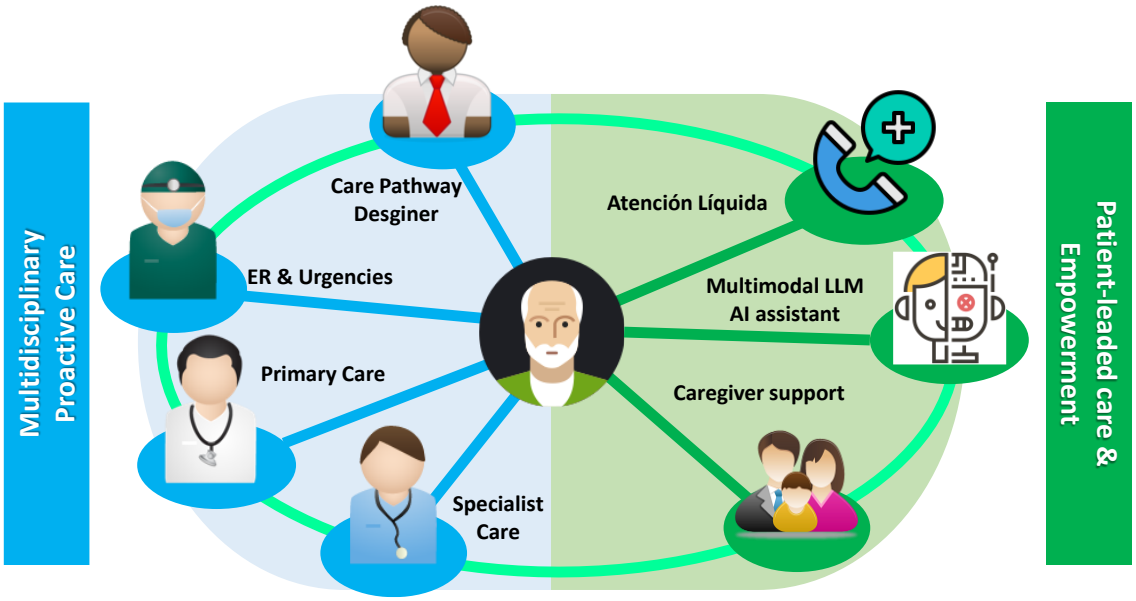

Figure 1. PALDOC Integrated Care Paradigm

PALDOC provides products, services, content, education, guidance and a baseline technology. This might help in improving standards of care. Meta-platforms like PALDOC are the way of the future for the enterprising in healthcare with tremendous untapped potential.

- **Meta-platform capacity**: provides a TRL9 set of modules co-creators use to model its own service portfolio. New services are available as soon as co-creators define them, and can be real-time-changed, addressing wrong-design scenarios without stopping a project. This provides an incredibly powerful asset to co-creation teams, not tied by IT developers to "play" its creative role and to change its mind as many times as needed.

- **Test disruptive technologies "on the fly"**: add new services to your pilot if you want to. Test new HTML5 Web-RTC synchronous communication features. Train your own AI assistant to support users, relying on your Health Resources repositories. Transform every record into normalized data codified in SNOMED-CT, OMOP or ICD ontologies. PALDOC regularly delivers new features, as AdsuM++ platform liberates them. PALDOC may use them to expand pilot impact.

- **Born to interoperate**: integration is 100% guaranteed, even in pilot stages. Reusing available data boosts PALDOC potential to unsuspected thresholds.

- **Scale up without limits**: from pilot to production, from one HCO to an entire region, from one clinical condition to multi-morbidity scenarios, from local data repositories to European Observatories aggregating invaluable data.

- **Hybrid business models**: when moving to post-pilot phases different architecture setups might be considered. Clinician interfaces might be hosted at SMS premises, but Patient

interfaces will need to be available in Internet. PALDOC supports this "hybrid architecture" model ensuring all security policies from HCO are observed.

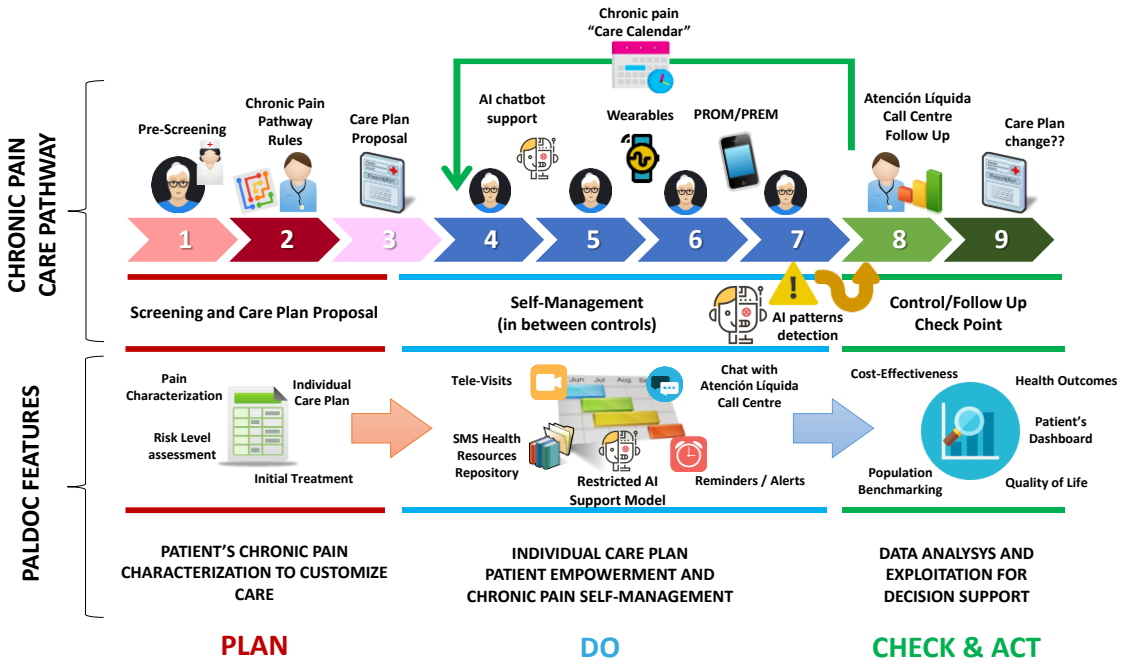

Figure 2. PALDOC Chronic Pain Service Outline

Work to be done by the leading SME

WP1 – Co-creation process coordination

Here IDI EIKON (Leading SME) will manage the co-creation design process, by planning a set of requirements' capture meetings with the SMS in between month 1 and 8 (T1.1). Then, co-creation follow-up meetings will be held to track PALDOC development progresses, readdressing wrong designs and validating releases with end users (T1.2). Follow up activities will be tracked since month 9 (T1.2) and co-creation business agreements exploration will start on month 15 (T1.3).

WP1 Milestones:

- M1 (month 8): PALDOC Chronic Pain Care Pathway final design document.
- M5 (month 18): PALDOC post-pilot exploitation agreement signed.

WP2 – PALDOC infrastructure set-up

IDI EIKON will handle all technical works to ensure the cloud-based infrastructure (T2.1 – T2.2) hosting PALDOC and interoperability mechanisms with SMS IT systems (T2.3) are up and running before pilot activities kick-off.

WP2 Milestone:

- M2 (month 9): PALDOC infrastructure deployment completed.

WP3 – PALDOC tailored features development

Relying on the final design document produced by WP1, PALDOC Development Team will manage the works to customize PALDOC Platform modules. Based on the inputs from WP1, PALDOC AI assistants will be trained leveraging on available Health Resources repositories (T3.1, T3.4), Wearable and Medical devices data will be integrated as an additional data source (T3.2) and synchronous communication tools in between patients and care providers using videoconferencing will be fine-tuned (T3.3).

WP4 – Pilot Deployment

Pilot activities will be kicked-off in month 14 and will run up to month 18. Process will start with end users' recruitment (T4.1) with SMS support for this process (inclusion criteria, consent forms, ethical committees…). Regular monitoring activities will happen (T4.2), including support to end users and follow-up coordination within the co-creation team.

WP4 Milestone:

- M3 (month 14): PALDOC pilot deployment report.

WP5 – Impact Evaluation

Measuring impact is a key part of PALDOC solution. In order to do so, we will perform a "before pilot" measurement for the KPI set proposed (T5.1), covering project impact, health outcomes achieved and satisfaction/usability dimensions. Final set of KPIs will be agreed within WP1 Co-Creation Process Coordination. An additional "after pilot" evaluation of KPIs (T5.2) will happen in month 18, and a final Impact Evaluation Report will be generated.

WP5 Milestone:

- M4 (month 18): PALDOC Impact Evaluation Report.

WP6 – Business model, dissemination and communication

All tasks related with post-pilot exploitation, scalability and new stakeholders/promoters' engagement will be addressed here (T6.1 – T6.2). To do so, we will rely on HealthChain project support resources and Follower SME contributions.

month	mar-24	abr-24	may-24	jun-24	jul-24	ago-24	sep-24	oct-24	nov-24	dic-24	ene-25	feb-25	mar-25	abr-25	may-25	jun-25	jul-25	ago-25
WORK PACKAGE / TASK	**M1**	**M2**	**M3**	**M4**	**M5**	**M6**	**M7**	**M8**	**M9**	**M10**	**M11**	**M12**	**M13**	**M14**	**M15**	**M16**	**M17**	**M18**
WP1: co-creation process coordination																		
T1.1 - SMS co-creation meetings								**m1**										
T1.2 - Co-creation follow-up meetings																		
T1.3 - PALDOC exploitation agreements																		**m5**
WP2: PALDOC infrastructure set up																		
T2.1 - Cloud-based architecture set up																		
T2.2 - Architecture deployment									**m2**									
T2.3 - PALDOC - SMS Interoperability mechanisms																		
WP3: PALDOC tailored features development																		
T3.1 - AI assistant training																		
T3.2 - Wearables data integration in PALDOC																		
T3.3 - Video-conferencing in PALDOC																		
T3.4 - Health resources repository publication																		
WP4: Pilot deployment																		
T4.1 - Users recruiting																		
T4.2 - PALDOC Chronic Pain Care Pathway usage support														**m3**				
WP5: Impact evaluation																		
T5.1 - "Before" pilot KPI measurements																		
T5.2 - "After" pilot KPI measurements																		**m4**
WP6: Business Model, Dissemination and Communication																		
T6.1 - Post-pilot business modelling																		
T6.2 - Dissemination and Communication																		

Figure 3. PALDOC Gantt Chart

Follower SME

Scope of work performed by the follower SME

IDI EIKON is a software development, interoperability expert and value-based healthcare models provider company that contributes a licence on its Care Pathways Management platform (AdsuM++) as the basis supporting almost all requirements (mandatory and desirable) included in PASPADOC challenge.

Additional adaptations of AdsuM++ agreed in the initial co-creation process with the SMS can be addressed by IDI EIKON's IT Team (participants, roles and experience of this team is detailed in the previous section of this document).

However, IDI EIKON is looking for an SME that can provide the following services:

- **Ability to provide (or generate) additional Health Resources related to Chronic Pain that might be integrated in PALDOC repositories and used to train PALDOC AI assistant.** To be integrated in WP3 (T3.4):
    - Empowering patient's ability to self-manage their chronic pain condition is a key goal in PALDOC. To do so, an AI-based personal assistant will be offered to patients. This AI will need specific materials and advice on how to deal with Chronic Pain on a daily basis. We are looking for a Follower SME that can support us in validating the available content and materials from the PALDOC HCO while contributing new resources and materials for training the AI-based assistant. Specific expertise in generating "patient friendly" documentation will be appreciated.

- **Active participation from co-creation follow-up meetings, contributing new ideas and validating previous decisions.** To be integrated in WP1 (T1.2).

- **Contribution to develop an Internet of Things layer (IoT) for PALDOC, where Wearable devices and their data (preferably obtained from the Follower SME own "data concentrators") are integrated into AdsuM++.** To be integrated in WP3 (T3.2):
    - PALDOC has a beyond-pilot sustainability goal. Leveraging on partners that can provide added value to our proposal will help us in extending PALDOC across Europe. We do think that ensuring interoperability with providers that are already offering their own Wearables devices and related platforms in the market can contribute to PALDOC expansion. We do foresee to integrate in PALDOC platform data measured by wearable devices that provide insights on chronic pain management (sleep quality, walking activity, falls and similar KPIs) so this data can be used to trigger specific alerts and advice, by fusing it with other PALDOC inputs. We do foresee to pick up this data directly from the data concentrator platform collecting data from individual devices, in order to reach a seamlessly integration we can widely reuse in different implementation scenarios.

- **Contribution to develop an Internet of Things layer (IoT) for PALDOC, where medical devices and their data (preferably obtained from the Follower SME own "data concentrators") are integrated into AdsuM++.** To be integrated in WP3 (T3.2):
    - Continuing efforts planned for wearable devices, we also do foresee to integrate in PALDOC platform data measured by medical devices that provide insights on chronic pain management (neurostimulators, drug pumps and similar devices) so this data can be used to trigger specific alerts and advice, by fusing it with other

PALDOC inputs. We do foresee to pick up this data directly from the data concentrator platform collecting data from individual devices, in order to reach a seamlessly integration we can widely reuse in different implementation scenarios. Medical devices and related management platform should be EC certified and classified accordingly under EU Medical Device Regulation.