Topic: Improving patient access, understanding and adherence to healthcare information: an integrated digital health information project

All information regarding future IMI Call topics is indicative and subject to change. Final information about future IMI Calls will be communicated after approval by the IMI Governing Board.

Topic details

Action type	Research and Innovation Action (RIA)
Submission and evaluation process	2 stages

Specific challenges to be addressed

The ability to access and understand high-quality health information is central to health literacy, and this affects the day-to-day decisions citizens make in the management of their health and care [1] that will ultimately determine adherence to treatment [2]. A lack of adherence is an established public health concern, with significant effects on the individual patient, as well as healthcare systems as a whole [3].

A multitude of health-related information resources are now available to patients, tapping into demands for greater engagement with personal healthcare. This digital era, however, is compromised by two major concerns. Firstly, the sheer volume of information available has become disorientating to users, many of whom have poor health literacy [4] to start with, and do not know which source to trust for up-to-date guidance. Distribution of this information across different source locations only compounds the issue. Secondly, existing health-related resources are generally not personalised to their specific needs or health literacy level, and therefore large amounts of the information available are irrelevant to the patient[1]. Indeed, product information is a prime example of this phenomenon, with little direct evidence to suggest that patients are actively reading, understanding and adhering to details in the patient leaflet (PL)[2]. Bearing in mind that the product information is considered for most products to be the primary risk minimisation measure, this paradigm clearly needs to change.

There is therefore the need to lay the foundations for the application of digital technologies to health information in order to transform citizens' understanding of their health and care, thereby promoting adherence to prescribed treatments, and ultimately contributing to better outcomes. The topic is consistent with the EU Digital Single Market Strategy, which highlights the need and opportunity to introduce a digital transformation of health and care[3], and is aligned with the IMI Strategic Research Agenda under Axis 4 'Patient Tailored Adherence Programmes'[4]. The topic is also consistent with the key benefits noted in the European Medicines Agency (EMA) Action Plan on e-Product Information (ePI)[5] and subsequently in the draft key principles for electronic product information published by EMA[6] following an EMA/HMA/EC stakeholder workshop.[7] During the workshop, this topic was presented alongside other initiatives in the context of a future

[1] The most frequently quoted example of this is pregnancy information for male patients.
[2] The authoritative source of information provided to patients about their medicine is the patient leaflet which must be provided unless all information can be included on the outer packaging (Directive 2001/83/EC Article 58). This single document is provided to all patients irrespective of their health literacy, patient profile, medical history, or preference. In addition, the current format of the package leaflet is widely acknowledged to need improvement (Report from the European Commission on the shortcomings of product information published 22 March 2017)
[3] Communication on Transformation of Health and Care in the Digital Single Market (April 2018)
[4] IMI Strategic Research Agenda.
[5] EMA Product Information Action Plan was published on 10 October 2017
[6] Electronic-product-information-human-medicines-european-union-draft-key-principles - consultation period 31-Jan-19 to 31-Jul-19
[7] European Medicines Agency (EMA) / Heads of Medicines Agencies (HMA) / European Commission (EC). Stakeholder presentations and the workshop report including details of the mapping of ongoing initiatives have been published. See: https://www.ema.europa.eu/en/events/european-medicines-agency-ema-heads-medicines-agencies-hma-european-commission-ec-workshop

vision for electronic product information in the broader digital health landscape, and the EMA also shared details of their mapping of ongoing ePI initiatives, illustrating the very considerable degree of interest and activity in this area at the present time.

Need and opportunity for public-private collaborative research

While there are already digital tools available that enable patients to access product information electronically (e.g. electronic Medicines Compendium (eMC) in the UK, LIF in Denmark, FASS in Sweden, and the Gebrauchsinformation 4.0 project in Germany)[8], and ePI texts may also be available via health authority websites, these do not at this time comprehensively address the broader information needs noted above, there is limited flexibility to tailor the information available to individual needs, and equivalent digital tools are not available to all patients in all countries.

To address the challenges and undertake a project of such a transformational nature, an active partnership from a range of contributors across the public and private sectors is necessary. The project must balance the need for interoperability with national healthcare systems, align with other key principles mentioned in the EMA ePI draft key principles document, address concerns from industry to enhance the effectiveness of the ePI as a primary risk minimisation measure, and provide all of this in an intuitive and user-friendly design which meets citizens' unmet needs as noted above. This includes:

- perspectives from patient and healthcare professional organisations to understand patient health information/literacy needs and ensure that proposed solutions are fit-for-purpose, acceptable to all stakeholders and truly value-added from the user perspective, and to enable measures to be defined of relevance to these stakeholders;
- academic and research institutions and appropriate health literacy experts who can support the development of appropriate methodology to test patient understanding and impact and contribute to development of appropriate key performance indicators (KPIs) in relation to the project objectives;
- current providers of ePIs and associated product information to enable existing best practices/expertise to be leveraged, and other technology organisations who can develop and integrate the envisaged technology platform and digital applications that will be needed for the proof of concept testing, including considerations for data integration;
- public sector partners who can contribute to the identification of trusted sources of product information, electronic health records and health education materials for use within the project framework;
- contributors with appropriate expertise in the gathering/use/analysis of real-world data and risk-benefit assessment, to measure the effectiveness of the platform as a risk minimisation tool;
- advice from regulators (i.e. EMA, national competent authorities) to consider alignment with wider telematics initiatives and the impact of the proposed approaches on the current/future regulatory framework for the provision of health information to patients;
- contributors with legal and data privacy, as well as social science and ethical expertise to ensure that questions in relation to these areas can be addressed.

The establishment of a public-private partnership offers a unique mechanism for these diverse stakeholders to engage to deliver the range of input and expertise necessary for achieving the project aims and ensuring that a practical and sustainable solution is found.

Scope

The principle objective of this topic is to demonstrate how the use of an integrated, digital, user-centric health information solution could enable a tangible improvement in the ability of citizens to access and understand reliable, relevant health information from different sources.

Access to and understanding of health information are key components determining health literacy, and the health literacy level of a citizen underlies their decision-making in regarding to management of their health and care, including adherence to treatment. Accordingly, a secondary objective will be to measure how improved access to and understanding of health information translates into higher levels of treatment adherence, safer

[8] For example, see the Swedish FASS website at http://www.fass.se; mp3 audio files on http://www.laakeinfo.fi, videos on https://www.indlaegssedler.dk, and the 'Gebrauchsinformation 4.0 project in Germany: www.gebrauchsinformation4-0.de

use of medicines and consequently better health outcomes, with new insights into how health information can be optimised to act as an effective risk minimisation measure.

The topic objectives will be achieved by a phased approach, in which later stages build on the outputs of the earlier research activities in an agile manner:

1. **Establishing stakeholder needs and development of appropriate KPIs**

Research will be conducted to establish an in-depth understanding of citizens'[9] expectations and aspirations for the provision of healthcare information in a digital setting to form the basis for future project activities and design-planning for technology development. Specific contexts/patient journeys will be mapped at this stage either on specific therapy areas or other product-type scenarios, such as non-prescription medicines or vaccines. The needs of different patient populations, including vulnerable patients, will also be considered. KPIs will be developed in relation to the two key objectives outlined above to enable the measurement of the success of the proposed integrated digital health information approach versus the current paradigm (which typically relies on paper-based product information for the patient and/or fragmented digital sources).

2. **Technology platform and digital solution**

Development of an **underlying open source technology platform,** and a **digital solution** to enable testing and measurement of the effectiveness of a digital approach to meet defined user needs.

The initial focus will be on product information, electronic health records (EHRs) and a two-way communication channel with the patient. Appropriate, trusted data sources will be linked to the platform taking into account applicable data security and General Data Protection Regulation (GDPR[10]) considerations. A digital solution with tailored information in line with patient needs will be developed for the proof of concept testing of understanding and acceptability. Alignment with the key principles on the common standard for ePI coming from the EMA Action Plan will also be taken into account[11]. Depending on technical progress with product information and EHRs, the latter stages of the project may include a wider range of trusted health educational materials (HEMs) within the platform, with the aim of further enhancing patient understanding.

3. **Evaluation of the ability of digital solutions to enhance risk minimisation approaches through the generation of real-world evidence**

Feedback gathered via the digital tool can be used to assess understandability and options can be evaluated for how to further assess the effectiveness of the platform as a risk minimisation tool.

Ongoing: Development and execution of a sustainability plan

A sustainability plan will be developed over the life of the project which details recommendations for how successful concepts/technology approaches will be carried forward and implemented into the digital healthcare ecosystem at the national/regional level in a sustainable and practical manner. The draft plan will be developed early in the life of the project and adapted in an agile manner based on the project outcomes.

Any form of promotional materials will **not be in scope** for this project.

Expected key deliverables

The key deliverables will be an **open-source technology platform** and **digital technology solution**(s) that have been developed for testing.

- The **open-source technology platform** will integrate information from regulator-approved product information and electronic health records in the wider context of digital health. The platform will aim to make such information available via an application programming interface (API) to allow other

[9] Including patients, healthcare professionals and members of a patients' support network.
[10] See https://ec.europa.eu/info/law/law-topic/data-protection_en.
[11] EMA Product Information Action Plan was published on 10 October 2017.

companies/developers to use this as a basis for further market-specific applications, offering flexibility for the future evolution of the digital ecosystem.

- The **digital technology solution** will allow digital information to be presented to the patient in a tailored, user-friendly manner to more effectively serve the needs of patients in the management of their own health and care. A range of digital functionality will be built into the digital solution and tested with user groups to measure the effectiveness in improving understanding, adherence to treatment, and health outcomes.
  For example:
  - a user-friendly view of the patient's medical history and other pertinent characteristics;
  - tailored versions of the ePI dependent on patient circumstances and health literacy needs. A variety of formats will be made available based on the approved PLs, and integration across PLs for different products to generate a single 'treatment ePI' will also be investigated;
  - the solution will incorporate additional digital functionality to enhance the user experience and support understanding, adherence and health outcome measures. These features will be fully defined during the research studies but may include features such as dosage reminders, comprehension tests, linkage to healthcare systems to receive e-prescriptions or book appointments, and other off-the-shelf capabilities that already exist in different EU Member States;
  - users will have the ability to send information to the platform to be aggregated and analysed to improve outcome measures;
  - depending on progress with EHRs and ePI, the platform may also look to identify defined health educational materials at different health literacy levels that will help the patient understand their health, medical diagnosis, and prescribed treatments.

Other deliverables will include the following:

- a **series of study reports** will be published presenting the outcomes of research studies which seek firstly to demonstrate the benefit that this integrated digital approach offers to patients in accessing and understanding health information from the identified sources (primary objective), and in turn to applying this to enable improved adherence to treatment and health outcomes (secondary objective). Details of the KPIs developed for measurement of success in relation to these two objectives will be described;
- an evaluation will be completed to assess the potential ability of digital solutions to enhance risk minimisation approaches through the generation of real-world evidence;
- at the end of the project, the project team will publish **a white paper** that outlines the next steps that should occur in the EU to take advantage of the research findings from the proof of concept test phases. Depending on the results and demonstration of the success of different concepts, this may include a recommendation on adoption of the technology platform/digital solution as the starting point for national or regional implementation (with appropriate modifications), adoption of elements of the solution for further development, and what changes (if any) would be needed to EU legislation/regulation to allow for introduction of these elements;
- identification and **publication of key stakeholder needs** and preferences in terms of information, personalisation and functionality, which will then be used as a basis for design planning for a suitable digital solution;
- identification and publication of a set of **data source specifications** for integration into the digital solution via:
  - identification of the data standards for, and key elements of, electronic medical records and medical alerts for inclusion;
  - utilisation of regulator-approved product information in the appropriate data standard according to emerging ePI standards.
- report on the **key features of future data standards** for ePIs that would optimise functionality in relation to the provision of health information for consideration by regulators[12].

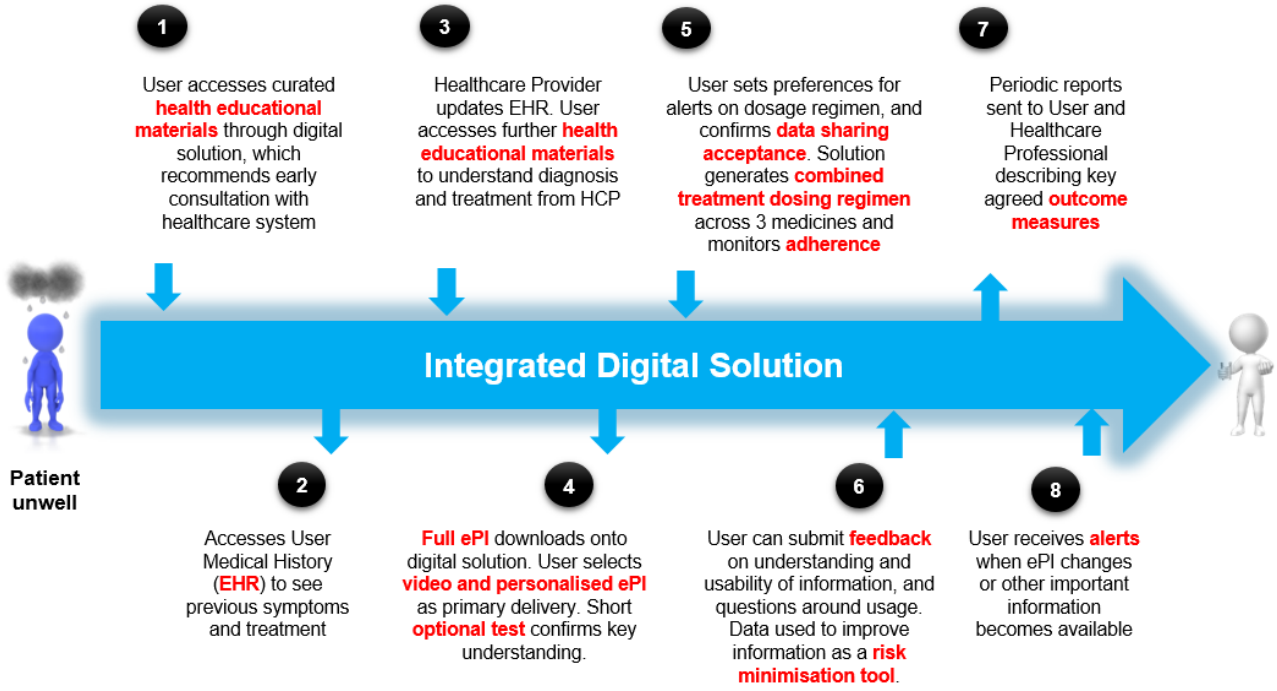
Expected impact

[12] Accordingly, the option of Article 28.2 IMI2 JU Grant Agreement regarding results contributing to standards should be activated and included in the text of the future funded action's Grant agreement.

Applicants should describe how the outputs of the proposed project will contribute to the following impacts and include baseline, targets and metrics to measure impact:

- allow individual patients to easily access **trusted health information, tailored to be relevant** to their specific needs. **Empower these patients** and better prepare them for informed interaction with national healthcare systems;
- further build patients' (digital) health literacy, so allowing for **better decision-making concerning their health care**, **disease prevention** and **health promotion**, to **maintain or improve quality of life** throughout the course of life;
- positively **impact healthcare at a societal level** through **enhanced adherence, better use of resources, and improved overall patient outcomes**; the approach may offer **particular benefits in complex scenarios**, for example where patients are managing multiple morbidities;
- improve the effectiveness of ePIs as a **primary risk minimisation measure** by surfacing greater insights on access, understanding and the usability of the information provided to them;
- the **technology platform/tools** developed for the purposes of the project will be made available **open-source**, and will be accessible to other companies/developers to use this as **a basis for further market-specific applications** which can accommodate the specifics of local digital ecosystems, allowing flexibility to best support longer-term implementation of the integrated digital healthcare approach;
- the implementation will enable relevant and approved updated trusted health information to be pushed in a timely manner to ensure adherence with changes in safety or usage information to continue to enhance patient adherence and safety after and with patient permission to receive alerts pertinent to them;
- the **digital approach and technology developed** under the project has the potential to transform the patient experience as they engage with and manage their health and care throughout their healthcare journey. The figure below illustrates how such a journey may be envisaged in the future, in an environment in which digital information sources are integrated effectively and tailored to the needs of the individual.

Figure 1. Illustrative use case (prescription scenario)



Applicants should indicate how their proposal will impact the competitiveness and industrial leadership of Europe by, for example, engaging suitable small and medium-sized enterprises (SMEs).

Potential synergies with existing consortia

This proposal is expected to develop synergies, build on results, and avoid duplication of efforts with existing consortia and current e-PI/EHR initiatives at national, EU, and international level. The development of the

global IDMP (ISO)[13] standard for the product database can further be regarded as a potential synergy to this project. Applicants should assess existing opportunities for synergies with other ongoing initiatives at a regional or national level, in particular in the fields of ePI and EHR and demonstrate in their proposals how they will synergise with such initiatives in order that the project can leverage relevant expertise to the maximum degree

Collaboration agreements

There is the potential for important synergies between the consortium selected under this topic and the one selected under IMI2 JU Call 18 topic 2 (Health Outcomes Observatories – empower patients with tools to measure their outcomes in a standardised manner creating transparency of health outcomes). On the one hand, for instance, while the consortium selected under this topic 3 should have access to sufficient EHRs and patients to meet its own objectives, this consortium could also leverage the observatory platform in order to obtain access to and analyse additional relevant electronic health record (EHR) data, in compliance with applicable regulation, gathered under topic 2. On the other hand, the consortium selected under this topic could become an additional important use-case for the observatories under topic 2 and improve their usefulness. Additionally, the perspectives brought by the consortium selected under topic 3 can contribute to development of the governance and operational model of the observatories, under topic 2. It could also help future-proof them as a neutral guardian of patients' health data which could then be made available in the future with the appropriate safeguards for applications, such as those envisaged under topic 3.

To explore these potential synergies between actions funded under these two topics, the selected consortia are expected to cooperate in common boards/structures and provide access to their results for specific activities when relevant. Therefore the grants awarded under IMI2 JU Call 18 topics 2 and 3 will be complementary grants. The respective options under Article 2, Article 31.6 and Article 41.4 of the IMI2 JU Model Grant Agreement[14] will apply. Accordingly, the relevant consortia will conclude collaboration agreement(s) to ensure the exchange of relevant information, exploration of synergies, collaboration where appropriate.

Industry consortium

The industry consortium is composed of the following EFPIA companies:

- Pfizer (Lead)
- Astra Zeneca
- Bayer
- Grunenthal
- Lilly
- Medidata
- Mylan
- Novartis
- Roche
- UCB

In addition, the industry consortium includes the following IMI2 JU Associated Partners:

- Datapharm
- Medicines for Europe

The scope of the research proposed is wide-ranging, and hence the industry contributors are offering functional expertise across a range of disciplines aligned to the project scope and objectives. These areas of expertise include: knowledge of development and maintenance of product information, and its central place in pharmacovigilance and risk management/minimisation methodologies; the importance of health literacy and the provision of high quality medical information; the use of real-world data to improve understanding of product safety and effectiveness; business technology expertise concerning development of systems;

[13] Identification of Medicinal Products (International Organization for Standardization). See https://www.ema.europa.eu/en/human-regulatory/overview/data-medicines-iso-idmp-standards-overview

[14] See: https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/h2020-mgaimi_en_v5.pdf

processes, and data standards to support regulatory processes; and knowledge of development and implementation of EHR systems.

Indicative duration of the action

The indicative duration of the action is 60 months.

Indicative budget

The indicative in-kind and financial contribution from EFPIA partners and IMI2 JU Associated Partners is EUR 9 280 000

This contribution comprises an indicative EFPIA in-kind contribution of EUR 9 070 000 and an indicative IMI2 JU Associated Partners in kind contribution of EUR 210 000.

Due to the global nature of the participating industry partners and IMI2 JU Associated Partners, it is anticipated that some elements of the contributions will be non-EU/H2020 Associated Countries in-kind contributions.

The financial contribution from IMI2 JU is a maximum of EUR 9 280 000.

Applicant consortium

The applicant consortium will be selected on the basis of the submitted short proposals.

The applicant consortium is expected to address all the research objectives and make key contributions to the defined deliverables in synergy with the industry consortium, which will join the selected applicant consortium in preparation of the full proposal for stage 2.

This may require mobilising, as appropriate the following expertise:

- **patient groups/healthcare professional groups** to ensure that the perspective of the end user is taken into account fully in the research scope, the development of appropriate KPIs relating to the two key objectives, and also for the proof of concept testing;
- **academic and research institutes** specialising in the **provision/use/understanding of health information**, who can support the definition of appropriate KPIs relating to the two key objectives, and development of an appropriate methodology for testing to demonstrate patient understanding and impact;
- expertise **in gathering/use/analysis of real-world data and risk-benefit assessment**, to consider the effectiveness of the platform as a risk minimisation tool;
- expertise on the **legal, ethical, social science and GDPR questions** arising from the proposed work;
- **technology partners**, including SMEs, who have proven experience **in electronic health records, provision of health information (for example current leaders of national electronic product information initiatives)**, platform integration and development of user-centric solutions within a highly secure environment, and provision of business/regulatory information technology. User-centric solutions need to be designed with the patient journey in mind, covering measures which will improve patient adherence to treatment (e.g. adherence checks), patient understanding of the product information (e.g. novel interactive question and answer features), and the delivery of novel forms of personalised product information (e.g. video, pictorial, digital assistant) based on defined criteria coming from EHRs or other data-entry methods. **Interest from SMEs** who can offer technical expertise that could support the development of the technology envisaged under the project is welcomed;
- ideally, **national competent authorities** would be part of the applicant consortium to ensure alignment with national initiatives.

It may also require mobilising, as appropriate, the following resources:

- applicants should demonstrate access to appropriate data sources spanning product information and EHRs in at least one country. It is proposed to conduct the study in several markets;
- existing relevant digital technologies that can be further developed during the project.

Experience and engagement with relevant digital health initiatives

Applicants should demonstrate how they will seek to take advantage of established/planned digital health initiatives within relevant member states, in particular in relation to ePIs and EHRs.

Interaction with regulators

In their proposals, applicants should have a plan for engaging with regulators (for example, seeking scientific advice from the European Medicines Agency and/or national competent authorities). This is to ensure alignment with any new e-labelling principles across the region, but also to consider the potential impact on legislation to allow the development of recommendations for the introduction of successfully proven solutions in due course. At a minimum, it is anticipated this will occur prior to initiation of testing activities in the specific Member States and during the development of implementation recommendations in the later phases of the project. Suitable resources should be dedicated to these activities.

Data management

In their short proposal, applicants should give due visibility to 'data management'. Applicants should include proposals for how concerns relating to data privacy/GDPR may potentially be addressed. At stage 2, applicants should include a draft data management plan (DMP) in the full proposal, outlining how research data will be handled and made available during the project and after it is completed.

Dissemination, exploitation and communication activities

In their short proposal, applicants should give due visibility to the dissemination, exploitation and communication of the project's results. At stage 2, in their full proposal, applicants should further develop these activities.

Partnership with the industry consortium

In their short proposal, applicants should outline a strategy to create a successful partnership with the industry consortium.

Sustainability planning

In their short proposal, applicants should outline how they have considered the longer-term sustainability of the project outputs.

Suggested architecture of the full proposal

The applicant consortium should submit a short proposal which includes their suggestions for creating a full proposal architecture, taking into consideration the industry participation including their contributions and expertise provided below.

In the spirit of the partnership, and to reflect how IMI2 JU call topics are built on identified scientific priorities agreed together with EFPIA beneficiaries/large industrial beneficiaries, these beneficiaries intend to significantly contribute to the programme and project leadership as well as project financial management. The final architecture of the full proposal will be defined by the participants in compliance with the IMI2 JU rules and with a view to the achievement of the project objectives. The allocation of a leading role within the consortium will be discussed in the course of the drafting of the full proposal to be submitted at stage 2. To facilitate the formation of the final consortium, until the roles are formally appointed through the consortium agreement, the proposed project leader from among EFPIA beneficiaries/large industrial beneficiaries shall facilitate an efficient negotiation of project content and required agreements. All beneficiaries are encouraged to discuss the project architecture and governance and the weighting of responsibilities and priorities therein.

The architecture outlined below for the full proposal is a suggestion. The architecture of the full proposal should be designed to fulfil the objectives and key deliverables within the scope of this topic.

The proposed project should be phased with an initial focus on product information, then moving on to linkages with electronic health records, and the development of a two-way communication channel to the patient to assess the potential of the platform as an effective risk minimisation tool. A final phase of the

proposed project should focus on the expansion of content within the platform to include a wider scope of health educational materials will be considered after the project has proven the utility of the integrated platform across product information and EHRs. In each phase of the proposed project, attention will be paid to ensuring that the platform is delivering a *meaningful* effect on patient understanding and adherence before moving to the next stage.

Phase 1: Establishing stakeholder needs and development of appropriate KPIs

Research activities to define key patient/user needs and preferences in terms of information, personalisation and functionality as described above across product information and EHRs. Testing scenarios will be assessed during this phase. In addition, technology contributors/partners will be assessing the feedback and analysing its feasibility and complexity for consideration in technology development planning. KPI development will begin to enable measurement of enhanced understanding/adherence during the planned studies.

Phase 2: Sourcing, developing, testing, and measuring the effectiveness of digital solutions to meet defined user needs through a series of proof-of-concept projects

Work packages across both of the initial information areas (product information & EHR) will manage the next phase of activities during which technologies will be built and tested in initial proof–of-concept studies.

In parallel, the technical development and evaluation of the ability of digital solutions to enhance risk minimisation approaches through the generation of real-world data will begin, so that this element of functionality can be incorporated into the digital tool as a basis for further testing. The work packages will proceed in parallel.

Phase 3a: Sourcing, developing, testing, and measuring the integrated digital solutions to meet defined user needs in a proof-of-concept study

Proof-of-concept testing of the fully integrated prototype digital solution to demonstrate a benefit on identified measures relevant to patient health.

Phase 3b: Extension to include health educational materials

This last phase will only proceed if Phase 3a is successful and will look to identify and include trusted sources of health educational material to further enhance patient understanding. The methodology will be developed to define how such sources may be identified, assessed, and included (either linked or embedded) within the platform and tested with users.

Ongoing: Development and execution of a sustainability plan

A sustainability plan will be developed over the life of the project, and then executed to allow the development of recommendations based on project outputs that would consider how successful concepts will be carried forward and implemented. The initial plan will be developed at an early stage of the project, and then adapted in an agile manner in response to project outcomes. Horizon-scanning/landscape mapping to allow for identification of relevant digital health initiatives will also occur during the life of the project to ensure that the project outputs can be integrated successfully into the wider digital health ecosystem. Explore future case scenarios and drive thought leadership for next generation activities relevant to product information.

References

[1] Sabate E (2003). World Health Organization. Adherence to Long Term Therapies. Evidence for Action. Geneva. WHO. Available at: https://www.who.int/chp/knowledge/publications/adherence_report/en/

[2] Medication adherence is defined as 'the extent to which the patients' behaviour matches agreed recommendations from the prescriber' and thus illustrates the importance of the patients' decisions. See: Horne RWJ, Barber N , Elliot R , et al. Concordance, adherence and compliance in medicine taking. Report for the national coordinating centre for NHS service delivery and organization R & D (NCCSDO), 2005. http://www.netscc.ac.uk/hsdr/files/project/SDO_FR_08-1412-076_V01.pdf

[3] Viswanathan M, Golin CE, et al. Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review, 4 Dec. 2012. https://doi.org/10.7326/0003-4819-157-11-201212040-00538

[4] Health literacy entails 'people's knowledge, motivation and competencies to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course'. Sorensen K et al. (2012), Health literacy and public health: A systematic review and integration of definitions and models BMC Public Health 12:80 https://doi.org/10.1186/1471-2458-12-80