IHI Call Days | Call 9

AI and Digital Health Platform for Clinical Research

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Links to the IHI brokerage platform:

- Proposal sharing tool: Link to Proposal
- Participant profile: Link to Participant profile

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Challenges and objectives

- **The problem**: Coping with the increasing amount of data sources and data volumes generated by various novel technologies and medical procedures has become a major challenge for today's healthcare sectors. It has led to complex data management processes and significant resource burden to conduct clinical research, as well as patient-centric medical care.

- **Matching IHI SO3**: demonstrate the feasibility of people-centred, integrated health care solutions

- **Unmet public health need**: The fragmented data silos and digital technologies in healthcare. Lack of the insights from patients to make regulatory and health technology assessments.

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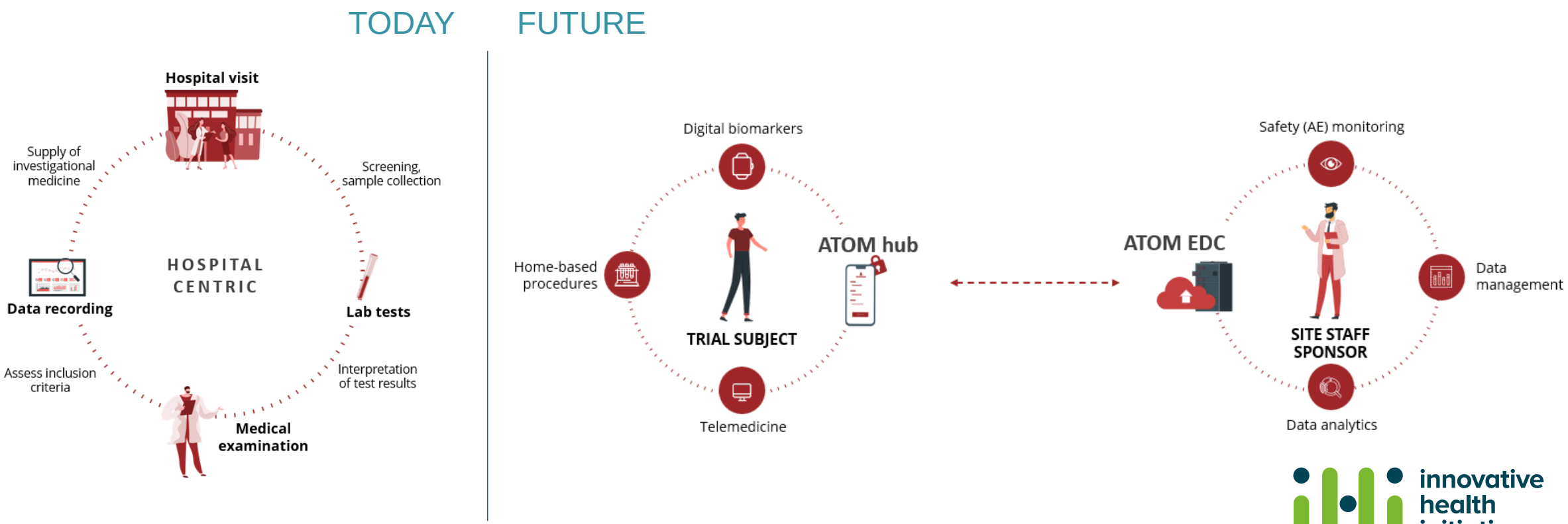
Our approach

- Implementation of a Digital Health Platform with Patient APP and AI/ML capabilities for Advanced Clinical Research Data Collection



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Is our project suitable for IHI?

- The harmonization of medical data collection and analysis requires close collaborations with all major players in the healthcare sectors, including research organizations, patient groups, hospitals, pharma/biotech, medical device companies and regulatory agencies (EMA/FDA).
- The accelerated development of novel therapeutics, innovative digital health technologies and smart medical devices lowers the barrier of bringing novel diagnostic or treatment options to the public.
- With the patient-facing APP and AI-powered analytics, it brings the patients' voices to a central position of the medical care. It also enhances patients' awareness of health condition and contributes to the disease prevention.
- The platform aggregates trial data and medical insights overtime, providing valuable Real-World Evidence (RWE) for HCPs, biopharma, medtech, and digital health industries to further optimize their treatment solutions.

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Outcomes and Impact

- The expected outcome will be a patient-centric, AI-powered digital solution to accelerate the development process and clinical research required for novel diagnostic or therapeutic products.
- The successful outcome of the project will speed up the translational research of innovative medicine and closing the gap of bringing a novel treatment candidate from pre-clinical to clinical. This will further strengthen EU's position as the leader in clinical innovations.
- The ability to efficiently delivering novel therapeutic and diagnostic solutions from lab bench to market will eventually lead to the improved public health and lower the cost burden of the EU-wide healthcare systems.
- With the patient-facing APP, it not only reduces the patient's travel burden of taking part in a clinical study or a healthcare routine, but also empowers the patients to get their voices heard and their health insights integrated into the product development process. This fosters patient-centric healthcare towards the reality.

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Expertise and resources

- Expertise we will bring:
  - Fully validated, GCP/GDPR compliant data collection platform to conduct multi-data source clinical studies
  - Expertise of study design, regulatory path analysis, trial operation, data management
  - Technical capability to develop the patient app to suit the particular project needs
  - In-house AI/ML capabilities for the development of advanced analytics
- We are looking for:
  - An existing or forming consortium led by research organizations or hospitals, as well as biotech/medtech SMEs to join.

We intend to bring in-kind contributions IKOP* for the setup and operation of digital health platform to the consortium.

* IKOP - in-kind contributions to operational activities

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