Are you submitting the idea:
☐ in your personal capacity?
☒ on behalf of an organisation?

Please indicate the name of the group organisation: Mediceus SA

Please select from the list below the type of stakeholders your organization represents: Small & medium enterprise (SME)

1 Title of your idea

Please provide a short title that accurately reflects the objective(s) of your idea:
Reconciling the technical and legal requirements of the European Health Data Space

2 Scope

Explain the specific challenges/problems to be addressed by your idea and how these affect relevant stakeholders, taking into account what is already known and/or available in the field:
The proposed Regulation on the European Health Data Space presents important challenges for decision-makers, data operators, researchers, innovators, health care providers and not least patients, as its seeks to create a new operating environment for health data processing where access to the data must be enabled, without affecting personal data protection and the rights of citizens to privacy. There is a need to reconcile the citizen-centric approach of GDPR with the opportunities of the institution-centric EHDS by developing a technical solutions and a data platform which place the citizen at its centre and allow the data sharing envisioned by EHDS without compromising privacy rights.

Please indicate which IHI specific objective(s) (SO), as described in the IHI Strategic Research and Innovation Agenda (SRIA), your idea addresses:

“SO2: integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users”
“SO3: demonstrate the feasibility of people-centered, integrate health care solutions”
“SO4: exploit the full potential of digitalisation and data exchange in heath care”
“SO5: enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated health care solutions”
“SO1: contribute towards a better understanding of the determinants of health and priority disease areas”
Please select the keywords that are most relevant to your idea:
"Disease management"
"Digital health"
"Health technology"
"Diagnosis"
"Detection"
"Prevention"
"Prediction"
"Treatment"
"Interception"

In alignment with the IHI specific objective(s) selected above, specify the objectives of your idea:

EHDS proposes two essential networks, MyHealth@EU for easy access to health data by citizens and health care professionals, for the purpose of treatment (the primary use), and HealthData@EU to enable researchers to create new scientific knowledge for better treatment, more effective products, better public health policies and better health care treatment (the secondary use). While the citizen keeps control of its data for primary use, the proposed regulation on the EHDS does away with individual consent for secondary use, which was required by GDPR. Even if the final Regulation, now being evaluated by member-states, re-instates the need for consent for secondary use, the need remains to reconcile, at the technical level, the various features of GDPR and EHDS.

The objectives of this idea are to promote:
1. The creation of consortia in the health space and academia where working models of a GDPR-compliant and EHDS-compliant health data platforms may be designed, developed, tested, implemented and rolled out.
2. The creation of cryptographic methods which enable selectably reversible and irreversible data anonymisation. User data identification, deidentification and reidentification are all needed to fulfill the objectives of EHDS, but present specific technical hurdles which can be overcome.
3. The development of new software tools, sensors and mobile applications, all connected to a common data repository where the user has a unique anonymous identity across the various systems, and where vital new information for the anonymous person's health revealed by scientific research projects, can be traced back and communicated to its owner.
3. The creation and funding of communications campaigns to invite citizens to adhere to EHDS en masse, through the accurate description of its benefits to health and the identification of the privacy preserving measures adopted, so as to create an atmosphere of trust in the system and respect for the citizen.
4. The creation of post-graduate courses in data science applied to health, so that Europe becomes the leader in the creation of scientific knowledge derived from the large-scale processing of health and wellbeing data.
3 Expected impacts to be achieved by your idea

Briefly describe the expected impacts to be achieved by your idea, ensuring that they contribute to IHI general and relevant specific objectives, as described in the IHI SRIA:

**Impacts** are wider long-term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments. Impacts generally occur sometime after the end of the project, e.g. successful implementation of digital solutions supporting people-centred care.

**IHI general objectives:**
1. contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations;
2. foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contribution to ‘Europe’s Beating Cancer Plan’;
3. drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.

IHI General objectives:
1. This project idea aims to make EHDS a success, by reconciling the citizen-centric demands of GDPR with the institution-oriented features of EHDS, with a three-pronged approach: systems and cryptography development, communicating to the people the benefits of registering with EHDS platforms, and educating our scientists and engineers in data science oriented to health data.
2. Since one of the requirements of EHDS is to make health data interoperable across borders, this means interoperability needs to start within Member-state health care providers. EHDS will demand a large investment in data formatting and data curation at the health care provider level, so that when it is transmitted to health data operators responsible for its safe-keeping, management and sharing, it is ready to be used interoperably across the European Union, both for primary use and for secondary use.
3. Specific examples of the benefits of developing a privacy-preserving eHealth system following the requirements of GDPR and the opportunities of EHDS include:
   a) Centrally storing and managing patient health records, ready to share with the anonymised data owner, the health care professional and, as part of an approved research project, with researchers, innovators, regulators and academics,
   b) Enabling parents and carers to easily manage the health data of their young children and elderly patients under their care.
   c) Offering data-based tools for Precision Medicine to the health care professional: the possibility to treat an individual patient based on the recorded outcomes of drugs and treatments prescribed in the past to other patients sharing the same diagnosis as well as having similar physical, biological, clinical, genetic and lifestyle characteristics.
   d) Enabling direct communication with an anonymised patient for fast, agile recruitment for clinical trials, where the patient meets the selection criteria for the trial.
   e) Offering unprecedented insights in the actual performance of drugs, in different levels of disease severity, in different categories of patients and in complex co-morbidity scenarios, so as to guide the physician in the best treatment strategy, and enable the pharmaceutical industry to promote their drugs based on the actual, real-world, evidence-supported performance of their products.
   f) Offering the researcher datasets, where all the legal and administrative hurdles are managed by health data operators, and the scientists can concentrate on their work.
   g) Providing curated datasets for those diseases that are data-rich, namely cancer, diabetes, cardiovascular disease and infection.

4 Why should your idea become an IHI call topic?

Explain why collaboration through a cross-sectoral and multidisciplinary public private partnership is needed in particular:

Why does it require collaboration among several industry sectors (e.g. pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging health ICT)?
Why does it require collaboration between private (industry) and public partners (e.g. academia, healthcare practitioners, patients, regulators)?

An integrated, privacy-preserving eHealth platform requires the participation and engagement of everyone: patients and health care professionals, health care providers and the health industries, academics and researchers, regulators and health authorities. All of them are brought together by health data operators, who provide the infrastructure for data storing and sharing and are responsible, as data controllers, for lawful and ethical processing. This collaboration is needed, first and foremost, because of the need of communications standards and uniform coding systems. Fortunately, there is widespread agreement on this issue and data standards, notably HL7 and FHIR are rapidly becoming established and accepted by all. Secondly, EHDS specifies data sharing which, in many cases, needs to be immediate and free of charge. The only way to have all stakeholders accept high costs without remuneration is if there are significant benefits to participation, which can be translated into lower operating costs and better efficiencies, or become sources of revenue, though the monetization of knowledge. These benefits can only be achieved through collaborative networks of all stakeholders.

Collaborations that can be envisaged include:
1. Between hospitals and all pharma, device and equipment manufacturers for large-scale, virtual clinical trials, where new products can be tested in well-controlled patient universes, as opposed to much smaller conventional Phase III trial populations of 1500-3000 patients. The precedent for this new clinical research model is to use the teachings of the Covid-19 vaccine development and approval process (42,000 patients leading to an approval in 10 months) and see how these benefits could be extended to non-emergency products.
2. Between the pharmaceutical industry and regulators, sharing clinical data almost in real-time (as was the case for the Covid-19 vaccines), in a new regulatory and legal environment where trial protocols may be dynamically adapted as a result of valuable and unexpected data being obtained during the trial. We need to aim for a development and approval process that lasts 5 instead of 10 years, but remains as safe.
3. Between academia and the scientific research community, health care professionals and public health authorities for the development of medical guidelines where the personal experience of medical experts is supplemented by real-world data.
4. Between health care professionals, the pharmaceutical industry and regulators, so that the outcome of off-label prescriptions may be systematically monitored and its benefits properly evaluated.

Why is the contribution of industry needed to achieve the expected impacts?

Contribution of Industry: Large companies that are members of the IHI industry partners (i.e. COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe) contribute to the programme, primarily through ‘in-kind’ contributions (e.g. their researchers’ time, laboratories, data, compounds). At least 45% of each project’s total costs have to be in-kind contribution.

The results achieved by the consortia described in 13.1 would be shared for the advancement of EHDS.