Topic: Blockchain Enabled Healthcare

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 pharmaceutical value chain and the extended healthcare ecosystem have many areas that suffer from complexity, a lack of transparency, coordination and trust. Examples include:

- Counterfeit medicines market estimated at EUR 160 billion with a huge impact on patient health;
- Lack of access to medicines, especially in developing countries, impacting patient health;
- Data accessibility leading to lost opportunities for improved research and new innovative medicines;
- Patient privacy considerations (patient consent) hindering clinical trial recruitment and execution;
- Lack of visibility and shared “source of truth” leading to friction and cost in development and distribution;
- Increasing risk of cyber threats, especially with central data storage and sharing;
- By addressing these challenges through a public-private consortium, the evaluation, design, and accelerated adoption of blockchain-enabled healthcare solutions across the industry can be fostered which will facilitate the delivery of true innovation benefiting both patients and the industry.

Need and opportunity for public-private collaborative research

Blockchain adoption in the healthcare industry requires consensus across multiple parties and needs to have representation from all segments of the pharmaceutical value chain to ensure end-to-end operability, scalability and connectivity. This includes but is not limited to:

- Patient representatives who will ensure patient needs are prioritized;
- Clinical parties (Investigators, labs, Clinical Research Organisations) supporting drug development;
- Health Care Providers such as hospitals, clinics, pharmacies as patient-facing organisations;
- Manufacturing and Supply chain partners including carriers, distributors, and re-packagers responsible for end-to-end product tracking and product quality;
- Health Authorities that define regulations for drug submission, distribution and data handling;
- SMEs (Small and Medium-sized Enterprises) including technology vendors with expertise and capability to realise blockchain technology solutions;
- Academia to support advancement in computer science and medical innovation.

By combining forces in a public-private consortium, an effective solution utilising blockchain can address the challenges mentioned above.

Scope

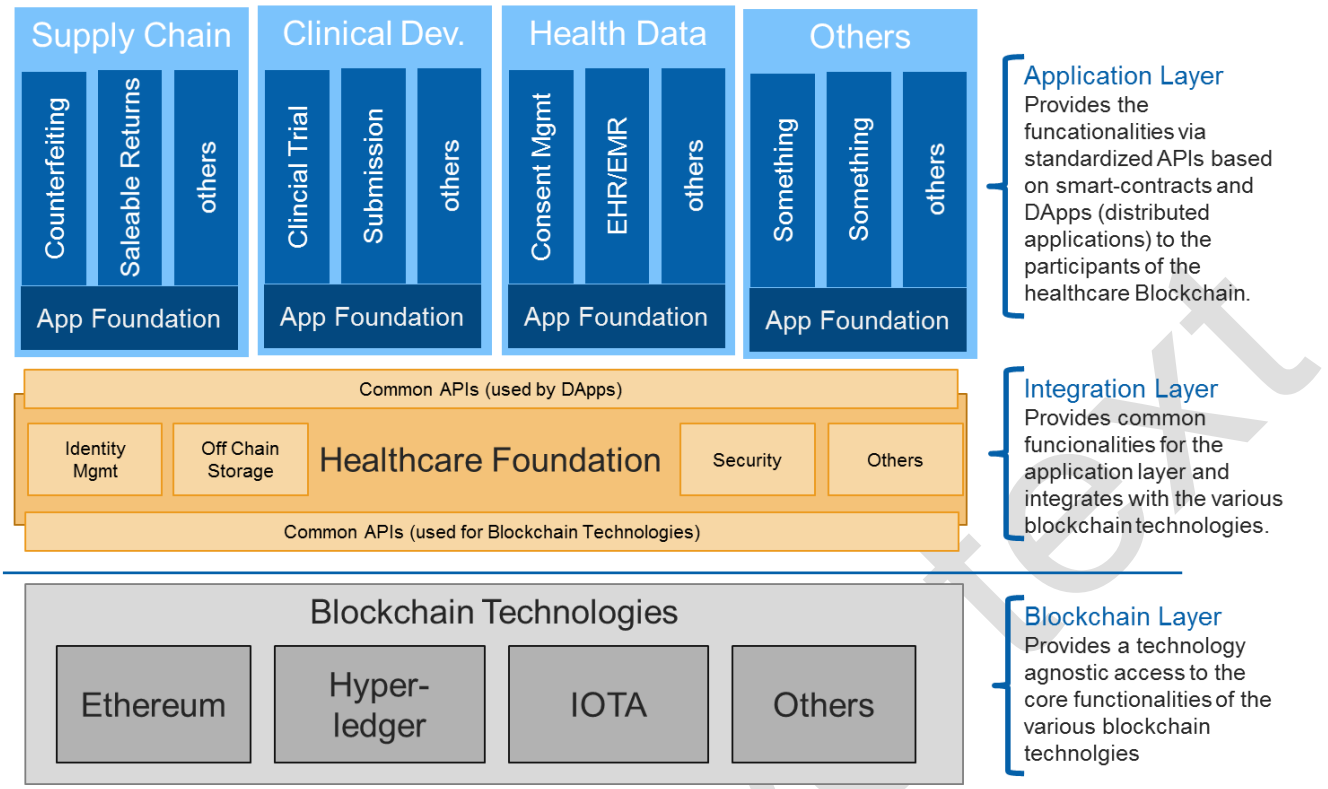
The overall objective of the agile project generated by this topic is to establish a common blockchain ecosystem for pharmaceutical development, manufacturing, and distribution that provides an incentive and serves as the basis for all participants to engage, adopt, and benefit.

The project will initially establish an effective governance organisation and approach to enable continuous improvement and open competition among service providers while ensuring that critical factors such as data integrity, privacy, regulatory compliance and efficiency are built into a “Healthcare Foundation,” which serves as an integration layer between underlying blockchain technologies and business application layer (see architecture diagram).

The project aims to drive the agile delivery of use cases prioritised by clearly defined business value, benefits (return on investment, ROI) and feasibility. Use cases fall into the domains of Supply Chain, focusing on supply chain integrity and efficiency, Clinical Development, focusing on clinical trials and submission, and Health Data, which among others should enable blockchain-based machine learning data marketplaces. A likely focus for prioritised delivery is enabling end-to-end product tracking with blockchain technology to address the issue of counterfeit medicines. The initial technology deliverable is an architectural framework enabling such factors as digital identity management, efficient consensus mechanism, off-chain storage, global scalability, security, and high performance. Other use cases can be added based on a value analysis during the project lifetime and proposals from the selected applicant consortium. The scope includes a reference implementation of the solution but does not include specific industry partner implementations.

The project envisions a future state where application of blockchain technology extends beyond use cases in scope as an enabler for digital transformation of the industry. Therefore, the project deliverables must ensure scalability after the project has finished and ensure sustainability of the solutions.

The following diagram depicts the high-level architecture of the three-level blockchain-enabled healthcare system:



Expected key deliverables

Comprehensive project planning and preparation coupled with an agile methodology will enable accelerated delivery and realisation of benefits. At this time, the intention is that all deliverables are public, in order to increase credibility through transparency, one of the core benefits of blockchain itself.

- **Governance**. Formalisation of an independent governance model with equitable representation by all participants for oversight accountability to enable sustainability, and the continuous improvement of the healthcare blockchain framework. This deliverable is framework (not project) governance;
- **Business Use Cases**. Definition of common requirements and evaluation of blockchain technology benefits for pharmaceutical value chain and healthcare ecosystem processes. Design of process, system, data and organisational model for each use case. Clearly defined business value and ROI for each use case and an agreed implementation plan based on the use case priority. The use case requirements and benefits evaluation will be completed approximately within the first six months of the project;
- **Healthcare Blockchain Standards**. Leveraging existing standards such as Ethereum, Hyperledger Fabric/Sawtooth or standardisation activities like ISO TC 307 or IEEE BCI and development of complementary standards if required. The focus is on enabling services that directly benefit patients with trusted data available in drug development and supply chain (e.g. providing data integrity in clinical trials and data transparency for patients where their data could form part of their electronic health records, consent management, trial recruitment, product authentication, provenance, updated electronic safety labelling, recalls, and drug interaction). It also includes evaluation and proposal of standards for integration of medical devices (IoT) and services on the blockchain. The analysis and requirements for new standards will be a major deliverable of the first year of the project (approximately in the first 12 months of the project);
- **Framework and Reference Implementation**. Definition and implementation of an open-source reference architecture for an industry-wide blockchain network or networks as the basis for application specific solutions such as anti-counterfeiting or clinical trials as specified in the business use cases. The project delivers an operational reference implementation of the solution to validate the design and operation;

- **Regulatory, Legal & Data Privacy**. Identification of and compliance with existing and anticipated drug development, manufacturing and distribution regulations, which could be harmonized to benefit patients and strengthen overall security and data integrity. Clarification of Intellectual Property considerations as well as legality of "Smart Contracts". Compliance with the EU General Data Protection Regulation (EU GDPR)[1] and country-specific data privacy regulations;
- **Change Management**. Includes a methodology adoption or how-to "handbook" tailored to small, medium or large industry partners. Addresses both technical and organisational components.

Expected impact

The project generated by this topic will generally position the industry as a leader in innovation and serve to improve the overall trust and reputation of participants:

- Patients will have earlier access to both the medicines they need and information of drug provenance; this will improve the overall transparency, thus trust and reputation of the industry. The supply chain will be more secure through anti-counterfeiting measures. The project will evaluate and define additional potential patient-centric services;
- Permissioned and secure healthcare data sharing will be enabled between patients, healthcare providers, researchers and other stakeholders. Patients will have full control of their health data and be able to join clinical, sensor and behavioural data into a self-sovereign 360 degree health record. Patients will be able to donate data or grant access to their data for a defined / limited time or purpose to research and real world registries in a trusted and anonymous manner. If seeking information on clinical trials, patients will have recommendations made to them based on their health profiles;
- Healthcare providers will use limited resources more efficiently by streamlining clinical trials and eliminating expenses for counterfeit and substandard medicines. Automation of processes and reliability of data will enable significant improvements to the current status quo;
- The pharmaceutical industry will benefit from widely accepted standards and demonstrated actions to ensure the integrity of drug development and distribution to the patient. Accelerated adoption of digital technology will additionally result in efficiencies across the industry with improved transparency, visibility and availability of drugs to the market. It can also better position the industry for new innovative therapies relying on the patient's own cells (Chain of Identity);
- The applicant consortium will benefit from investments in research programmes and early adoption of innovative solutions.

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

Applicants should take into consideration, while preparing their short proposal, relevant national, European (both research projects as well as research infrastructure initiatives), and non-European initiatives. Synergies and complementarities should be considered in order to incorporate past achievements, available data and lessons learned where possible, thus avoiding unnecessary overlap and duplication of efforts.

Synergies are apparent with existing consortia and the project would continuously strive to leverage existing and emerging advances wherever possible. Examples:

[1] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, OJ L 119, 4.5.2016, p. 1–88.

- **MyHealthMyData** (MHMD) http://www.myhealthmydata.eu/ is a Horizon 2020 Research and Innovation Action that aims at fundamentally changing the way sensitive data are shared. MHMD is poised to be the first open biomedical information network centred on the connection between organisations and individuals, encouraging hospitals to start making anonymised data available for open research, while prompting citizens to become the ultimate owners and controllers of their health data.
- **PhUSE Blockchain project** (http://www.phusewiki.org/wiki/index.php?title=Blockchain_Technology), started in 2017 by UCB as lead and co-lead with other companies to increase awareness of the new technology as well as a need for an initiative to accelerate the adoption of blockchain in the pharmaceutical and healthcare industries. It includes at least 17 companies (continues to grow) from pharmaceutical companies, academia, professional organisations, consulting and service companies, vendors, and patient advocate group. PhUSE is a non-profit organisation which collaborates with the FDA and EMA, and allows all participants to share and exchange information freely. The first project consists of writing a white paper to explain the characteristics of blockchain and propose at least two use cases for proof-of-concept (expected to be released in May 2018). The second project is to start piloting one of the use cases.

Industry consortium

Industry participants will provide primarily resources in the form of experts in the areas of:

- Clinical trial and drug submission experts;
- Procurement professionals experienced in supplier qualification and raw material purchasing;
- Pharmaceutical manufacturing and logistics professionals;
- Quality experts in drug development, manufacturing and distribution;
- IT Technology and integration architects, blockchain developers, project managers.

The industry consortium will leverage its membership or relationships to other pharmaceutical industry associations (distributors, investigators, laboratories, hospitals, pharmacies, payers, governments) and industry/ supply chain associations (such as GS1, IEEE, ISO, EMVO, EFPIA, GIRP, Medicines for Europe, PGEU, HOPE).

Indicative duration of the action

The indicative duration of the action is 36 months.

There will be an agile/iterative approach to assure a tight integration between the high-level requirements, evolving regulations and the rapidly maturing blockchain technology. It will also adopt a multi-speed approach to apply different timelines for different use cases depending on complexity.

Future Project Expansion

Potential applicants must be aware that the Innovative Medicines Initiative 2 (IMI2) Joint Undertaking may, if exceptionally needed, publish at a later stage another Call for proposals restricted to the consortium already selected under this topic, in order to enhance their results and achievements by extending their duration and funding. The consortium will be entitled to open to other beneficiaries as they see fit. Such further work could include additional use cases.

Applicant consortium

The applicant consortium will be selected based on submitted short proposals. Given the agile nature of the project in a rapidly evolving environment, it is very important that the consortium covers the scope of the project but does so with a manageable number of organisations/size in order to ensure consistent communications and efficient alignment. The applicant consortia must be ready to “hit the ground running” in the project without significant ramp-up or on-boarding time.

The applicant consortium must address the objectives and make key contributions to the defined deliverables in synergy with the industry consortium that will join the selected applicant consortium in preparation of the full proposal. It is also expected that the applicant consortium will include a project management capability experienced in delivery of healthcare industry, multi-disciplinary, multi-company and multi-cultural programmes (ideally with IMI programme experience).

The applicant consortium must have knowledge of the healthcare industry and processes and bring evidence of its capacity to mobilise, as appropriate, the following expertise as part of the consortium:

- Patient, Patient representatives, and Public health institutes and non-governmental agencies (i.e. World Health Organisation);
- Universities and Research Institutions: Researchers related to pharmaceutical drug development and operations and Blockchain and distributed ledger technology;
- Health Care Providers (hospitals, pharmacies, payers, governments);
- Regulatory agencies: Regulatory experts in health industry compliance;
- Solution Providers of IT technology and system integrators, blockchain developers, project managers, software and technology experts;

Applicants should bring a unique value proposition to the project but are also encouraged to leverage existing working groups, standards and solutions. Ideally the applicants have experience in blockchain technology projects and can demonstrate thought leadership with evidence (white papers, viable products, reference projects). There are numerous working groups, projects and standards that must be leveraged to the maximum extent possible (from Healthcare industry and other industries). It is not the intention to “reinvent the wheel” when existing or developing industry standards or solutions can be leveraged to avoid duplication of effort and redundancy. The principle of this project is to leverage what exists, to complement with standards that needs to be defined to enable healthcare with blockchain.

Suggested Architecture of the Proposal

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

The final architecture of the full proposal will be defined by the participants in compliance with the IMI2 rules and with a view to the achievement of the project objectives.

In the spirit of the partnership, and to reflect how IMI2 Call topics are built on identified scientific priorities agreed together with EFPIA beneficiaries/large industrial beneficiaries, it is envisaged that IMI2 proposals and projects may allocate a leading role within the consortium to an EFPIA beneficiary/large industrial beneficiary. Within an applicant consortium discussing the full proposal to be submitted at stage 2, it is expected that one of the EFPIA beneficiaries/large industrial beneficiaries may elect to become the coordinator or the project leader. Therefore to facilitate the formation of the final consortium, all beneficiaries are encouraged to discuss the weighting of responsibilities and priorities therein. Until the roles are formally appointed through a Consortium Agreement the proposed project leader shall facilitate an efficient negotiation of project content and required agreements.

The full consortium will define project aspects such as governance, guiding principles and project plan.The below architecture for the full proposal is a suggestion; different innovative project designs are welcome, if properly justified.

Work package 1 – Business Use Cases

The goals of this work package will be as follows:

Define use case strategy and build up use cases with benefit realisation and define industry requirements for each use case. Potential to have one workstream per group of use cases (e.g. supply chain, clinical development)

Deliverables

- Evaluation of **blockchain technology benefits** for pharmaceutical value chain including Good Lab, Good Manufacturing, Good Clinical Research and Good Distribution Practices (GLP, GMP, GCP and GDP);
- **Use case identification** and user story for each use case;
- **Industry requirements** for identified use cases (e.g: Counterfeiting, consent management, etc.);
- Design of process, system, data and organisational model for each use case;
- Clearly defined business value and ROI for each use case and an agreed implementation plan based on the use case priority.

Work package 2 – Healthcare Blockchain Standards & Solutions

The goals of this work package will be as follows:

Identify existing standards, develop complementary standards if required, develop specifications and build the solution with identified partners for each use case. This workstream could be split in several subworkstreams for each use case (e.g.: Supply chain solutions, Clinical Development Solutions).

Deliverables

- **Standards** which includes Identification of existing standards for each use case and creation of complementary standard as per need;
- **Standards for enabling patient-centric value-adding services** which include securing the supply chain against counterfeit medicines but also defining additional areas where patients can directly benefit from trusted data available in the drug supply chain (i.e. provenance, shelf-life expiration notifications, updated electronic safety labelling, recalls, and drug interaction);
- **Standards** for providing data integrity in clinical trials and data transparency for patients where their data could form part of their electronic health records;
- **Standards** for other solutions as per defined and agreed use cases.

Work Package 3 – Architecture Framework & Healthcare foundation

The goals of this work package will be as follows:

Provide architecture framework, design and develop the blockchain healthcare foundations. This may result in a healthcare private blockchain network to be installed by healthcare companies.

Deliverables

- Development of a **framework and a roadmap for blockchain-enablement** where there are incentives and clear benefits for patients and partners to be realized, while minimizing barriers for adoption;
- Evaluation and proposal of standards for **integration of medical devices** (IoT) and services on the blockchain;
- Definition and implementation of an **open-source based foundation** for an industry-wide blockchain network or networks as the basis for application specific solutions such as anti-counterfeiting, consent management or others.

Work Package 4 – Governance, Operating Model

The goals of this work package will be as follows:

Formalisation of an independent governance model enabling sustainability, continuous improvement and equitable representation by all industry participants.

Deliverables

- Formalisation of an independent governance model enabling sustainability, continuous improvement and equitable representation by all industry participants;

Work Package 5 – Regulatory, Legal & Data Privacy Framework

The goals of this work package will be as follows:

Define the regulation, legal and data privacy framework for healthcare blockchain.

Deliverables

- Identification of and compliance with **existing and anticipated drug development, manufacturing and distribution regulations** which could be harmonized to benefit patients and strengthen overall security and data integrity.

Work Package 6 – Culture & Adoption

The goals of this work package will be as follows:

Drive shift in mindset (e.g. “distributed ledger”) and ensure fast adoption.

Deliverables

- Collaboration platform;
- Development of a methodology for blockchain technology adoption or how-to “handbook” tailored to small, medium or large industry partners;
- Marketing campaigns and public Healthcare Blockchain events.

Regulatory strategy

As indicated above, the consortium is expected to have a strategy for the translation of the relevant project outputs into regulatory practices, regulatory, clinical and healthcare practice. A plan for interactions with Regulatory Agencies/health technology assessment bodies with relevant milestones, resources allocated should be proposed to ensure this e.g. qualification advice on the proposed methods for novel methodologies for drug development, qualification opinion.[2]

Sustainability

A plan for aspects related to sustainability, facilitating continuation beyond the duration of the project should also be proposed as part of their full proposal.

[2] See http://europa.eu/!ww84Xw

Dissemination

Applicants should provide a draft 'plan for the dissemination and exploitation of the project's results' as part of their full proposal.

Data management plan

Applicants should include an outline Data Management Plan (DMP) outlining how research data will be handled and made available during the project, and after it is completed, as part of their full proposal.[3]

[3] See http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf