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 costs 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. This 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 prioritised;
- clinical parties (investigators, labs, clinical research organisations) supporting drug development;
- healthcare 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. As the realisation and prioritisation of the use cases in the

project will depend upon their initial evaluation, the project will focus the stakeholder engagement on this evaluation.

Scope

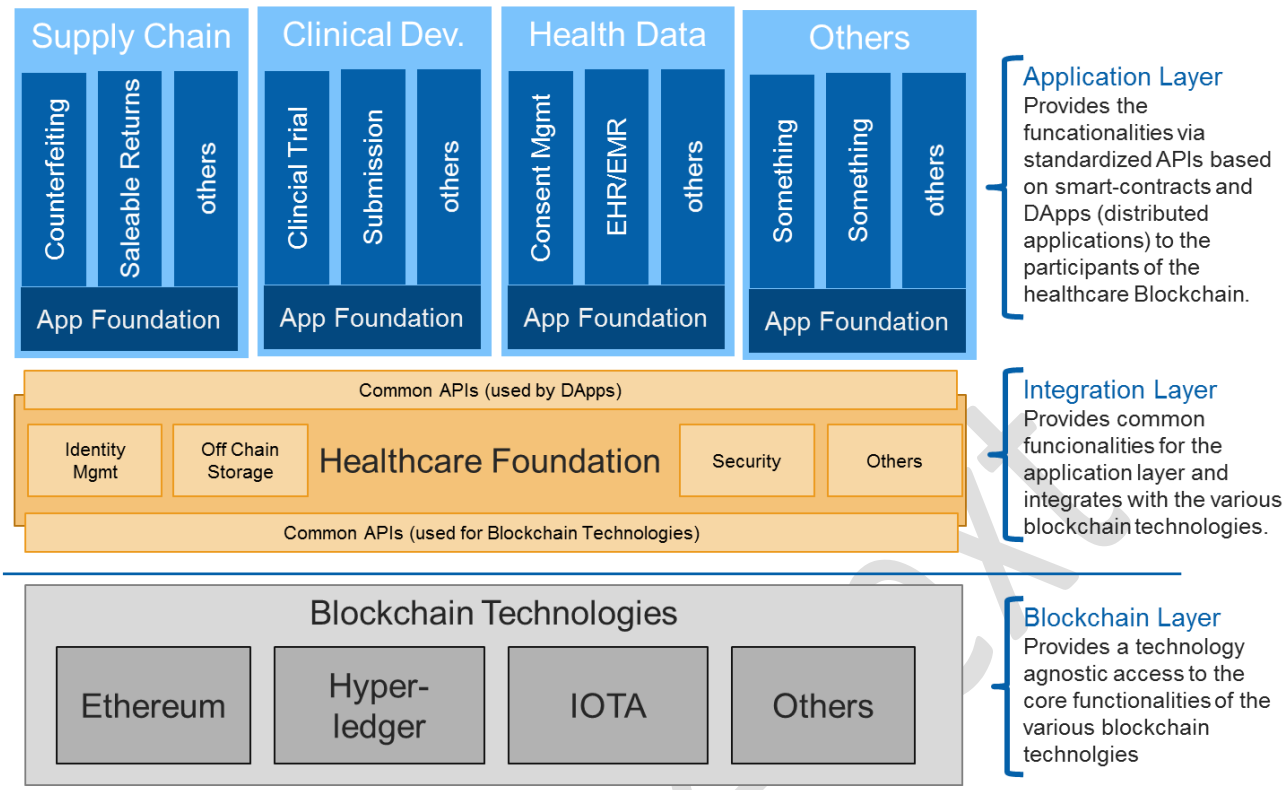
The overall objective of the agile project generated by this topic is to establish a common blockchain ecosystem for pharmaceutical development, manufacturing, and distribution that provides an incentive and serves as the basis for all participants to engage, adopt, and benefit from.

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 the 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, taking into account existing initiatives such as the proposed European Medicines Verification System. The project will also evaluate the use of medical devices across multiple use cases in order to ensure the integrity of device, data and services to enable the benefits of the internet of things (IoT). 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 the 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 by around the sixth month of the project. The evaluation serves to focus the delivery of the project and to clearly identify which use cases can benefit from blockchain adoption, and those use cases which at the current time do not provide benefit over existing technologies.
- **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 the 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 design and operation. The reference implementation will enable realisation of the prioritised use cases and serve as a foundation for future use cases. Therefore the design will ensure the sustainability of the solution beyond the life of the project.
- **Regulatory, legal & data privacy**. Identification of and compliance with existing and anticipated drug development, manufacturing and distribution regulations, which could be harmonised 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. Full realisation of the envisioned benefits will require a transformation of many core processes in organisations over several years beyond the life of the project. The project will establish a strong foundation to enable these benefits in accelerated manner. Envisioned long term benefits include:

- Patients will have earlier access to both the medicines they need and information on drug provenance; this will improve overall transparency, and with it trust in and the reputation of the industry. The supply chain will be more secure through anti-counterfeiting measures, building on the solutions designed to fulfil the Falsified Medicines Directive (FMD). 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 SMEs.

[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.

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:

- **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.
- The **PhUSE Blockchain project** (http://www.phusewiki.org/wiki/index.php?title=Blockchain_Technology) was 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 (and continues to grow) from pharmaceutical companies, academia, professional organisations, consulting and service companies, vendors, and patient advocate groups. PhUSE is a non-profit organisation which collaborates with the FDA (Food and Drug Administration) and EMA (European Medicines Agency), 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. The second project is to start piloting one of the use cases.
- The **EU Blockchain Observatory and Forum** (https://www.eublockchainforum.eu/) was launched in February 2018 as a European initiative to accelerate blockchain innovation and the development of the blockchain ecosystem within the EU and so help cement Europe's position as a global leader in this transformative new technology. The mission is to promote blockchain in Europe by mapping existing blockchain initiatives, analysing and reporting on important blockchain themes, promoting blockchain education and knowledge sharing,and holding events to promote debate and discussion

Industry consortium

The industry consortium is composed of the following EFPIA companies:

- Novartis (lead)
- Abbvie
- AstraZeneca
- Bayer
- Johnson & Johnson
- Novo Nordisk
- Pfizer
- Sanofi
- UCB

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

- clinical trial and drug submission experts; regulatory affairs experts;
- procurement experts experienced in supplier qualification and raw material purchasing;
- pharmaceutical packaging experts including specialists in artwork, anti-counterfeiting, serialisation and product tracking and tracing;
- pharmaceutical manufacturing and supply chain experts including experts in trade compliance, temperature monitoring, personalised medicine logistics;
- quality experts in drug development, manufacturing and distribution;
- IT enterprise, technology and integration architects, blockchain developers, business analysts, project managers;
- product security, information security, cyber security, compliance, data privacy, legal, risk, integrity, environmental, and financial experts.

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.

Indicative budget

The indicative EFPIA in-kind contribution is EUR 9 680 000.

Due to the global nature of the participating industry 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 8 330 000.

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. Project expansion is only considered in an exceptional case. The preferred approach is for a new, separate project.

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 the 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:

- patients, patient representatives, and public health institutes and non-governmental agencies (e.g., World Health Organisation);
- universities, research institutions and SMEs: researchers related to pharmaceutical drug development and operations and blockchain and distributed ledger technology;
- healthcare 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. This could include relevant SMEs.

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 the 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 need 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 JU rules and with a view to the achievement of the project objectives.

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

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.

Work package 1 – Business use cases

The goal of this work package will be to define a use case strategy and build up use cases with benefit realisation, and define industry requirements for each use case. There is the 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 goal of this work package will be to 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 into 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 goal of this work package will be to provide an architecture framework, and 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 realised, while minimising 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 to formalise an independent governance model enabling sustainability, continuous improvement and equitable representation by all key stakeholders.

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 to 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 harmonised to benefit patients and strengthen overall security and data integrity.

Work Package 6 – Culture & adoption

The goals of this work package will be to drive a 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, clinical and healthcare practice. A plan for interactions with regulatory agencies/health technology assessment bodies with relevant milestones and sufficient resources should be proposed to ensure that advice can be obtained on the proposed methods for novel methodologies for drug development[2].

Sustainability

A draft plan for aspects related to sustainability, facilitating continuation beyond the duration of the project should be provided in the short proposal and further detailed in the full proposal.

Dissemination

A draft 'plan for the dissemination and exploitation of the project's results' should be provided in the short proposal and further detailed in the full proposal.

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

Data management plan

A draft data management plan (DMP) outlining how research data will be handled and made available during the project, and after it is completed, should be provided in the short proposal and further detailed as part of the 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