



Webinar | IMI2 - Call 15

Blockchain enabled healthcare

17.07.2018

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Colm Carroll, IMI
- The Call topic – Marco Cuomo and Dan Fritz, Novartis
- Involvement of SMEs, patient groups, regulators – Colm Carroll, IMI
- Questions & answers

How to use GoToWebinar

Expand / minimise control panel →

Microphone status →

Full screen →

Raise / lower your hand
e.g. if you want to ask a
question orally

Send a question in writing →

The screenshot shows the GoToWebinar interface with several key elements highlighted by a red border and green arrows. At the top, there is a menu bar with 'File', 'View', and 'Help'. Below it is the 'Audio' control panel, which includes a 'Sound Check' indicator and two radio buttons for 'Computer audio' (selected) and 'Phone call'. A prominent orange 'MUTED' status is displayed, along with a dropdown menu for the transmit device (Plantronics Savi 7xx-M) and a volume slider. Below the audio controls, the current speaker is identified as 'Liz Davis'. A 'Questions' section is visible, featuring a text input field with the placeholder '[Enter a question for staff]' and a 'Send' button. At the bottom of the interface, the webinar title 'Webinar Housekeeping' and ID '608-865-371' are shown, along with the GoToWebinar logo.

How to use GoToWebinar - audio

To listen via your computer, select **Computer audio**

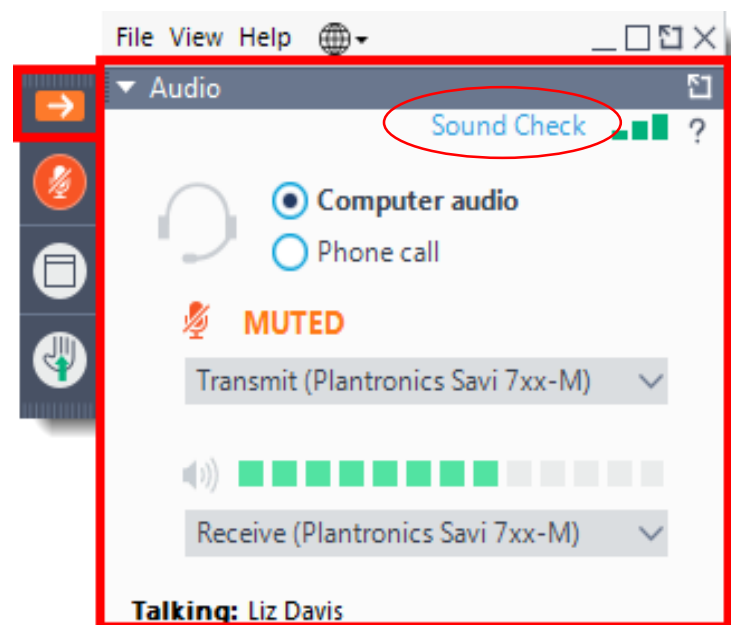
Can't hear us?

- Check your **speakers are switched on and not muted**
- Do a **Sound Check** to make sure GoToWebinar is picking up the right speakers
- Still not working? Select **Phone call** and dial the numbers given on your phone

To listen in via your phone, select **Phone call**, pick your country, and dial the numbers given

Can't hear us?

- Check you have selected **Phone call** in the audio panel
- Try **another country's** phone number
- Still not working? Select **Computer audio** and listen over your computer's speakers



Before we start...

- This webinar is being recorded and will be published on the IMI website and / or IMI YouTube channel
- Presentation slides will be published on the webinar web page
- A participant list will be circulated and published on the website
- 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.



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Blockchain enabled healthcare

Colm Carroll
IMI webinar • 17.07.2018

Today's webinar

Will cover all aspects of the Call topic

- Introduction to IMI programme
- Proposed project

Will not cover rules and procedures

- A webinar on rules and procedures took place on **Tuesday 10 July**

View the recording and download the participant list at:

<http://europa.eu/!Yg99yW>

IMI – Europe's partnership for health

IMI mission

IMI facilitates open collaboration in research to advance the development of, and accelerate patient access to, personalised medicines for the health and wellbeing of all, especially in areas of unmet medical need.

IMI 2 budget (2014 – 2024)

EU funding goes to:

Universities
Hospitals
SMEs
Mid-sized companies
Patient groups



€1.638 bn



€1.425 bn

Other
€213 m

IMI 2 total budget
€3.276 billion

EFPIA companies

receive no funding
contribute to projects 'in kind'

Associated Partners
e.g. charities, non-EFPIA companies

IMI – Ecosystem for innovative collaborations

- Allow engagement in a cross-sector, multi-disciplinary consortium at the forefront of cutting-edge research
- Provide the necessary scale by combining funding, expertise, knowledge, skills and resources
- Build a collaboration based on trust, creativity and innovative and critical thinking
- Learn from each other - new knowledge, skills, ways of working
- Take part in transformative research that will make a difference in drug development and ultimately patients' lives

IMI is a **neutral platform** where **all involved** in drug development can engage in **open collaboration** on **shared challenges**.

How a topic is generated

Industrial partners align themselves around a real challenge for industry and agree to work together **and commit resources**

New ideas from public sector, universities, SMEs etc. are needed to address the challenge

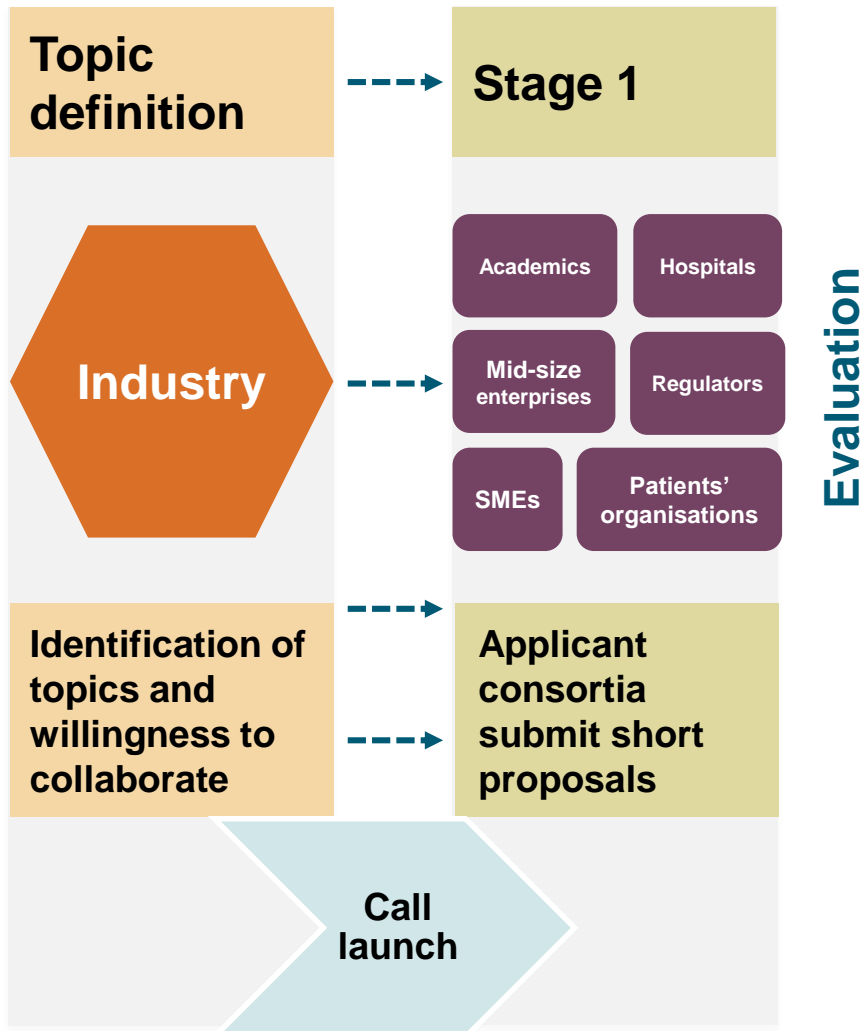
Scale is a key to success and is provided through IMI funding

Outcomes should be transformative for the industry as well as having a clear “public” value

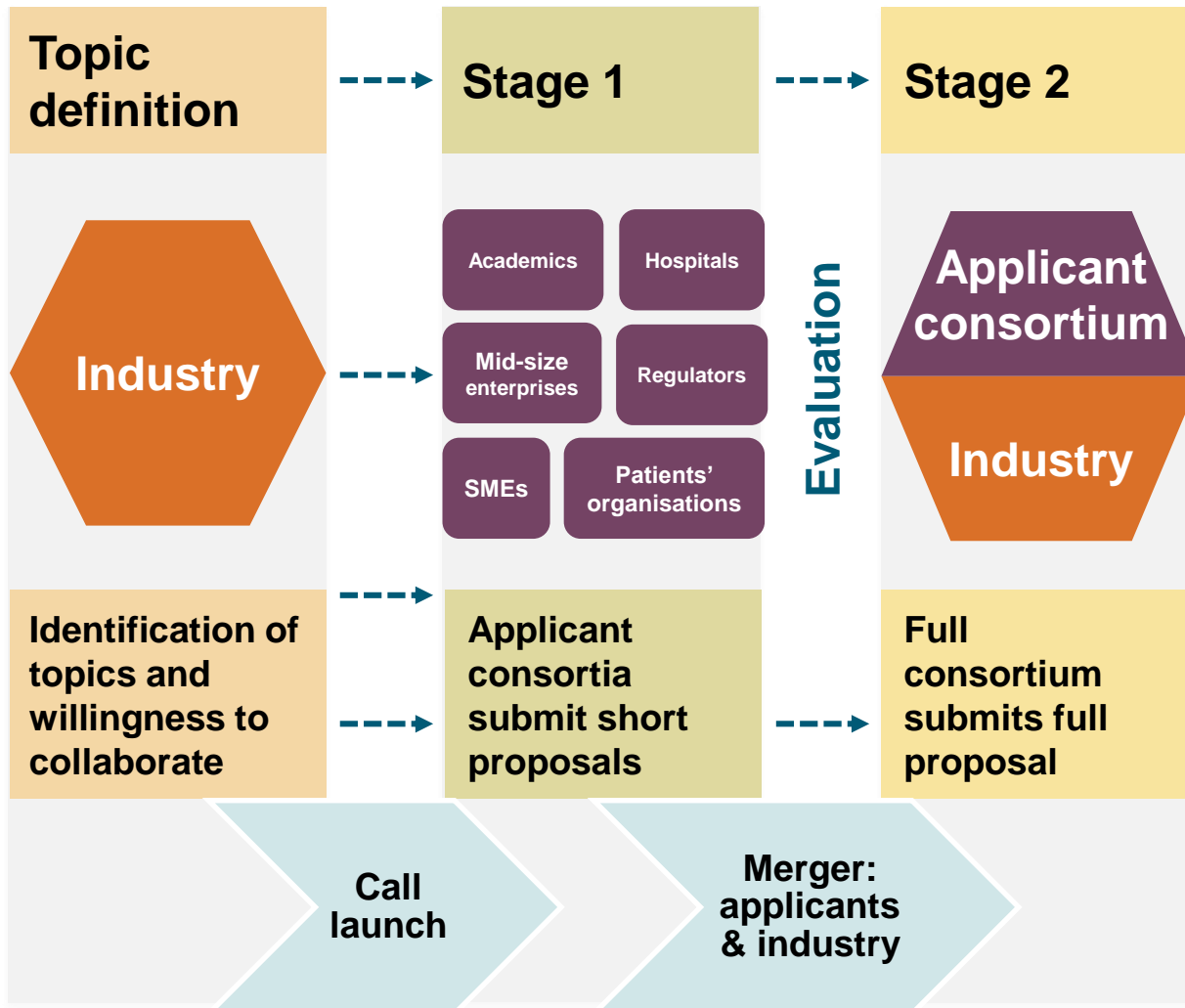
Typical IMI project life cycle



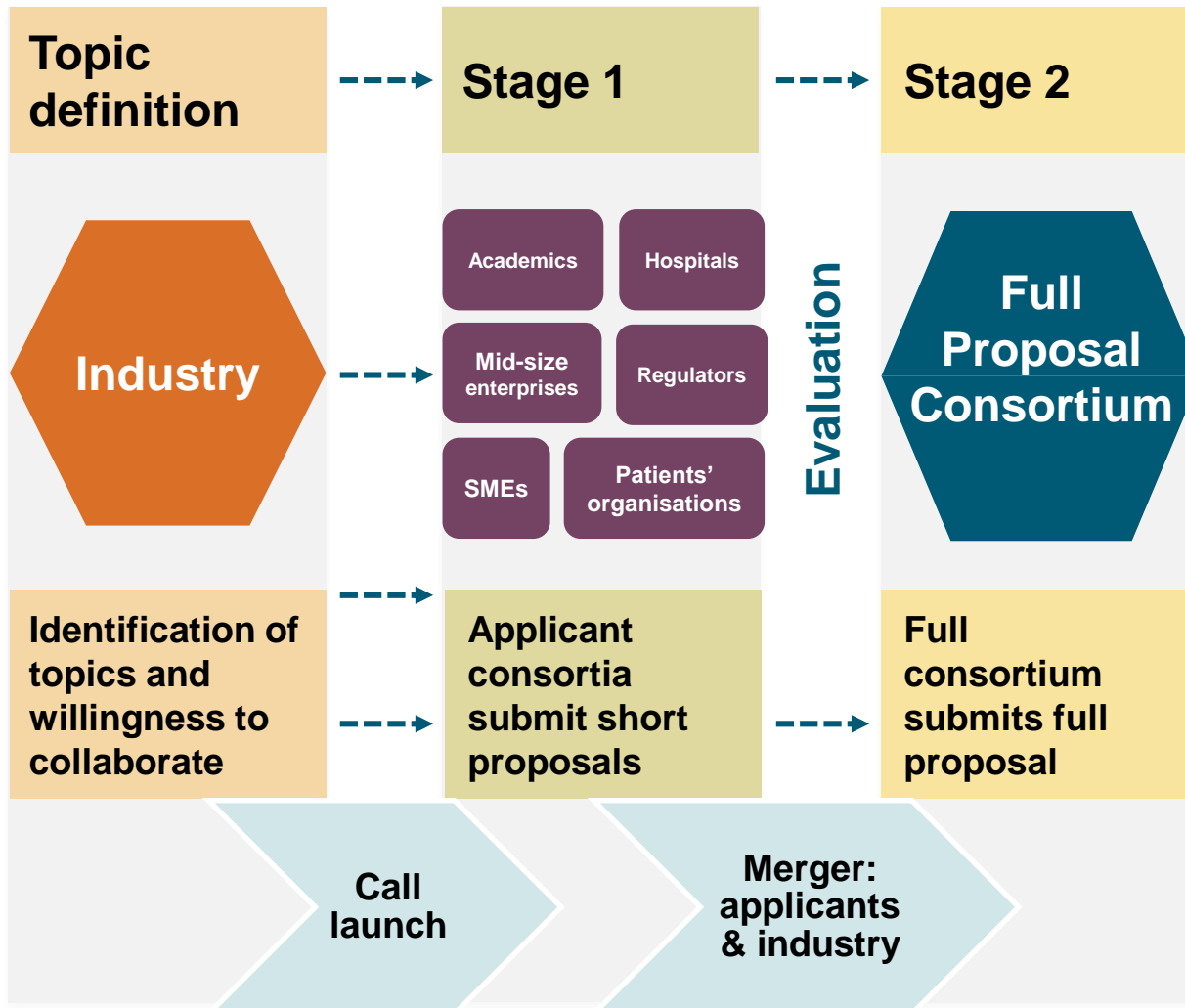
Typical IMI project life cycle



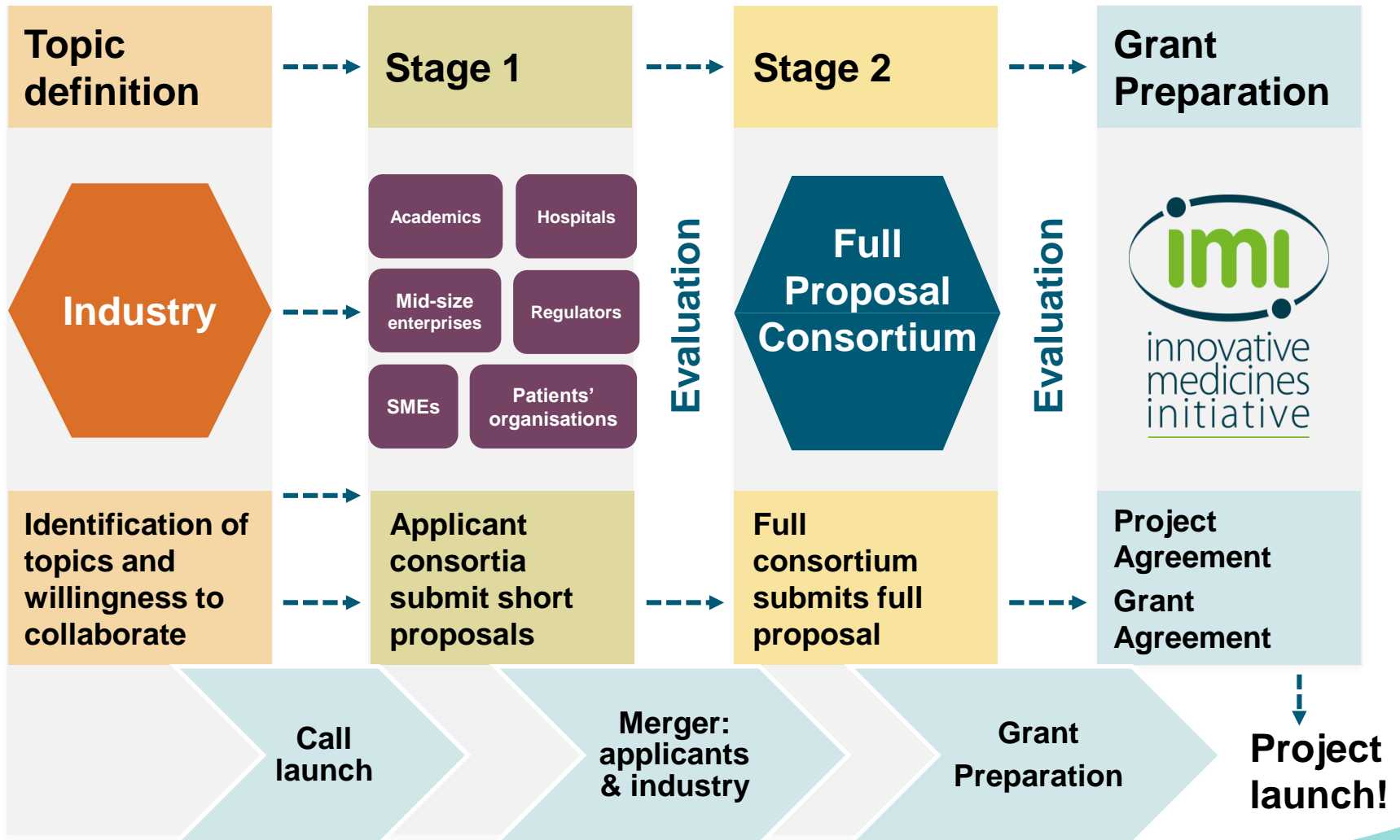
Typical IMI project life cycle



Typical IMI project life cycle



Typical IMI project life cycle



Submitting a proposal

- <http://europa.eu/!Mg84kq>

The screenshot displays the 'Participant Portal' for 'RESEARCH & INNOVATION' under the 'European Commission'. The breadcrumb trail is 'European Commission > Research & Innovation > Participant Portal > Calls'. The navigation menu includes 'HOME', 'FUNDING OPPORTUNITIES', 'HOW TO PARTICIPATE', 'EXPERTS', and 'SUPPORT'. A search bar and 'LOGIN'/'REGISTER' buttons are also present.

The main content area is titled 'Calls for Proposals' and features a 'Horizon 2020' section. A sidebar on the left lists 'EU Programmes 2014-2020' with categories like 'Search Topics', 'Updates', and 'Calls'. The 'Calls' section is expanded to show 'H2020' and other programs such as '3rd Health Programme', 'Asylum, Migration and Integration Fund', 'Consumer Programme', 'COSME', 'Internal Security Fund - Borders', 'Internal Security Fund - Police', and 'Justice Programme'.

The 'Horizon 2020' section includes a list of topics with checkboxes: 'Excellent Science' (with sub-topics: 'European Research Council (ERC)', 'Future and Emerging Technologies (FET)', 'Marie-Sklodowska-Curie Actions', 'Research Infrastructures') and 'Industrial Leadership' (with sub-topics: 'Leadership in enabling and industrial technologies (LEIT)', 'Information and Communication Technologies'). A link for 'Advanced search for topics Calls for tenders on TED' is provided.

Below the topic list, there are filters for 'Status' (checked for 'Calls with forthcoming topics', 'Calls with open topics', and 'Calls with only closed topics') and 'Sort by' (radio buttons for 'Call title', 'Call identifier', and 'Publication date'). A search input field contains 'IMI2' and a 'FILTER' button is next to it.

Proposal Template

- Available on IMI website & H2020 submission tool
- For first stage proposals, the page limit is **30 pages**.

Title of Proposal

List of participants

Table of Contents

1. EXCELLENCE	3. IMPLEMENTATION
1.1 Objectives	3.1 Outline of project plan — Work packages, and major deliverables
1.2 Relation to the call topic text.	3.2 Management structure and procedures
1.3 Concept and approach	3.3 Consortium as a whole
1.4 Ambition	3.4 Table 3.1a: List of work packages
2. IMPACT	4. PARTICIPANTS
1 Expected impacts	4.1. Participants (applicants)

Evaluation Criteria (1/2)

■ Excellence

- Clarity and pertinence of the proposal to meet all key objectives of the topic;
- Credibility of the proposed approach;
- Soundness of the concept, including trans-disciplinary considerations, where relevant;
- Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art;
- Mobilisation of the necessary expertise to achieve the objectives of the topic, ensure engagement of all relevant key stakeholders.

■ Impact

- The expected impacts of the proposed approach as mentioned in the Call for proposals;
- Added value from the public private partnership approach on R&D, regulatory, clinical and healthcare practice as relevant;
- Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges;
- Improving European citizens' health and wellbeing and contribute to the IMI2 objectives.

Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
 - Coherence and effectiveness of the outline of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and approximate budget;
 - Complementarity of the participants within the consortium (where relevant) and strategy to create a successful partnership with the industry consortium as mentioned in the topic description in the Call for proposal;
 - Appropriateness of the proposed management structures and procedures, including manageability of the consortium.

Tips for writing a successful proposal

- Read **all the call-relevant material**:
<https://www.imi.europa.eu/apply-funding>
- Begin forming your consortium **early**
Partner search tools & networking events
- Provide **reviewers** with all the information requested to allow them to evaluate your proposal
- **Finalise and submit your proposal early**
- Contact the **Programme Office** (**NOT** topic writers):
infodesk@imi.europa.eu

Common mistakes

- Admissibility/Eligibility criteria not met:
 - submission **deadline** missed
 - minimum of **3 legal entities** from **3 H2020 member & associated states** not met
- The proposal does **not address all the objectives** of the topic
- A proposal is **scientifically excellent** but will have **limited impact**
- **Complementarity** with Industry consortium not well described.

Find project partners

- Network with **your contacts**
- **Network** with fellow webinar participants
- Use **Partner Search Tools**:
 - H2020 portal: <http://europa.eu/!Mg84kq>
 - German NCP version: <http://www.imi-partnering.eu>
- Get in touch with your **local IMI contact point**:
www.imi.europa.eu/content/states-representatives-groups
- Talk to your **Health National Contact Point (NCP)**
- Network on **social media** (e.g. IMI LinkedIn group)

Participation of SMEs, patient groups, regulators

We encourage the participation of a wide range of health research and drug development stakeholders in our projects.

- SMEs and mid-sized companies
- Patient organisations
- Regulatory bodies
- Companies / organisations from related fields (e.g. diagnostics, animal health, IT, imaging etc...)



Blockchain Enabled Healthcare







Marco Cuomo and Dan Fritz
17.07.2018 • IMI webinar

Need for public-private collaboration

The pharmaceutical ecosystem have many areas that suffer from complexity, a lack of transparency, coordination and trust:

- Counterfeit medicines market estimated at EUR 160 billion
- Lack of access to medicines, especially in developing countries
- Data accessibility leading to lost opportunities for improved research and new innovative medicines
- Patient privacy considerations hindering clinical trial recruitment
- 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

Objectives of the full project & deliverables

Objectives	Deliverables
 Governance, Operating model	Formalization of an independent governance model with equitable representation by all industry participants for oversight accountability to enable sustainability, 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 organizational model for each use case.
 Healthcare Blockchain Standards & Solutions	Leveraging existing standards and development of complementary standards if required. The analysis and requirements for new standards will be a major deliverable of the first year 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.
 Regulatory, Legal & Data privacy framework	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.
 Change Management	Includes a methodology adoption or how-to “handbook” tailored to small, medium or large industry partners. Addresses both technical and organizational components.

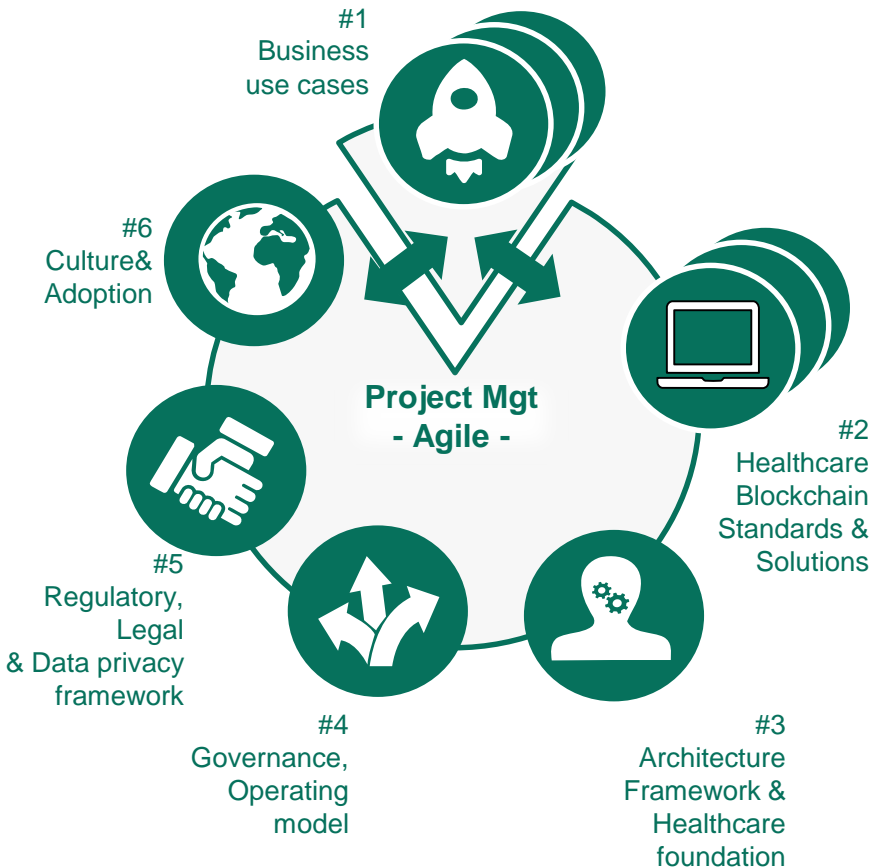
Pre-competitive nature

- Blockchain is a technology that requires collaboration to be effective
- Blockchain is about the ecosystem
- Network effect for a distributed ledger : The greater the number of users, the more valuable the technology is to all of them.
- Consortia allow companies to take advantage of blockchain network effects from day one, by providing a vehicle to create a governance structure around this collaboration, often among players that compete against one other

Expected impact (visionary)

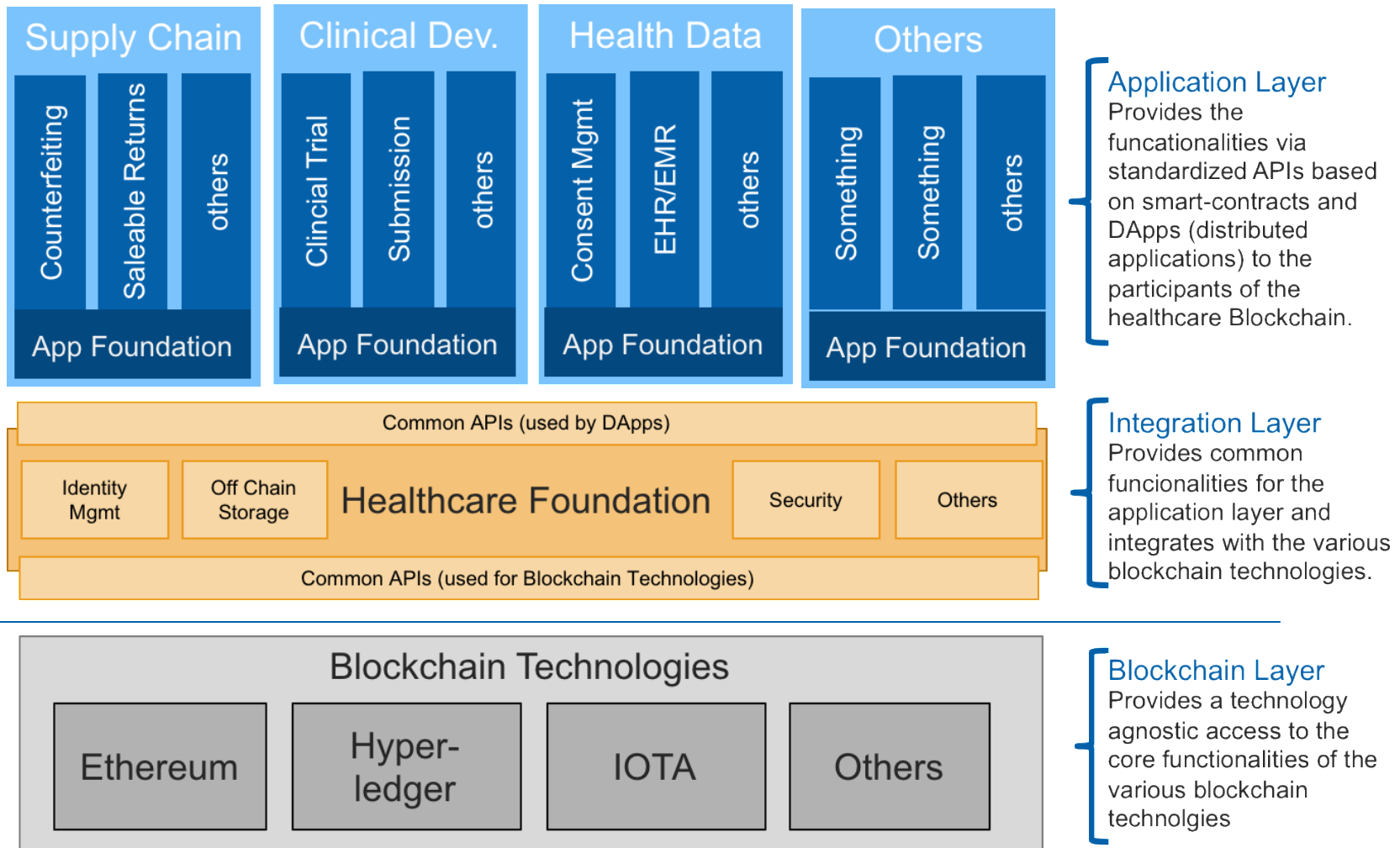
- Patients will have earlier access to both the medicines they need and information of drug provenance
- Permissioned and secure healthcare data sharing will be enabled between patients, healthcare providers, researchers and other stakeholders.
- Healthcare providers will use limited resources more efficiently by streamlining clinical trials and eliminating expenses for counterfeit and substandard medicines
- The pharmaceutical industry will benefit from widely accepted standards and demonstrated actions to ensure the integrity of drug development and distribution to the patient
- The applicant consortium will benefit from investments in research programmes and early adoption of innovative solutions

Suggested architecture of the project



- **#1** Define **use case strategy** and build up use case with benefit realization. Potential to have one workpackage per group of use cases (e.g: supply chain)
- **#2** Healthcare Blockchain **Standards & Solutions**
- **#3** Provide **architecture Framework**, design and develop the **Blockchain healthcare foundations**
- **#4** Formalization of an **independent governance model enabling sustainability**, continuous improvement and equitable representation by all industry participants
- **#5** Define the regulation, legal and data Privacy framework for healthcare blockchain
- **#6** Drive **shift in mindset** (e.g. “distributed ledger”) and ensure fast adoption

High Level Architecture Framework



Expected contributions of the applicants

- Experience in blockchain technology and can demonstrate thought leadership with evidence
- Knowledge of the healthcare industry and processes and related to pharmaceutical drug development and operations
- There are numerous working groups, projects and standards that must be leveraged to the maximum extent possible (from Healthcare industry and other industries)
- Patient, Patient representatives, and Public health institutes and non-governmental agencies must be represented

Expected (in kind) contributions of industry consortium

- Experts in various pharmaceutical areas such as Clinical trial and drug submission, regulatory affairs, supplier qualification, packaging, anti-counterfeiting, manufacturing and distribution, supply chain, etc.
- IT Enterprise, technology and integration architects, blockchain application developers, business analysts, project managers
- Product security, information security, cyber security, compliance, data privacy, legal, risk, integrity, environmental, and financial experts

What's in it for you?

- Helping patients by building the foundation
- Be at the forefront of new technology
- Defining standards for the whole healthcare industry
- Engagement with subject matter experts from the industry
- Put the power in the hand of the patient



Thank you

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@IMI_JU

Involvement of SMEs, patient groups & regulators

SME Participation

IMI encourages the participation of SMEs in applicant consortia as they can offer a complementary perspective to other organisations.

In particular, in this topic, SMEs can participate by bringing expertise in:

- researchers related to pharmaceutical drug development and operations and blockchain and distributed ledger technology;
- solution providers of IT technology and system integrators, blockchain developers, project managers, software and technology experts.

Patient Participation

There are many ways you can improve project performance by working with patients as partners:

- Ensure patient needs are prioritised
- Inclusion of patient privacy considerations (eg patient consent)
- Community outreach, dissemination and adoption

“The patient, doctor and researcher – each is a different kind of expert.”

Interactions with regulators

- **Have a plan for interaction** with relevant **milestones** and **resources** allocated, as needed
- Consider the **formal regulatory process** to ensure **regulatory acceptance of project results** (e.g. qualification procedure for biomarkers)
- Get familiar with **services offered for dialogue** (e.g. at EMA through qualification advice, Innovation Task Force, briefing meetings)
- Consider involving regulators as project participants or in the **advisory board**
- Have a plan for dialogue with **HTA bodies / payers**, if relevant

To maximise impact of science generated by projects



Engage in dialogue with regulatory authorities

More info:

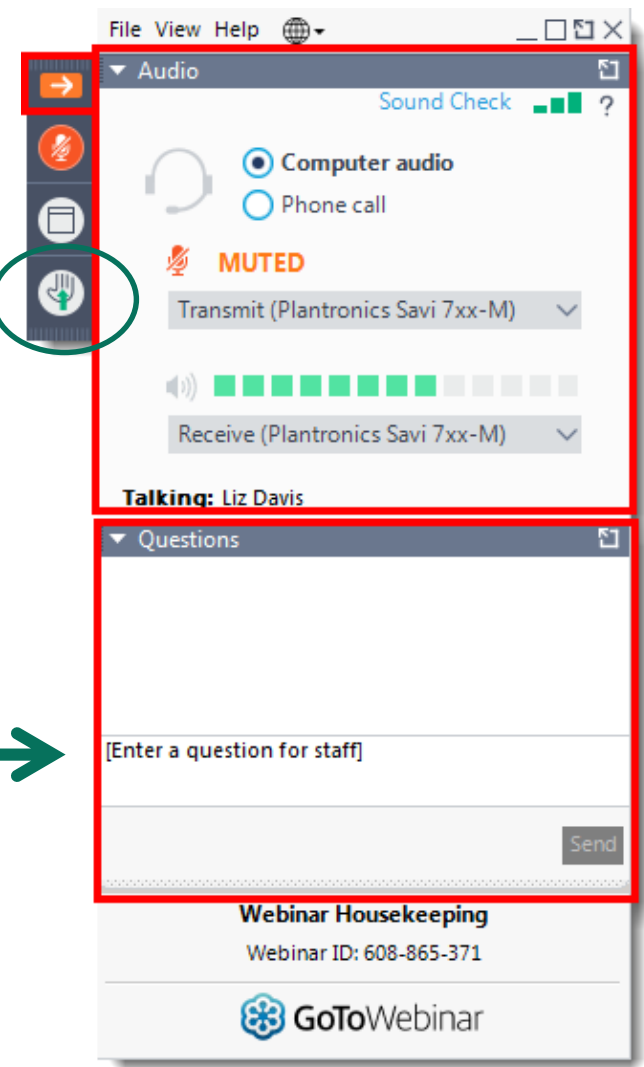
- [Webinar & presentations](#) 'How to engage with regulators EMA / FDA'
- 'Raising awareness of regulatory requirements: [A guidance tool for researchers](#)'



Questions & answers

Questions?

Raise your hand if you want to ask a question orally



Send a question in writing



After the webinar, send any questions to the **IMI Programme Office**
applicants@imi.europa.eu



Thank you!