



Webinar | IMI2 – Call 14 Centre of excellence – remote decentralised clinical trials

28 March 2018

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Colm Carroll, IMI
- The Call topic – Kimberly Hawkins, Sanofi
- Involvement of SMEs, patients, regulators – Colm Carroll, IMI
- Questions & answers

How to use GoToWebinar - audio

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

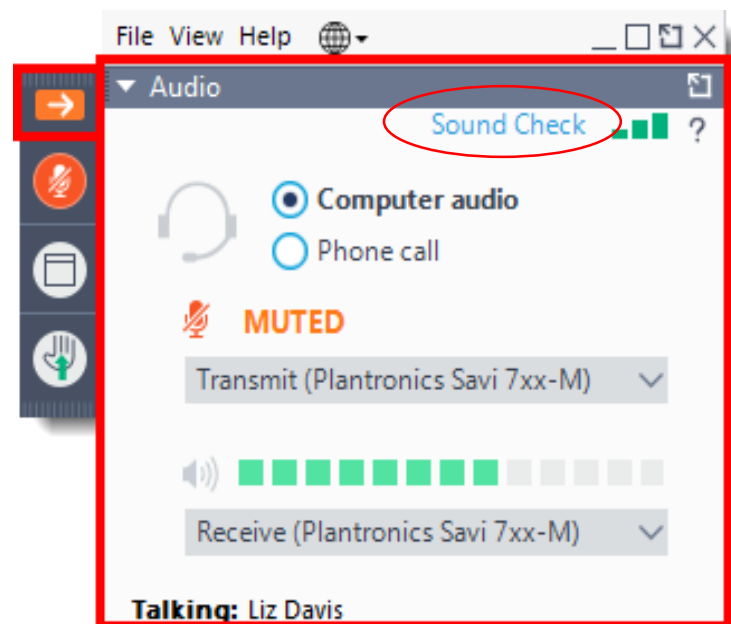
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- Do a **Sound Check** to make sure GoToWebinar is picking up the right speakers
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How to use GoToWebinar

Expand / minimise control panel →

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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:

- Expand / minimise control panel:** A red circle highlights the right-pointing arrow icon at the top of the control panel.
- Microphone status:** A red circle highlights the microphone icon with a slash through it, indicating it is muted.
- Full screen:** A red circle highlights the full-screen icon (a square with a smaller square inside).
- Raise / lower your hand:** A red circle highlights the hand icon with a green dot, indicating the hand is raised.
- Send a question in writing:** A red circle highlights the text input field containing the placeholder "[Enter a question for staff]" and the "Send" button.

The interface also displays the following information:

- File View Help
- Audio
- Sound Check
- Computer audio (selected) / Phone call
- MUTED
- Transmit (Plantronics Savi 7xx-M)
- Receive (Plantronics Savi 7xx-M)
- Talking: Liz Davis
- Questions
- Webinar Housekeeping
- Webinar ID: 608-865-371
- GoToWebinar logo

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
- IMI2 – Call 14 has been launched and all Call documents & details of how to apply can be found on the IMI website

Webinar | IMI2 - Call 14 Centre Of Excellence - Decentralised Clinical Trials

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 will take place on **Wednesday 11 April, 10:30 - 12:00**
Register [here](#)

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

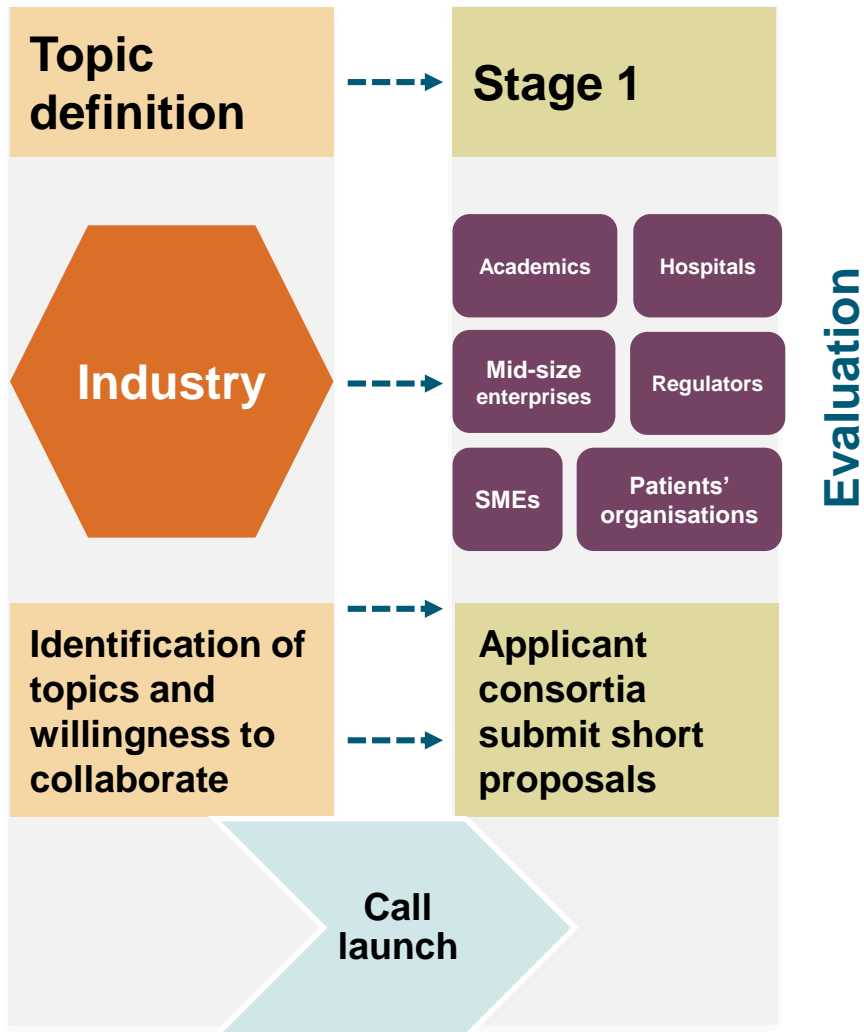
Scale is a key to success and is provided through IMI funding

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

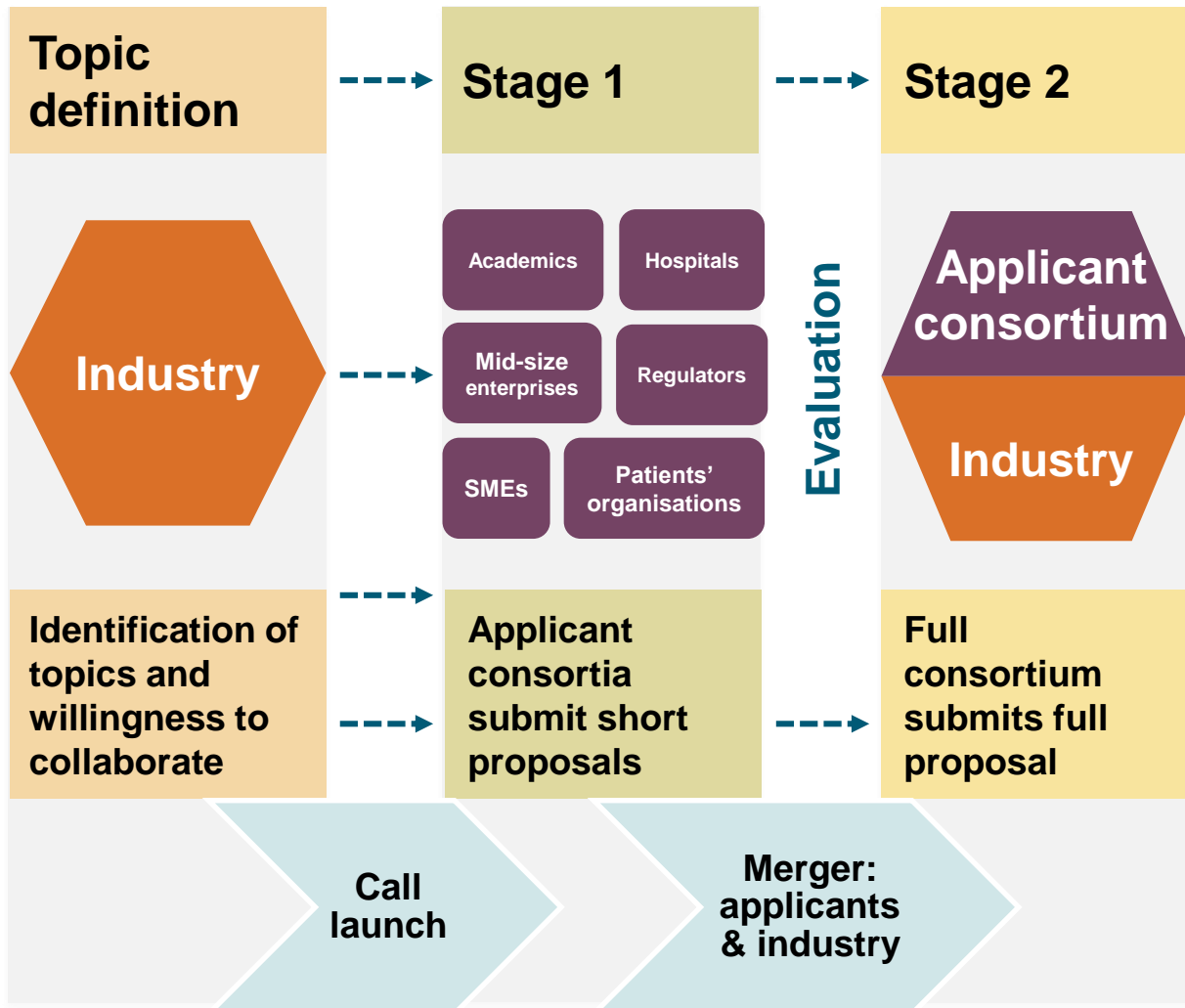
Typical IMI project life cycle



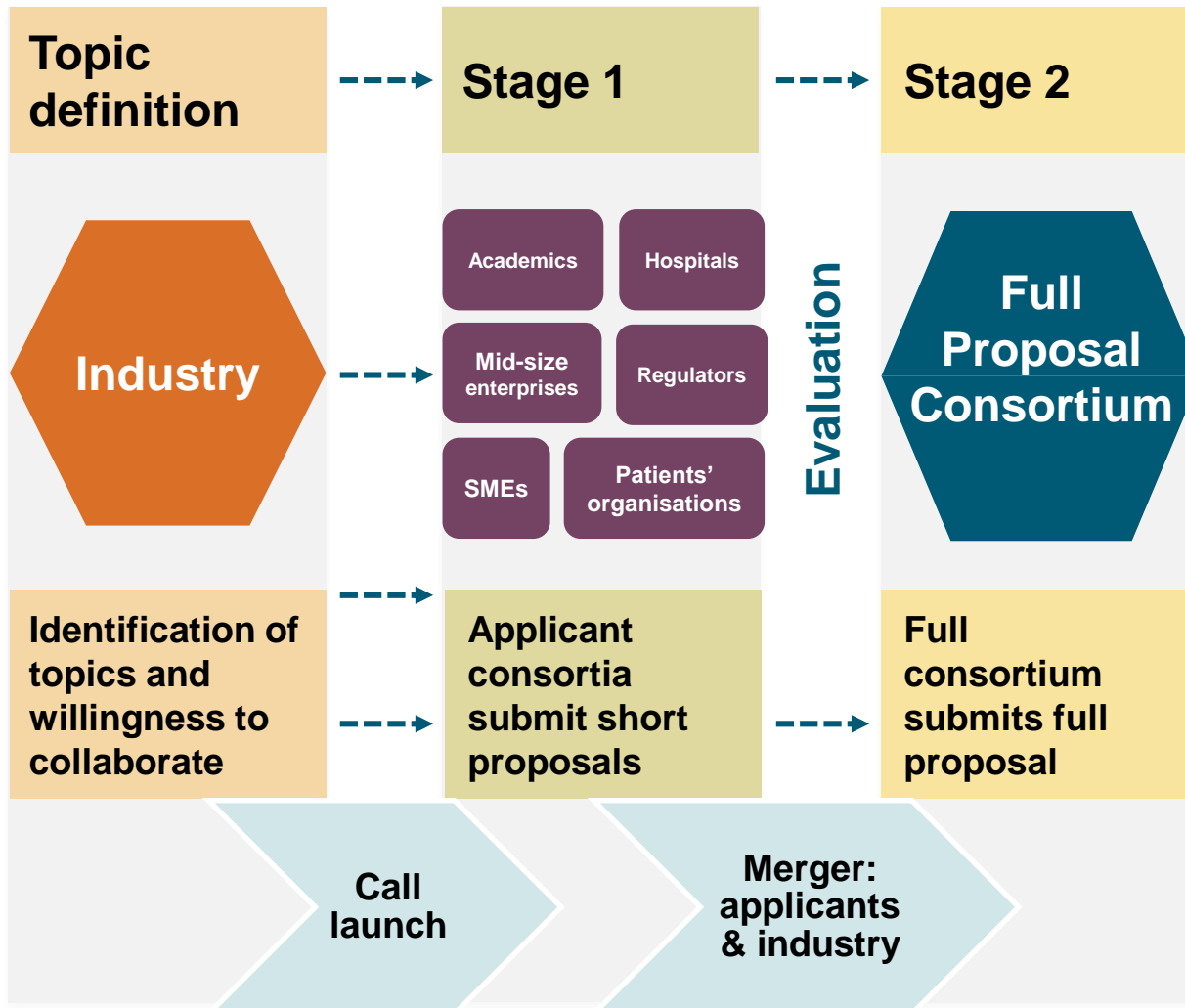
Typical IMI project life cycle



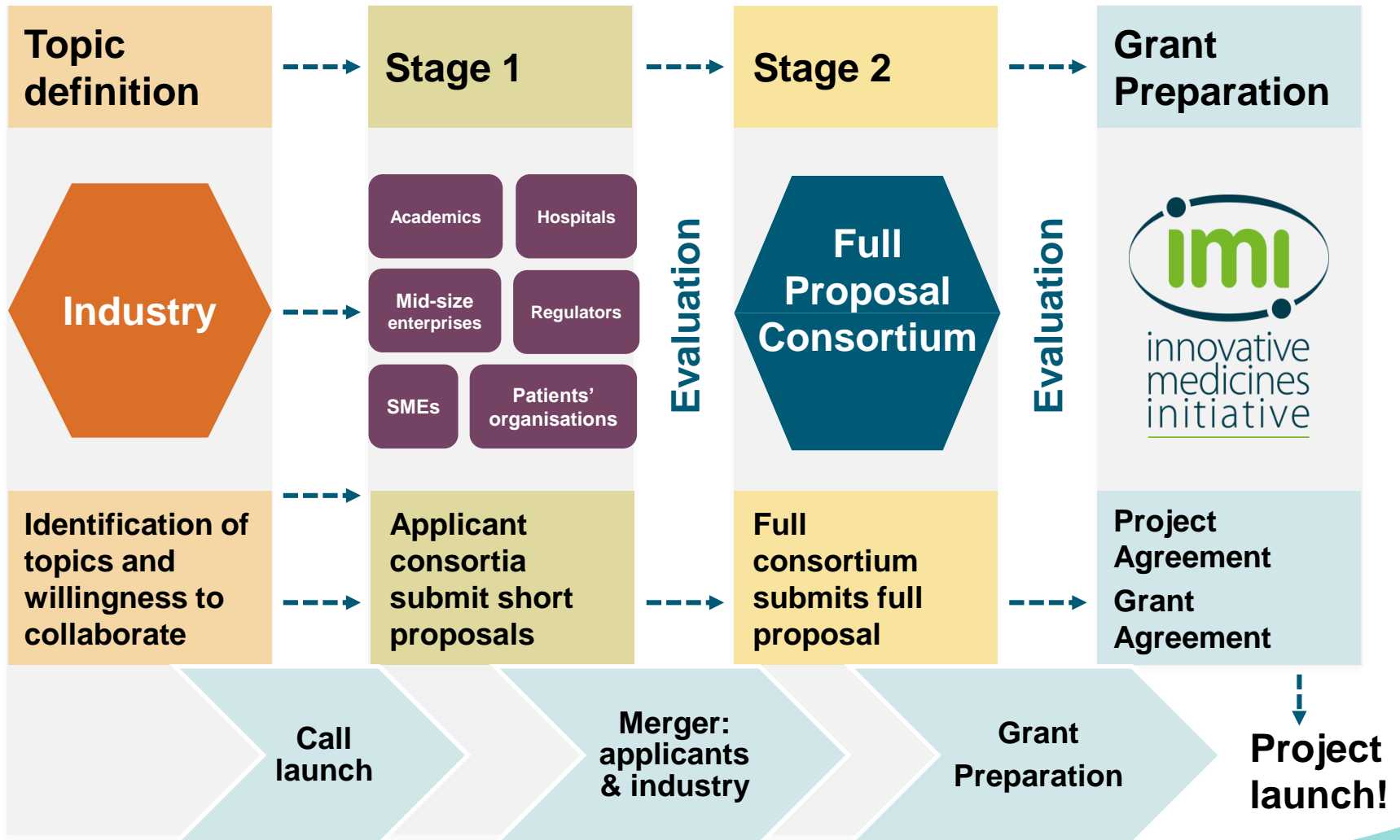
Typical IMI project life cycle



Typical IMI project life cycle



Typical IMI project life cycle



Submitting a proposal

- <http://europa.eu/!CX83GR>

The screenshot displays the 'Participant Portal' for the European Commission's Research & Innovation. The main heading is 'Calls for Proposals' under the 'Horizon 2020' banner. A sidebar on the left lists 'EU Programmes 2014-2020' with 'H2020' highlighted. The main content area features a list of topics with checkboxes: 'Excellent Science' (including ERC, FET, Marie-Sklodowska-Curie Actions, and Research Infrastructures) and 'Industrial Leadership' (including LEIT and ICT). Below this, there are filters for 'Status' (Calls with forthcoming topics, Calls with open topics, Calls with only closed topics) and 'Sort by' (Call title, Call identifier, Publication date). A search box contains 'IMI2' and a 'FILTER' button is visible.

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:
<http://www.imi.europa.eu/apply-funding/open-calls/imi2-call-14>
- Begin **forming your consortium early**:
 - Partner search tools & networking events
- Provide reviewers with **all the information requested** to allow them to evaluate your proposal
- **Submit your proposal early**
- Contact the **Programme Office** (**NOT** topic writers):
infodesk@imi.europa.eu

Common Mistakes

- The proposal does not address **all the objectives of the topic**
- A proposal is scientifically excellent but will **have limited impact**
- Necessary expertise **not fully mobilised**
- **Admissibility/Eligibility** criteria not met:
 - submission deadline missed
 - minimum of 3 legal entities from 3 member states & H2020 associated countries not met.

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)

SME Participation

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

For example, being closer to the market, SMEs can drive the tangible outputs of the project, and help ensure these outputs are sustained beyond the project lifetime and therefore help lead to faster impact on healthcare.

Therefore, where possible, include SMEs in your Short Proposal.




Centre Of Excellence Remote Decentralised Clinical Trials

Background

Developing new medicines/health solutions and improving patient health rely on the successful conduct of clinical trials to generate relevant safety and efficacy data

Recruitment and retention of patients are one of the most challenging aspects in clinical trial protocol adherence. Main barriers/hurdles are


- Lack of patients' awareness of clinical trials
- Distance to the clinical site
- The burden on patients, including the duration and number of clinical visits
- 30% dropout rate of patients who consented

 Emerging digital technology enables **Decentralised Clinical Trials (DCTs)**, a disruptive approach setting the trial around the patient rather than a centralised trial setting

Need for public-private collaborative research

Definition of DCT implementation requires broad stakeholder interaction:

- Patients
- Healthcare providers
- Regulators
- Small and medium-sized enterprises (SMEs)
- Pharmaceutical industry

 Regulatory acceptance of new approaches/updating ICH guidelines process

Objectives of the project

- Develop a clinical study approach built around the patient, during which all/most of assessments/services are organized at home
- Potential variants to the full remote approach best fitting to Europe &/or to the specific disease (e.g. rare disease)

The proposed work is based on a 3-step approach

- **Step 1:** Define the best practices for the conduct of remote DCTs using individual partner case studies (US and EU) and identify the positioning of such trials among clinical development
- **Step 2:** Analyse the EU clinical environment and accordingly upgrade the best practices for remote DCTs at EU level using the outcomes of the individual partner case studies analyzed in step 1
- **Step 3:** Design and run a pan-EU pilot remote DCT and define the positioning of full remote or hybrid model regarding clinical development
- **Transversal objective:** Contribute to the update of ICH guidelines on remote DCTs and provide recommendations with supporting tools for implementing full remote DCTs in the EU.

Expected impact

- Increase flexibility of patient follow-up during clinical trials, reducing the geographic burden both on patients and hospitals
- Increase the frequency and quality of data collection
- Improve patient recruitment and retention in trials
- Accelerate clinical research and the access of the patients to innovative therapies
- Increase the participation of more diverse populations in clinical trials
- Adapt to specific patient populations such as rare diseases where geography can be limiting to participation

Planned duration: **60 Months**

Indicative Budget: **€ 21.600.360 in-kind**

€ 19.037.000 IMI funding

Suggested architecture of the project

- Example of project architecture that could be set up

Work package 1 – Collecting and analysing study information on previous and ongoing experiences of remote DCTs (benefits, process, patient’s surveys, process data) and compilation of best practices / recommendations (liaise with WP3)

Work package 2 – Pan-EU ‘remote DCTs’ pilot (liaise with WP3)

Work package 4 – Ethics, data privacy, legal, GCP, regulatory issues and recommendations

Work package 5 – Communication, dissemination and stakeholders’ engagement in changing the paradigm of remote DCTs

Work package 6 – Project Management

Work package 3 Technologies – identification of barriers and enablers and data management

Scope and objectives of the workpackages 1/4

- **WP1 - Collecting and analysing study information on remote DCTs and compilation of best practices / recommendations**
 - defining criteria for analysing the DCTs model and processes, including the set-up, recruitment, enrolment, informed consent process, and data collection, data quality and relevance;
 - analysing process information from 'individual partner studies' (either US or EU if any) including challenges confronted and solutions
 - defining good practices and detailed SWOT on setting up
 - upgrading the 'individual partner studies' using the good practices developed in this funded action';
 - guidelines to set up the pan-EU pilot remote DCT
 - analysing protocol suitability for remote DCT including how to establish criteria for selecting trials for the remote DCT model

Scope and objectives of the workpackages 2/4

- **WP2 - Pan-EU 'remote DCTs' pilot**
 - design a pan-EU pilot using guidelines developed in WP1 and integrate & tailor the 'technology package' approved by the external review panel for the pan-EU pilot remote DCT;
 - set-up and run the pan-EU pilot remote DCT;
 - analysing process information from the pan-EU pilot to define the scientific and operational quality of the pilot and proposed optimisations;
 - refining key performance indicators (KPIs) to qualify and quantify the flow of activities in the pan-EU pilot,
- **WP3 - Technologies – identification of barriers and enablers and data management**
 - data quality and management (WP1 and 2) - activity flows;
 - assessment of a wide range of 'technology packages'
 - recommendations on technologies evaluated and data quality/data relevance;
 - propose refinement of work package 3 activities after the selection of the 'technology package';
 - tailor the technology package to be used for the pan-EU pilot remote DCT.

Scope and objectives of the workpackages 3/4

- **WP4 - Ethics, data privacy, legal, GCP, regulatory issues and recommendations**
 - continuous assessment of EU environment and the EU regulation (including digital policy, GDPR, CTR...) to be implemented for remote DCT approach;
 - ethics organisation of remote DCTs in EU;
 - defining the legal, GCP and data management for 'remote DCT' approach including data quality and regulatory acceptability of DCT approach;
 - upgrading using regulation changes;
 - stakeholders' working group to align the strategy of remote DCTs with ethics, data privacy.
-

Scope and objectives of the workpackages 4/4

- **WP5 - Communication, dissemination and stakeholders' engagement in changing the paradigm of remote DCTs**
 - interviews of stakeholders on the EU view and EU experience in remote DCTs to reassess the barriers and enablers;
 - mapping of paradigm change on patients and HCPs between current approach and induced changes in remote DCTs;
 - assess and tailor the related services of the 'technology package' for the communication activities;
 - check-list on best practices for setting-up a remote DCT in EU (public deliverable);
 - training kits for deploying pan-EU 'remote DCTs' for principal investigators, HCPs, patients, inspectors, pharmaceutical companies, clinical research organisations;
 - company providers/developers of technologies to be deployed for remote DCTs.
- **WP6 – Project management**
 - establish effective governance and internal communication;
 - fulfil the administrative tasks associated with management of this project;
 - ensure management of the 'technology package' and inclusion of new technology partners.

Contributions of the industry consortium

The industry partners will bring the following expertise:

- Clinical operations
- Clinical statistics
- Supply chain
- Telemedicine, medical technology and digital health
- Quality control and quality assessment
- Legal matters for DCT (patients' rights, data collection, data transfer, data analysis)
- Regulatory
- Public affairs
- Patient advocacy

The industry partners will bring at least 5 remote DCT case studies (either as hybrid or fully remote DCTs).

Expected contributions of the applicant consortium

- Academia, Research organisations, Clinical Centres
 - Co-design and implement remote DCT, managing trial programs that could be adapted to DCT approach
 - Academics involved in medical device development to contribute to the technology scan of the remote DCT in an end-to-end journey and the subsequent deployment within the pan-EU pilot
- SMEs
 - Experience on remote DCTs and deep expertise in Good Clinical Practice (GCP) using technology for recruiting and monitoring patients
 - Telemedicine, medical technology to contribute to the new integrated mobile environment of patients incl. expertise in data validation,
 - Experience in application of medical devices for data capture and continuous monitoring within clinical trials
 - Data management, consortium coordination and communication

Expected contributions of the applicant consortium

- Patient organizations and patient groups
 - Ensure the collaborative approach with patients in the remote DCT design and execution, as members/advisors work on guidance and patient-specific challenges
- Regulatory agencies
 - Contribute to the definition of guidance for remote DCTs and ensure the alignment with the update of ICH guidelines
- Health insurance organisations
 - Support the telemedicine approach at patients' homes

The applicant consortium should also take into account a well-balanced representation of the EU countries to ensure the set-up of the pan-EU remote DCT pilot and the wider acceptance of this model regarding EU regulation

Key deliverables of the full project

1. SWOT analysis of the barriers and enablers for the implementation of remote DCTs in EU for ethics, data privacy, regulation...;
2. Assessment of a broad technology range to enable seamless communication, data monitoring and collection from distant locations;
3. Tailored 'technology package' for running the pan-EU pilot to be deployed in the pan-EU pilot remote DCT;
4. Definition of best practices / recommendations for remote DCTs (to be implemented in the pan-EU pilot remote DCT);
5. Set-up and run the FIRST pan-EU pilot remote DCT;
6. Evaluation of the pan-EU pilot;
7. Mapping of paradigm changes in the relationships between HCPs and patients;
8. Report on changing stakeholders' roles and responsibilities and proposals from stakeholders to overcome any challenges;
9. Set of tools for remote DCT including training materials for stakeholders.

Involvement of SMEs, patients, regulators

SME Participation

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

- Experience on remote DCTs and deep expertise in Good Clinical Practice (GCP) using technology for recruiting and monitoring patients
- Telemedicine, medical technology to contribute to the new integrated mobile environment of patients incl. expertise in data validation,
- Experience in application of medical devices for data capture and continuous monitoring within clinical trials
- Data management, consortium coordination and communication

SME webinar participant list: <http://europa.eu/!uc38UJ>

Patient Participation

There are many ways you can improve project performance by working with your patient partners:

- ensure the co-design approach of patients in the remote DCT
- input into clinical protocols
- development of materials to encourage patient recruitment
- input into the wording of informed consents
- community outreach and dissemination

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

Interaction with Regulators

To maximise impact of science generated by projects



Engage dialogue with Regulatory Authorities

- Consider a plan for interaction with regulators
 - Allocate sufficient resources
- If not consortium participants, consider regulators as advisory board members
- For more info see “Raising Awareness of Regulatory Requirements: A guidance tool for researchers” available at <http://europa.eu/!mk96JR>
- Consider also plan for dialogue with HTA bodies/payers as relevant



Questions

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

A screenshot of the GoToWebinar audio control interface. The 'Audio' panel is at the top, showing 'Computer audio' selected, 'MUTED' status, and a volume slider. Below it is the 'Questions' panel, which is empty and has a 'Send' button at the bottom right. The interface also shows 'Talking: Liz Davis' and 'Webinar Housekeeping' information at the bottom, including the webinar ID '608-865-371' and the GoToWebinar logo. A red box highlights the 'Audio' and 'Questions' panels, and a green circle highlights the 'Raise Hand' icon in the audio panel's toolbar.