

# Webinar | IMI2 - Call 20

## Proton versus photon therapy for oesophageal cancer – a trimodality strategy

28/01/2020

# Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Colm Carroll, IMI
- The Call topic – Michael Schillo, Varian Medical Systems Particle Therapy GmbH; Aymeric Harmant, Ion Beam Applications SA
- Involvement of patient groups – 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:

- Expand / minimise control panel:** A green arrow points to a red circle around the expand/collapse icon (a right-pointing arrow) in the top-left corner of the control panel.
- Microphone status:** A green arrow points to the microphone icon in the control panel, which is currently muted (indicated by a red slash).
- Full screen:** A green arrow points to the full-screen icon (a square with a diagonal line) in the control panel.
- Raise / lower your hand:** A green arrow points to the hand icon in the control panel, which is currently raised (indicated by a green hand).
- Send a question in writing:** A green arrow points to the text input field in the "Questions" section, which contains the placeholder text "[Enter a question for staff]".

The interface also displays the following information:

- Audio settings: "Computer audio" is selected, "Phone call" is unselected. The status is "MUTED".
- Microphone: "Transmit (Plantronics Savi 7xx-M)" and "Receive (Plantronics Savi 7xx-M)".
- Volume: A green volume bar is shown.
- Current speaker: "Talking: Liz Davis".
- Webinar title: "Webinar Housekeeping".
- Webinar ID: "Webinar ID: 608-865-371".
- GoToWebinar logo.

# How to use GoToWebinar - audio

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

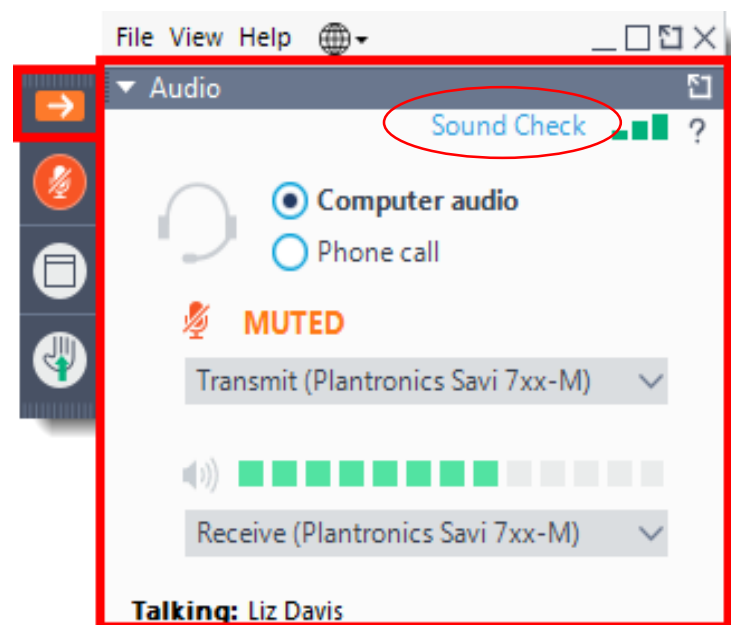
## Can't hear us?

- 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 published on the website
- IMI2 – Call 20 has been launched and all Call documents & details of how to apply can be found on the IMI website

**Webinar | IMI2 - Call 20**  
**Proton versus photon therapy for**  
**oesophageal cancer – a trimodality**  
**strategy**

Colm Carroll  
28.01.2020

# Today's webinar

## Will cover all aspects of the Call topic

- Introduction to IMI programme
- IMI Call Process
- Tips on Writing & Submitting Proposals
- Information on the Proposed Project

## Will not cover rules and procedures

- A webinar on rules and procedures will take place on **Wednesday 29 Jan 2020**

Recording will be available at: <https://europa.eu/!gX89wR>

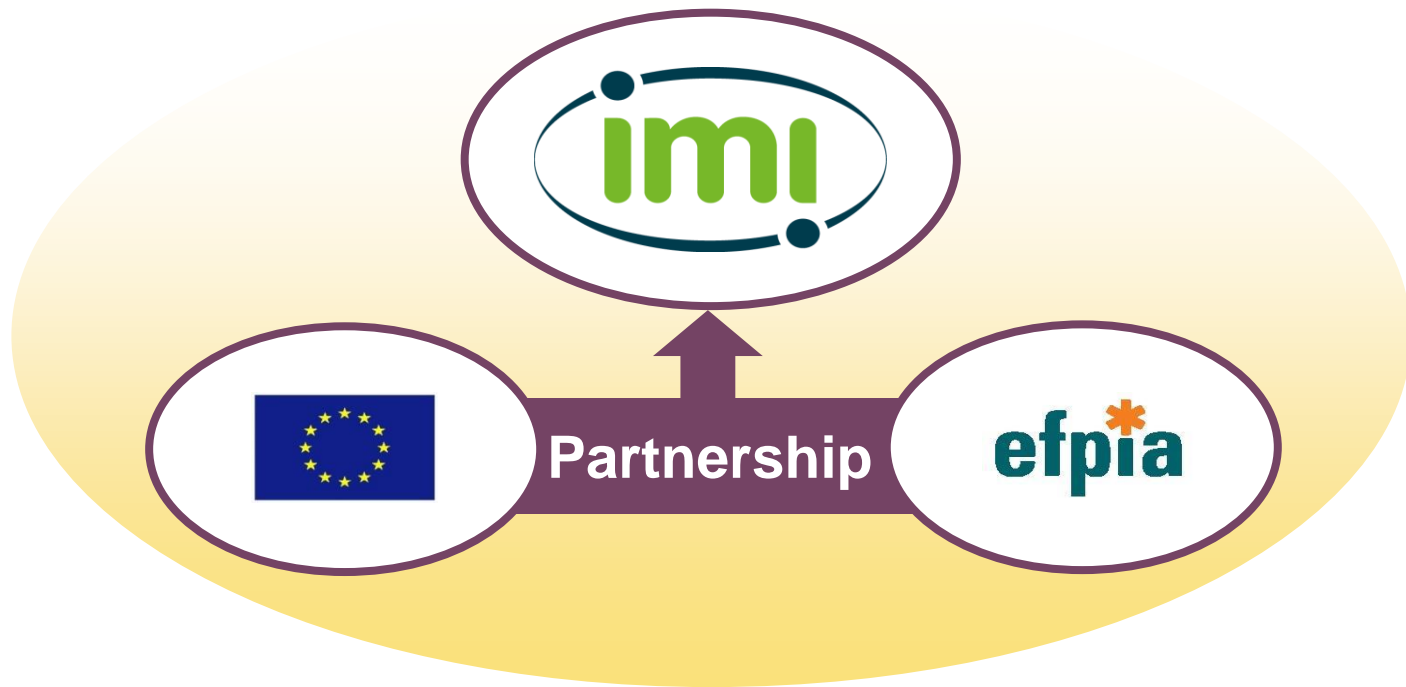
# Why is a partnership in health needed?

Because development of health technologies is still very...





# What is the Innovative Medicines Initiative?



**IMI is a platform where all involved in health technology development can collaborate on shared challenges**

# From Idea to Project: IMI2 calls for proposals

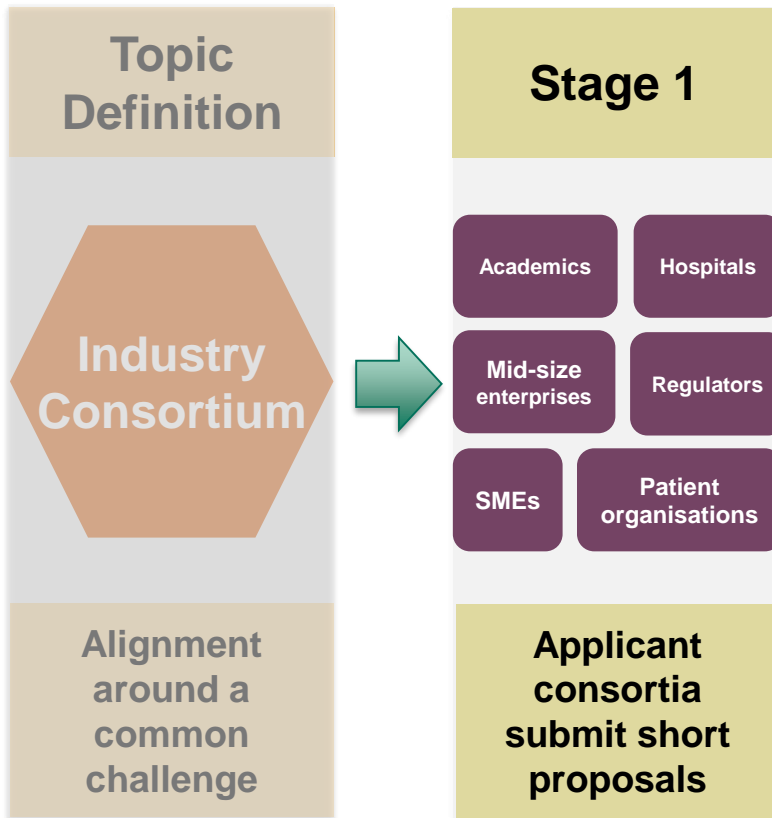
# Idea to Project: IMI2 Calls for Proposals

**Topic  
Definition**

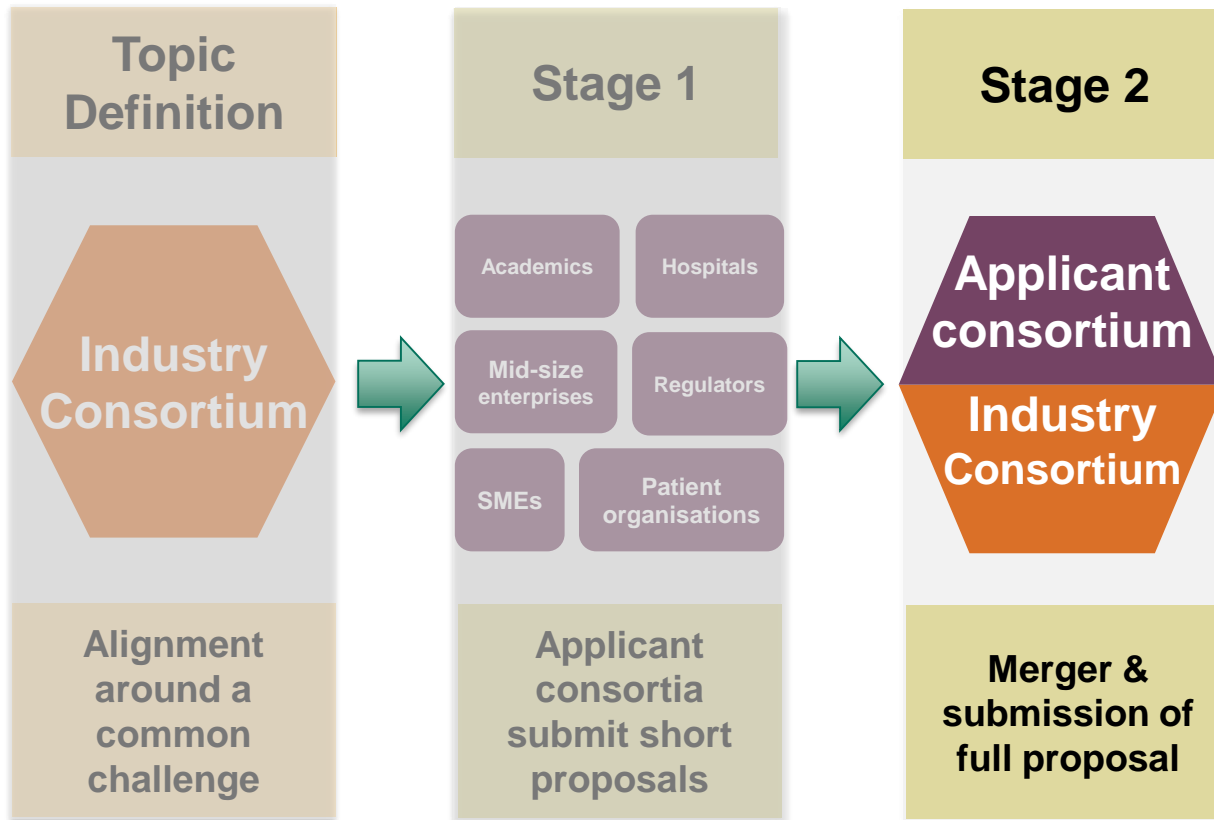
**Industry  
Consortium**

**Alignment  
around a  
common  
challenge**

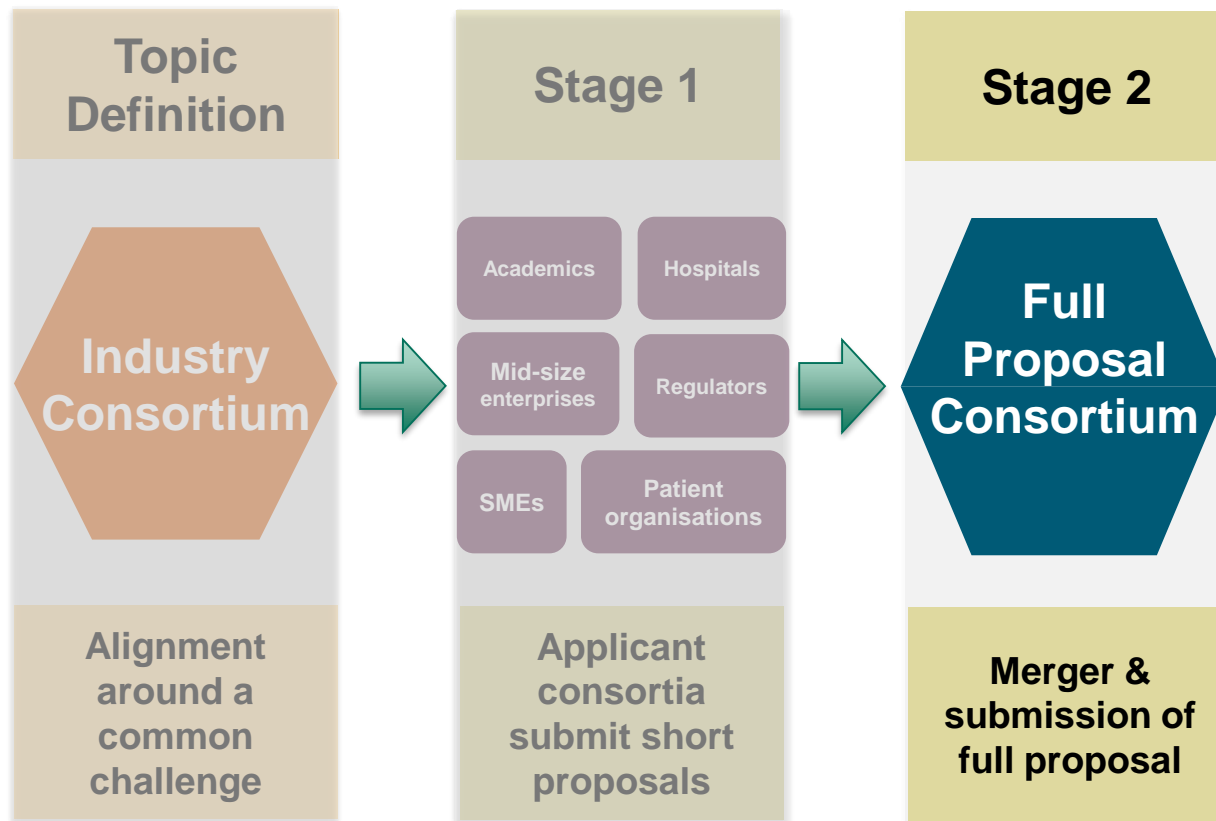
# Idea to Project: IMI2 Calls for Proposals



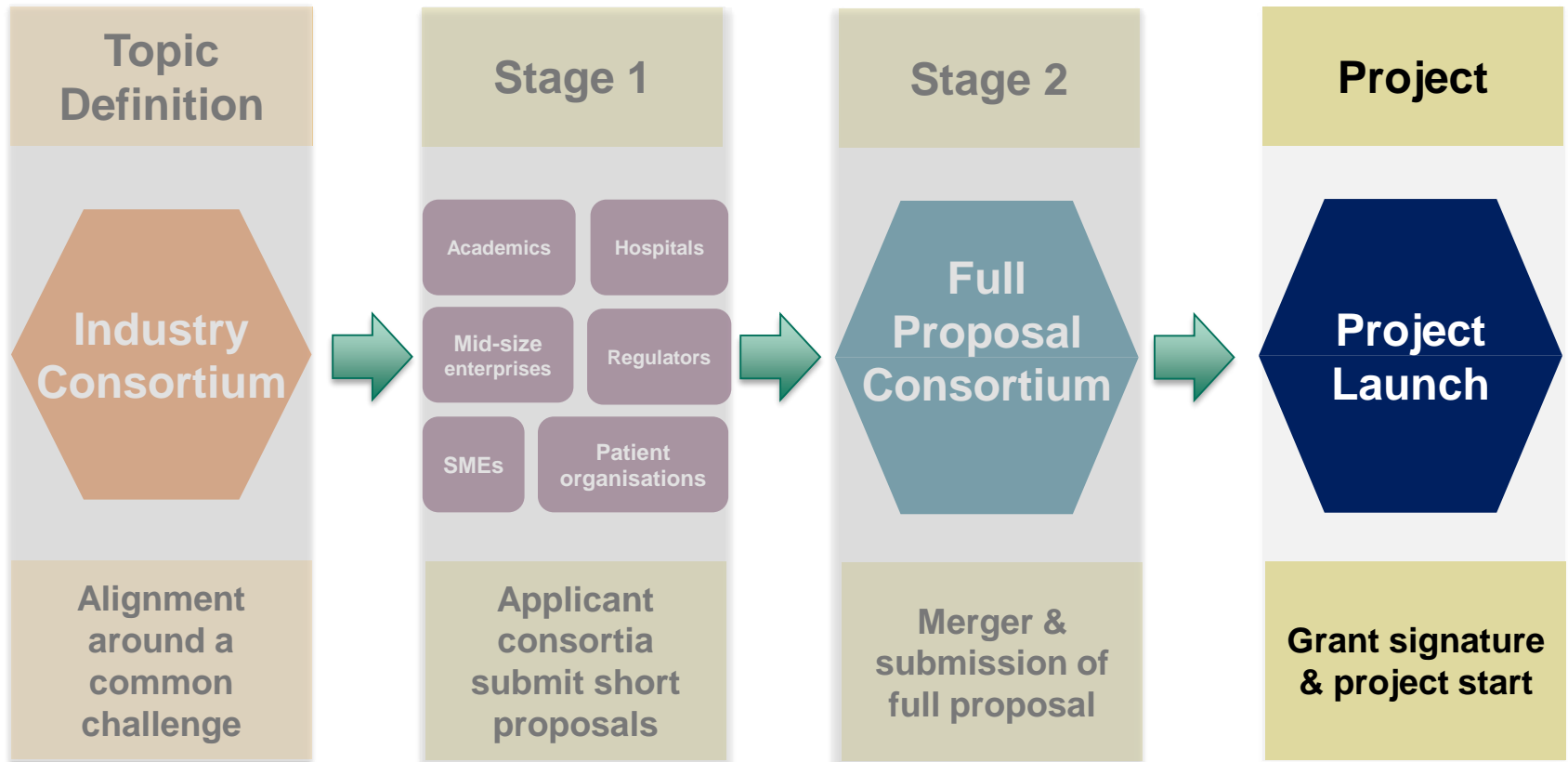
# Idea to Project: IMI2 Calls for Proposals



# Idea to Project: IMI2 Calls for Proposals



# Idea to Project: IMI2 Calls for Proposals



# Submitting a proposal

Via the Funding and Tenders Portal:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home>

European Commission | Funding & tender opportunities  
Single Electronic Data Interchange Area (SEDIA)

English EN  
Register Login

SEARCH FUNDING & TENDERS | HOW TO PARTICIPATE | PROJECTS & RESULTS | WORK AS AN EXPERT | SUPPORT

The Funding & Tenders Portal is the entry point (the Single Electronic Data Interchange Area) for participants and experts in funding programmes and tenders managed by the European Commission and other EU bodies.

Find calls for proposals and tenders

Search for proposals and tenders by key words (e.g. 'IMI2')

Search

Calls for proposals by EU Programme

|  |   |                          |   |                                      |   |                                       |  |
|--|---|--------------------------|---|--------------------------------------|---|---------------------------------------|--|
| 3rd Health Programme (3HP)                     | Asylum, Migration and Integration Fund (AMIF) | Consumer Programme (CP)  | Creative Europe (CREA)                        | Erasmus+ Programme (EPLUS)           | European Maritime and Fisheries Fund (EMFF) | HERCULE III (HERC)                    | Horizon 2020 Framework Programme (H2020)   |
| Internal Security Fund Borders and Visa (ISFB) | Internal Security Fund Police (ISFP)          | Justice Programme (JUST) | Pilot Projects and Preparatory Actions (PPPA) | Programme for the Competitiveness of | Promotion of Agricultural Products (AGRIP)  | Research Fund for Coal & Steel (RFCS) | Rights, Equality and Citizenship Programme |



# 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**

**1.1 Objectives**

**1.2 Concept and methodology**

**1.3 Ambition**

## **2. IMPACT**

**2.1 Expected impacts**

**2.2 Outline Measures to maximise impact**

## **3. IMPLEMENTATION**

**3.1 Outline of project work plan — Work packages, and major deliverables**

**3.2 Management structure and procedures**

**3.3 Consortium as a whole**

**3.4 List of work packages**

## **4. PARTICIPANTS**

**4.1. Participants (applicants)**

# Evaluation Criteria (1/2)

## ■ Excellence

- Level to which all the objectives of the Call topic text are addressed;
- Soundness of the concept and credibility of the proposed methodology;
- Extent that the proposed work is beyond the state of the art and demonstrates innovation potential;
- Appropriate consideration of interdisciplinary approaches and use of stakeholder knowledge.

## ■ Impact

- Demonstration of how the outputs of the project will contribute to each of the expected impacts mentioned in the relevant Call topic text;
- Outline of how the project plans to leverage the public-private partnership model to achieve greater impact on innovation within research and development, regulatory, clinical and healthcare practices, as relevant ;
- Impacts on competitiveness and growth of companies including SMEs;
- Quality of the proposed outline to:
  - Disseminate, exploit and sustain the project results;
  - Manage research data;
  - Communicate the project activities to relevant target audiences.

# Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Quality and effectiveness of the work plan outline, including extent to which the resources assigned to work packages are in line with their objectives and deliverables;
  - Appropriateness of the outline management structures and procedures;
  - Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role;
  - Complementarity of the participants and extent to which the consortium as whole brings together the necessary expertise;
  - Strategy to create a successful partnership with the industry consortium as mentioned in the Call topic text.

# Tips for writing a successful proposal (1/2)

- Read **all the call-relevant material**:
  - [www.imi.europa.eu/apply-funding/open-calls/imi2-call-20](http://www.imi.europa.eu/apply-funding/open-calls/imi2-call-20)
- Begin forming your consortium **early**
  - Network with **your contacts**, on **social media**, with fellow **webinar participants**
  - Use **Partner Search Tools**:
    - EU Funding & Tenders portal: <https://europa.eu/!QU87Nx>
    - German NCP partner search tool: [www.imi-partnering.eu](http://www.imi-partnering.eu)
  - **Local IMI contact point**: <https://europa.eu/!xb69Gg>
- Finalise and **submit your proposal on time**

# Tips for writing a successful proposal (2/2)

- Provide **reviewers** with all the information requested to allow them to evaluate your proposal
  - **Impact**
    - *Include **baseline, targets and metrics** to measure impact.*
    - **Outline measures to maximise impact**
      - *Dissemination, exploitation and sustainability of the results*
      - *Management of research data*
      - *Communication measures*
  - **Implementation**
    - *Describe a **strategy to create a successful partnership** with the industry consortium*

# 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
  - **Impact:** *Outline how the project will **impact on competitiveness** and **growth of companies including SMEs.***
- Patient organisations, regulatory & HTA bodies
  - **Implementation:** Describe engagement and input of relevant stakeholders (e.g. patients, health-care professionals, regulators, payers etc.) that would need to be involved to meet the project's objectives
- Companies / organisations from related fields (e.g. diagnostics, animal health, IT, imaging etc...)

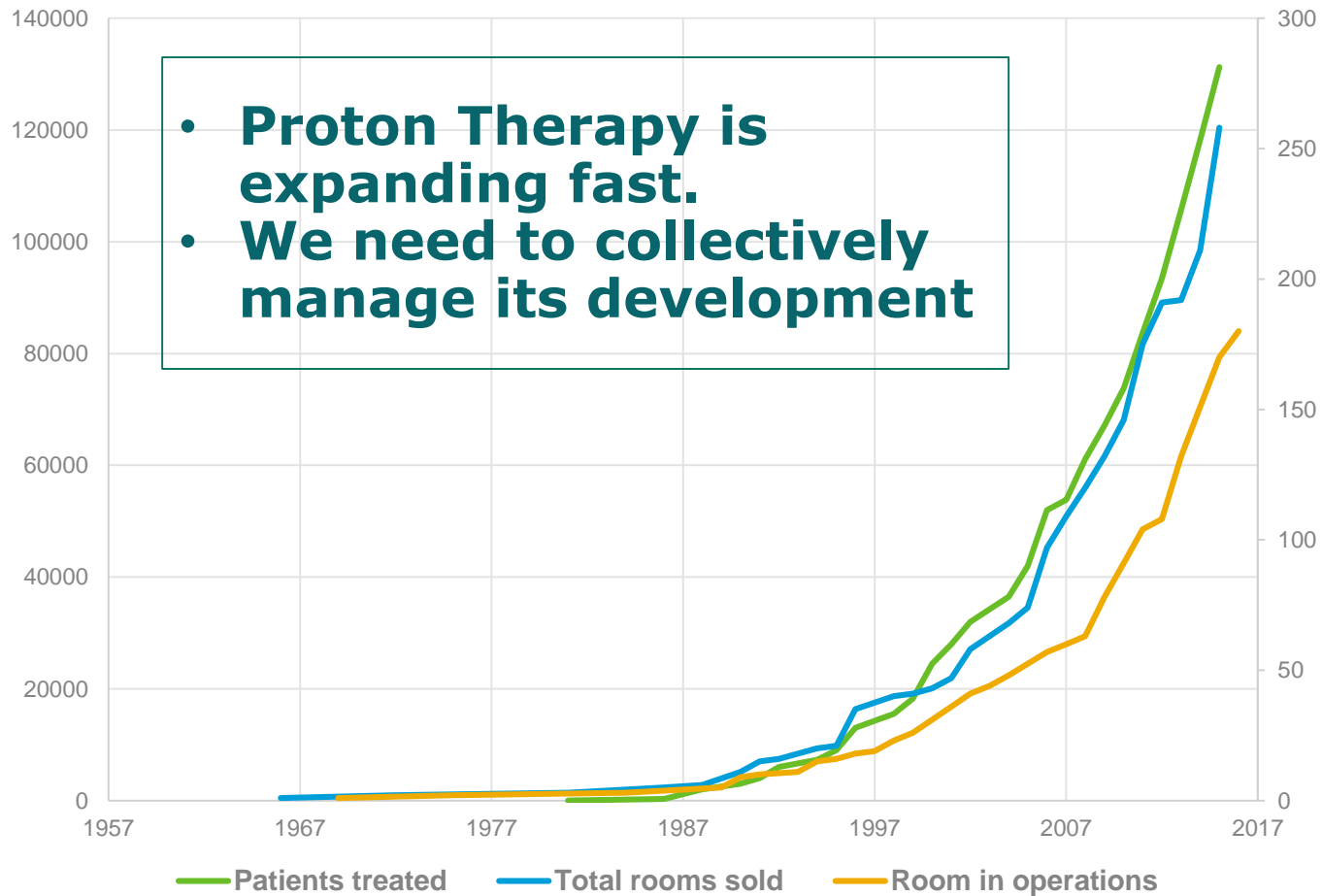
# Topic 5 Proton versus photon therapy for oesophageal cancer– a trimodality strategy

**Aymeric Harmant / Michael Schillo**

28.01.2020 • IMI webinar

# Need for public-private collaboration

## Proton Therapy Treatment Evolution





# Current Challenges on Proton Therapy

- Limited existing clinical evidence
  - Many publications but a higher level of evidence is needed
  - Stronger coordination needed between the current PT Centers (e.g. shared registry infrastructure)
- Incremental cost of PT requires scientific justification
- Well designed RCT's are needed but are challenging:
  - Rapidly evolving technology
  - Long lead times to recruit patients:
    - Many rare indications
    - Sub-optimal patient referrals
    - Equipoise
  - Very long studies needed to demonstrate the long term benefits of PT

# Current situation in EU

- Very diverse indications coverage and reimbursement in EU
  - conservative in BE Vs progressive in NL
- Difficult patient identification and selection undermining referral flow
- Limited access to PT for many patients who could benefit from it leading to a risk of Under-utilisation of PT
- Under financing of RT vs other treatment modalities in cancer care leads to under financing of PT

# Public private partnership is needed in order to provide:

- Robust evidence base to assess the potential of PT in oesophageal and other cancers, neutral and unbiased
- Multi-centre international trials to overcome current diversity of reimbursement and coverage policies across the EU.
- Public-private collaboration of proton therapy oncologists, treatment centres, software developers and equipment manufacturers in order to define a methodology in PT on a European scale.
- Inherent degree of independence and neutrality required by the highest standards in clinical research

# Objectives of the full project

- Primary objective
  - To compare outcomes between pencil-beam scanning proton therapy and intensity-modulated radiation therapy (IMRT). The study will determine if proton therapy in a trimodality (radiotherapy-chemotherapy-surgery) treatment :
    - reduces treatment-related cardio-pulmonary toxicity;
    - increases loco-regional tumour control and pathological complete response and the influence of dose escalation;
    - improves disease-free and overall survival.
- Secondary objective
  - To use the evidence generated during the oesophageal cancer study to reach a consensus on which methodology is most suitable to evaluate PT treatment for other indications.

# Scope of the project

- Study protocol proposal for:
  - non-blinded multi-centre randomised phase III study
  - pre-operative concomitant chemo-radiation and randomized between either RT or PT
  - Statistically significant number of patients
  - rapid, clinically relevant primary endpoint
- European methodology for multi-centric clinical trials in Proton

# Expected impact

- The outcome of this research is potentially practice-changing as it may define a new and improved standard for the treatment of oesophageal cancer patients and potentially patients with other cancer indications.
- The morbidity data from the study will allow better understanding of the dose-volume relationships for normal tissue complications, enabling refined selection of patients for proton therapy in the future.
- The results should allow health authorities and healthcare providers to improve the quality of care through better evidence of benefits and patient outcomes and support reimbursement decisions.

# Expected contributions of the applicants

- Expertise in **application of radiotherapy and proton therapy**
- Clinical expertise in the area of **oesophageal cancer**
- Proven ability to design and conduct relevant studies to obtain high quality clinical data
- Participating centres with the ability to include a statistically significant number of patients over the duration of the action.
- Experience in dealing with integration of multi-centre patient-derived data, as well as data-processing and management practices (e.g. privacy).
- Candidates should mention how they plan to integrate possible bias resulting from centre-specificity in the data analysis;

# Expected (in kind) contributions of industry consortium

- In-depth knowledge of proton therapy solutions, including equipment and treatment planning software
- Contribution to development of dissemination and communication materials
- Indicative budget:
  - financial contribution IMI2 JU EUR 1 500 000,
  - Stage 1 applicants should allocate **EUR 2 500 000**
- Indicative duration **60 months**



# Key deliverables of the full project

- A **study protocol** for a non-blinded multi-centre randomised phase III study
- **Annual updates** on the progress of the study to include:
  - recruitment reports;
  - data collection reports;
- A final **dataset** collected in compliance with the FAIR principles;
- A proposal for a European methodology for multi-centric clinical trials in proton therapy;
- Publications & conference presentations on the results of the study;
- Publication and active dissemination of a **summary of results** to relevant authorities (e.g. healthcare providers, HTA bodies, payers)



**Thank you**

[www.imi.europa.eu](http://www.imi.europa.eu)



@IMI\_JU



# Involvement of patient groups

# 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
  - Examples:
    - Facilitation of *“the recruitment of a statistically significant number of patients”*
    - *“expertise from oesophageal patients or patient groups in an advisory capacity would be considered an advantage.”*

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



# 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](mailto:applicants@imi.europa.eu)

