Webinar | IMI2 - Call 20
Tumour plasticity

24.01.2020

Agenda

- How to use GoToWebinar – Alessandra Paccamiccio, IMI
- Introduction – Oussama Karroum, IMI
- The Call topic – David M. Andrews & Ultan McDermott, AstraZeneca
- Involvement of SMEs, patient groups, regulators – Oussama Karroum, IMI
- Questions & answers

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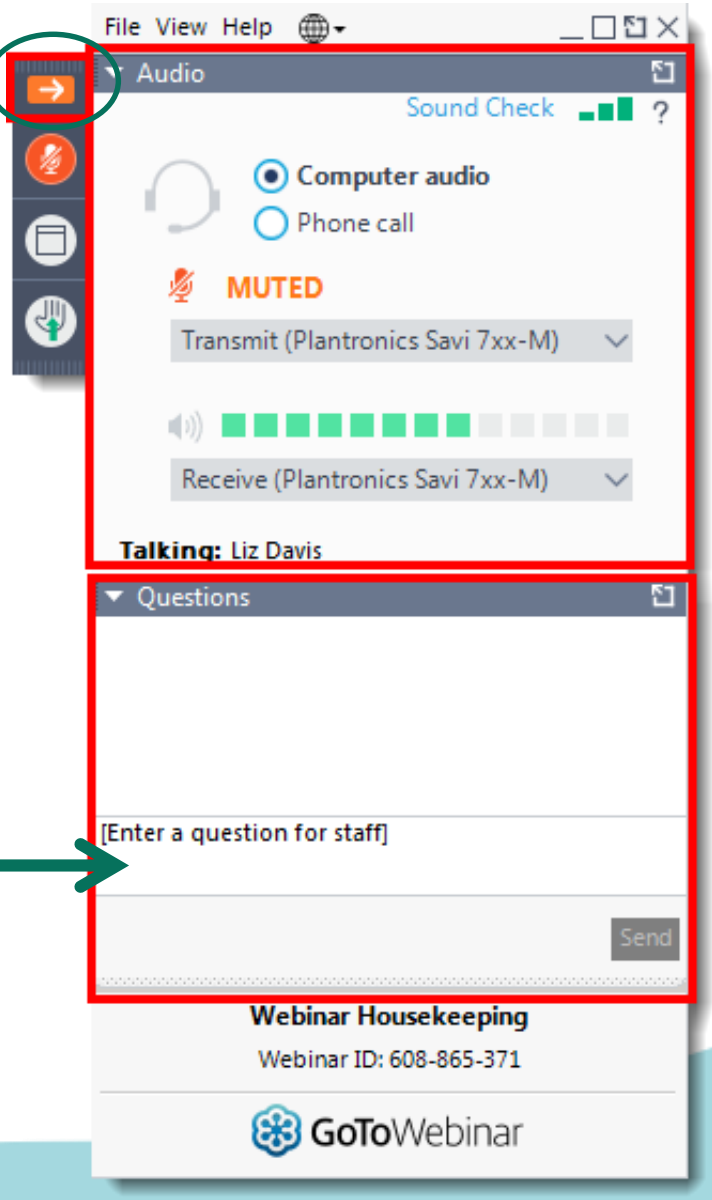

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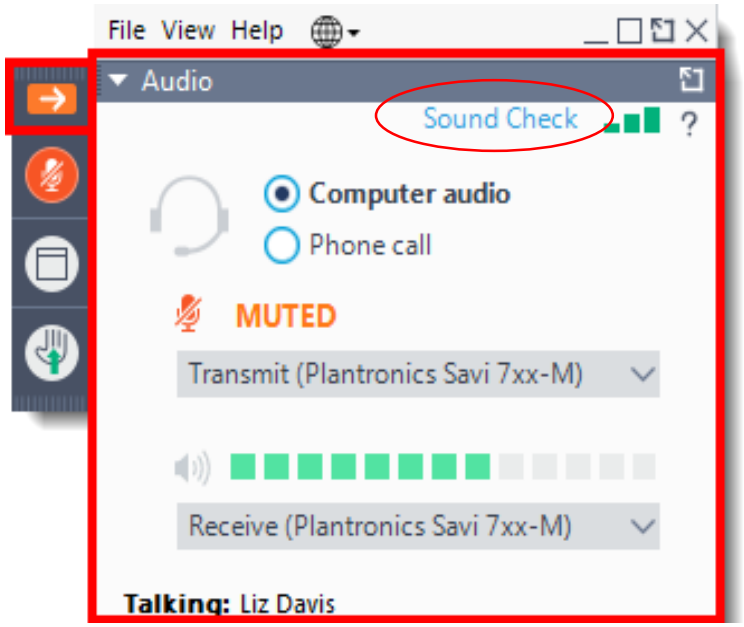

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Before we start…

- 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

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Webinar | IMI2 - Call 20
Tumour plasticity

Oussama Karroum
IMI Scientific Officer
24 01 2020 - Brussels

Today's webinar

Will cover all aspects of the Call topic

- Introduction to IMI programme
- Proposed project
  - Objectives, need for public-private collaborative research
  - Key deliverables
  - Structure of the project
  - Expected contribution of the applicants
  - Contribution of industry consortium

Will not cover rules and procedures

- A webinar on rules and procedures will take place on Thursday 29 January, 11:00 – 12:30

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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.

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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**.

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IMI partnership 2008-2020

IMI 1:

- 2008-2013
- €2 bn budget
- 59 projects

IMI 2:

- 2014-2020
- €3.3 bn budget
- More ambitious, more open, greater scope

€2.5 bn

EU contributions from FP7 / H2020

€ 2.5 bn

Pharma contributions in-kind

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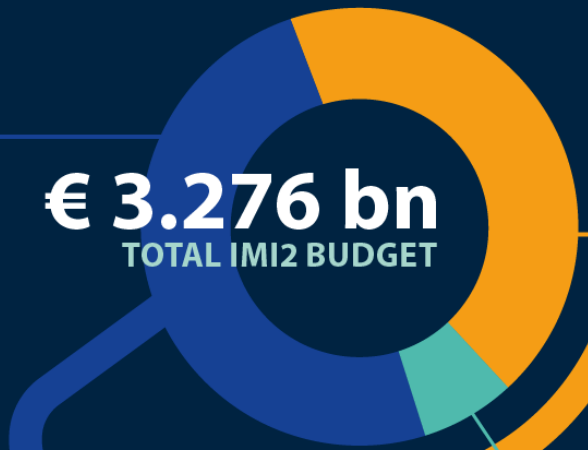
IMI2 funding
(2014-2020)

IMI FUNDING MODEL

efpia

IN-KIND PRIVATE CONTRIBUTION
€1.425 bn
EFPIA companies receive no funding

public contribution
€1.638 bn
funding from Horizon 2020



OTHER CONTRIBUTIONS
€213 MILLION
(Associated Partners, e.g. charities, non-EFPIA companies)

EU funding goes to

SMES
UNIVERSITIES
PATIENTS, REGULATORS...

EFPIA contribute researchers, laboratories, generation of data, curation of compounds, and cash

Public and private partners collaborate in IMI2 projects

Accelerating research and development

Speeding up patient access to innovative treatments

Improving patient outcomes and safety of medicines

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

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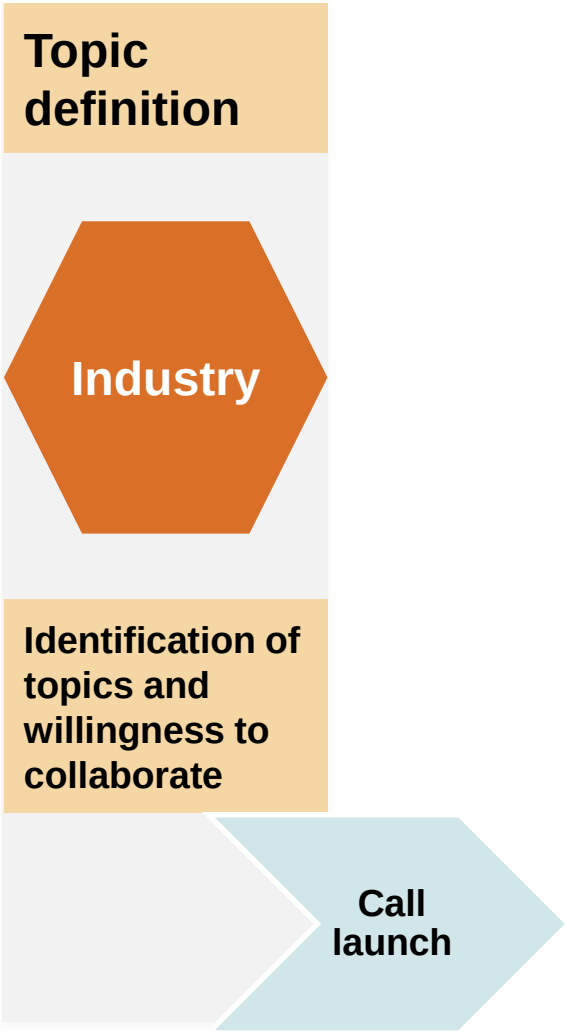
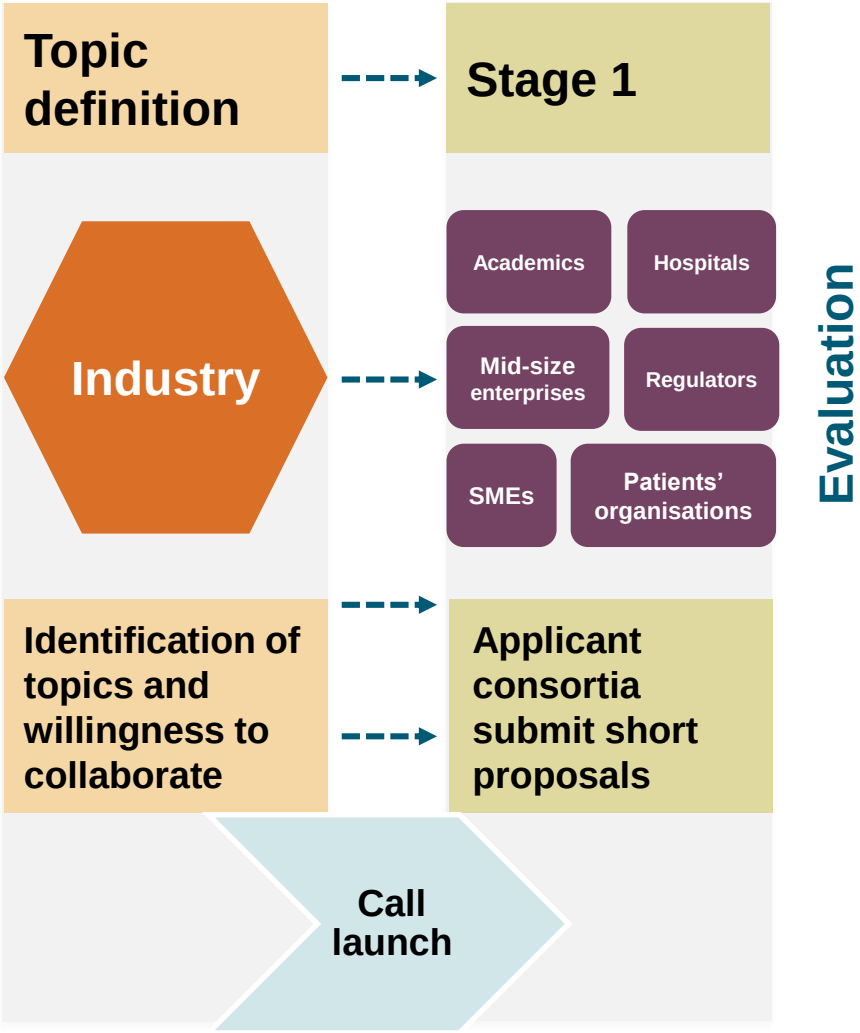
Typical IMI project life cycle



Typical IMI project life cycle



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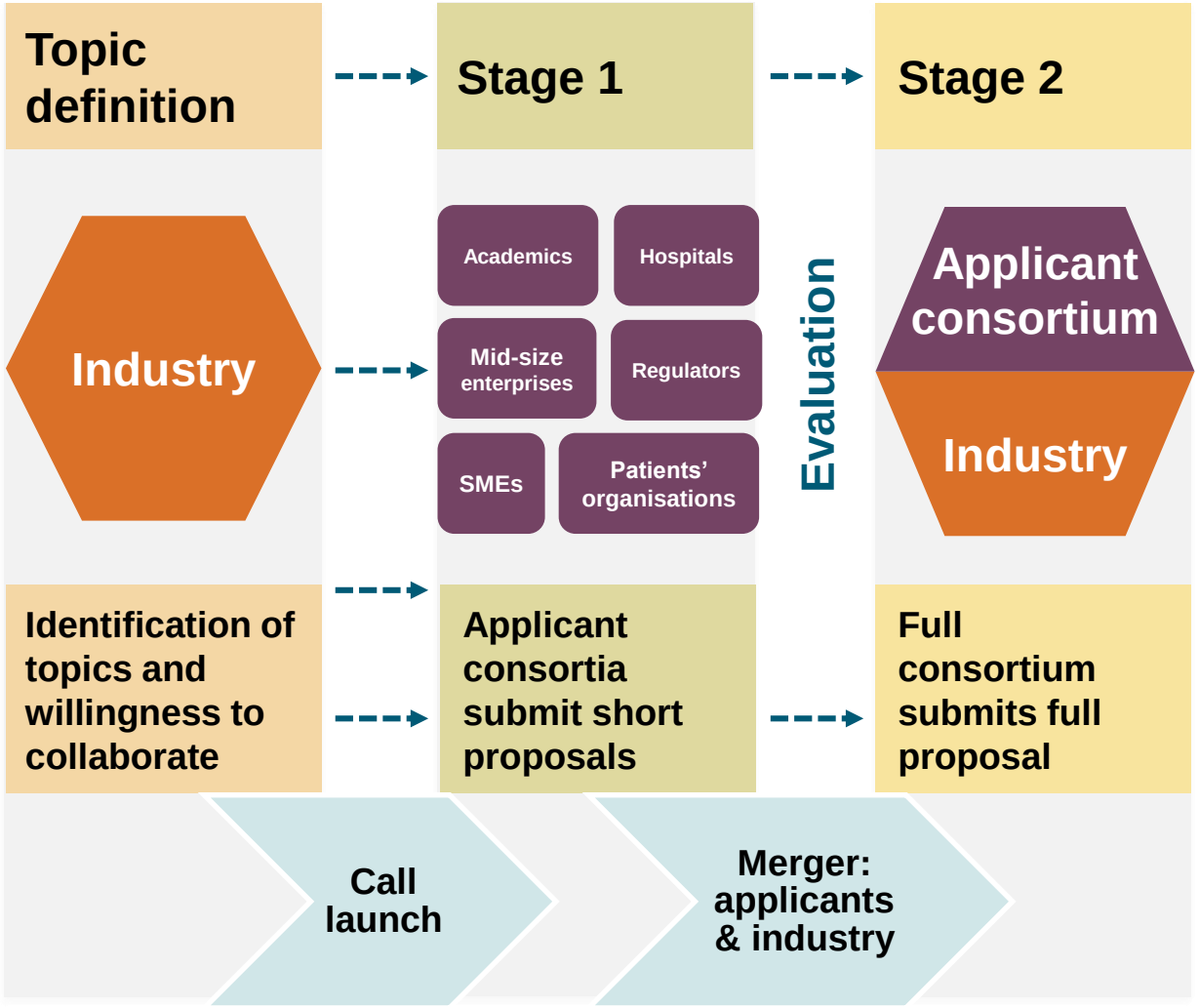
Typical IMI project life cycle



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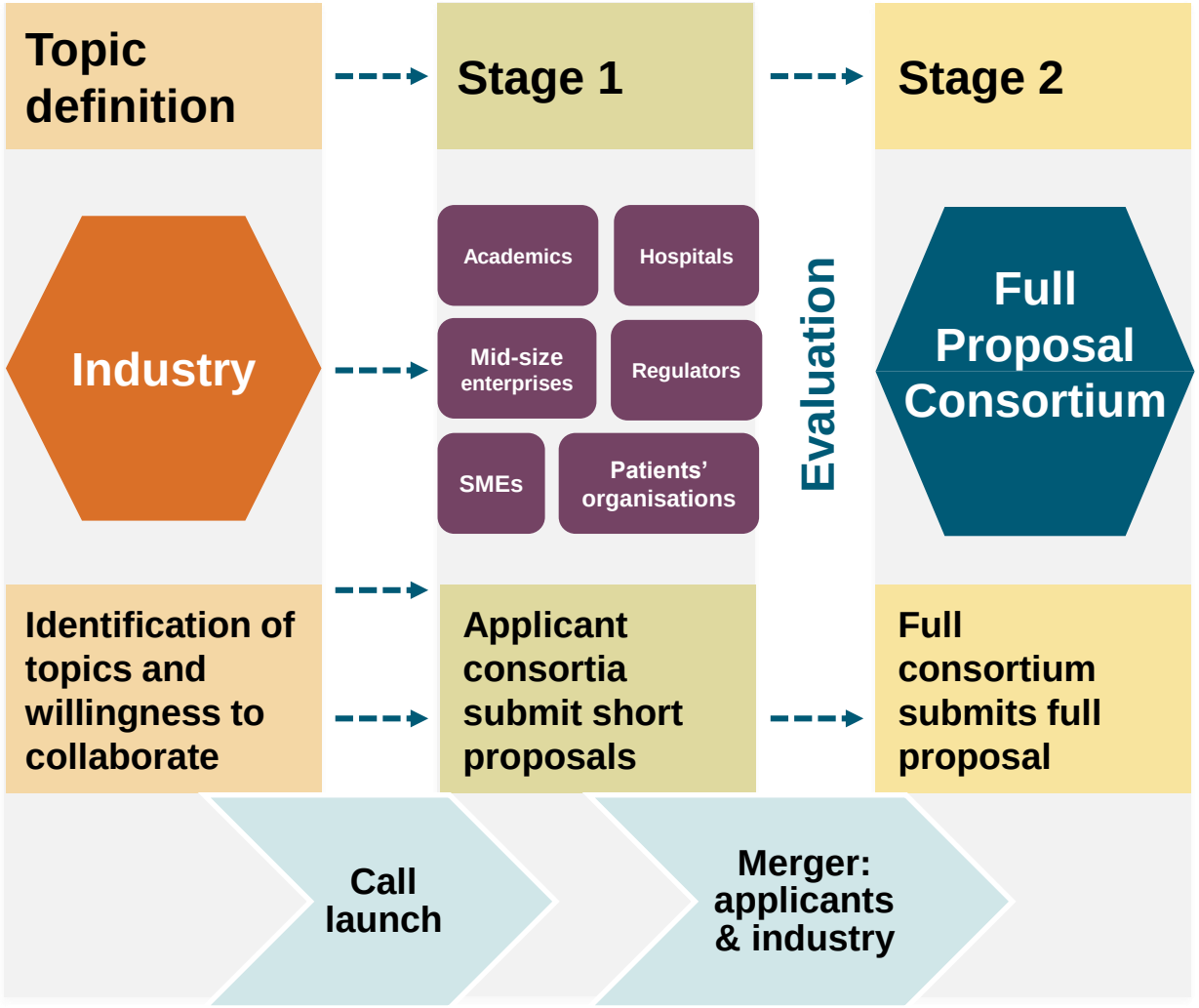
Typical IMI project life cycle



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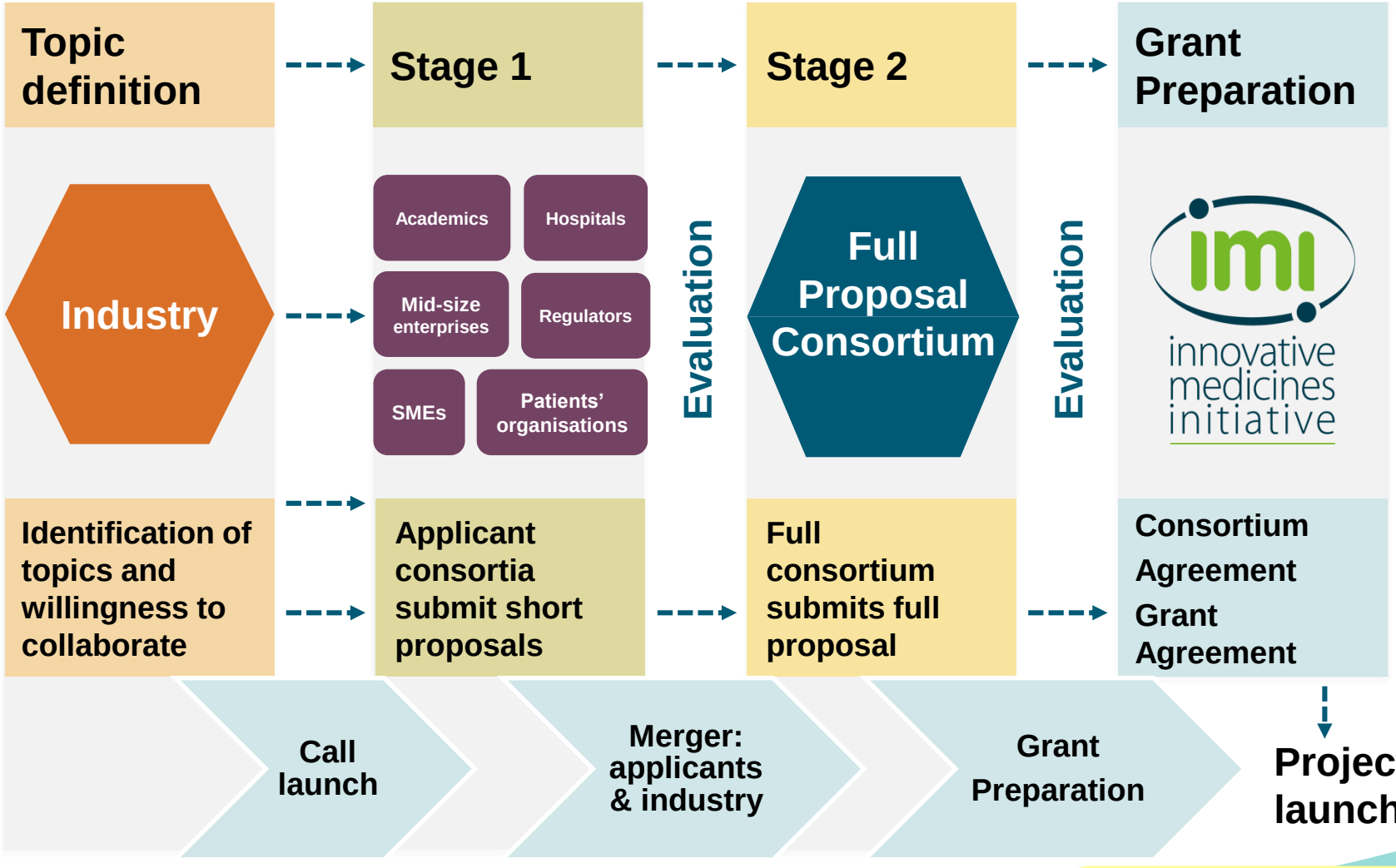
Typical IMI project life cycle



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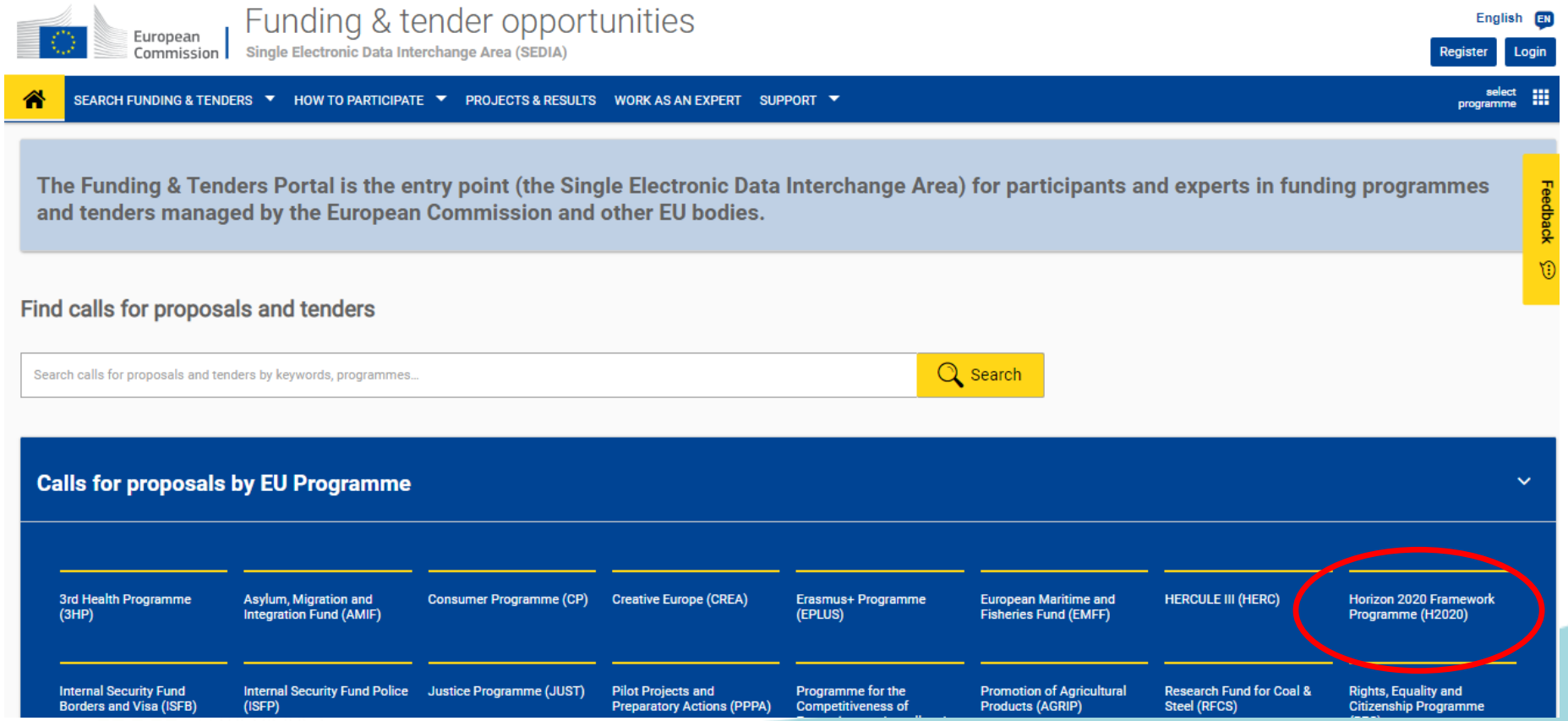
Expected GA signature – Spring 2021

Submitting a proposal

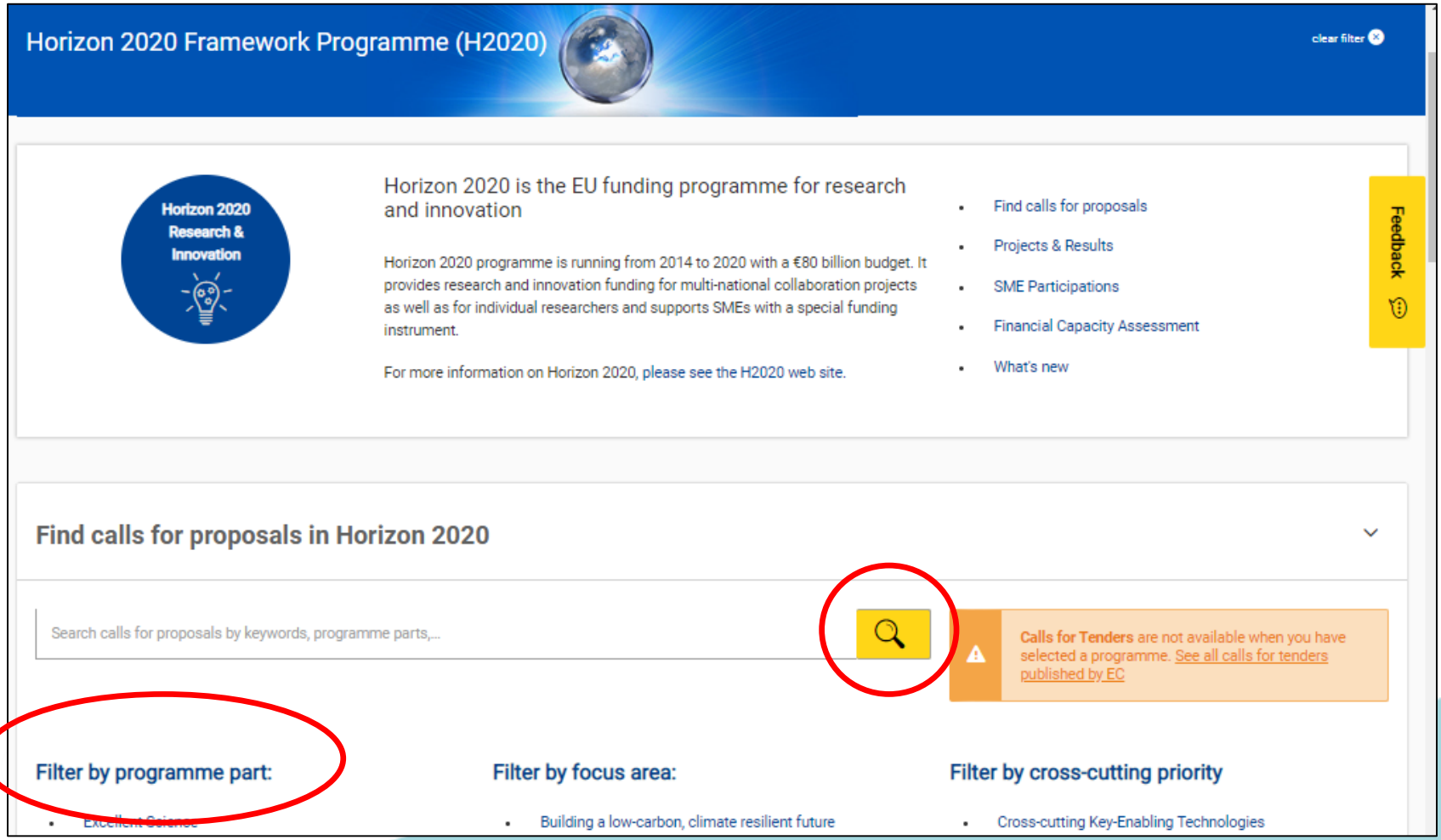
Via the **new** Funding and Tenders Portal

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



New Funding and Tenders Portal Horizon 2020 section

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/programmes/h2020



Proposal Template – Newly updated

- 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)**

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Evaluation Criteria (1/2) – Newly updated

- **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) – Newly updated

- **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.

New thresholds:

- 3 for each of the evaluation criteria ‘excellence’, ‘impact’ and ‘quality and efficiency of the implementation’
- the overall threshold is 10

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Tips for writing a successful proposal

- Read **all the call-relevant material:**
  www.imi.europa.eu
- 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 **IMI Office** (**NOT** industry topic writers):
  infodesk@imi.europa.eu

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Common mistakes

- Admissibility/Eligibility criteria not met**:**
  - submission **deadline** missed
  - minimum of **3 legal entities** from **3 member states & H2020 associated countries** 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.

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Find project partners

- Network with **your contacts**
- **Network** with fellow webinar participants
- Use **Partner Search Tools:**
  - EU Funding & Tenders portal: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/partner-search
  - German NCP partner search tool: www.imi-partnering.eu
- Get in touch with your **local IMI contact point**: www.imi.europa.eu/about-imi/governance/states-representatives-group
- Talk to your **Health National Contact Point** (NCP)
- Network on **social media** (e.g. IMI LinkedIn group)

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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…)

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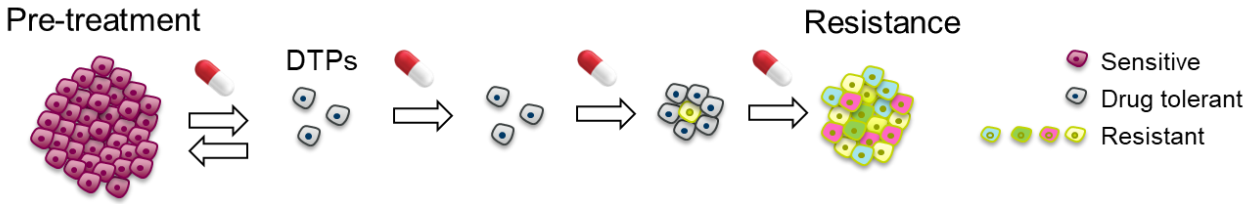
Tumour Plasticity

David Andrews, Ultan McDermott
AstraZeneca
24.01.2020 • IMI webinar

Need for public-private collaboration



- Drug resistance in cancer is a major healthcare problem.
- Advances in single-cell sequencing allow characterisation of drug tolerant persister cells (DTPs).

Industry expertise

- Models
- Drug development
- Novel target ID

Academic expertise

- Single-cell sequencing
- Computational
- Models

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Objectives of the full project

- To characterise the biology of drug tolerant persister (DTP) cells & identify novel drug targets to overcome this
- To better understand the tumour microenvironment
- Generation of single cell RNA-seq data from adult and childhood cancers –predominantly three adult cancers*
- To develop best practise in clinical validation and single-cell sequencing & clinical validation
- To create gold standards protocols for single cell collection
- To develop core analytical methods
- To build EU capability in single-cell sequencing

* from year 3 of the funded project, specific childhood cancers may be considered for inclusion

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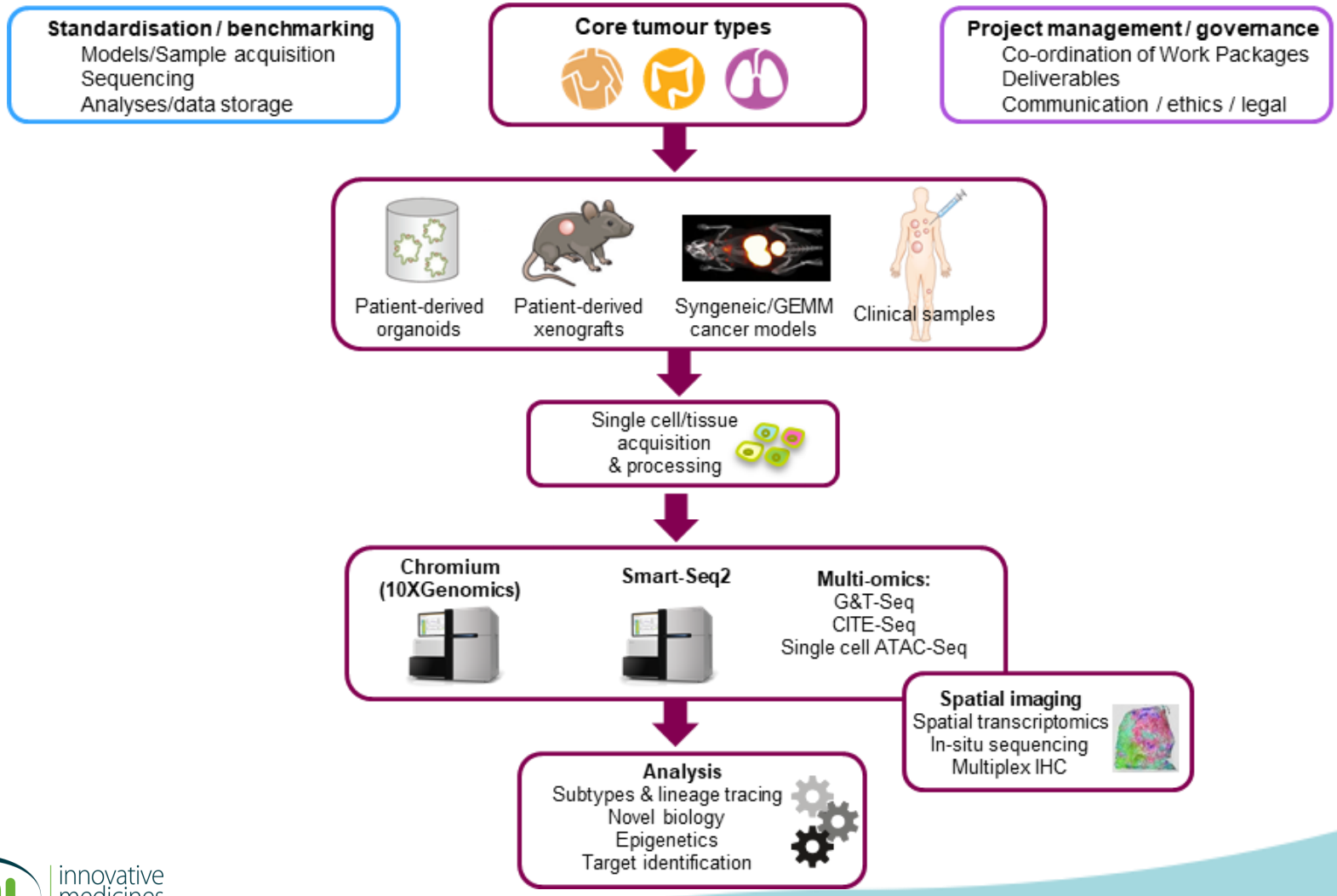
Workflow of the project



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Pre-competitive nature

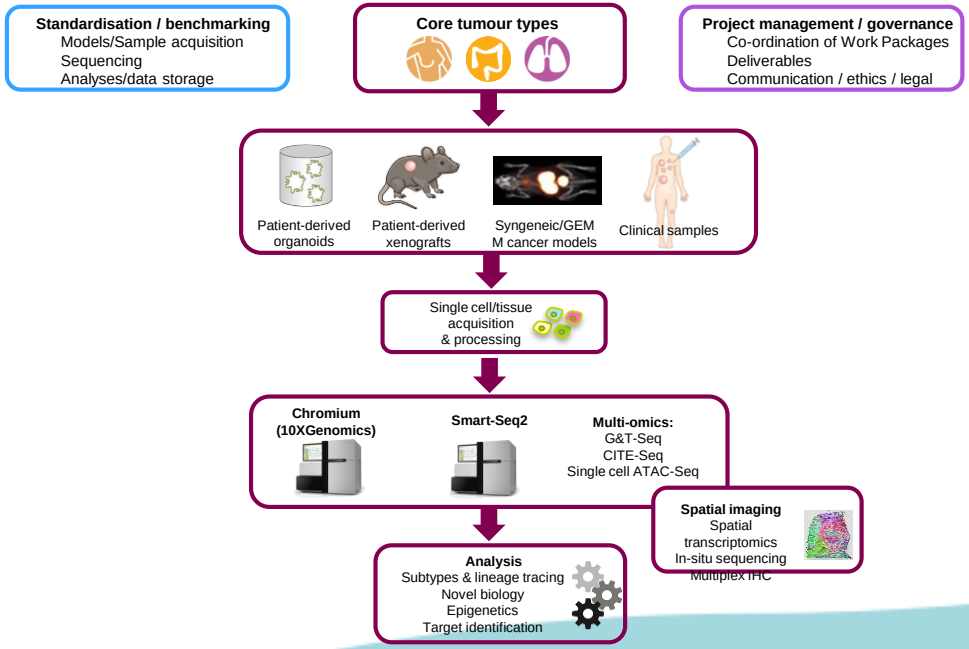
- Combining single-cell sequencing, use of patient-derived xenografts (PDX) and patient-derived organoids (PDO), and clinical tissue imaging will create the opportunity to better understand cancer drug resistance.
- Each of these areas is a rapidly advancing field
- Standardised collection and sorting of cells is well-aligned to the capabilities of **industry partners** and at-scale is an activity that academic groups are often not well set up to deliver.
- The techniques for evaluating single cells and the computational methods for interpretation of data are under constant development - mainly in **academic labs**.
- Industry partners are ideally placed to interrogate different drug mechanisms against common tumour backgrounds (or vice versa).
- The consortium will co-create insightful data : measurement raw data; preclinical treatment and outcome data; clinical treatment and outcome data

Expected impact

- Better understanding of the contribution of tumour heterogeneity and plasticity to drug resistance in cancer
- Development of a public database for single-cell data
- Harmonisation of protocols for single cell experiments
- Development of gold standards for the analysis of single-cell sequencing data
- Access to comparative data on different pre-clinical and clinical models and better understanding of the biology of DTPs in cancer with a high likelihood of spin-off projects
- Improvements in single cell sequencing and spatial imaging with potential for commercial development
- Gold standard methods for the delivery of single cell projects

Suggested architecture of the project

- The public partners are expected to carry out most of the sequencing work whereas industry partners contribute in kind in the form of single cells (collected specifically for this programme) so that work can be carried out centrally with clear streamlined processes.
- Both industry and public partners will collaborate in the analysis of the data



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Expected contributions of the applicants

- Technical expertise in single-cell sequencing.
- Ability to evaluate and internalise new sequencing technologies.
- Expertise in computational approaches, including integration of data across platforms and studies.
- Create standardised data formats.
- Provision of single cells from specific models.
- Database build for public dissemination at project end.
- Ability to co-ordinate a large research initiative.

Expected (in kind) contributions of industry consortium

- Single cells from a range of biological models & therapies (organoid, PDX, syngeneic, GEMM, clinical).
- Main (80%) focus on lung, breast and colon cancer.
- 20% of the studies can be proposed in different tumour types, including childhood cancers.
- Each industry partner will nominate tumour types/drug treatments in alignment with overall programme scale and agreed objectives.
- Nomination of study systems will be in consultation with academic consortium partners.

What's in it for you?

- Member of consortium – the largest use of single-cell sequencing to address drug resistance in cancer
- Contribute to the development of a global database of single-cell data in DTPs
- Access to samples from a range of biological models treated with clinical and experimental cancer therapeutics
- Opportunity to develop mechanistic data and publications with individual pharma partners for each tumour type/drug treatment
- Collaborate with expert academic groups to develop state-of-art protocols for single-cell studies
- Aim for high impact publications and white papers

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Key deliverables of the full project

- Benchmarked and standardised protocols for single cell identification and collection from PDX/PDO models.
- Gold standard methods for tissue-based spatial imaging.
- Multi-omics methods for characterising single cells. mouse models.
- DTPs and metadata/annotation from human and mouse models
- State-of-the-art analysis methods of single-cell sequencing.
- Single-cell measurement data combined with treatment and outcome data / clinical outcome data.
- Gold standard methods for the validation of key transcriptional changes.
- Tools to allow cross-study analyses of single-sequencing data.
- A raw data repository with access for all consortium partners.
- White paper on single-cell sequencing to characterise DTP biology.

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Thank you

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Involvement of SMEs and regulators

Oussama Karroum
IMI Scientific Officer
24 01 2020 - Brussels

SME participation

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

Contribution of SMEs would be considered especially beneficial in providing as example the following expertise and activities :

- Relevant technology companies, in particular SMEs, along with academic centres that have expertise in single-cell sequencing and analysis of sequencing data, as well as spatial transcriptomics, should be part of the successful consortium.

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'

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Thank you

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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

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