

European  
Innovation  
Council



# Backing visionary entrepreneurs

EIC Financial Instruments and  
EIC Health and Biotech portfolio

*for the BII, Kobenhavn Workshop:  
Best practices on supporting early stages of  
life science start-ups across European borders*

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# European Innovation Council

## Europe's most effective catalyst of breakthrough science into disruptive innovation

€10 bn programme to identify, develop  
and scale up breakthrough technologies  
and disruptive innovations in Europe

Three financial instruments:  
Pathfinder, Transition, Accelerator

EIC deep-tech VC Fund (over €3 bn)

Portfolio approach, Challenge Calls,  
Programme Managers



# EIC Pathfinder



For advanced research to underpin breakthrough / game-changing technologies

Mainly open ("bottom up"), but also Pathfinder challenges (for emerging health, energy and digital technologies)

Mainly collaborative (3 or more partners)

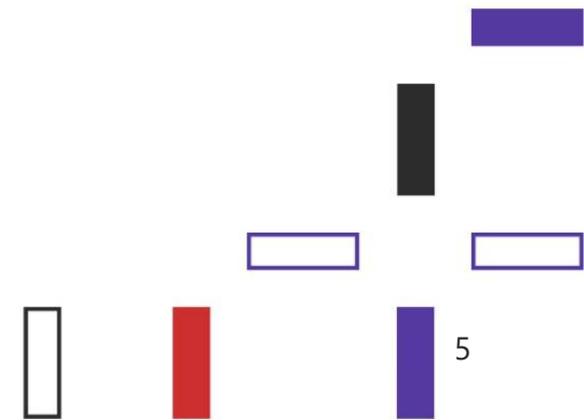
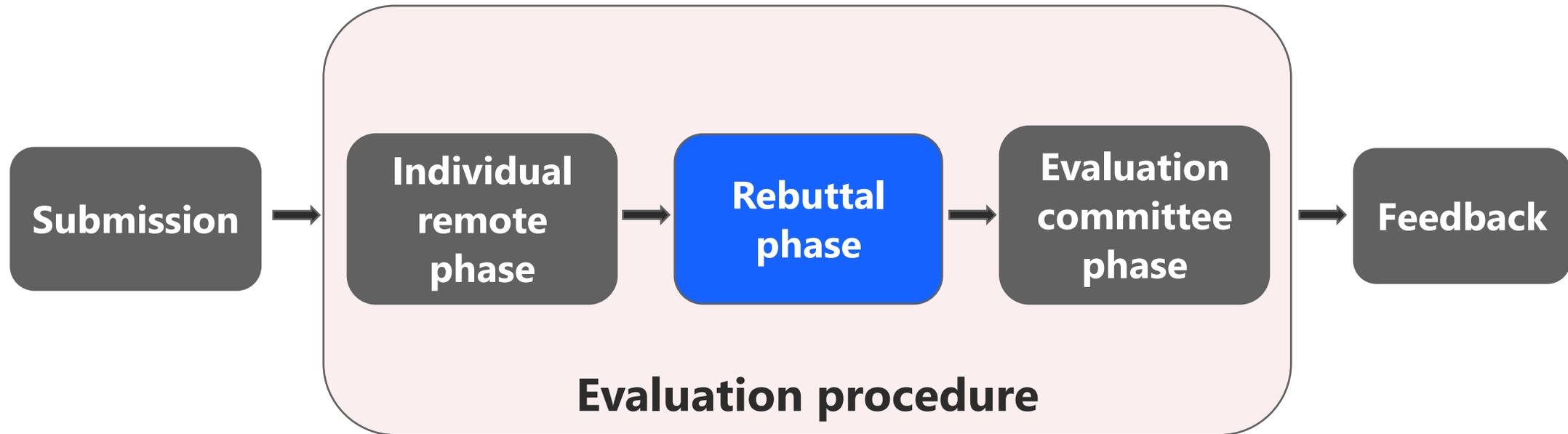
Grants up to €3/4 Mt €3/4 million

Management of portfolios of projects by Programme Managers



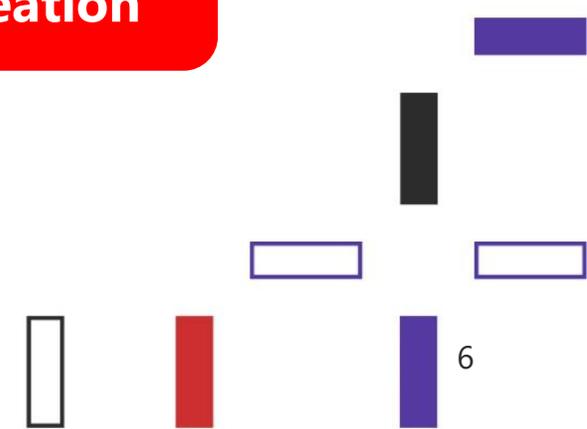
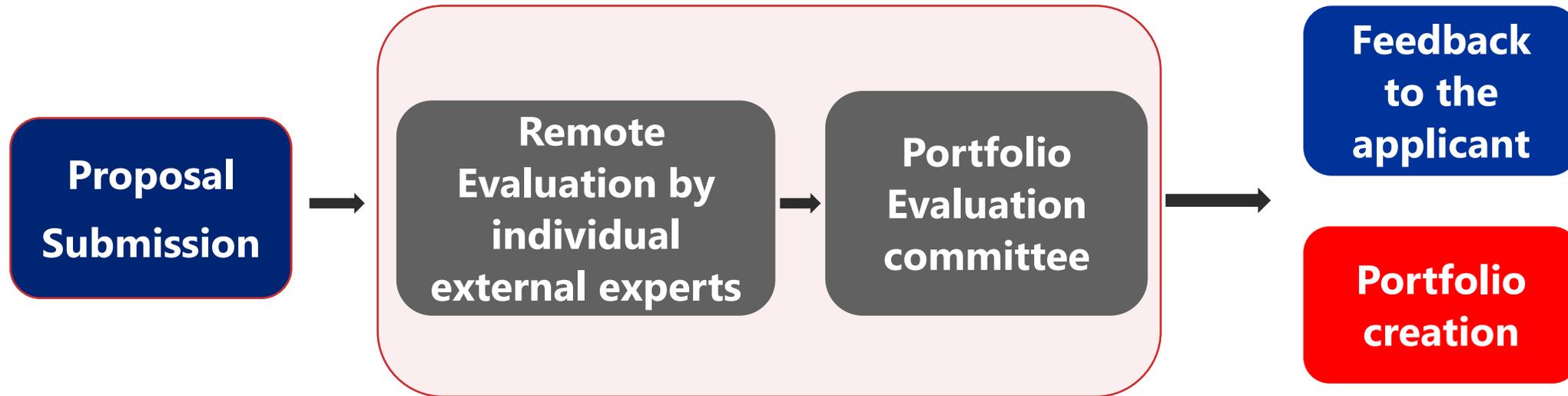
# Pathfinder **Open** proposals evaluation scheme

Applicant has the right to address evaluators' comments





# Pathfinder **Challenge** proposals evaluation scheme leading to the creation of portfolios





# EIC Pathfinder Challenge Call 2021 in Health & Biotechnology

## EMERGING TECHNOLOGIES IN CELL AND GENE THERAPY

*(Programme Manager for Health & Biotechnology: Iordanis Arzimanoglou)*

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# EIC Pathfinder Challenge Call 2021 in Medical Devices

## TOOLS TO MEASURE AND STIMULATE ACTIVITY IN BRAIN TISSUE

*(Programme Manager for Medical Devices and Medical Technologies: Enric Claverol)*





# EIC Pathfinder Challenge Call 2021

## ENGINEERED LIVING MATERIALS

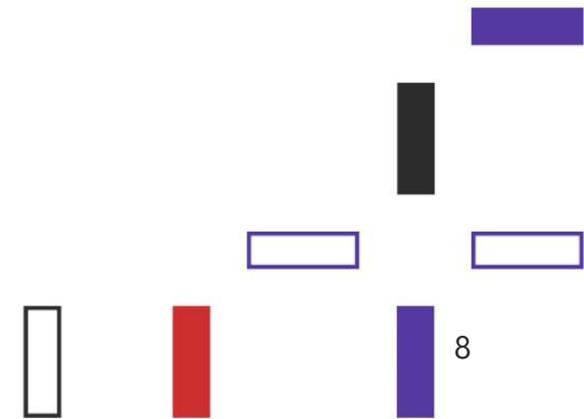
*(Acting Programme Manager: Barbara Gerratana)*

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Integration of expertise in:

Synthetic biology/Morphogenesis, Materials engineering,

Control Engineering/AI





# Additional opportunities for Pathfinder projects

**Projects or their beneficiaries funded through EIC Pathfinder are eligible**

to receive additional **Ad hoc grants** (up to 3 per project or more if duly justified) with fixed amounts of up to €50,000 :

a) for complementary activities to explore potential pathways to commercialization

b) for portfolio activities.

to submit a proposal to the **EIC Transition** for transforming their research results into innovation opportunities;

to submit an **EIC Accelerator** proposal via the **Fast Track** scheme;

to receive free access to a wide range of **Business Acceleration Services**





## For transforming research results into innovation opportunities

New funding scheme to bridge gap between research phase (proof of concept) and innovation application	Mainly open ("bottom up"), but also Transition challenges (for medtech, energy storage)	Single applicants or small collaborations (max. 5 partners)	Grants up to 2.5M	In first phase, only for follow up to results from EIC Pathfinder and ERC PoC
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## Eligibility time wise :

- Pathfinder projects and ERC Proof of Concept. Start date of the grant is more than 12 months before the date of the Transition call deadline and end date of the grant for the eligible project is less than 24 months from the date of the Transition call deadline

## IP status:

- You do not have to be the owner of the IP or one of the original beneficiaries, but have the right to use the IP or know-how generated in the initial project.





# EIC **Transition** Challenge Call 2021: Medical Devices: From Lab to patient

*(Programme Manager Enric Claverol)*

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# EIC **Transition** Challenge 2022: RNA-based therapies and diagnostics for complex or rare genetic diseases

*(Programme Manager Iordanis Arzimanoglou)*

**TOPIC ID: HORIZON-EIC-2022-TRANSITIONCHALLENGES-03**  
*EIC Transition 2022 (HORIZON-EIC-2022-TRANSITION-01)*

**Opening date:**  
**01 March 2022 CET**

**Deadline dates:**  
**04 May 2022 17:00 CET**  
**28 September 2022 17:00 CET**



# mRNA-based therapeutics Challenges

Synthesis and optimization (Size of mRNA is significantly larger than other types of RNAs)

Stabilisation of mRNA under physiological conditions

Novel delivery strategies providing more effective and safer delivery of mRNA to targeted cells, are needed





# EIC Transition Challenge

## Other than mRNA types of RNA Challenges

### Transfer RNA (tRNA)

- Suboptimal delivery

### Small interfering RNA (siRNAs)

- Expression of disease-causing genes in tissues outside the liver and kidney has been reported

### Micro RNAs (miRNAs)

- Possible induction of off-target effects



# EIC Transition Challenge

## Specific Objectives

Enable effective and safe delivery of mRNA into the cells

Design, develop and preclinically validate novel RNAs therapeutics (miRNA lncRNA, tRNA or siRNA-based) for complex or rare genetic diseases

Develop and validate novel RNA-based diagnostics and RNA-based predictive biomarkers to allow for more accurate diagnosis and post-treatment prognosis

# EIC Accelerator



For startups & SMEs to develop and scale up innovations with high risk and high impact

- For individual companies (startups, SMEs)
- Continuously open for applications (also from individuals intending to start a company and investors intend to support a company)
- Mainly open but also Accelerator challenges in Green Deal, Strategic Digital & Health Technologies
- Mainly blended finance (grant + investment), but options for “grant only” and “grant first” (with investment follow up)





# EIC Accelerator: a four-step evaluation process

**1**

- You have a disruptive / deep tech idea with a potential to scale up
- **Tell us your story** with short application at any time

**2**

- You prepare a full application with your **business plan**
- We will help you with a dedicated AI tool and free coaching

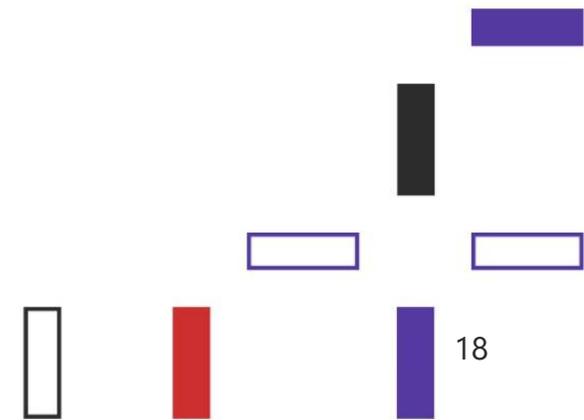
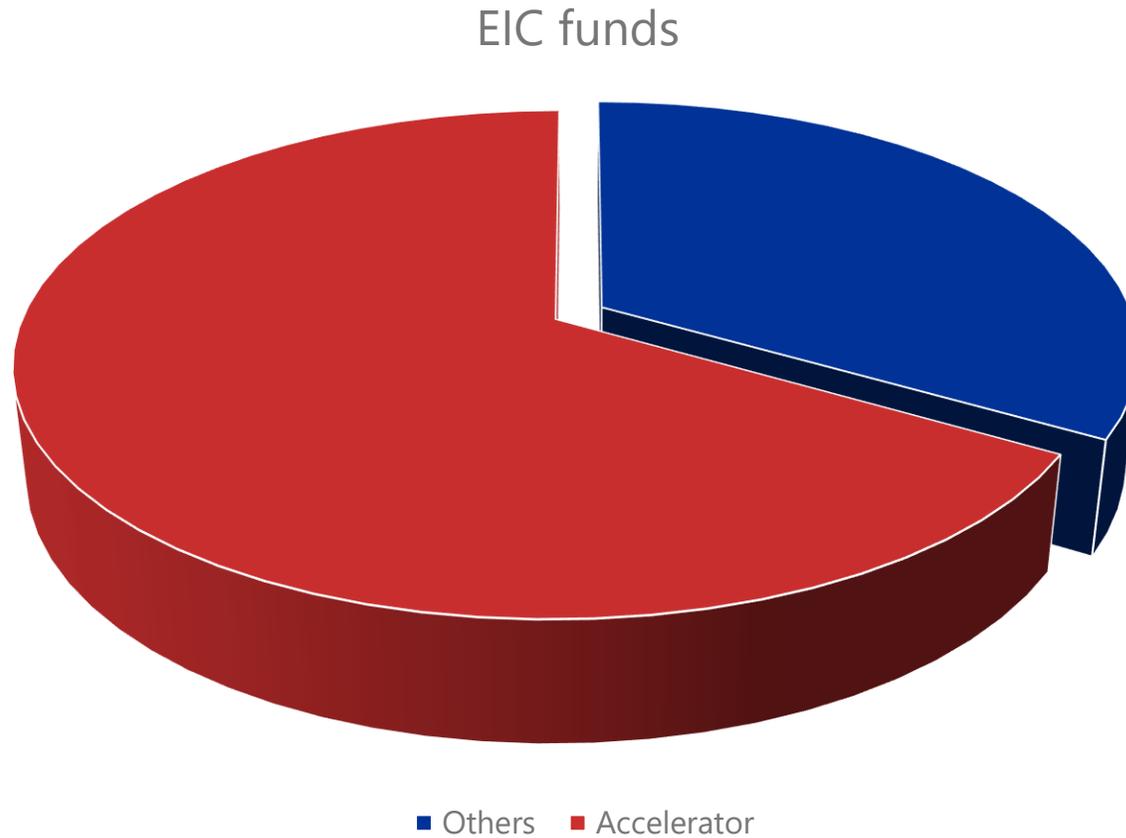
**3**

- **You submit your full proposal** at one of the regular cut-off dates
- Your application will be assessed by expert evaluators matched to your field

**4**

- **You pitch** your innovation to a Jury of experienced investors/ entrepreneurs
- If selected, you will sign the grant and start due diligence for the equity

# Why the majority of the funds of the EIC are directed to Accelerator SME beneficiaries?



# How important are the Small and Mid-sized companies in the US biotech sector and innovation pipeline

71%

*of jobs*

Employment

76%

*of pipelines*

Share of novel therapies (**5000 of 6700** according to BIO) within the clinical stage pipeline either led by small and medium-sized firms or these small firms are in partnered research programs with large corporations

60%

*FDA approvals*

Over the past three years (2017-19) smaller firms accounted for over 60% or more of all FDA approvals each year



# Key objectives for the PMs

## Recognised in field

- as leading/ influential player for emerging technologies (*through strategic intelligence, outreach, selected partnerships/ initiatives*)

## Defining and achieving challenges

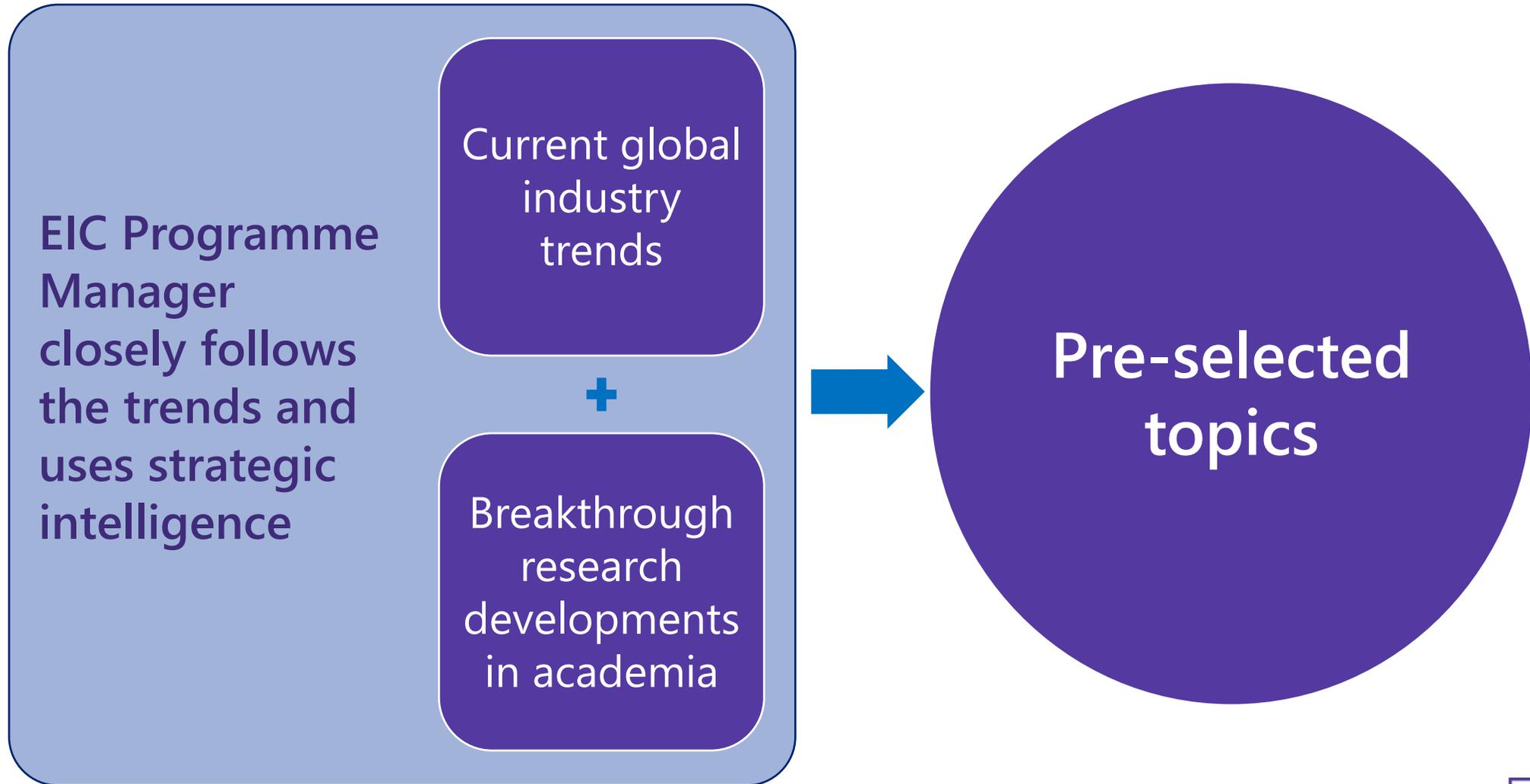
- for technological breakthroughs (*through defining challenges in WP, challenge guides & roadmaps, proactive management of portfolios*)

## Impact in transitioning research to transition, to accelerator, to commercial deals

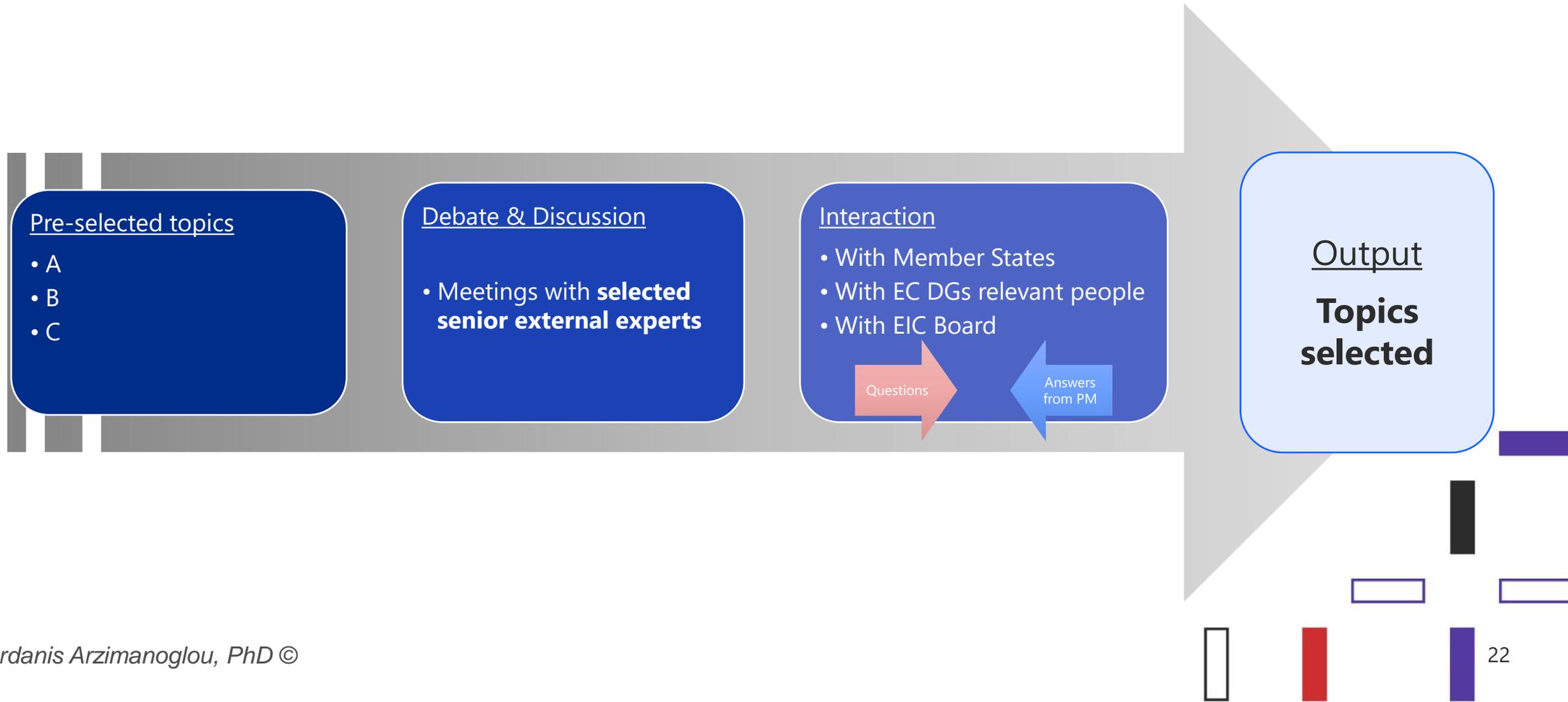
- through proactive management of challenges, selective thematic portfolios/ projects, outreach/ initiatives



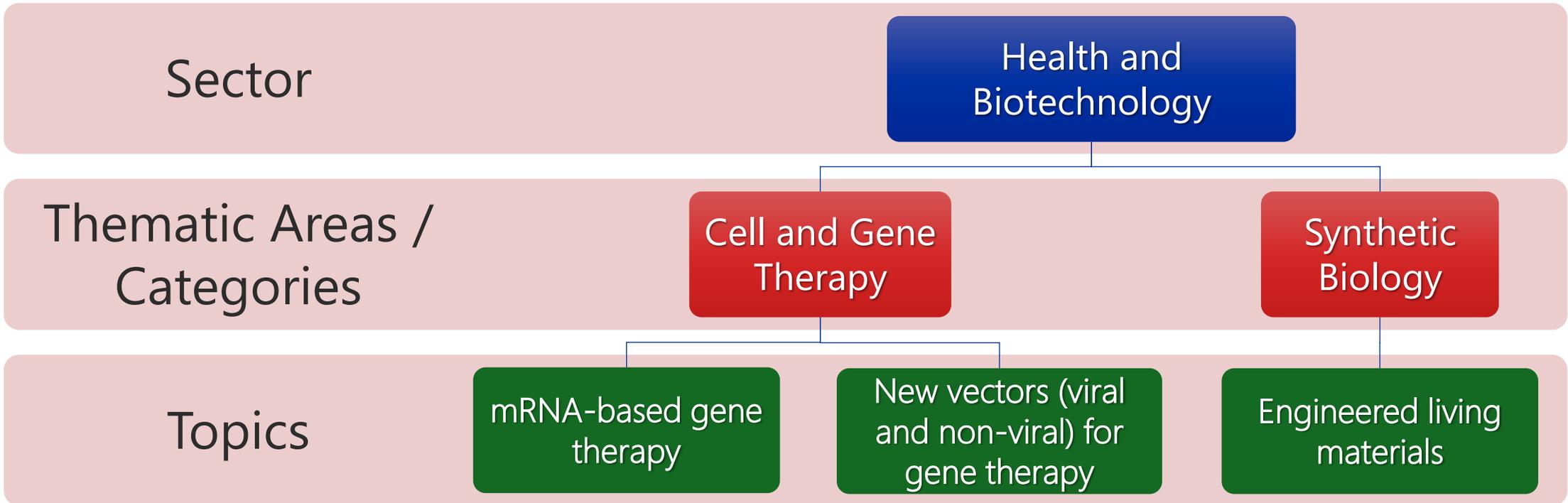
# EIC Programme Manager: How they pre-select topics



# EIC Programme Managers: How do they debate and validate topics



# EIC Programme Managers: From sector to topic





# Why cell and gene Therapy?

## Current Market outlook (I)

- A single gene therapy SME acquisition/deal can exceed the annual budget of EIC (~1.5bn)
- Bayer acquired gene therapy company Asklepios BioPharma for \$2 bn upfront and a potential further \$2 bn in success-based milestones because of the company's gene therapy capabilities in AAV and manufacturing process (2021)
- Bristol Myers Squibb agreed to acquire cardiovascular company MyoKardia for \$3.1 bn through an all-cash deal (2020): [www.nature.com/articles/d43747-020-01182-1](https://www.nature.com/articles/d43747-020-01182-1)
- Roche acquired Spark Therapeutics Inc for \$4.3 bn (2019)





# Why cell and gene Therapy?

## Current market outlook (II)

- Gene therapy is a market on the rise and significant growth should be expected
- New technology will increase the number of therapeutics (e.g. >\$1bn was invested in gene editing-based start-ups by 2018 with the first human trials in 2019)
- However, the gene editing-based therapeutics/drugs are unlikely to have significant clinical impact before 2025





# Why cell and gene Therapy?

## Current market outlook (III)

- According to the 2020 Pharma report "*Medicines in Development for Cell and Gene Therapy*" (<https://www.phrma.org/en/Report/Medicines-in-Development-for-Cell-and-Gene-Therapy-2020>), **362** cell or gene therapies were in the pipeline in 2019, 25% increase compared to the same figure in 2018. This number exceeded **800** trials in 2020
- However, currently approved gene therapies in the US market, are only a handful with RNA therapeutics being the first 2 therapies approved
- Despite the above figures, **5-10** CGT approvals per year are foreseen for the next 5 years



# Why cell and gene Therapy? Challenges



Safety

In vivo efficacy

Manufacturing





# Why cell and gene Therapy?

## Challenges in manufacturing

Despite the undeniable ability of viral vectors to deliver pay and despite the remarkable potential of this approach to treat a wide range of diseases, gene therapy manufacturing is being faced with serious challenges such as:

- Scalability
- Advanced analytics to maintain quality and meet regulatory requirements
- Cost effectiveness
- Difficulty in maintaining productivity
- Accessibility



## EIC's response to CGT challenges:

### 1: EIC Pathfinder Challenge call in the Work Program 2021:

Expanding CAR-T cell therapies to solid tumors

Other than T cell Type effective Cell Therapies

Development and Manufacturing of autologous and allogeneic CAR-T cells

New gene therapeutic approaches

Improving gene delivery systems (viral and non-viral vectors)

Improving cell and gene therapy manufacturing



# EIC's response to CGT challenges:

## 2: Cell and gene therapy: the first ever EIC-ERC workshop

29 June 2021

The e-report for the cell and gene therapy workshop held last June, is now available on the EISMEA's website:

[https://eic.ec.europa.eu/news/cell-and-gene-therapy-first-eic-erc-workshop-recordings-and-presentations-available-now-2021\\_en](https://eic.ec.europa.eu/news/cell-and-gene-therapy-first-eic-erc-workshop-recordings-and-presentations-available-now-2021_en)

The e-report encompasses all presentations, 3 recordings, a Statement by the two Chairs and a summary Statement:

[Statement from the EIC-ERC contact group co-chairs \(europa.eu\)](#)

[Statement from EIC Programme Manager Iordanis Arzimanoglou \(europa.eu\)](#)

Proposed the idea that the EIC should strategically and systematically focus on CGT

First presentation for future candidature EIC Pathfinder

Iordanis Arzimanoglou + ERCEA screen ERC portfolio, that will be presented to ERC & EIC Board: CGT Workshop proposed

2020



July-August



September-October



October - November

Post-workshop event: Dutch Medical Universities

1<sup>st</sup> ever Workshop EIC – ERC Cell Gene Therapy

“Emerging technologies on CGT” EIC Pathfinder Call



October

June 29

June



2021

*The importance of the Call was highly acknowledged by leading industry in the field, with a letter sent to the President von der Leyen*

EIC Pathfinder Challenge Evaluation

French Ministerial Conference on Health Industries; Roundtable “Strategic ambitions and European Vision, the keys to build an industrial health policy”

EIC Transition Challenge : “RNA-based therapies and diagnostics for complex or rare genetic diseases” (two cut-offs)

2022



January



March 3



4 May  
28 September