



# ***IMI-PARADIGM: Towards sustainable patient engagement***

Elisa Ferrer Mallol

EURORDIS CEF meeting 11 Dec 2018

**EURORDIS.ORG**



# THE CONSORTIUM



# Mission

- To provide a framework that allows structured, meaningful, ethical and sustainable patient engagement in medicines research and development
- Making patient engagement “the norm”
- Ensuring synergies with other initiatives (EUPATI, PFMD)
- Understanding the needs and expectations of all stakeholders
- Development of metrics to measure the “return on engagement”
- Development of recommendations on capabilities required by all stakeholders and tools and templates for the effective implementation of patient engagement
- Development of a strategy to ensure long-term sustainability of patient engagement in medicines R&D



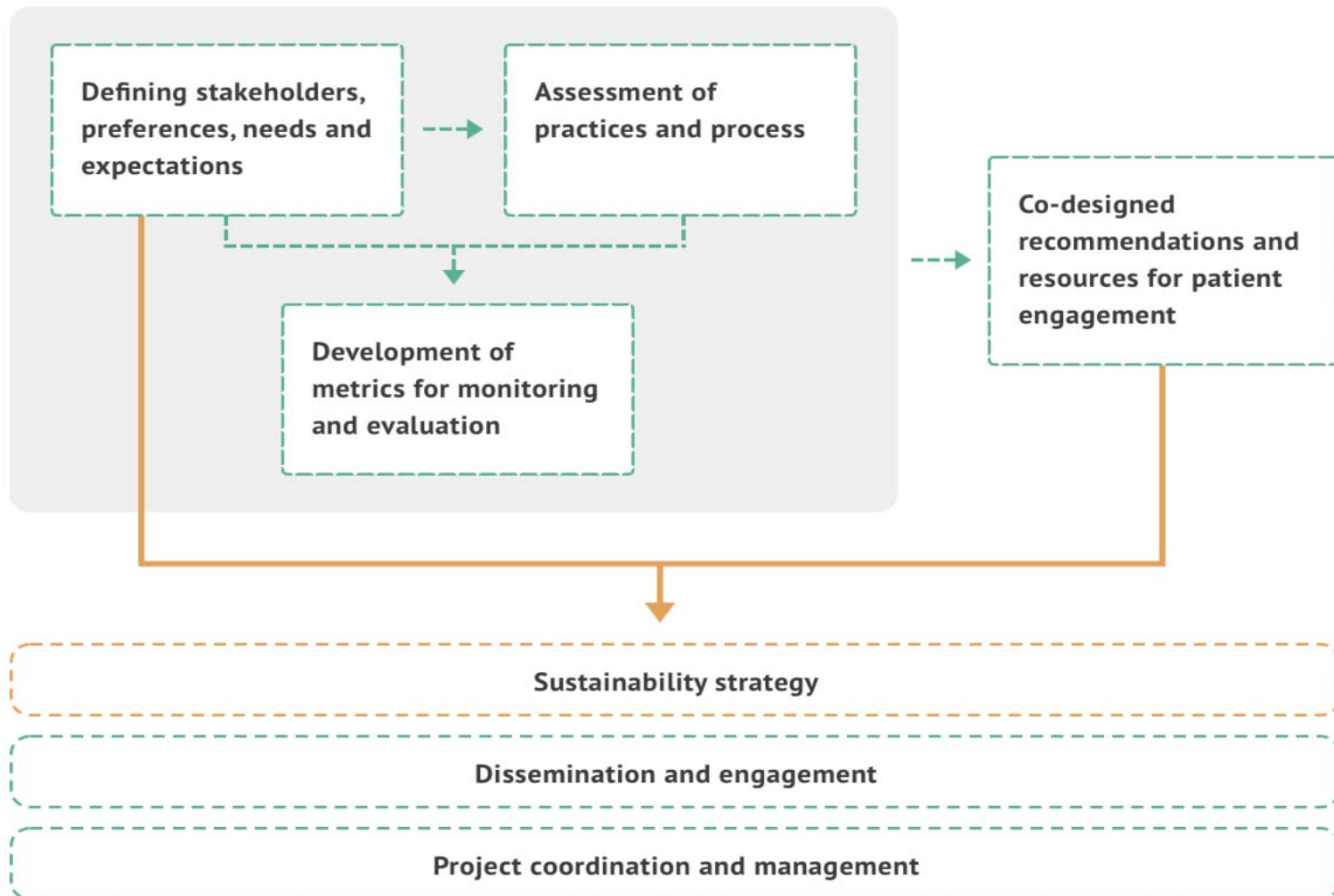
**Research and  
priority setting**



**Design of  
clinical trials**



**Early dialogues with  
regulators and HTA bodies**



# Milestones achieved so far

## 1. Defining stakeholders' needs and expectations

- Patient groups prepared for PE but needing extra help
- Challenges: delays in bureaucratic processes, poor communication among stakeholders
- Patients engaged in decision-making, but influencing it?

1

## 2. Assessment of existing practices and processes

- Creation of database (resources: PFMD, EUPATI) to identify gaps in current processes

2

## 4. Tools and resources for PE

- Recommendations on required capabilities to implement PE
- Gaps identified will inform the development of tools/templates/code of conduct

4

## 3. Metrics for monitoring and evaluation

- Demonstrate "return on engagement"
- Preliminary framework developed and ongoing testing on retrospective cases
- Improved framework will be applied to prospective cases

3

6

## 6. Sustainability strategy

- Currently developing potential sustainability scenarios

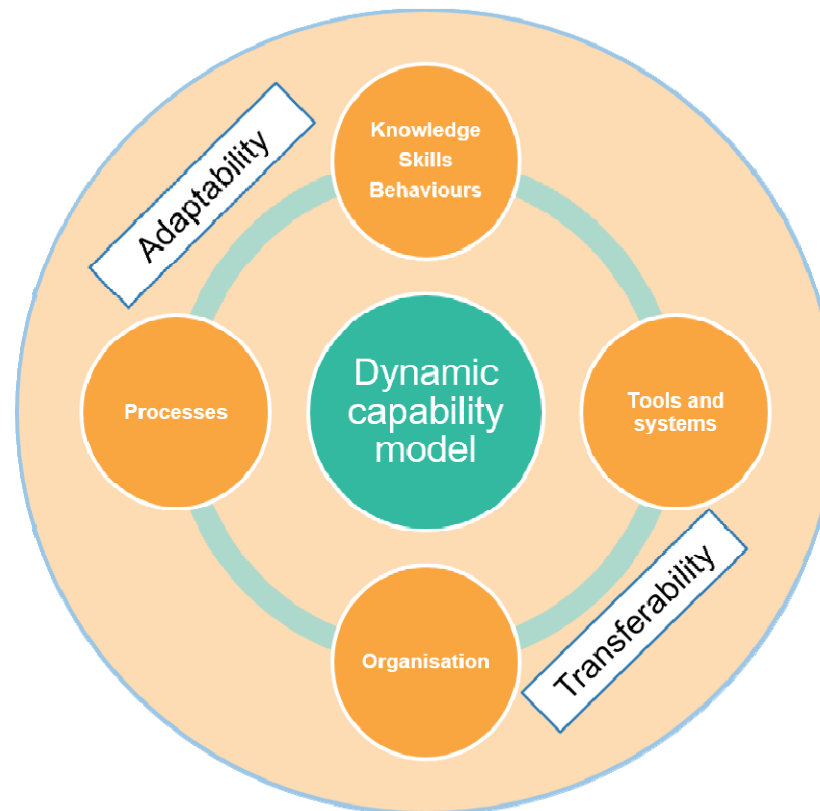
# EURORDIS IN PARADIGM

- General assembly and steering group (EPF, EFPIA, EURORDIS, BAYER, MSD, UCB, SYNAPSE)
- Co-leaders of WP6 – Development of the sustainability strategy
- WP4: Recommendations and tools  
Leaders of Task 4.1 Development of recommendations on the required capabilities for patient engagement for all stakeholders
- Involved in all work packages as major or minor contributor

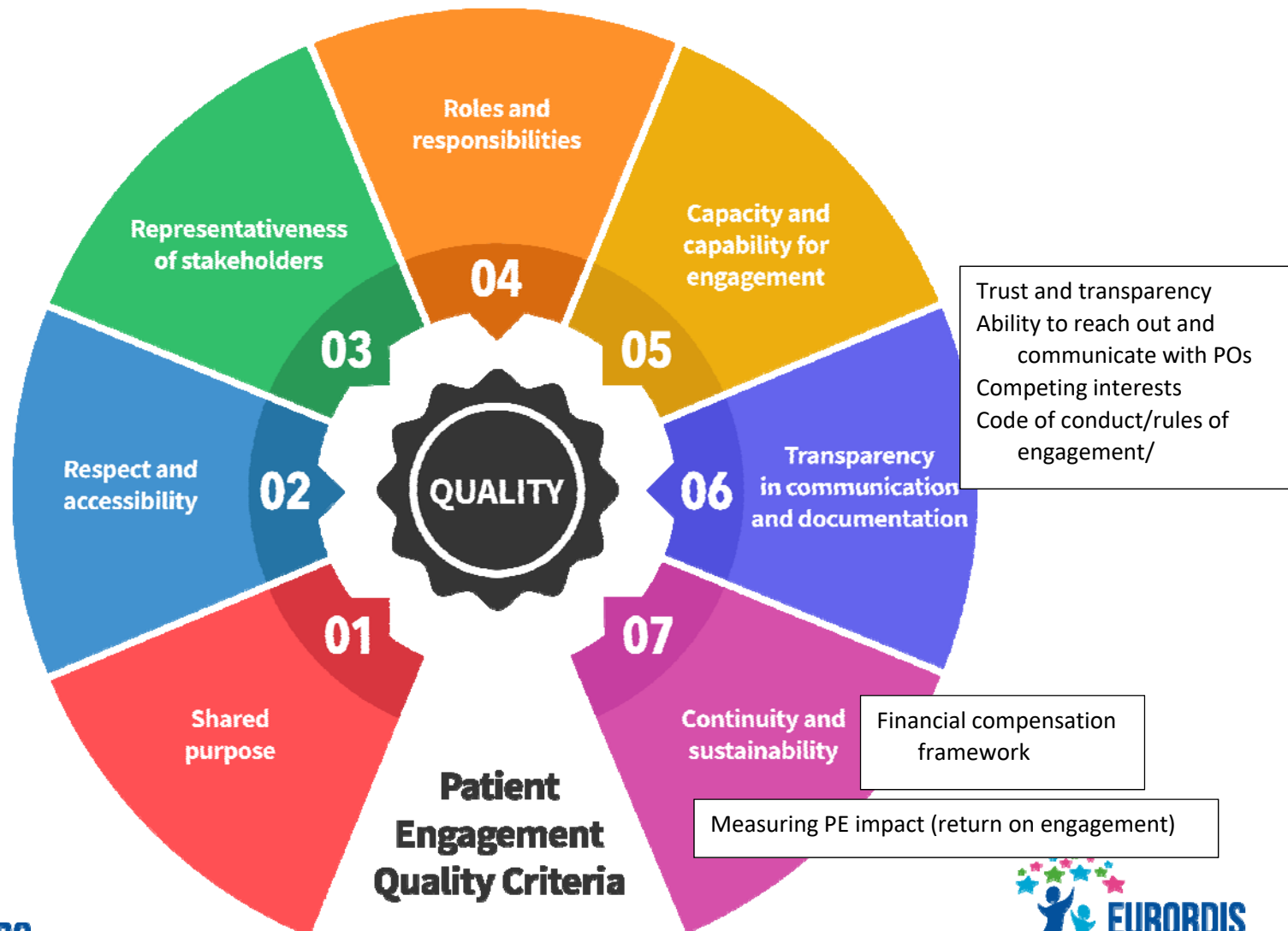
# Required capabilities to implement patient engagement

- The *skills, knowledge and competencies* that each stakeholder type should aspire to have in place in order to be able to undertake the planning, implementation and reflection of effective, ethical and sustainable patient engagement activities

**Combination of human and organisational capabilities**



## Recommendations on the capabilities required will be aligned to the seven patient engagement quality criteria developed by Patient-Focused Medicines Development





A decorative graphic on the left side of the page, consisting of a blue shape in the upper left and a green shape in the lower left, both with rounded corners. The blue shape is a square with its top-right corner rounded, and the green shape is a square with its bottom-right corner rounded. They meet at a diagonal line.

# SUSTAINABILITY STRATEGY

# What makes patient engagement sustainable?

## Culture

To drive the necessary cultural changes to make PE the norm. It refers also to system readiness.

## Process

Fostering relationships between individuals and cohesion among these. Driving stakeholders together - Trust



## Resources

Revenue stream, funding - mobilizing the resources towards a non-profit objective

# How to go about it?

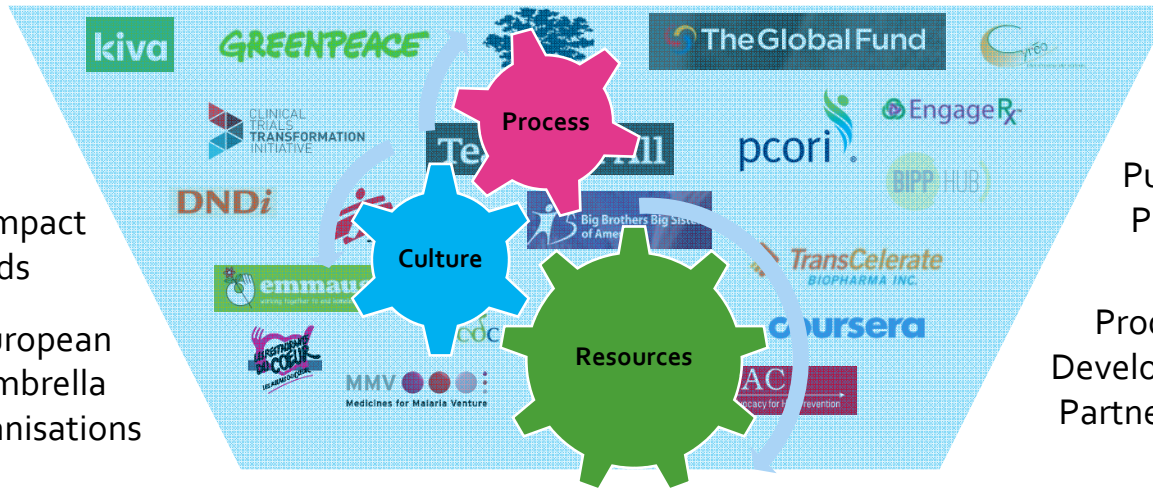
- Co-design the survey questions related to sustainability
- Benchmarking of existing sustainability models from similar ecosystems including outside health care and patient engagement – to learn from what it's out there!
- Development of sustainability models with needs and expectations in PARADIGM – Select one model that fits
- Definition of the services – what will be delivered by the new entity/structure
- Sustainability roadmap – goal of providing **one common entry point** to all stakeholders point and will ensure that their needs and requirements in terms of confidentiality, compliance, level of independency of patients, etc. are addressed.

Shared value

Collective impact

Social impact bonds

European umbrella organisations



Private equity

Public Private Partnerships

Product Development Partnerships



# Assessment review of existing sustainability scenarios



Figure 4: initiatives selected

## CULTURE

- Transparency
- Build trust
- Keep consistency with vision and mission
- Involve all stakeholders / openness / win-win
- Communication is essential
- Solid governance

## PROCESS

- Organisational flexibility / agility (ability to evolve and adapt to changing needs)
- Complementarity with existing resources

## RESOURCES

- Importance of the legal framework
- Metrics to assess value
- Independence (not only financial)
- Compensation to participants

Figure 5: Common topics across interviews

# EURORDIS internal consultation on PE sustainability

- Session conducted in the context of ExPRESS: Expert Patient and Researcher EURORDIS Summer School
- Call for expression of interest launched among all students
- Selected: 9 participants – 6 nationalities
- Discussion structured into 2 parts:
  - Part 1 : What makes patient engagement sustainable
  - Part 2: Who should organize it and the business model

# Part 1: What makes patient engagement sustainable

Responses shared some common elements:

- Better training and communication – all stakeholders should be equal partners. To break down language barriers.
- Motivation/to feel valued and acknowledged – to measure satisfaction and impact
- To demonstrate the value of patient engagement to all stakeholders
- Funding to support functioning of patient organisations
- Making it easy for patients to participate – costs reimbursed, adapting to patient schedules (time and location of meetings)



## Part 2: Who should organize patient engagement in medicines R&D and the business model

- Participants were presented with a series of options including:
  - a partnership between the EFPIA and the EMA
  - a foundation from a patient organisation
  - disease-specific patient organisations (European Federations)
  - Umbrella patient organisations, a body from a EU public institution
- To trigger a discussion on the governance, trust and financial viability of this new organisation/structure – based on their experience from their own organisations/programmes

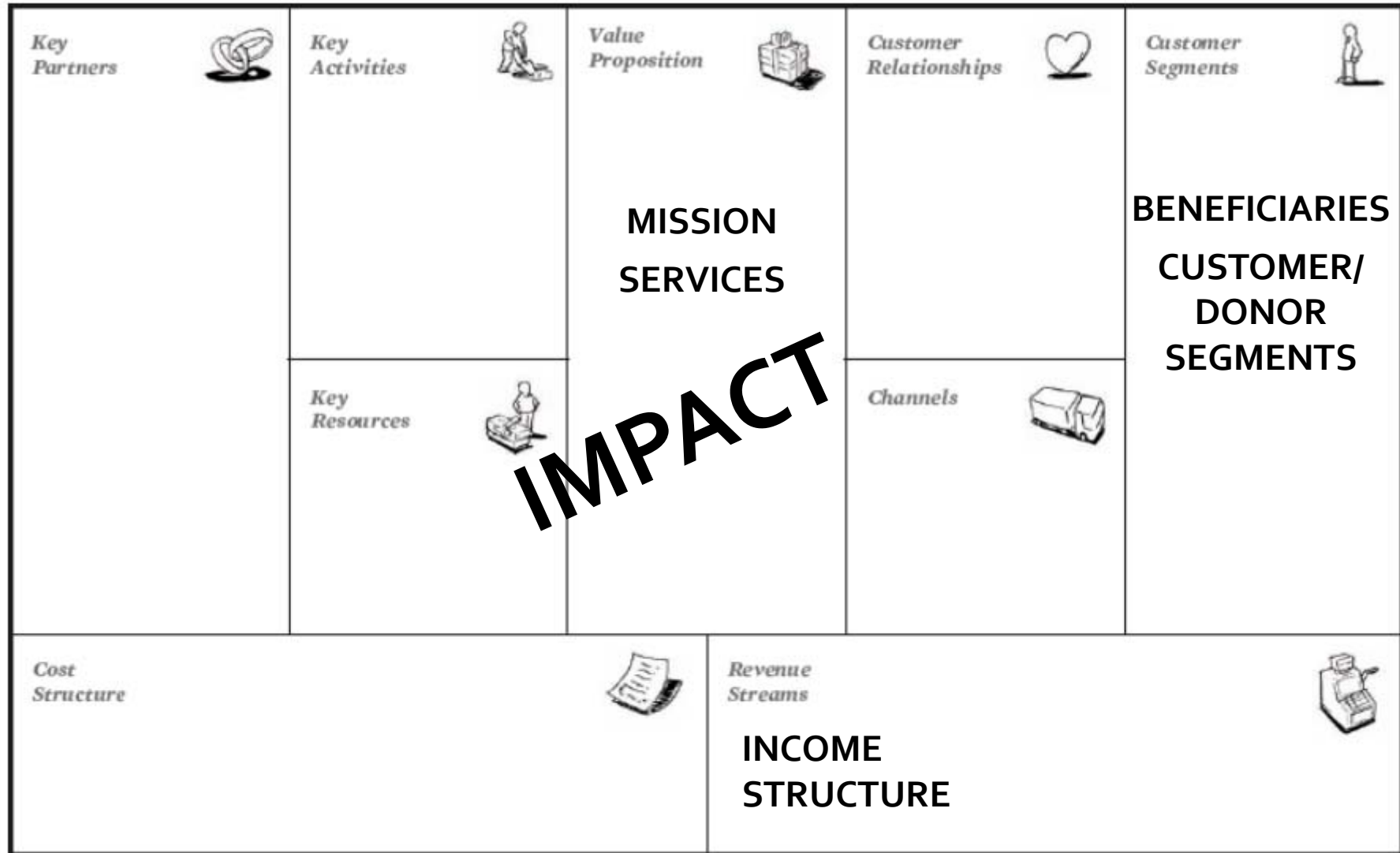
## Part 2: Who should organize patient engagement and the business model

- No agreement on which type of structure but ideally an European body (regulators/industry) partnering with an umbrella PO with a rotating executive board to avoid prioritisation of one disease vs another
- Key elements: Trust and Transparency: open communication, charter, agreement on common goals, having allies, driving a culture change
- Discussion on business model: fee-for-service vs suscription model (membership) or others
- Different opinions
- Apply corporate social responsibility model – contribution not only from pharma but from general consumer sector – needs to trigger a bigger culture change

# Workshop: Developing sustainability models

- Stakeholder representation: patient organisations – industry (50/50)
- Methodology used: Business model canvas
- Tool that allows structured brainstorming across nine building blocks of a business model
- Tool adapted to non-profit scenario
- Outcomes of the workshop: 4 preliminary models developed
- Next steps: analysis to refine models into a shortlist that will be published for multi-stakeholder consultation

# Business Model Canvas



# Workshop: Developing sustainability scenarios



# Common elements to all models

- **Services**
  - PE operations
  - Methods and tools – guidance to perform PE
  - Training and capacity-building
  - Matchmaking
  - Others included: quality control and value measurement
- **Partners**
  - Usual suspects: patient organisations, pharma, regulators, HTA
  - But also PFMD, EUPATI as providers of some services (tools and training)
  - PILG and other experts
  - New actors such as Tech companies and the media

# Common elements

- **Income structure**
  - Fee-for-service
  - Subscription model
  - Private donations
  - Fee waivers, free access and in-kind donations
- **Key resources**
  - Volunteers and paid staff
  - Others depending on the model: IT platforms
- **Cost structure**
  - Staff and volunteers
  - IT tool maintenance and others may vary depending on the activities, resources and partnerships defined

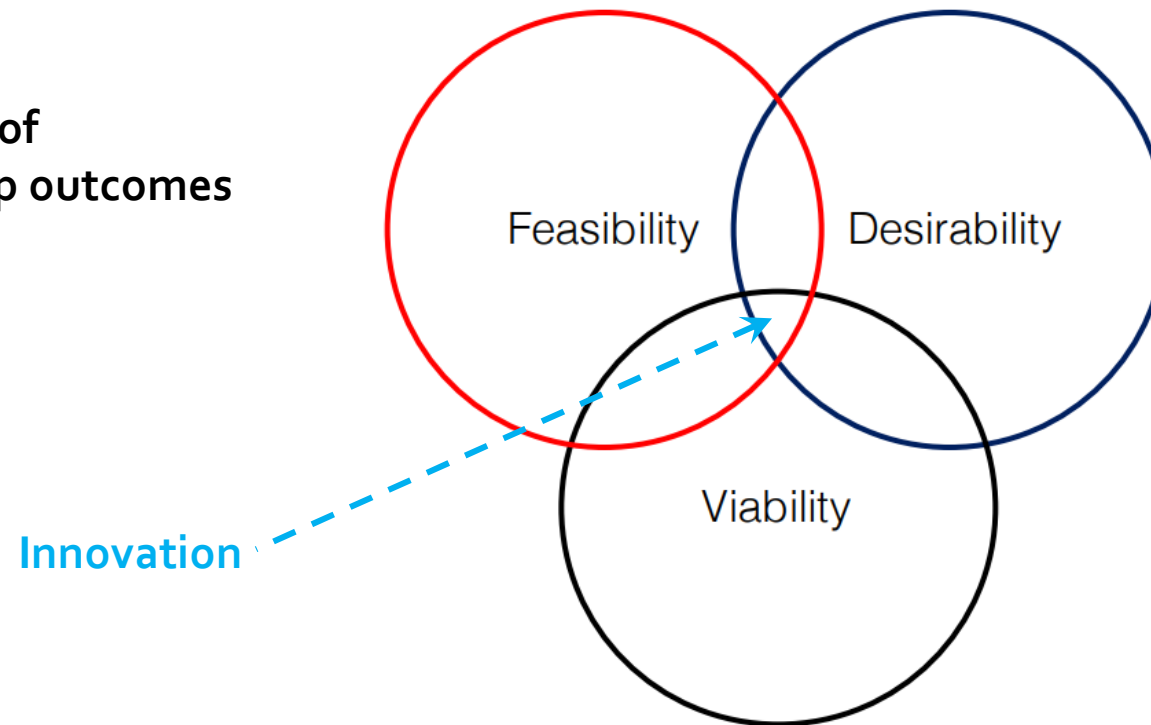
# Differences

- **Mission**
  - No agreement on the mission between the different canvases
  - Confusion between mission and impact
- **Key activities**
  - No agreement in the activities and they should not be confused with the services
- **Beneficiaries and customer/donor segments**
  - No agreement sometimes in who is a beneficiary and who is a customer
  - New actors venture capitalists



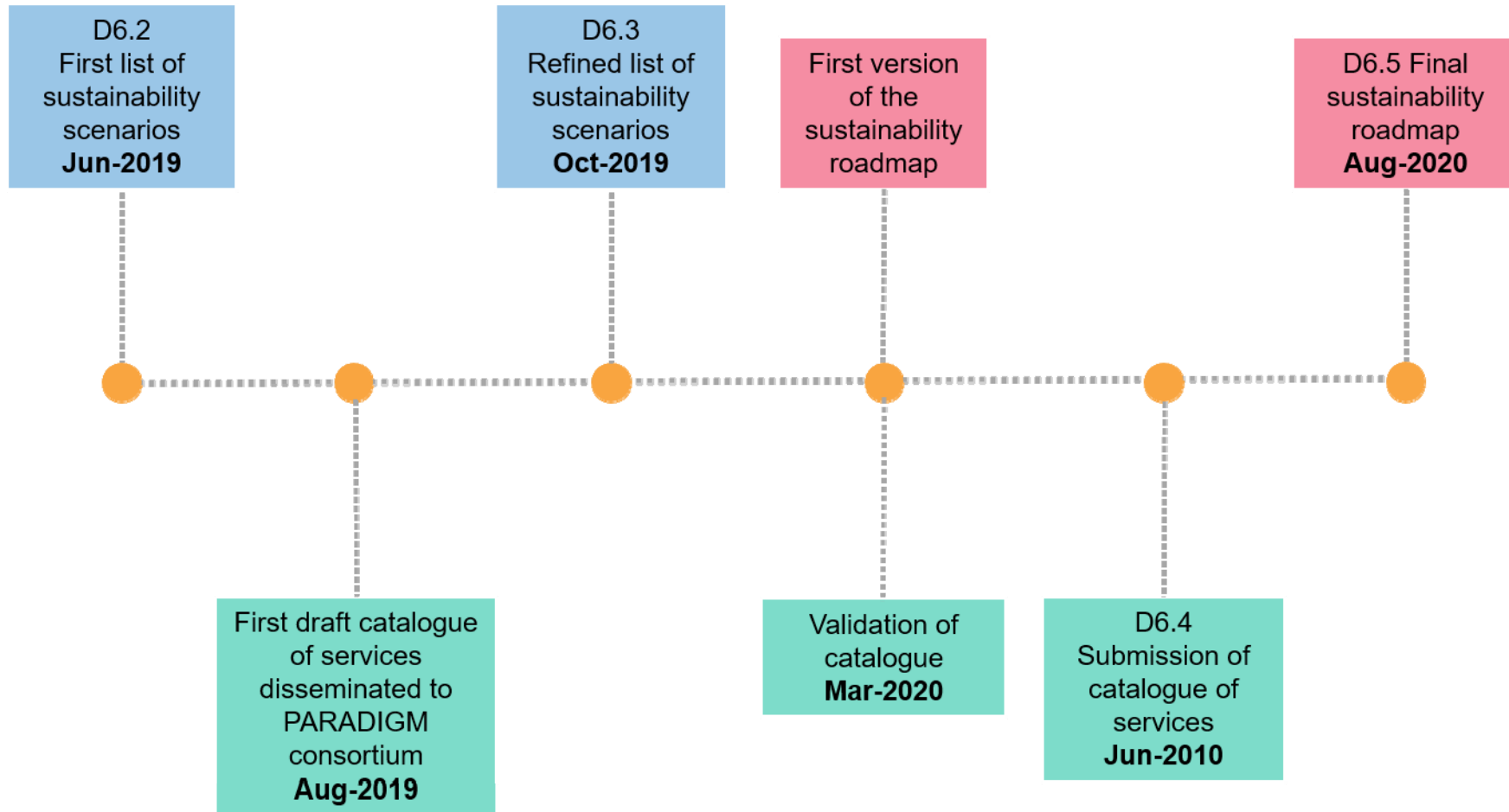
## Next steps

- Analysis of workshop outcomes



- Multi-stakeholder consultation to reach a final list of sustainability scenarios

# 20 months to go



# Final sustainability roadmap will include:

- Catalogue of services
- Definition of a multi-modular framework to provide one common entry point for all stakeholders
- Business model
- The associated partners and the governance strategy
  - to include new partners
  - establish/strengthen links with initiatives and organisations in the EU and internationally
- Operational plan for a sustainable long-term approach
- Financial plan to underpin sustainability
- The next concrete steps towards implementation of the sustainability strategy



A decorative graphic on the left side of the slide, consisting of a blue shape in the upper left and a green shape in the lower left, both with rounded corners. The blue shape is a square with its top-right corner rounded, and the green shape is a square with its bottom-right corner rounded. They meet at a diagonal line.

**Call for expression of  
interest: engaging in  
PARADIGM activities**

# Useful information

- Open until 28 Dec 2018
- Be an experienced patient representative
- Have a keen interest in medicines R&D
- Proficiency in English
- Selection criteria:
  - Motivation for applying – what are your objectives and goals, what do you expect to learn, how does your experience prepare you, how will the patient community benefit from your participation
  - Experience/knowledge related to patient engagement in medicines R&D and to the specific topic of the activity
  - Experience in interacting /collaborating with relevant stakeholders

# Workshops and consultations

<b>Workshops</b>	<b>Number of patients (estimation)</b>	<b>2019</b>
Consensus workshop on metrics (impact measurement)	1	Q1
Workshop: Developing patient engagement sustainability models	2	Q1
Stakeholder consultation: patient engagement sustainability models	1	Q2
Consensus building workshop on tools and templates to conduct patient engagement	1	Q2
Consultation: Catalogue of services (sustainability framework)	2	Q3
PARADIGM 2 <sup>nd</sup> Open Forum	1	Q3
Code of conduct workshop	1	Q4
<b>Workshops</b>	<b>Number of patients (estimation)</b>	<b>2020</b>
Alignment workshop on metrics (impact measurement)	1	Q2
Joint workshop: Code of conduct – Sustainability roadmap	2	Q2



**Thank you!**

**EURORDIS.ORG**