

# Webinar on issues of Co-funded partnerships – definition and implementation of additional activities beyond joint calls

24 January 2024



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## Welcome and introduction



# Aim of the webinar

## Scope of the webinar:

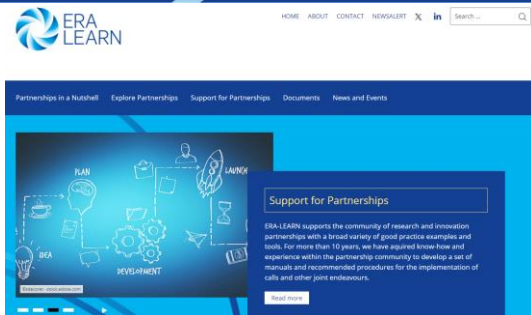
- to explain the concept of “additional activities”
- to give clear practical examples
- to discuss (common) challenges

## Out of scope:

- Implementation of joint calls, application procedures
- Reporting of costs in co-funded European Partnerships → separate webinar planned
- Synergies with Cohesion Policy Funds → see previous webinar 5/2023:  
<https://www.era-learn.eu/news-events/events/synergies-with-cohesion-policy-funds>
- Partnerships in 2<sup>nd</sup> Strategic Plan and FP10

# **ERA-LEARN: central information hub for European Partnerships**

# Central information hub: the ERA-LEARN portal <https://www.era-learn.eu>



## ERA-LEARN reaches out to all stakeholders:

- Policy level
- Network administrators
- Researchers

- Partnerships in a nutshell
- Explore Partnerships
- Support for Partnerships
  - Background information on Partnerships:
    - Strategic Coordinating Process
    - Annual Reports
    - Country Reports
    - Facts and Figures



**ERA-LEARN ... providing support & guidance to the community since 2009**

# Supporting the practical implementation of Partnerships

Partnerships in a Nutshell | Explore Partnerships | Support for Partnerships | Documents | News and Events

Partnerships in a Nutshell	Explore Partnerships	Support for Partnerships	Documents	News and Events
<b>GOVERNANCE, ADMINISTRATION &amp; LEGAL BASE</b>	<b>IMPLEMENTING JOINT CALLS</b>	<b>ADDITIONAL ACTIVITIES &amp; CROSS CUTTING ISSUES</b>	<b>PARTNERSHIPS IN HORIZON EUROPE AND HORIZON 2020</b>	
Governance structure and committees	Call planning & preparation	Alignment	Co-funded European Partnerships	
Agreements	Submission	Coherence & Collaboration	ERA-NET Cofund	
Financial Issues	Evaluation	Foresight	European Joint Programme Cofund (EJPCofund)	
Responsible Research & Innovation	Funding of Projects	Openness & Transparency		
Monitoring and Assessment				

- **guiding material**
- **manuals and tools**
- **examples of good practice**
  - governance models and legal issues
  - implementation of joint calls
  - additional activities by the Partnerships

In this section ERA-LEARN brings you information on the implementation of European Partnership governance structures of Europe where these structures are regulated.

We furthermore want to support you in understanding what is behind the idea of responsible Partnerships. Finally, monitoring and assessment in Horizon Europe. Thus, some of the

## Support for Partnerships

Home / Support for Partnerships / Implementing Joint Calls

### Implementing Joint Calls

We have compiled the following guidelines to provide the Partner sound basis for the implementation of transnational calls for proposals, information, practical examples and templates. Click on one of the more:

1. Call Planning & Preparation  
2. Submission  
3. Evaluation  
4. Funding Decisions  
5. After the Call

## Additional Activities & Cross Cutting Issues

Home / Support for Partnerships / Additional Activities & Cross Cutting Issues / Coherence & Collaboration

### Coherence & Collaboration

Horizon Europe orients R&I partnerships towards the achievement of policy impacts with the expectation that they take a systematic and transformational approach to the achievement of objectives. This means that partnerships need to exploit synergies with other relevant R&I initiatives, including between themselves, and reflect this in their governance models and joint actions.

Taking appropriate actions to ensure coherence and engage in collaboration are therefore important functions for Partnerships. **Coherence** can be defined as the quality of being logical and consistent, the quality of forming a unified whole. **Collaboration** can be envisaged on two main levels:

1. Exploiting **synergies** between European Partnerships and with other EU R&I initiatives to their mutual benefit in achievement of objectives and policy impacts.
2. Demonstrating coordinated efforts with respect to the new Commission priorities and/or the UN Sustainable Development Goals.

Options for collaboration

- Exploiting synergies with other programmes

Related Files

Report: Coherence and Synergies of candidate European Partnerships under Horizon Europe

- Alignment
- Coherence & Collaboration
- Foresight
- Openness & Transparency
- Societal and Market Uptake
- Strategic Research and Innovation Agendas
- Synergies with the Cohesion Policy Funds
- Other Additional Activities

# ERA-LEARN: interaction with community

<https://www.era-learn.eu/news-events/events>

## ❖ annual large events

- Annual Partnership Stakeholder Forum (5-6 Dec 2023)

## ❖ workshops/webinars on specific issues

- Implementing co-funded Partnerships (April 2023)
- Synergies with Cohesion Policy Funds (May 2023)
- Monitoring & Evaluation framework (Sep 2023)

➤ **register to our news alert:**

<https://www.era-learn.eu/newsletter>



## Events

Home / News and Events / Events / European Partnership Stakeholder Forum 2023 - from idea to impact

### European Partnership Stakeholder Forum 2023 - from idea to impact

Date: 05/12/2023 - 06/12/2023

EC-DG RTD, with the support of ERA-LEARN, hosted the second edition of the Partnership Stakeholder Forum in Brussels. The event brought together the entire European Partnership stakeholder community to discuss policy and practical aspects related to European Partnerships. It also provided a space for networking, broadening engagement and sharing experiences.

Objectives:

- Review the state of play of implementation of the European Partnerships launched under the first Strategic Plan, as well as a first look on the interim evaluation of Horizon Europe.
- Present and discuss the enlargement of the partnerships portfolio under the second Strategic Plan.
- Have a first exchange of views with the community at large on European Partnerships in the next Framework Programme.

The agenda featured plenary and parallel sessions addressing a range of issues. Opportunities for networking were provided.

[Download Main Agenda](#)

[Download Agenda parallel Sessions Day 1](#)

[Download Agenda parallel Session Day 2](#)

[Download Slides of the parallel workshop sessions](#)

### Recordings of the live stream

The plenary session was streamed live on both days. Recordings of the stream are available on YouTube.

Day 1



Related Files



[European Partnership Stakeholder Forum 2023 - Preliminary Results](#)

The second Partnership Stakeholder Forum was organised by European Commission and ERA-LEARN and took place in Brussels, 5-6 December 2023.

[More...](#)

[Download](#)



[European Partnership Stakeholder Forum 2023 - Workshop slides](#)

Slides of the parallel workshop sessions

[More...](#)

[Download](#)

# **What is a Co-funded European Partnership**



# Basics

Horizon Europe distinguishes between **3 types of European Partnership**:

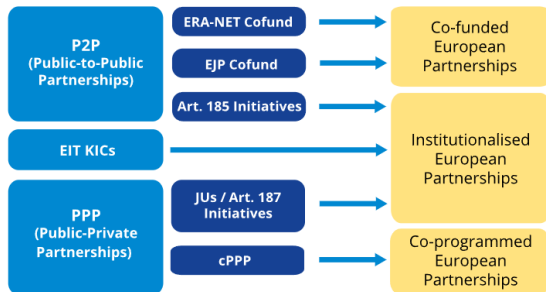
- Co-funded
- Co-programmed
- Institutionalised

## Co-funded Partnerships:

- are successors of Horizon 2020 ERA-NET Cofund and European Joint Programme (EJP) Cofund
- involve mainly **research funders, other public authorities** and **research performing organisations** from EU MS/AC at the core of the consortium
- implement a **joint work programme** agreed between the EC and the consortium, pooling national/regional resources with EU co-funding

Horizon 2020

Horizon Europe



© ERA-LEARN

## Legal background on Co-funded European Partnerships

### Co-funded European Partnerships

- are implemented in **Horizon Europe** as **Programme Co-fund Actions**
- are based on a **Grant Agreement** signed with the EU following the **submission of a proposals** to a topic in the Horizon Europe work programme
- receive **EU co-funding at a constant rate per Grant Agreement** (typically 30%) which is generated by **eligible costs**
- generate costs **eligible for EU co-funding** by following the **rules for financial management for any Horizon Europe action**
- **usually** implement **two types of activities** defined in their work programmes: **calls for proposals** (using Financial Support to Third Parties) and **additional activities**.

## Calls for proposals

- co-funded European Partnerships **launch joint calls**
- these calls are listed on **EC funding & tender opportunities portal & ERA-LEARN portal**
- applicants to these calls (e.g. research institutions, companies) **apply for funding according to the national/regional funding rules** mentioned in the particular call
- national/regional **research funders** provide **financial support to third parties** –they transfer the EU co-funding received via the Co-funded Partnership Grant Agreement to recipients that are not party to the GA, previously known as '**cascading funding**'

## Additional activities

- Additional activities include **any activity that is distinct from** and complements the **financial support to third parties** (“joint calls”).
- Typical “in-house activities and non-financial assets” - a few examples:
  - access to data and services
  - shared use of infrastructure
  - capacity building
  - mobilisation and engagement of stakeholders
- The partners implementing these activities are mainly beneficiaries in the Grant Agreement

## Internal arrangements for the practical implementation

### Co-funded Partnerships

- implement a **joint work programme** agreed between the EC and the consortium
- **set up a Consortium Agreement to define internally how the EU co-funding is used best** (= distributed internally) **depending on their respective needs**, similar to ERA-NET Cofund & EJP Cofund actions in Horizon 2020)
- may decide internally to apply **different internal funding rates for different activities**, e.g.
  - **higher (>30%) internal funding rates** e.g. for coordination and other project activities (e.g. increased workload provided by the call secretariat or task leaders for the benefit of the whole consortium)
  - **lower (<30%) internal funding rates** for the funding of trans-national research projects (cost category D1). This requires increased national/regional contributions to still receive the EC contribution foreseen in the GA as the reported costs need to be the same.

## Conclusion

A co-funded European Partnership is a Horizon Europe project implemented as a Programme Co-fund Action under **the same rules as any other Horizon Europe project.**

All **additional activities have to comply with the budget categories** of the Horizon Europe Framework.

### **ERA-LEARN Support**

<https://www.era-learn.eu/support-for-partnerships>

<https://www.era-learn.eu/news-events/events>

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# Presentation of the legal and financial context regarding the model grant agreement: Participants in action, type of costs and personnel costs

Video



# **Internal Arrangements – Consortium Agreement**



## Horizon Europe: Co-funded Partnerships

- Co-funded Partnership implement **two types of activities** which generate **eligible costs**: external **calls** for proposals (using Financial Support to Third Parties) and additional **in-kind activities**
- **Eligible costs have to be actually reported costs. Estimated costs are not eligible.**
- **EU co-funding is distributed according to internal agreements defined in the Consortium Agreement** with possible deviations from the strict **Horizon Europe** funding rate
- **Why:**
  - activities carried out by core partners for the benefit of the whole partnership usually get a higher funding rate to cover the higher costs of these core partners
  - parts of EU financial contribution should be used to balance available and requested funding in the joint calls to avoid some funding agencies blocking the selection list
- **where needed, internal rules/arrangements can go beyond Horizon Europe rules**

## Internal arrangements for the practical implementation

### Co-funded Partnerships

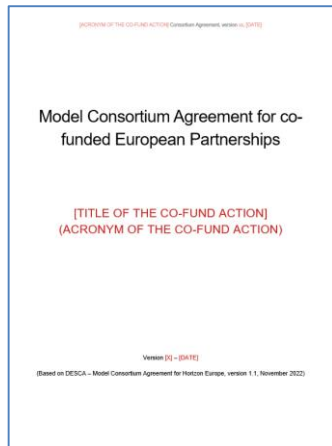
- implement a **joint work programme** agreed between the EC and the consortium
- **set up a Consortium Agreement to define internally how the EU co-funding is used efficiently** (= distributed internally) **depending on their respective needs** (similar to ERA-NET Cofund & EJP Cofund actions in Horizon 2020)
- may decide internally to apply **internal funding rates for different activities**, e.g.
  - **higher (>30%) internal funding rates** e.g. for coordination and other project activities (e.g. increased workload provided by the call secretariat or task leaders for the benefit of the whole consortium)
  - **lower (<30%) internal funding rates** for the funding of trans-national research projects (cost category D1). This requires increased national/regional contributions to still receive the EC contribution foreseen in the GA

# ERA-LEARN: Model Consortium Agreement for Co-funded Partnerships

ERA-LEARN provides a Model Consortium Agreement:

[https://www.era-learn.eu/documents/modelca\\_co-funded\\_eps.docx](https://www.era-learn.eu/documents/modelca_co-funded_eps.docx)

- Based on DESCA – Model Consortium Agreement for Horizon Europe, version 1.1, November 2022 (to be consulted)
- adaptations according to the co-fund needs, in particular:
  - Section 1 (Definitions)
  - Section 6 (Governance structure)
  - Section 7 (Financial provisions)
  - Section 8 (Call implementation) (new)
  - Section 9 (Results)
  - Section 10 (Access Rights)
  - Section 12 (Data Management) (new) and paragraph 13.8 (Settlement of disputes)



based on examples of European Partnership Consortium Agreements

## Model Consortium Agreement

**ERA-LEARN suggests using** a model for the distribution of EU co-funding based on **the following principles:**

- **keep it as simple** as possible
- apply the **same principles of reporting internally as towards the EC**
- consider **adapting internal funding rates** for different cost categories – e.g. lower funding rate for cost category D1 (→ increased national/regional contributions)
- consider **adapting internal funding rates** for different work packages/types of activity if suitable
- **foresee a reserve fund to be able to cover unexpected situations**, e.g. by setting aside the EU funding related to indirect costs

The Partnership consortium needs to agree which **core activities** are essential for the implementation of the Co-Fund Action to **prioritise** the distribution of the EU co-funding (define activities with internal higher/ lower funding rates).

# Example 1: different internal funding rates for different cost categories

## Real costs and reporting to EC

	Purchase costs					Financial support to third parties/€ (actual costs)	Indirect costs/€	Total eligible costs/€	corresponding requested EU contribution/€	theoretical funding rate
	Personnel costs/€	Subcontracting costs/€	Travel and subsistence/€	Equipment/€	Other goods, works and services/€					
Ben. 1	830 000	8 000 000	40 000	500 000	500 000		467 500	10 337 500	3 101 250	30%
Ben. 2	2 000 000	1 000 000	20 000	20 000		12 000 000	510 000	15 550 000	4 665 000	30%
Ben. 3	130 000		40 000				42 500	212 500	63 750	30%
.....	15 401 000	-	1 122 500	-	2 100 000	232 800 000	4 655 875	256 079 375	76 823 813	30%
<b>Total</b>	<b>18 361 000</b>	<b>9 000 000</b>	<b>1 222 500</b>	<b>520 000</b>	<b>2 600 000</b>	<b>244 800 000</b>	<b>5 675 875</b>	<b>282 179 375</b>	<b>84 653 813</b>	<b>30%</b>

## Use of EC contribution: internal agreements for reimbursements

	Purchase costs					Support for FCTP adjusted to internal agreements (mixed mode)	Indirect costs/€	Reserve fund	Total internally agreed EC funding allocation/€	real funding rate
	Personnel costs/€	Subcontracting costs/€	Travel and subsistence/€	Equipment/€	Other goods, works and services/€					
Ben. 1	830 000	8 000 000	40 000	500 000	500 000	-	-		9 870 000	95%
Ben. 2	2 000 000	1 000 000	20 000	20 000		3 000 000	-		6 040 000	39%
Ben. 3	130 000		40 000				-		170 000	80%
.....	15 401 000	-	1 122 500	-	2 100 000	48 247 550	-		66 871 050	26%
<b>Total</b>	<b>18 361 000</b>	<b>9 000 000</b>	<b>1 222 500</b>	<b>520 000</b>	<b>2 600 000</b>	<b>51 247 550</b>	<b>-</b>	<b>1 702 763</b>	<b>84 653 813</b>	<b>30%</b>
<b>funding rate</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>21%</b>	<b>0%</b>			

## Example 2: different internal funding rates for different WPs/types of activity

Activities	Costs			EC funding (30% funding rate)			internal distribution of EC funding			
	Core partners	Partners in some activities	Partners in calls only	Core partners	Partners in some activities	Partners in calls only	Core partners	Partners in some activities	Partners in calls only	
Coord./Met.	500 000 €			150 000 €			500 000 €			internal funding rate 100%
activity A	100 000 €	500 000 €		30 000 €	150 000 €		100 000 €	500 000 €		internal funding rate 100%
activity B	300 000 €	200 000 €		90 000 €	60 000 €		300 000 €	200 000 €		internal funding rate 100%
etc.	...	...		...	...		...	...		...
co-funded call	30 000 000 €	3 000 000 €	50 000 000 €	9 000 000 €	900 000 €	15 000 000 €	9 000 000 €	900 000 €	15 000 000 €	funding rate 30% does not work
Total	30 900 000 €	3 700 000 €	50 000 000 €	9 270 000 €	1 110 000 €	15 000 000 €	9 900 000 €	1 600 000 €	15 000 000 €	
	84 600 000 €			25 380 000 €			26 500 000 €			-1 120 000 € deficit
co-funded call	30 000 000 €	3 000 000 €	50 000 000 €	9 000 000 €	900 000 €	15 000 000 €	8 400 000 €	840 000 €	14 000 000 €	internal average funding rate max. 28% due to other activities funded at 100% (note: individual funding rates can be agreed depending on gap filling mode)
Total	30 900 000 €	3 700 000 €	50 000 000 €	9 270 000 €	1 110 000 €	15 000 000 €	9 300 000 €	1 540 000 €	14 000 000 €	
	84 600 000 €			25 380 000 €			24 840 000 €			540 000 € reserve budget

## Firewall/ Information Barrier

- **beneficiaries of Co-funded Partnerships** (Grant Agreement) cannot be beneficiaries of competitive activities implemented in the context of the Co-Fund Action due to conflicts of interest
- in particular, they **cannot participate in proposals submitted to transnational calls unless** they have been explicitly listed and **allowed to do so in the Grant Agreement**
- the **Grant Agreement** indicates measures to **mitigate the conflicts of interests**, including but not limited to staff separation and information barriers
- the **Consortium Agreement** contains specific rules and procedures, e.g. meetings in compartmentalized sessions in order to separate topics and discussions
- a **management policy** addressing **potential conflicts of interests** could be helpful
- **technical barriers are needed** to prevent beneficiaries with a conflict of interest from accessing any critical information (emails, documents)

## Conclusions

You need to make yourself familiar with

- Horizon Europe rules on eligible costs
- principles of reporting
- cost categories
- internal arrangements of the particular Co-Funded Partnership
- types of activities of the particular Co-Funded Partnership and calculation models for internal reimbursement rates



# Webinar on issues of Co-funded European Partnerships – definition and implementation of additional activities beyond joint calls

Partnership for the Assessment of the Risks from Chemicals

PARC Coordination Team

24 January 2024

PARC



Co-funded by  
the European Union

# Plan of the presentation

- ❖ **General overview of PARC and its governance**
- ❖ **PARC's objectives and pathways to impacts**
- ❖ **Organisation of PARC activities**
  - Strategic Research and Innovation Agenda
  - A common science policy agenda and mapping of needs
- ❖ **Implementation of PARC activities**
  - R&I activities implemented as projects
  - Transversal activities
- ❖ **Financial construction behind PARC**
- ❖ **Challenges and issues**
- ❖ **Feedback and recommendations**

# The Partnership for the Assessment of Risks from Chemicals

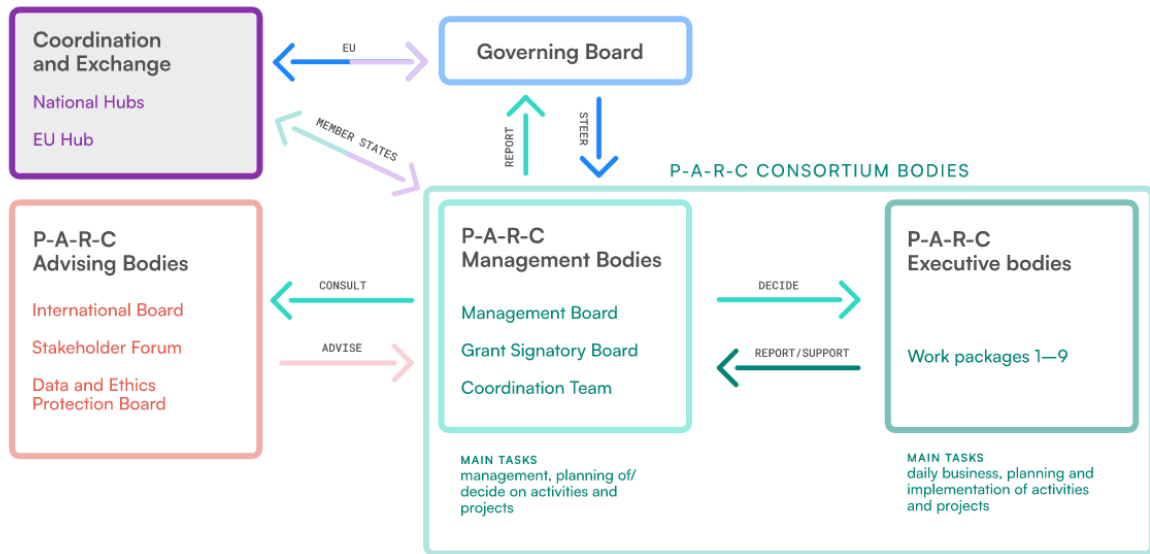


- Public-public **partnership**
- 50/50 co-funded **budget: 400 M€**
- 05/22 – 04/29
- ~200 partners from 29 countries:  
24 MS + CH, IL, IS, NO, UK, 3 EU agencies: ECHA, EEA, EFSA

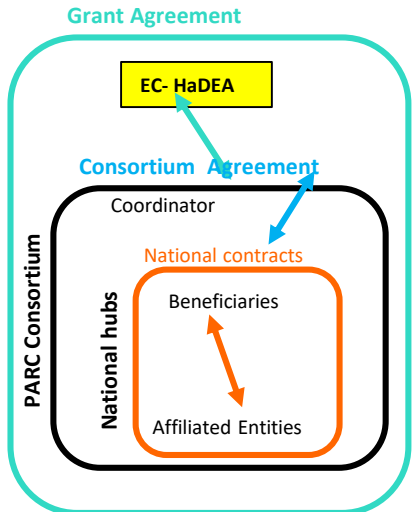


“PARC’s mission is to **address current, emerging and novel chemical safety challenges** and **enabling the transition to the Next Generation Risk Assessment (NGRA)**, in line with the European Green Deal’s zero-pollution ambition for a toxic free environment and in particular with the **Chemicals Strategy for Sustainability** Towards a Toxic-Free Environment.”

# PARC Governance



# PARC Agreements between Participants



**PARC Grant Agreement (GA)** = contractual document between the PARC consortium and the EC. It defines the rights and obligations related to the Partnership of the participants and the EC

**PARC Consortium Agreement (CA)** = internal contractual document stating the rules of collaboration between the participants mainly for:

- **Internal arrangements;**
- **Governance of the Partnership** and;
- **Financial issues**

Signed by Grant Signatory Board members (beneficiaries).

**Good practice** to conclude **national written contracts** between Beneficiaries and their AEs that ensures their AEs comply with the obligations of the GA and CA

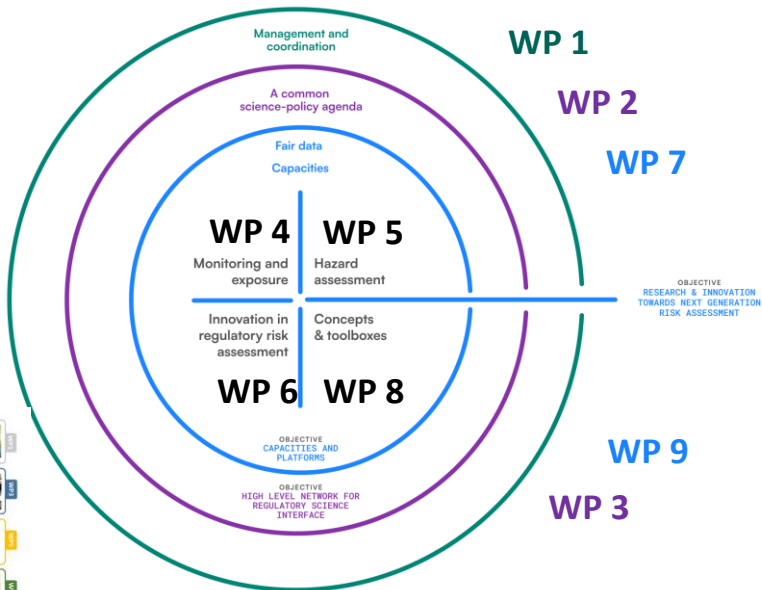
**EC- HaDEA is the Granting Authority**

# PARC aims

## General Objective

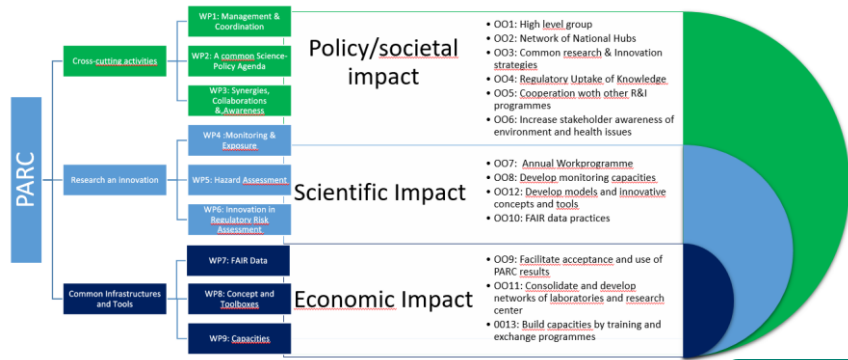
Consolidate and strengthen the EU's R&I capacity for chemical RA to protect human health and the environment and contribute to a non-toxic environment and a circular economy.

**Nine Workpackages** to reach our targets



## PARC MANAGEMENT BOARD

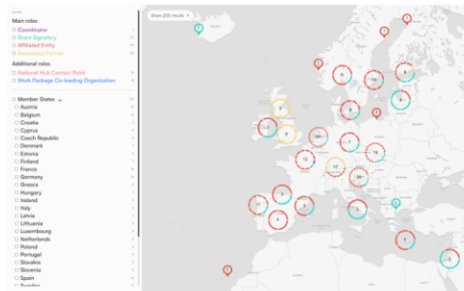
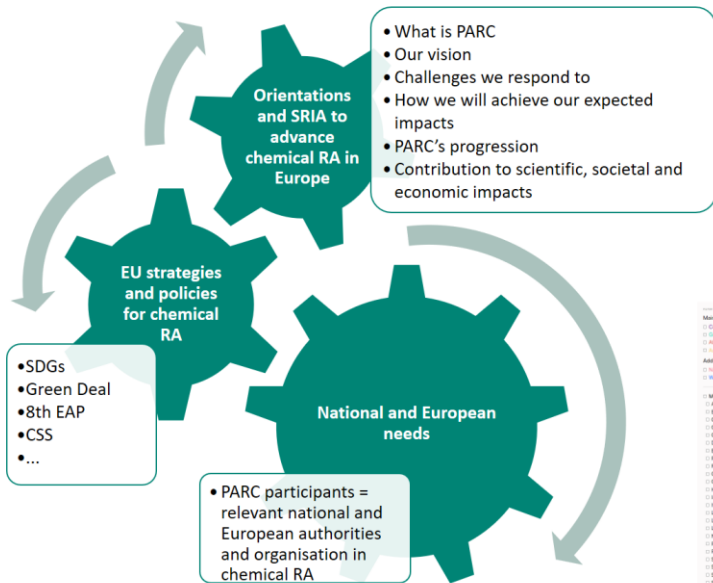

# Objectives and pathways to impacts



3 specific and 13 realistic, measurable, achievable and verifiable operational objectives have been defined to deliver the expected outcomes

- TO BUILD A SUSTAINABLE EUROPE WIDE RESEARCH AND INNOVATION PLATFORM FOR CHEMICAL RISK ASSESSMENT
- TO ESTABLISH SYNERGIES WITH RELEVANT ACTIVITIES FROM OTHER EU POLICY AREAS FOR SHARED UNDERSTANDING AND ADDRESSING NEEDS TO BETTER PROTECT ENVIRONMENT AND HEALTH
- TO EMPOWER THE COMMON EUROPEAN GREEN DEAL DATA SPACE
- TO ENHANCE COLLABORATION AND MOVE TOWARDS "ONE SUBSTANCE-ONE ASSESSMENT" WITH SHARED EVIDENCE TOOLS AND METHODOLOGIES
- TO SUPPORT PUBLIC AUTHORITIES AND INDUSTRY IN IMPLEMENTING THE CHEMICAL STRATEGY FOR SUSTAINABILITY

# Organisation of PARC activities: SRIA

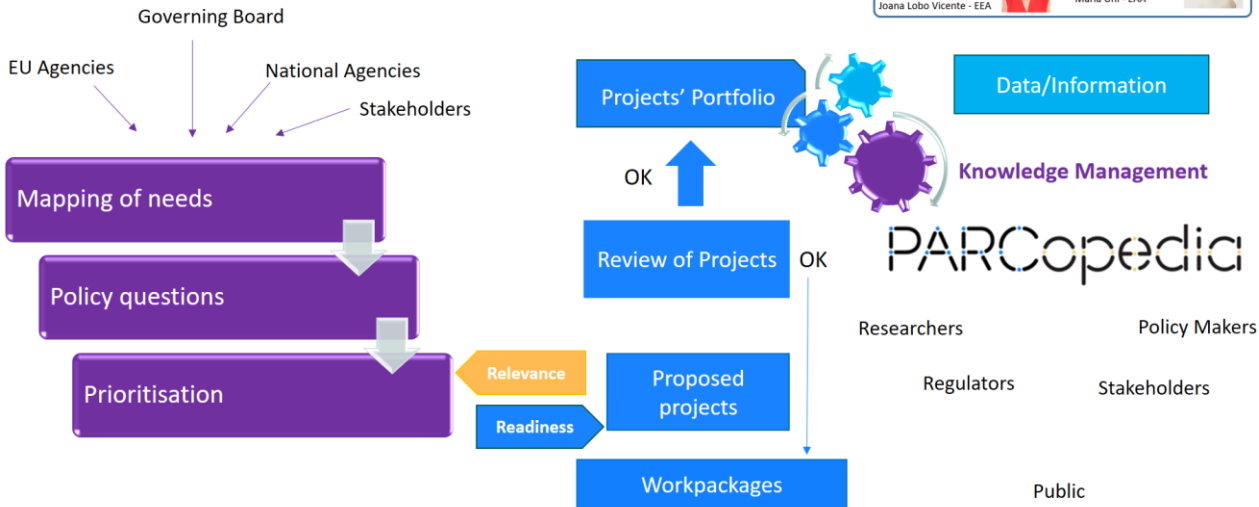


PARC network (website screenshot)

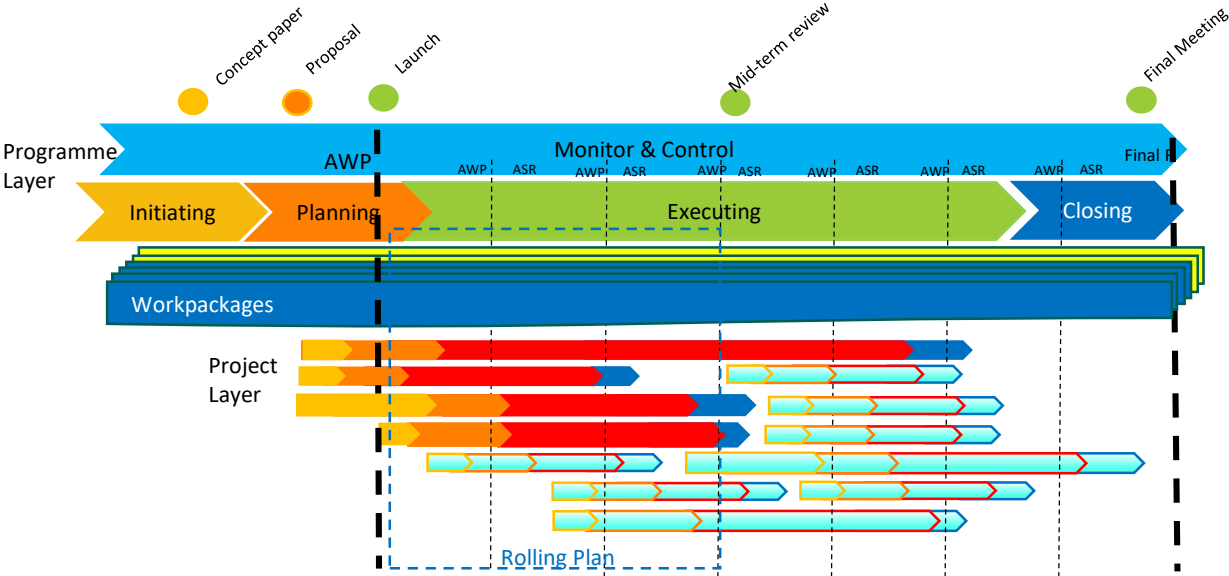


# Organisation of PARC activities: WP2

## A common science policy agenda



# PARC SRIA and projects



# From Mapping the Needs to Setting PARC Priorities

## ROUND 1

3<sup>rd</sup> prioritisation round in  
HBM4EU and PARC  
interim GB survey (2021)

2022

beyond

PARC

## ROUND 2

2<sup>nd</sup> prioritisation  
round  
2023-2024

2024

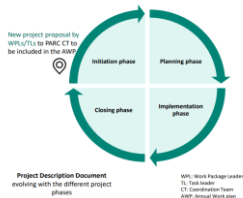
2025

2026

beyond

## Project Review Process

### A project life cycle



### Project reviewing criteria

- Specific**  
Does the proposed project indicate and explain which specific regulatory (National/EU) process or outcome will benefit in a tangible manner and does it explain how it fits into the bigger picture of regulatory challenges?
  - Measurable**  
Does the submitted project explain how it addresses the regulatory challenge (quantitatively/qualitatively) and which tangible benefits can be expected?
- Scoring range from 1 to 5:  
1 = completely not  
5 = completely yes

## Key Areas of Regulatory Challenge

### 1 Policy and Regulatory Relevance

- ✓ Discussions with agencies (e.g.: SCCS, ECHA, EEA, EFSA, etc.)
- ✓ Regulatory needs identified by PARC WPL/TL according to their WP/Task objectives
- ✓ "Chemical Strategy for Sustainability" and the "Strategic Research and Innovation Plan for Safe and Sustainable Chemicals and Materials"

### 2 Partnership: Synergy and Alignment

- ✓ Interactions and crosslinks with other WPs or Tasks within PARC
- ✓ Scientific activities done outside PARC
- ✓ Third round of Prioritisation done under HBM4EU
- ✓ Methods, endpoints and substances prioritised in the PARC interim GB's survey

### 3 Practicality: Feasibility and Technicality

- ✓ PARC partners' interests, their capacities and resources
- ✓ Available data and knowledge gaps
- ✓ Hazardous properties and characteristics of substances

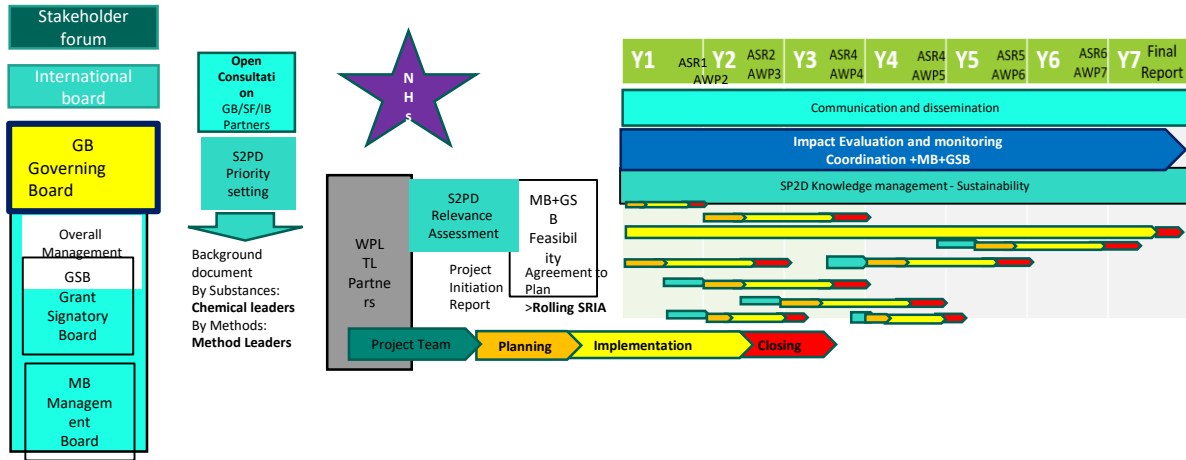
## ROUND 3

Last prioritisation  
round

2027

beyond

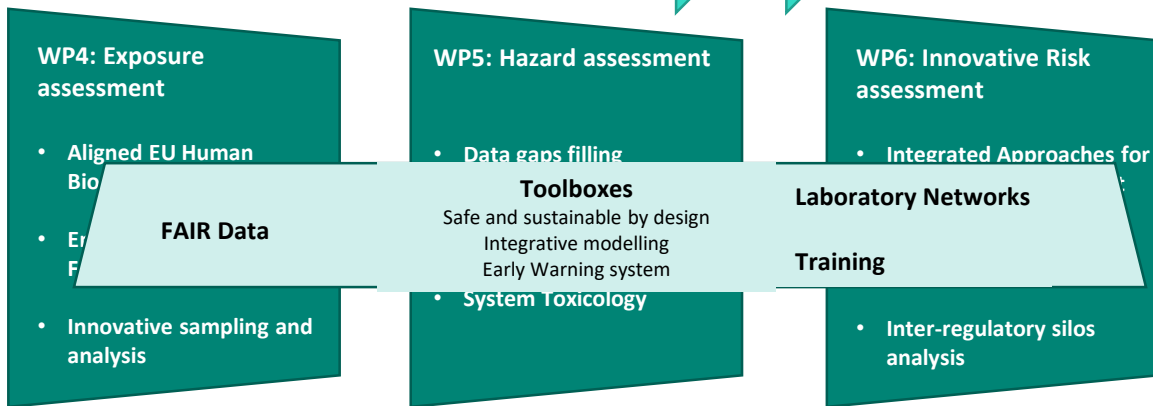
# SRIA: Process to initiate and select projects for implementation



# PARC Implementation: R&I activities and project portfolio

**PARC internal Projects** are scientific activities selected by the MB, managed by Project Leaders, to be implemented by several PARC partners for an average duration of 3 to 4 years

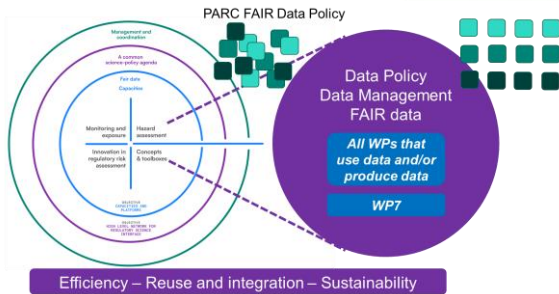
More than 70 projects and case studies are underway



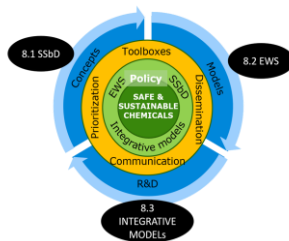
# PARC Implementation: transversal activities

- **Transversal activities** are cross-cutting activities planned for the whole duration of PARC which are not part of projects. They include activities under WP1, WP2, WP3, parts of WP7, WP8 and WP9 and other transversal scientific activities for the management of WPs 4-5-6 and their tasks.

## FAIR Data – WP7



## Concepts and toolboxes – WP8

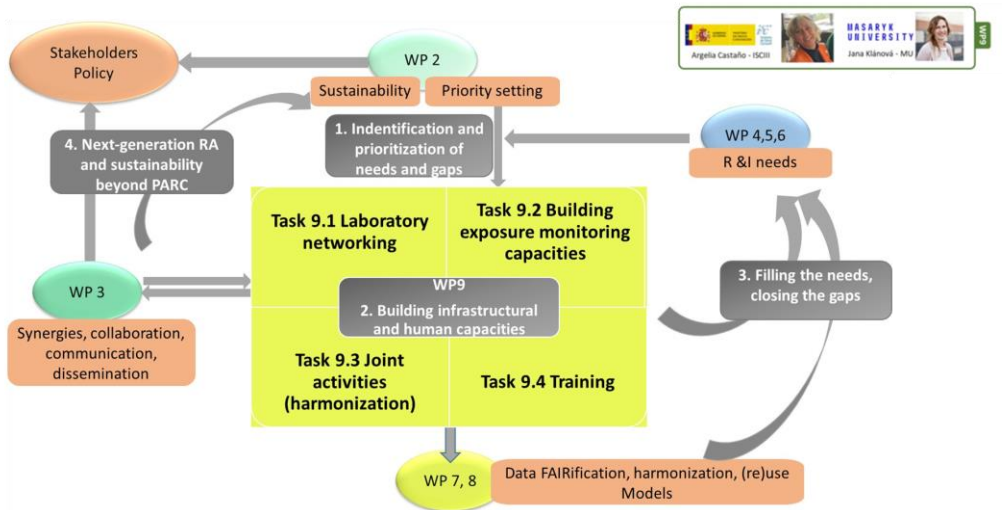


WP8 aims at supporting the development and consolidation of new concepts and approaches such as:

- **Safe and Sustainable by Design** chemicals, and their applications in materials and products (Task 8.1)
- Trans-regulatory approaches for **Early Warning Systems** for chemical risks, identification of information need (Task 8.2)
- **Integrative models** approaches for chemical exposure, hazard and risk assessment (Task 8.3)

# PARC Implementation: transversal activities

## Building infrastructural and human capacities –WP9



# PARC: Synergies, collaboration & awareness – WP3


**AAAE**  
 Institute for Applied  
 Analysis in Public Health  
 UNIVERSITY OF THE  
 SAO PAULO STATE CAMPUS  
 Aglaia Koutsodimou - GCSL



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**EdM**



e.g.

  
 The European Partnership  
 for Alternative Approaches to Animal Testing









  
 European Biodiversity Partnership



# PARC Communication – WP3



PARC (@PARC\_chemicals) / Twitter

A website: <https://www.eu-parc.eu>



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Sections:

- Opinion
- Science impact
- Regulatory news
- Top picks from national activities
- Insights
- PARC stories
- What's on
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PARCopedica

# In-kind contributions

PARC: Collaborative work between the institutions involved. No open calls

→ Only based on “in-kind” contributions

“in-kind” contributions = eligible costs - EU funding

Also known as match-funding

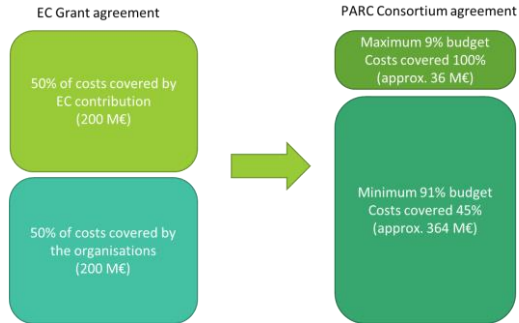
Apply to all costs claimed for PARC (personnel costs, other direct costs and subcontracting)

Must relate to the activities described in the DOA and AWP

Can originate from various institutional budgets and other sources as long as the **no double funding principle** is respected

Total match-funding from the participating organisations has to correspond to 50% of the total costs incurred for PARC

The other half is the EU contribution that will be reimbursed by HaDEA (the granting authority) as 50% of the total costs declared by the partners deemed eligible at the global Partnership level



# Financial construction behind PARC

Budget in GA (Annex 2) for the 7-years of the partnership BUT only indicative (max amount each Participant was willing to commit at submission)

- Envelopes par WP and Definition of costs to be funded 100% using the EC contribution
- Internal budget developed and updated according to actual involvement of each Participant in the WPs (implementation of projects and transversal activities)

Overall distribution of the budget per WP		
WPs	% of the total budget	Total budget
WP4-5-6	73,75%	295 000 000 €
WP4: Monitoring and exposure	27,50%	110 000 000 €
WP5: Hazard assessment	25,00%	100 000 000 €
WP6: Innovation in regulatory risk assessment	21,25%	85 000 000 €
Other WPs	26,25%	105 000 000 €
WP1: Management and coordination + WP1 buffer	4,63%	18 500 000 €
WP2: Common agenda	3,00%	12 000 000 €
WP3: Synergies	3,13%	12 500 000 €
WP7: FAIR data	7,50%	30 000 000 €
WP8: Concepts and toolboxes	4,00%	16 000 000 €
WP9: Capacities	4,00%	16 000 000 €

Step 1

- Definition of an order of magnitude of the **proportion of the total budget between all WPs**

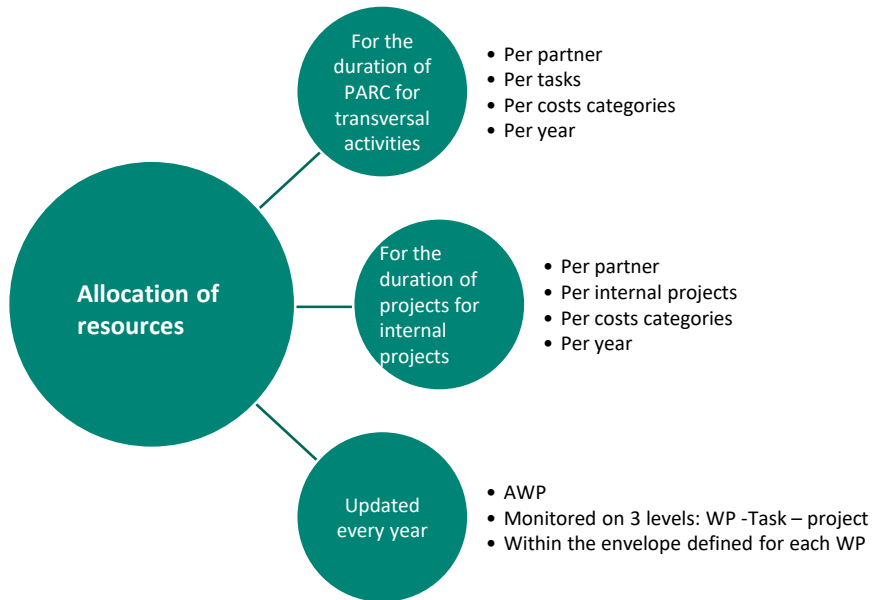
Step 2

- Definition of a process for applying for **activities/costs to be funded 100% using the EU contribution**
- Definition of a **minimum EU co-funding rate for the co-funded activities**

Step 3

- Definition by each WP of its activities, participants and resources
- **Planning of the resources** : *precise for the AWP; estimation for 7 yrs*
- *Organisations must have validated that they have the necessary backing and co-funding for their participation*

# Internal budget construction



# Challenges and issues

## Management of the consortium

- Different levels of knowledge/ understanding of European funding by the partners
- Some smaller partners understaffed for the management

## Management of the budget

- Understanding of the in-kind co-funding
- Finding the in-kind cofunding and securing it
- Obligation to have the 50% EC cofunding per partner in the GA → confuses the partners as not the reality
- Double accounting and financial monitoring: in relation to the EC and internal cofunding rate

## Management by the EC and Reporting

- One-size fits all: No consideration of the particularities of partnerships (size and structure)
- Evaluation and monitoring focused on the granting authority's needs and requirements
- Complicated and detailed reporting requirements (per project)
- Calendar too tight in light of the above

## Synergies

- Lack of concrete synergies between funding under HE and funding from other European programmes, either at the level of activities or/and at the level of expenditure

# Feedback and recommendations

## Management by the EC & Reporting

**Review rules** for applying and monitoring partnerships to **adapt to the specificities of the instrument** (closer to a programme than a collaborative research project)

Allow **flexibility** in implementation and follow-up, including budget-wise

A harmonisation of the mode of governance could be proposed, as all follow the same logic of co-construction and are part of a common impact monitoring plan

## Synergies

**Practical, simple and shared solutions**, particularly in terms of co-financing rules are needed

PARC ([eu-parc.eu](http://eu-parc.eu))

Thank you for your attention!

Contact: [Parc@anses.fr](mailto:Parc@anses.fr)



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# **Pandemic preparedness partnership – example for a partnership under development**





# EU response to the COVID-19 pandemic

- ERAvsCORONA action plan, April 2020
  - ❖ Better coordination of R&I funding against the Coronavirus
  - ❖ Supporting large EU wide trials for the clinical management of COVID-19 patients

## European Health Union

to improve EU-level protection, prevention, preparedness and response against human health hazard

### European Health Security Framework – crisis preparedness and response

Regulation on serious cross-border threats to health  
(2022/2371)

Reinforced mandate of EMA  
(2022/123)

Reinforced mandate of ECDC  
(2022/2370)

Set up of HERA and  
Emergency Framework  
Regulation (2022/2372)

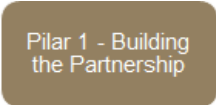
# Partnership on pandemic preparedness

- Responds to request for better coordination of R&I funding against the Coronavirus, as expressed in the context of the ERAvsCorona Action plan
- Was included in the first Horizon Europe strategic plan defining the main orientations for R&i investments over the period 2021-2024, the type of partnership was left open
- Partners (public authorities and European Commission) should develop and agree on an aligned multi-annual agenda with common objectives for R&I actions in pandemic preparedness

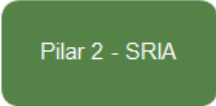
## COORDINATION AND SUPPORT ACTION

- Title : **Building a European strategic REsearch and innovation AREA in Direct sinergy with other eu-international initiatives for Pandemic Preparedness**
- TOPIC: Building a European Partnership for pandemic preparedness – “HORIZON-HLTH-2021-DISEASE-04-06
- Instrument: Coordination and Support Action (CSA) - Budget: 2 Million Euros
- 25 Partners from **13 European countries and 2 Associated countries** (Norway, UK) + Switzerland,
- General coordination by ANRS | Maladies infectieuses émergentes
- Duration : June 2023 – May 2025
- <https://beready4pandemics.eu/>

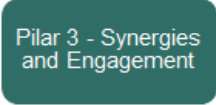
### Work Packages Organisation



Pilar 1 - Building  
the Partnership



Pilar 2 - SRIA



Pilar 3 - Synergies  
and Engagement

# ACT-EU

## Accelerating Clinical Trials in the EU

### Mapping & governance

Map existing initiatives and develop a governance rationalisation strategy (aligning different expert groups and working parties in the EMRN and ethics infrastructure).

### Implementation of the Clinical Trials Regulation

Successful and timely implementation of the CTR and its implementing acts by developing KPIs and dashboard to track performance of the European clinical trials environment, and the promotion of larger, multinational trials specifically in the academic setting.

### Multi-stakeholder platform

Establish a multi-stakeholder platform, including patients, after stakeholder analysis.

### Good clinical practice modernisation

Implementing the GCP modernisation informed by the development of guidance at ICH.

### Clinical trials analytics

Analyse data about clinical trials leveraging academic, non-profit, European, and international initiatives, improving the impact of policymaking and funding on research outputs to support evidence-based decision making.

### Targeted communications

Plan and launch a targeted communication campaigns to engage all enablers (including data protection experts, academia, SMEs, funders, HTA bodies, healthcare professionals).

### Scientific advice

Reinforce the coordination between scientific advice on CT approval and CT design and link to the methodologies working party domain.

### Clinical trial methodologies

Facilitating aligned clinical trial guidance development across the European network resulting in high impact guidance documents implemented in practice.

### Clinical trials safety

Successfully establish CT safety monitoring and bridge to the EU4Health Joint Action and start its integration into a pre and post-marketing safety monitoring framework.

### Clinical trials training curriculum

Deliver a clinical trials training curriculum including modules on drug development and regulatory science with links to universities and SMEs (serving as an educational 'ecosystem').

### Clinical trials in public health emergencies

Facilitating large and multinational clinical trials in the European Union (EU) to promptly tackle public health emergencies.

## EUROPEAN PARTNERSHIPS

- Pandemic Preparedness Partnership
- Rare Diseases Partnership
- ERA4Health Partnership

contribute to new **priority action 11** but also all other ACT-EU priority actions, notably **2, 4, 5, 8, 10**

# Clinical trials for public health emergencies

Recommendations from EMA's Emergency Taskforce and European Commission workshop  
(Amsterdam, 9 June 2023)

Guiding basis for EU Member States, European Commission, EMA to define roadmap towards enabling multinational trials in the EU in emergency contexts

**Process & regulatory approval** of large, multinational clinical trials in the EU during public health emergencies

- Better coordination within and across MS
- Enhanced flexibilities in emergencies



**Framework for funding clinical trials during emergencies and in preparedness in the EU**

## COORDINATION COMMITTEE

- Coordination of investments in warm-based clinical trials during preparedness
- Platform for quick decision-making in emergencies

# Development of pandemic preparedness partnership

- ❖ Key lessons learned from the COVID-19 pandemic were:
  - ❖ A too **fragmented research** landscape on pandemic preparedness
  - ❖ the **lack of a coordinated clinical trials infrastructure at EU level** that could have been activated early on.
- ❖ **The bottlenecks that hamper a swift set up of clinical trials** during public health emergencies were well identified at the onset of the Mpox outbreak.
- ❖ **Nevertheless**, the set-up of clinical trials was significantly delayed.

Need for network of ever-warm clinical trial sites across the EU and AC



# Pandemic Preparedness Partnership: two-fold objective

- To foster **transnational research on pandemic preparedness**
- To establish an **ever-warm network of clinical trials** sites to:
  - ensure a baseline of continuous clinical trial activity
  - quickly “pivot” to public health interventions to respond to a health emergency
- More suitable instrument: co-funded partnership (to be included in the amendment of the HE Work Programme 2024 pending final confirmation of the Health Programme Committee)
- Tentative start in 2025

→ **Contributing to ACT-EU Priority Action no. 11 “Clinical trials in public health emergencies”**

# New set-up of Pandemic Preparedness Partnership

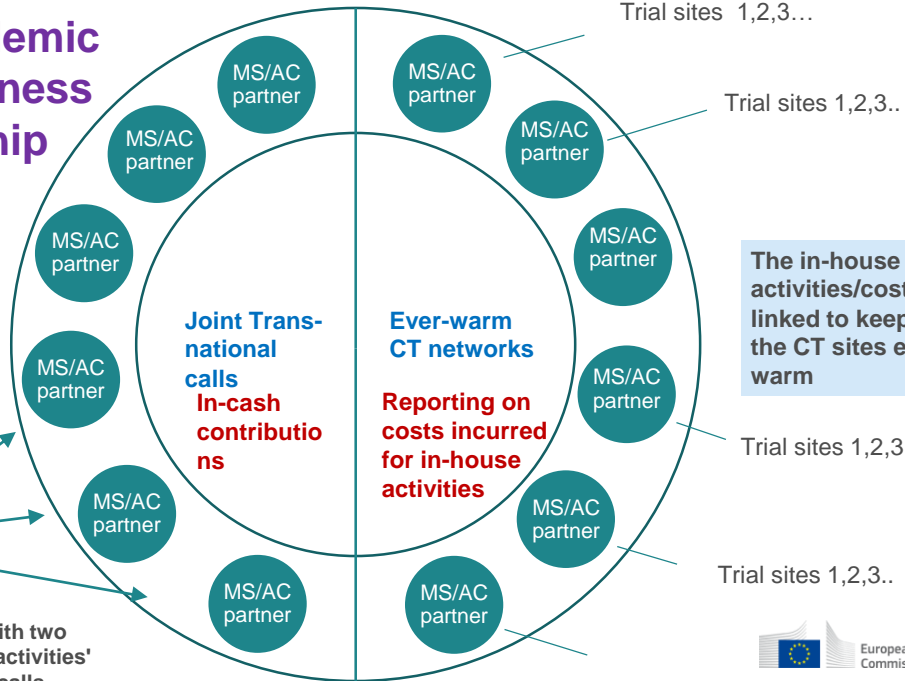
- The Pandemic Preparedness Partnership will be a mixed co-funded partnership comprising both 'in-house activities' and open joint transnational calls
- The in-house activities will mostly be carried out by clinical trial sites in Member states or Associated Countries (MS/AC)
- As multiple trial sites from each MS/AC are expected to join the partnership, making each site a partner/beneficiary of the partnership would potentially make the partnership difficult to manage



# The Pandemic Preparedness Partnership

Joint funding of R&I calls (e.g. NPI, PHSM, SSH, pre-clinical research)

Funders of R&I



The in-house activities/costs linked to keeping the CT sites ever-warm

A co-funded partnership with two main objectives: 'inhouse activities' & open joint transnational calls

# Keeping the partnership manageable (1)

## Options to link numerous clinical trial sites per country to the partnership

Member States/ Associated Countries can identify their ever-warm clinical trial sites as:

1. **Beneficiaries**
2. **Affiliated entities** (Article 8 of MGA): these are entities with a legal or capital link to the beneficiary that do not sign the grant agreement but carry out action tasks. Their budget and tasks must be defined during the project proposal stage. The costs they incur are eligible for EC co-funding
3. **Third parties** whereby the MS/AC Beneficiary (partner) will declare costs on the basis of a contract it has with one or multiple third parties

## Keeping the partnership manageable (2)

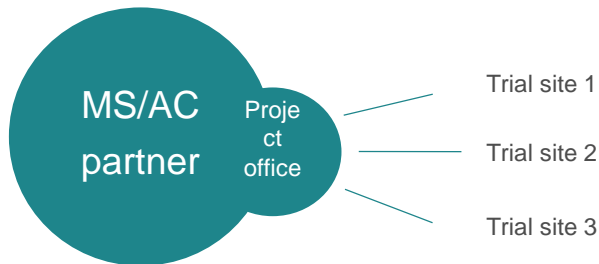
### Third parties can be either:

- **Subcontractors:** subcontracts concern the implementation of '*action tasks*' described in Annex 1 DoA (*Description of Actions*).
- **Suppliers of goods, works & services:** these purchases concern any other contracting cost (travel, equipment, goods, works, and services) necessary for beneficiaries to implement the work but *do not constitute action tasks* described in Annex 1 DoA.

For either ( subcontracting of purchasing), specific rules will apply and national laws on procurement need to be followed. Note that for the subcontracting it does not necessary entail a competitive process but value for money needs to be demonstrated

## Keeping the partnership manageable (3)

- To manage the implementation (if that cannot be done by the designated MS/AC Beneficiary itself), the Beneficiary can set up a **project office**
- This does not need to be a separate legal entity and the costs of running such an office would be eligible costs.



# Resources necessary to sustain an ever-warm clinical trial network (non-exhaustive list)

- **Research Staff:** researchers (Principal Investigators (Pis) – sub-PIs), research coordinators, and nurses (tasks e.g. recruitment, obtaining informed consent, data collection, and monitoring participant safety).
- **Trial population:** recruitment/management
- **Trial Sites:** infrastructure, facilities, and equipment (consumables)
- **Collaboration and Networking activities**
- **Data Management and Statistical Support Systems** for collecting, managing, and analysing trial data

# Costs incurred to sustain an ever-warm clinical trial sites network (non-exhaustive list) (1)

- **Personnel costs**

- **Coordination, recruitment, monitoring, data collection and analysis, training etc.**

- **Costs linked to infrastructures, facilities and equipment**

- **Use of equipment and depreciation costs of equipment, consumables and supplies**

**NB: the regular cost categories and requirements of the model grant agreement apply**

# Costs incurred to sustain an ever-warm clinical trial sites network (2)

- **Cost incurred need to be mapped against the cost categories of Horizon Europe (Annex 2 general MGA)**
  - **Personnel: employees, persons under direct contract or seconded, etc.**
  - **Subcontracting costs**
  - **Purchase costs (travel & subsistence, equipment, other goods, works and services)**
  - **Other cost categories**
  - **Indirect costs**



# Thank you!

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