

## **EU4Health 2021 work programme Information Session second wave of calls for action grants**

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# EU4Health Programme

for the Union's action  
in the field of health under the MFF 2021-27

Second wave open calls – Info Session

*DG SANTE Dir A*  
*Adrian Pereş*  
*Head of EU4Health Task Force*

# EU4Health – the Programme

*EU4Health is a clear message that public health is a priority for Europe and it is the instrument to pave the way to a European Health Union*

- **RESPONSE TO COVID-19** – supporting the fight against cross-border health threats and boosting the preparedness and capability to respond effectively to future health crises, including through the European Health Emergency preparedness and Response Authority (HERA)
- **AMBITIOUS VISION** – will go beyond crisis response to support and complement national health policies for strengthening and modernising health systems, reducing inequalities and overcome shared challenges
- **THE LARGEST EVER EU INVESTMENT IN HEALTH** – over €5.3 bn (current prices) invested in health during the next 7 years (2021-27)



## EU4Health – financial envelope

*The financial envelope for the implementation of the Programme for the period 2021 - 2027 shall be:*



**EUR 5.3 billion in current prices**



- Min. 20 % reserved for health promotion and disease prevention actions
- Max. 12,5 % reserved for procurement complementing national stockpiling of essential crisis-relevant products at Union level
- Max. 12,5 % reserved for supporting global commitments and health initiatives
- Max. 8 % reserved for covering administrative expenses



26 March 2021

# Regulation (EU) 2021/522 – EU4Health Programme

- Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014



Official Journal of the European Union L 107

English edition Legislation Volume 64 26 March 2021

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1 Legislative acts

REGULATIONS

★ Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (1) ..... 1

The image shows the cover page of the Official Journal of the European Union. It features the title 'Official Journal of the European Union' in a large serif font, with 'L 107' to its right. Below the title is the European Union flag. The text 'English edition' and 'Legislation' are on the left, and 'Volume 64' and '26 March 2021' are on the right. A horizontal line separates the header from the 'Contents' section. The contents list '1 Legislative acts' and 'REGULATIONS'. A specific regulation is highlighted with a star: '★ Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (1) ..... 1'.

# EU4Health – General objectives

*Four general objectives represent the breath and the ambitions of the programme*



- Improve & foster health in the Union



- Protect people from serious cross-border health threats



- Improve access to medicinal products, medical devices crisis-relevant products



- Strengthen health systems



# EU4Health – Specific objectives

*EU4Health will provide the means and the instruments for delivering on the EU Health policy along ten key areas of intervention*

## IMPROVE & FOSTER HEALTH



- **Health promotion and disease prevention; cancer**
- International health initiatives & cooperation.



## PROTECT PEOPLE



- **Prevention, preparedness & response to cross-border health threats;**
- Complementing national stockpiling of essential crisis-relevant products;
- Establishing a reserve of medical, healthcare & support staff.



## ACCESS TO MEDICINAL PRODUCTS & MEDICAL DEVICES



- Enhancement of availability, accessibility & affordability of medicinal products, medical devices and crisis-relevant products

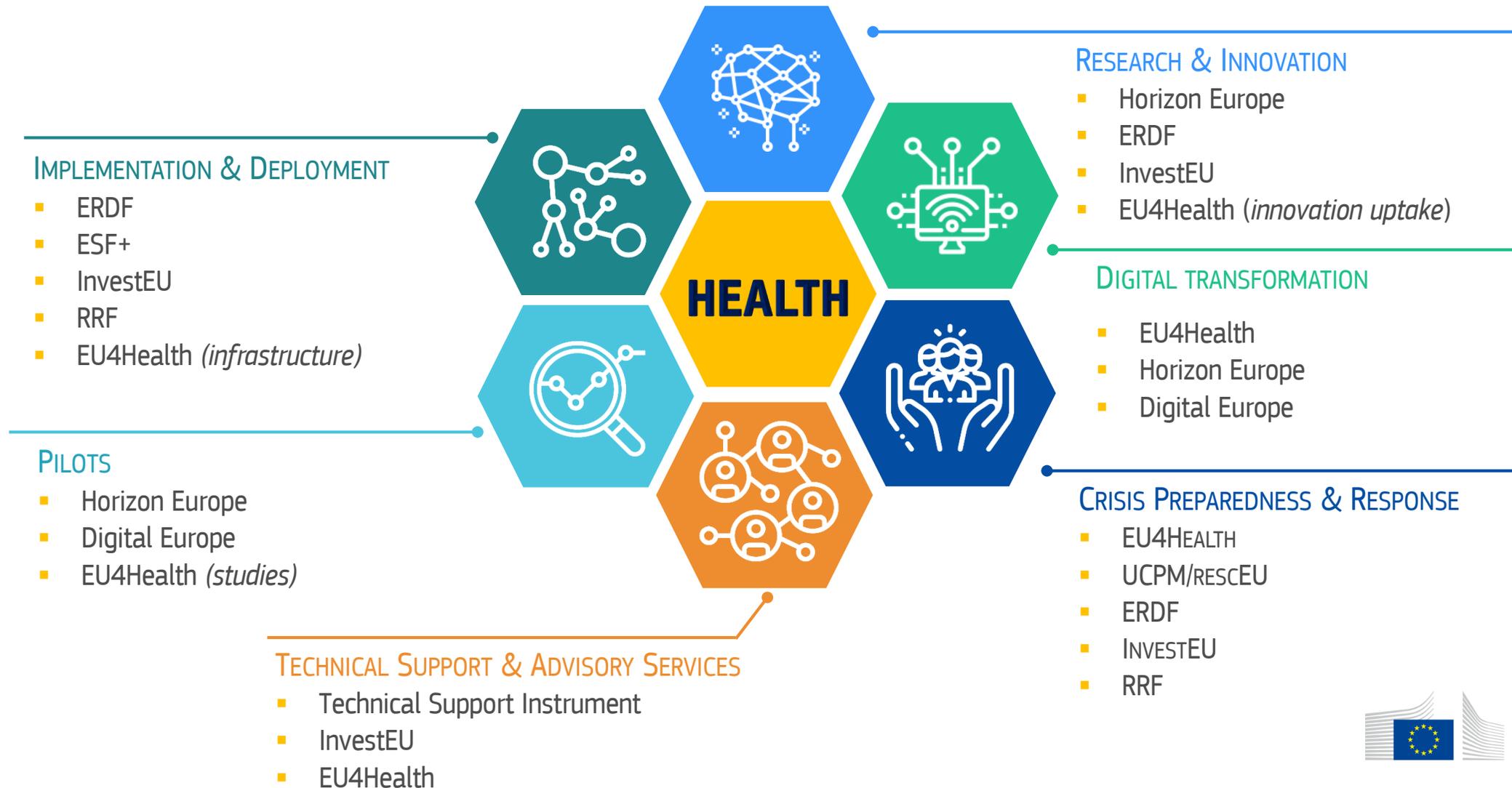
## STRENGTHEN HEALTH SYSTEMS



- **Strengthening health data, digital tools & services, digital transformation of healthcare;**
- Enhancing access to healthcare;
- Developing and **implementing EU health legislation** and evidence-based decision making;
- Integrated work among MS health systems.

# EU4Health – Synergies & Complementarities

*An approach by policy area: many instruments contributing to the same objective*



# EU4Health – Implementation

## “Public procurement”

*Contracts with economic operators to purchase services or goods on the account of the Commission, either through open tendering procedures or the use of existing framework contracts which were established following competitive procedures*

## “Grants”

*Direct financial contributions from the European Union budget awarded to beneficiaries engaged in activities that serve Union policies.*

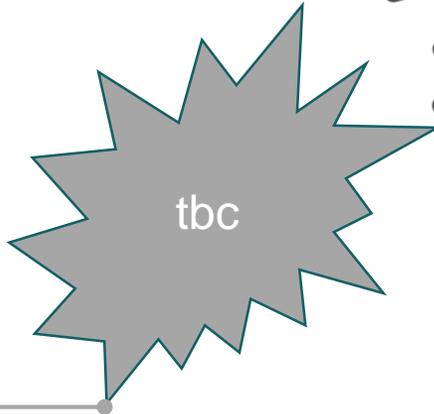
*Guiding principles:*

- *Equal treatment and transparency*
- *Co-financing by the beneficiary and non-profit rule applicable*
- *Non-cumulative, non-retroactive and absence of double financing*



## “other”

*possible forms of funding as allowed by the Financial Regulation*



## “Prizes”

*Contests to promote achievements of policy objectives of the Union where one or several beneficiaries are awarded a financial price following a evaluation*

# EU4Health – work programm



- **INPUT, CONSULTATION, INFORMATION** – on priorities and strategic orientation and need to be addressed



- **PREPARATION** – the Commission drafts the annual work programme



- **COMMITTEE PROCEDURE** – opinion of the EU4Health Programme Committee



- **ADOPTION** – implementing acts

STAKEHOLDERS  
(INPUT)

EU4HEALTH STEERING GROUP – MS  
(CONSULTATION)

EUROPEAN PARLIAMENT – ENVI COMM.  
(INFORMATION)

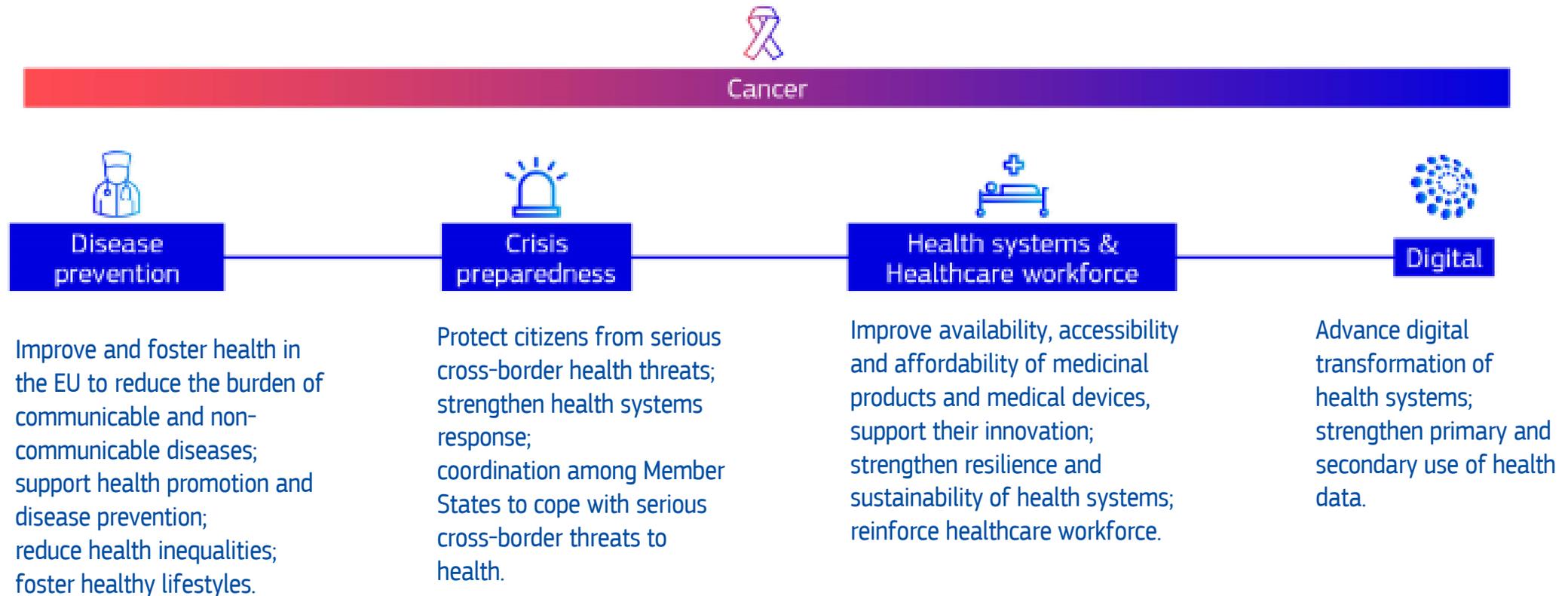
EUROPEAN COMMISSION  
DG SANTE

EU4HEALTH PROGRAMME COMMITTEE –  
MS (OPINION)

EUROPEAN COMMISSION  
(DECISION)

## EU4Health work programme 2021 – strand of actions

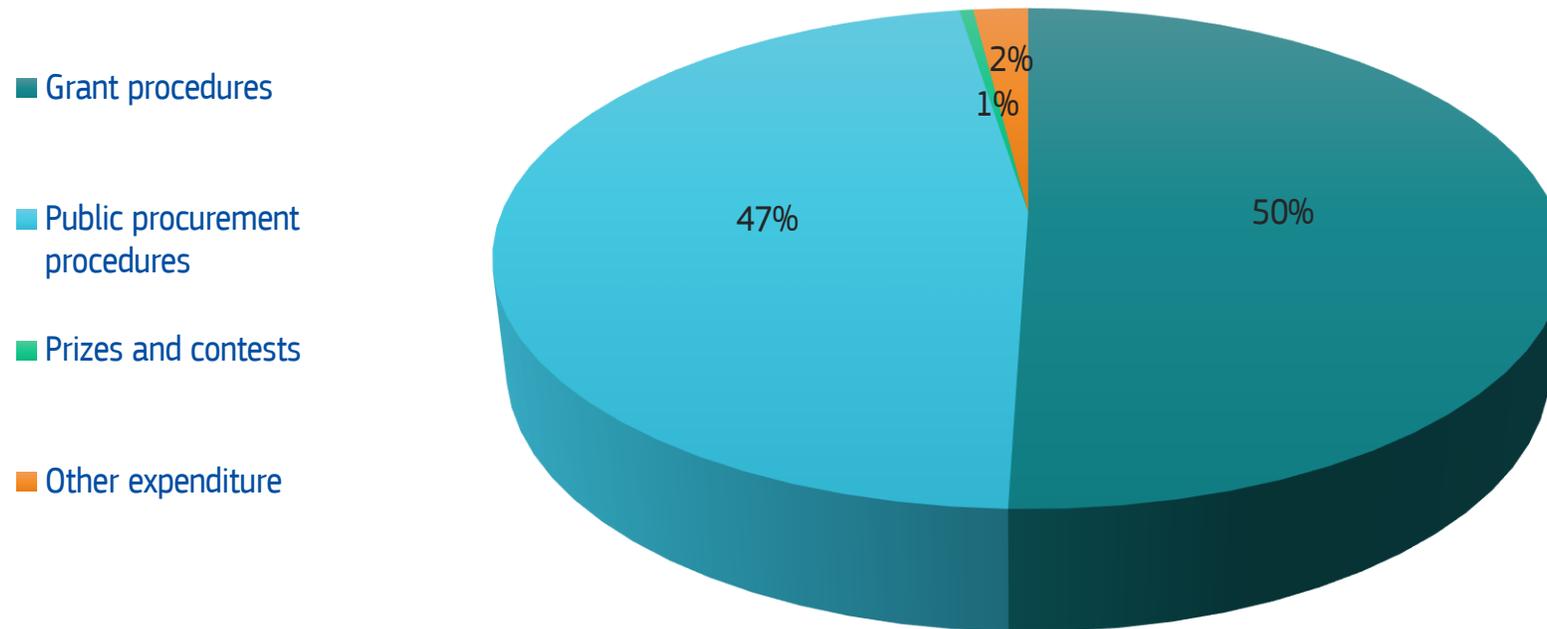
*EU4Health supports a **broad range of actions** under four overarching “strands” with a cross-cutting focus on cancer*



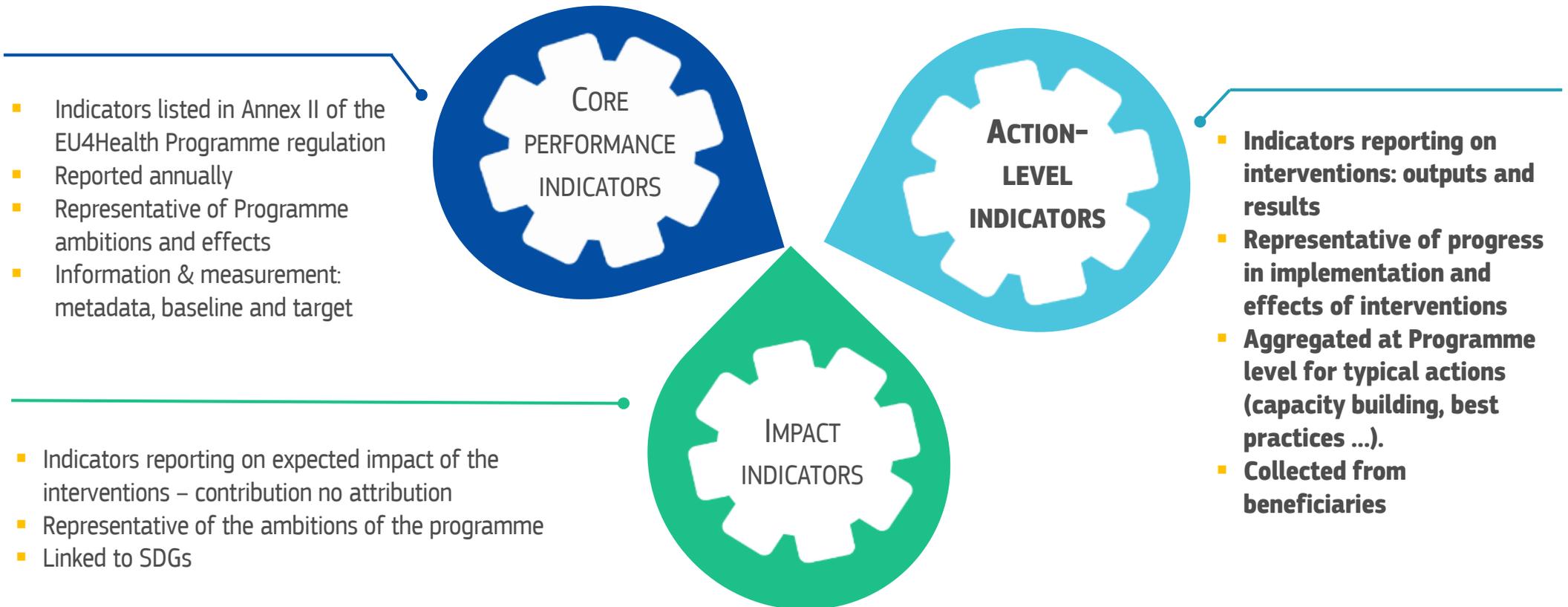
# Budget allocation

*EU4Health will be implemented by annual work programmes*

Overall budget 2021: approx. **311 Mio €**



# Performance framework - indicators



# EU4Health – state of affairs

24 March  
2021

- Adoption of the Programme Regulation (EU) 2021/522

24 June  
2021

- Adoption of the Work Programme 2021
- Almost 312 million EUR maximum Union contribution
- Four strands of action: crisis preparedness, disease prevention, health systems and the healthcare workforce, and digitalisation.

End 2021/  
early 2022

- **Preparatory work for identifying strategic orientations and priorities**
- **Targeted stakeholders' consultation**
- **Consulting Member States through the EU4Health Steering Group**
- **Adoption of the Work Programme 2022**

# Thank you

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# EU4Health Programme 2021-2027 – Action Grants (AWP 2021)

Structure of an open call, Project Management, Submission process

European Health and Digital Executive Agency (HaDEA)

*Brussels, 28 October 2021*



European  
Commission

# Who we are

# HaDEA Dept. A: Health & Food



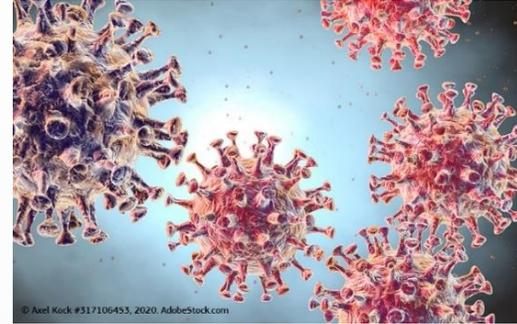
## EU4HEALTH

- Improve and foster health in the Union
- Protect people in the Union from serious cross-border threats to health
- Make medicines available and affordable
- Strengthen health systems, their resilience and resource efficiency



## Single Market Programme - Food safety

- Ensure a high level of health for humans, animals and plants, and the safety of food and feed
- Prevent, detect and eradicate animal diseases & plant pests
- Support the welfare of animals
- Fight against antimicrobial resistance
- Develop sustainable food production and consumption
- Ensure reliable official controls

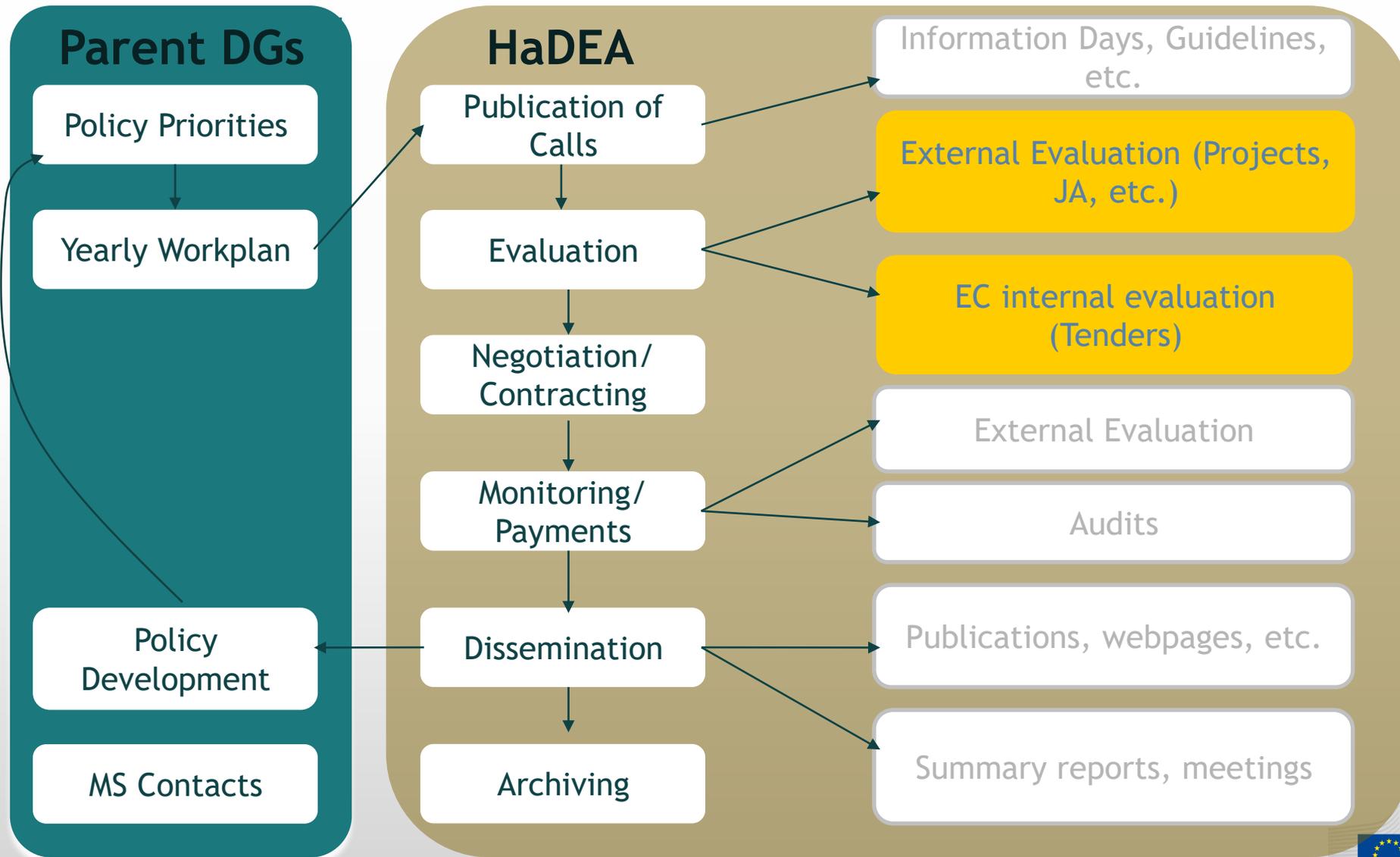


## HE Cluster 1 - Health

- D1: Staying healthy in a rapidly changing society
- D2: Living and working in a health-promoting environment
- D.3: Tackling diseases & reducing disease burden
- D4: Ensuring access to innovative, sustainable & high-quality Healthcare



- D.5: Unlocking the full potential of new tools, technologies and digital solutions for a healthy society
- D.6: Maintaining an innovative, sustainable & globally competitive health industry



# Process for an open call for proposals

Publication of calls for proposals

Submission of proposal

Evaluation

Grant Agreement Preparation

Signature, Accession of partners, Project Start



European  
Commission

*Steps, timelines*

# *Submission process*

# Submission of proposal



## EU4Health Programme (EU4H)

### Application Form

Administrative Forms (Part A)  
Technical Description (Part B)

EU4H Project Grants

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

My Organisation(s) | GRANTS | My Proposal(s) | My Project(s) | My Formal Notification(s) | My Expert Area

## 3rd Health Programme (3HP)

clear filter

Type your Keywords or

Match whole words only

GRANTS  TENDERS

Filter by submission status

FORTHCOMING  OPEN  CLOSED

Filter by programme (only for grants)

### Funding and tenders

Sort by:  opening date  title  ID  deadline

35 results

Download all funding and tender opportunities to your calendar or subscribe to the RSS feed (unfiltered).

"Find a grant"

See all calls for tenders published by EC

**Transferring the Wholegrain promotion initiative to other countries PJ-09-2018**

Types of action: Project | Programme: 3rd Health Programme

**EC Funding and Tenders Portal:**  
<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home>

Clear filters

Types of action: Project | Programme: 3rd Health Programme

**Closed** *Opening date: 12 June 2018* *Deadline model: single-stage*  
*Deadline date: 13 September 2018 17:00:00*  
*Brussels time*

### Step 3 Create a Draft Proposal

#### Create a Draft Proposal

Please enter the following information to create a draft proposal. Please note that fields marked with a star (\*) are **mandatory**.

HP-HA-2015

USER NAME  
Dirk MEUSEL

TOPIC

THU  
12 November 2015 17:00:00

14 days left until closure

Configuration OK

[Download Part B Templates](#)

[Visit our 'How to' user guide](#)

[Visit our 'H2020 Online Manual'](#)

#### Your organisation

Short name\*

938206408 Your name Test Street Luxembourg, LU VAT:

Organisations you have been previously associated with. Click to select.

PIC: 938206408  
Your name  
Test Street  
Luxembourg, LU

PIC: 948085955  
Croix-Rouge Luxembourgeoise  
44 Boulevard Joseph II  
Luxembourg, LU  
VAT: LU11877709

Search for your organisation PIC

#### Your Role

Please indicate your role in this proposal

Main contact

Contact person

Check data

Indicate your PIC

Download  
Part B Template



# Helpful information:

- Roles and Access Rights  
[https://ec.europa.eu/research/participants/docs/h2020-funding-guide/user-account-and-roles/roles-and-access-rights\\_en.htm](https://ec.europa.eu/research/participants/docs/h2020-funding-guide/user-account-and-roles/roles-and-access-rights_en.htm)
- LEAR Appointment  
[https://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/register-an-organisation/lear-appointment\\_en.htm](https://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/register-an-organisation/lear-appointment_en.htm)
- EU Login  
[https://ec.europa.eu/research/participants/docs/h2020-funding-guide/useraccount-and-roles/ecas-login\\_en.htm](https://ec.europa.eu/research/participants/docs/h2020-funding-guide/useraccount-and-roles/ecas-login_en.htm)

# *Structure of a proposal*

**Work Packages, Partners and roles, Governance**

# Structure of the Project Proposal

Administrative  
Part A,  
Includ. Overview  
Budget

Technical  
Narrative  
Part B,  
Includ. Detailed  
Budget

Audit report

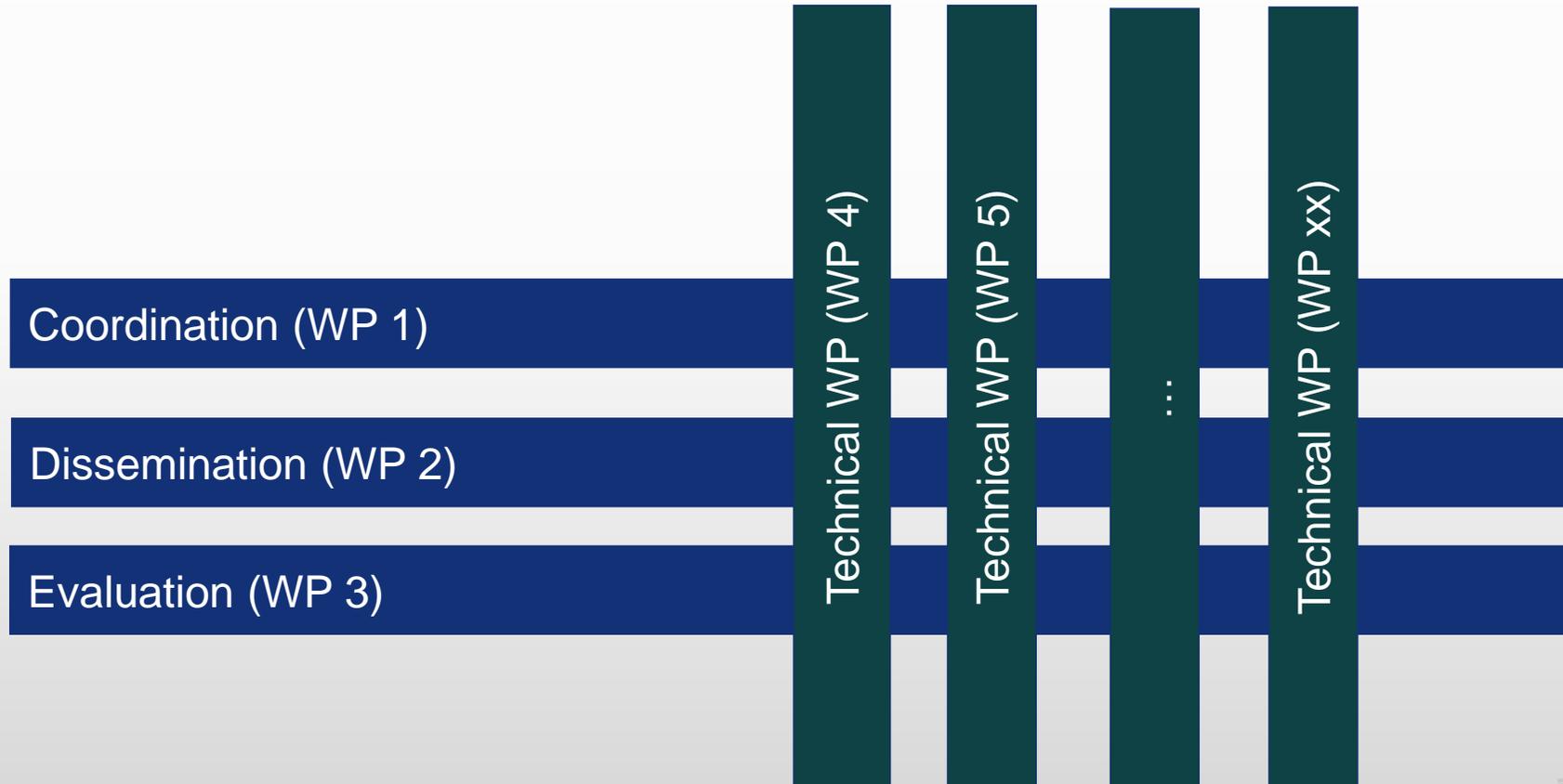
# Part A – Administrative Form

- Fill online (not to be downloaded)
  - Title, duration, abstract, keywords (page 2)
  - Confirm declarations (page 3)
  - Contact details of partners (section 2)
  - Overview budget (section 3, verify against detailed budget)
- Save
- Validate and correct warning errors (red)

## Part B – Technical narrative

- Problem analysis, General and specific objectives, linked indicators (Process, Output, Outcome/Impact)
- Target Groups, Political relevance, Methods and means, Expected outcome (!!!)
- Work Packages (3 mandatory), Deliverables (mainly public scope), Risk analysis, Timeline
- Budget: Staff efforts by work package, contributions by third parties, Detailed budget table

# Structure of a proposal



LOGIN   FUNDING SCHEME   CREATE DRAFT   PARTIES   EDIT PROPOSAL   SUBMIT

## Step 5

### Edit Proposal

HP-HA-2015

USER NAME  
Dirk MEUSEL

TOPIC

A.B.C.

THU  
12  
14

Configu

Download Part B Templates

Visit our 'How to' user guide

Visit our 'H2020 Online Manual'

### Edit Proposals' Forms

In this step you can edit the administrative forms and upload the proposal itself. ?

**WARNING:** This proposal contains changes that have not yet been submitted...

#### Administrative Forms

...s in Adobe Reader. ?

forms   view history   print preview

In this section you may upload the technical annex of the proposal (in PDF format only) and any other requested attachments. ?

upload   upload

<< Step 4 - Parties   validate   submit

done   Version: 20150922-1031 - Service Desk: DIGIT-EFP7-SEP-SUPPORT@ec.europa.eu (+32 (2) 29 92222)

Part A  
Administrative Form

Part B  
Technical Narrative

LOGIN FUNDING SCHEME CREATE DRAFT PARTIES EDIT PROPOSAL SUBMIT

## Step 5

### Edit Proposal

Edit Proposals' Forms

In this step you can edit the administrative forms and upload the proposal itself. ?

**WARNING:** This proposal contains changes that have not yet been submitted...

#### Administrative Forms

edit will open the forms in Adobe Reader. ?

[edit forms](#) [view history](#) [print preview](#)

you upload the technical annex of the proposal (in PDF format only) and any attachments. ?

**Part B** [upload](#) [?](#)

**Audit reports for participants requesting more than 750 000 E** [upload](#) [?](#)

Configuration OK ✓

[Download Part B Templates](#) ↓

[Visit our 'How to' user guide](#) ↗

[Visit our 'H2020 Online Manual'](#) ↗

<< Step 4 - Parties [validate](#) [submit](#)

done ✕

Version: 20150922-1031 - Service Desk: [DIGIT-EFP7-SEP-SUPPORT@ec.europa.eu](mailto:DIGIT-EFP7-SEP-SUPPORT@ec.europa.eu) (+32 (2) 29 92222)

Part B  
Upload  
Technical Narrative

Part B  
Download  
Template

LOGIN FUNDING SCHEME CREATE DRAFT PARTIES EDIT PROPOSAL SUBMIT

## Step 5

### Edit Proposal

**HP-HA-2015**

USER NAME  
Dirk MEUSEL

TOPIC  
HA-01-2015

A.B.C

DRAFT ID | SEP-210318730

THU 12 DEADLINE (Brussels Local Time)  
November 2015 17:00:00

14 days left until closure

Configuration OK

Download Part B Templates

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Visit our 'H2020' page

### Edit Proposals' Forms

In this step you can edit the administrative forms and upload the proposal itself. ?

**WARNING:** This proposal contains changes that have not yet been submitted...

#### Administrative Forms

Edit will open the forms in Adobe Reader. ?

edit forms view history print preview

#### Part B and Annexes

In this section you may upload the technical annex of the proposal (in PDF format only) and any other requested attachments. ?

Part B upload

Aud upload

validate submit

done Version: 20150922-1031 - Service Des (222)

Fill and validate Form A

Respect Deadline

Upload Part B and verify correct upload

Validate, correct errors, submit

# Awarding

## Award Criteria

# Award Criteria 1/2

- **Relevance:** clarity and consistency of project, objectives and planning; extent to which they match the themes and priorities and objectives of the call; contribution to the EU strategic and legislative context; European/trans-national dimension; impact/interest for a number of countries (EU or eligible non-EU countries); possibility to use the results in other countries; potential to develop mutual trust/cross-border cooperation (30 points)
- **Quality:**
- **Project design and implementation:** technical quality; logical links between the identified problems, needs and solutions proposed (logical frame concept); methodology for implementing the project (concept and methodology, management, procedures, timetable, risks and risk management, monitoring and evaluation); feasibility of the project within the proposed time frame; cost effectiveness (sufficient/appropriate budget for proper implementation; best value for money) (30 points)
- **Project team and cooperation arrangements:** quality of the consortium and project teams; appropriate procedures and problem-solving mechanisms for cooperating within the project teams and consortium (30 points)

## Award Criteria 2/2

- **Impact:** ambition and expected long-term impact of results on target groups/general public; appropriate dissemination strategy for ensuring sustainability and long-term impact; sustainability of results after EU funding ends (10 points).

Award criteria	Min pass score	Max score
Relevance	21	30
Quality — Project design and implementation	21	30
Quality — Project team and cooperation arrangements	21	30
Impact	7	10
<b>Overall (pass) scores</b>	<b>70</b>	<b>100</b>

•

# Grant Agreement

**Revision, Transfer to Grant Management System, Signature,  
Accession of partners**

# Structure of the Grant Agreement

Model Grant Agreement, filled with specific grant's data

Annex 1  
(Description of the action, Part A):  
Structured part  
(deliverables, ...)

Annex 1  
(Description of the action, Part B):  
Narrative part with  
detailed budget

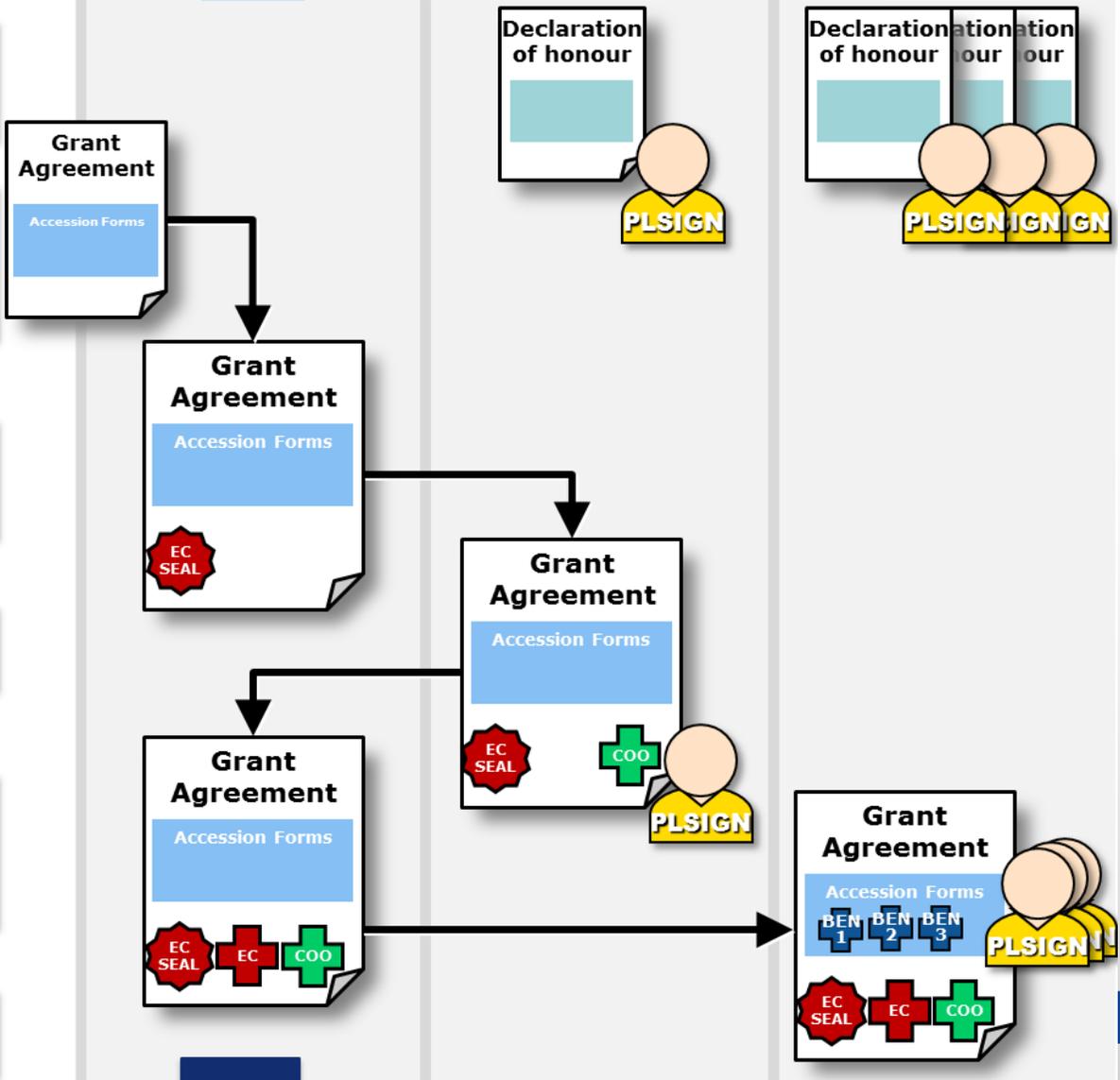
Annex 2: Overview  
budget

Further annexes...

# Electronic Grant preparation

- Grant preparation online (Participant Portal "My projects", deliverables, milestones and risks to be transferred)
- Each partner signs Declaration of Honour online (PLSIGN for partner required!)
- Electronic signature by PLSIGN of coordinator – no paper copies of grant agreement, but «notarised» signed PDF version downloadable for all partners
- Partners join the agreement after signature (Accession form, PLSIGN of each partner) **(within 30 days after signature)**
- Consortium Agreement

- 1 Before grant signature, each beneficiary has to sign the Declaration of honour.
- 2 When the grant preparation is finished, it is digitally sealed by the Commission, insuring the integrity of its contents.
- 3 The Legal Signatory of the coordinating entity signs the grant electronically.
- 4 The Commission signs the grant electronically.
- 5 Each beneficiary, through their Legal Signatories, must then sign electronically the "Accession forms" part.
- 6 The Grant Agreement is then finalised.



# Indicative timeline

**Publication Open Call:** 13/10/2021

**Opening for submission:** 14 /10/2021

**Deadline for Submission:** 25/01/2022

**Evaluation:** up to end of May 2022

**Information evaluation letters sent out:** early June 2022

**Grant agreement preparation:** Up to September 2022

**Signature of Grant agreement:** By end September 2022

**Starting date:** October 2022

# Thank you

# Your questions?

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# Annual Work Programme (AWP) 2021 Info day webinar

**FINANCIAL MANAGEMENT – GRANTS**

*28<sup>th</sup> October, 2021*

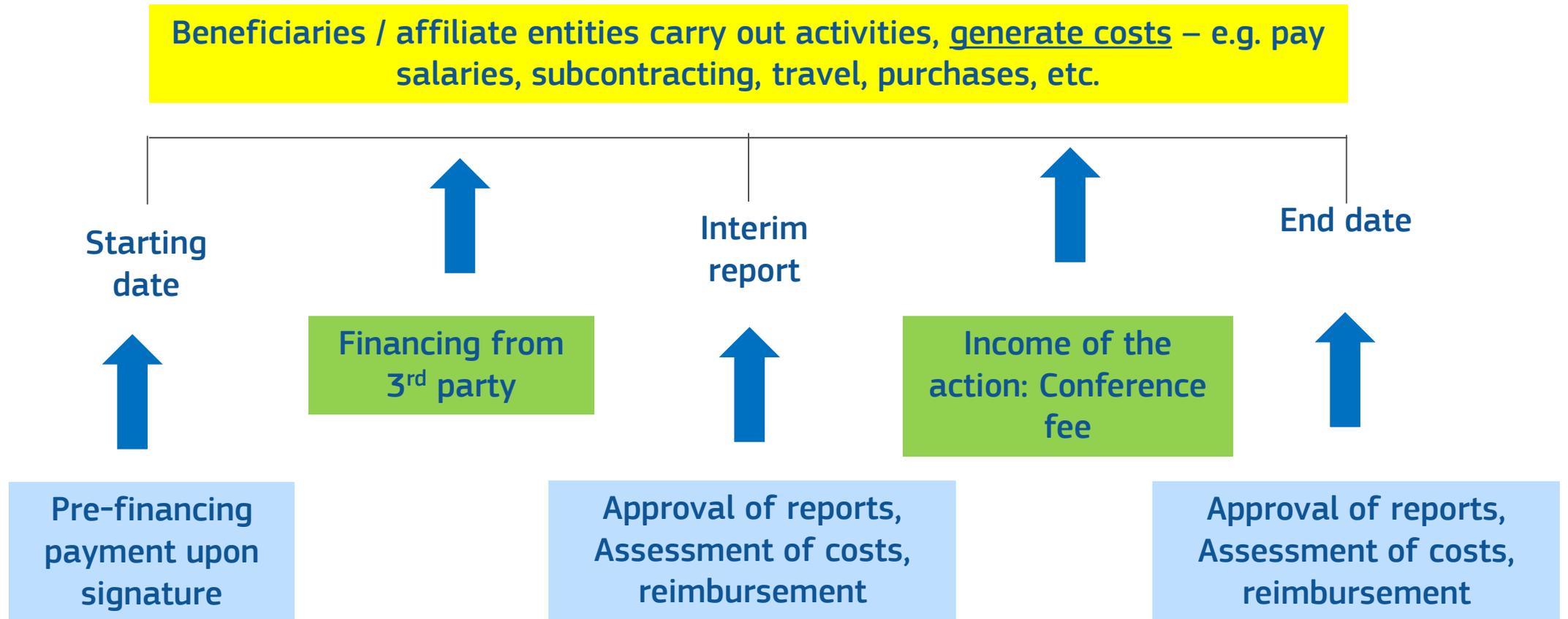
**Definition:** Grant is direct financial contribution to an action or functioning of a body

- **Co-funding rule:** external co-financing from a source other than EC funds is required (own resources or financial contributions from third parties, project income)
- **Non-profit rule:** the grant may not have the purpose or effect of producing a profit for the beneficiary
- **Non-retroactivity rule:** only costs incurred after the starting date stipulated in the grant agreement can be co-funded
- **Non-cumulative rule:** only one grant can be awarded for a specific action carried out by a given beneficiary

## Nature of the grant

- **Grant = partial reimbursement of eligible costs** that are incurred by beneficiaries and affiliated entities listed in the grant agreement **at the fixed reimbursement rate.**
- **“Maximum grant amount”** the maximum amount the Agency will pay as contribution to the action’s costs.
- **“Final grant amount”** equals to or is lower than the maximum grant amount. Established at the balance payment and based on eligible costs declared to the Agency.
- The maximum grant amount and the calculation with reimbursement rate represent a **double-ceiling of the grant**: maximum grant amount compared to the result of reimbursement rate applied to the consolidated total eligible costs of the action
- The grant is **not allocated** to any specific cost items or cost category. It is calculated over the total eligible costs of the action with the applicable reimbursement.

# Cash flow



# Eligible costs

## General conditions - Cumulative requirements:

- **Connected with the action as described in Annex 1 and included in the Estimated Budget (Annex 2);**
- **Necessary** for the implementation of the action;
- **Reasonable and justified** - “good housekeeping”;
- **Incurred within the duration;**
- **Actually incurred by the beneficiaries / affiliated entities of the grant;**
- **Identifiable and verifiable**, in particular being recorded in the accounting records of beneficiary / affiliated entity in accordance with accounting standards and the beneficiary’ accounting practices.

# Budget categories

## Direct Costs

- A. Direct personnel costs
- B. Subcontracting
- C. Purchase costs
  - a. Travel, accommodation and subsistence allowances
  - b. Equipment
  - c. Other goods and services
- D. *Financial support to third parties – defined in the call documents, if eligible*

## Indirect Costs

- E. Flat rate of 7% of total direct costs

# Personnel costs

## Cost of employees

- Costs claimed: salary + social security + taxes;
- Any other costs included in the remuneration (= statutory charges) based on national law or employment contracts;
- Supplementary payments

## Cost for natural persons with a direct contract and seconded persons against payment

- Similar conditions as employment: at the beneficiary's premises, results belong to the beneficiary with similar costs of employment

## The work of SME owners and natural person beneficiaries – not receiving salary

# Subcontracting

- Contracts awarded to cover the execution of an action / task described in Annex 1 of the grant agreement.
  - Activities undertaken by the project
  - Service contracts
  - Invoices (including taxes, charges, travel & subsistence costs)
- Core elements and technical / financial management of the action cannot be subcontracted
- Tasks subcontracted must be clearly set out in Annex 1;
- Requirement of transparency, best value for money and, if appropriate, lowest price. Conflict of interest must be avoided;
- Documents of procedures applied must be available.

## Travel and subsistence

Travel & subsistence incurred as costs by the beneficiary for all participants, except subcontractors shall be claimed here:

- Personnel
  - Collaborating stakeholders
  - Invited experts, speakers
  - Board members
  - Trainees, other participants
- 
- Option for unit costs or actual costs in line with beneficiary's usual practice and rules on travel and subsistence.

# Equipment

- **Specific equipment necessary for the action**
- **Costs eligible:**
  - Portion of **equipment's depreciation costs** only, for the period of the action, if recorded in the beneficiary's accounts. Purchase and depreciation is in accordance with international accounting principles and the beneficiary's usual accounting practices.
  - Costs of **renting** an equipment or **leasing** an equipment (excluding financing costs) – with limits to equivalent depreciation costs
- Office equipment and software (Microsoft Office, Excel, Word, furniture) are part of Indirect Costs

## Other goods and services

- Must be directly linked to and necessary to implement the action
- Requirement of **transparency, best value for money** and, if appropriate, lowest price. **Conflict of interest** must be avoided.
- Examples (non-exhaustive):
  - Dissemination of information;
  - Specific evaluation of the action;
  - Certificates of financial statements;
  - Translations, reproduction of reports;
  - Consumables and supplies (excluding general office supply);
  - Cost of financial guarantee, if applicable.

## Personal advice, tips and observations

Read the grant agreement and the guidelines available

Involve your HR, Accounting and Procurement from the beginning

Number of partners in the consortium

- All partners with specific knowledge crucial to the action
- Too many – difficult to manage
- Higher share in tasks – more commitment

Project manager coordinator + work packages, financial manager at coordinator

Avoid obvious over / under estimation

- Over-estimation may lead to decrease of final EU contribution
- Under-estimation: objectives are not achieved

Plan, build internal monitoring and reporting within the consortium, close follow-up of expenditure.

# Thank you



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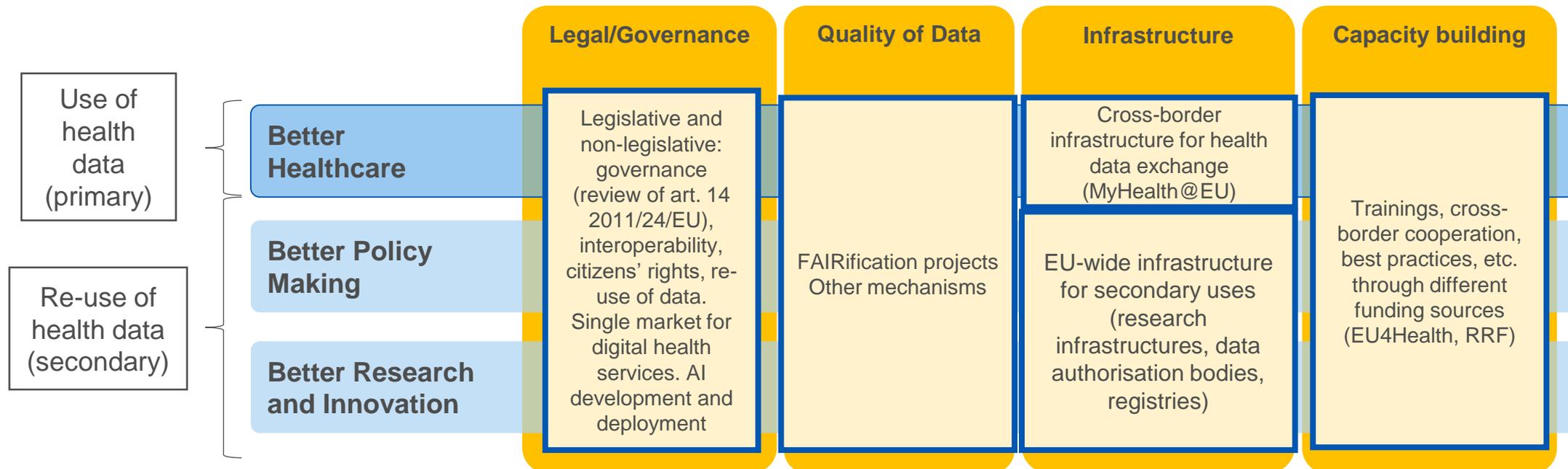
# European Health Data Space

**Action grants for developing a pilot project for an EU infrastructure ecosystem for the secondary use of health data for research, policy-making and regulatory purposes**



# Primary and secondary uses of health data

- Timely and simplified *exchange of and access to* health data for different use cases:
  - Healthcare provision, access and control of patient over their data, (cross-border) exchange of health data;
  - Digital health services (including telehealth and m-health);
  - Research (eg on cancer, rare diseases, COVID-19 etc), pharmacovigilance, public health, policy making



# European Health Data Space

Use of data for healthcare (primary)

Re-use of health data (secondary)

Sharing of health data for healthcare

## Problems

- Limited control of patients over their health data
- Limited interoperability between health care providers

## Areas of work

- Control of patients over their data
- Interoperability
- Role of e-health agencies
- Reinforced EU governance (eHealth Network)
- Reinforced MyHealth@EU

Single market for digital health products and services

## Problems

- Uneven national legislative frameworks
- Uneven quality framework
- Uneven procedures for prescriptions, reimbursement, liability

## Areas of work

- Eliminate barriers to free movement
  - Labelling
  - Interoperability
  - Reimbursement
  - Liability

Access to health data for research, innovation, public health policy making

## Problems

- Low re-use of health data
- Cumbersome cross-border access to health data
- Fragmented digital infrastructures

## Areas of work

- Governance and rules for access to health data
- Data FAIR-ification
- Digital infrastructure (EHDS2)

AI

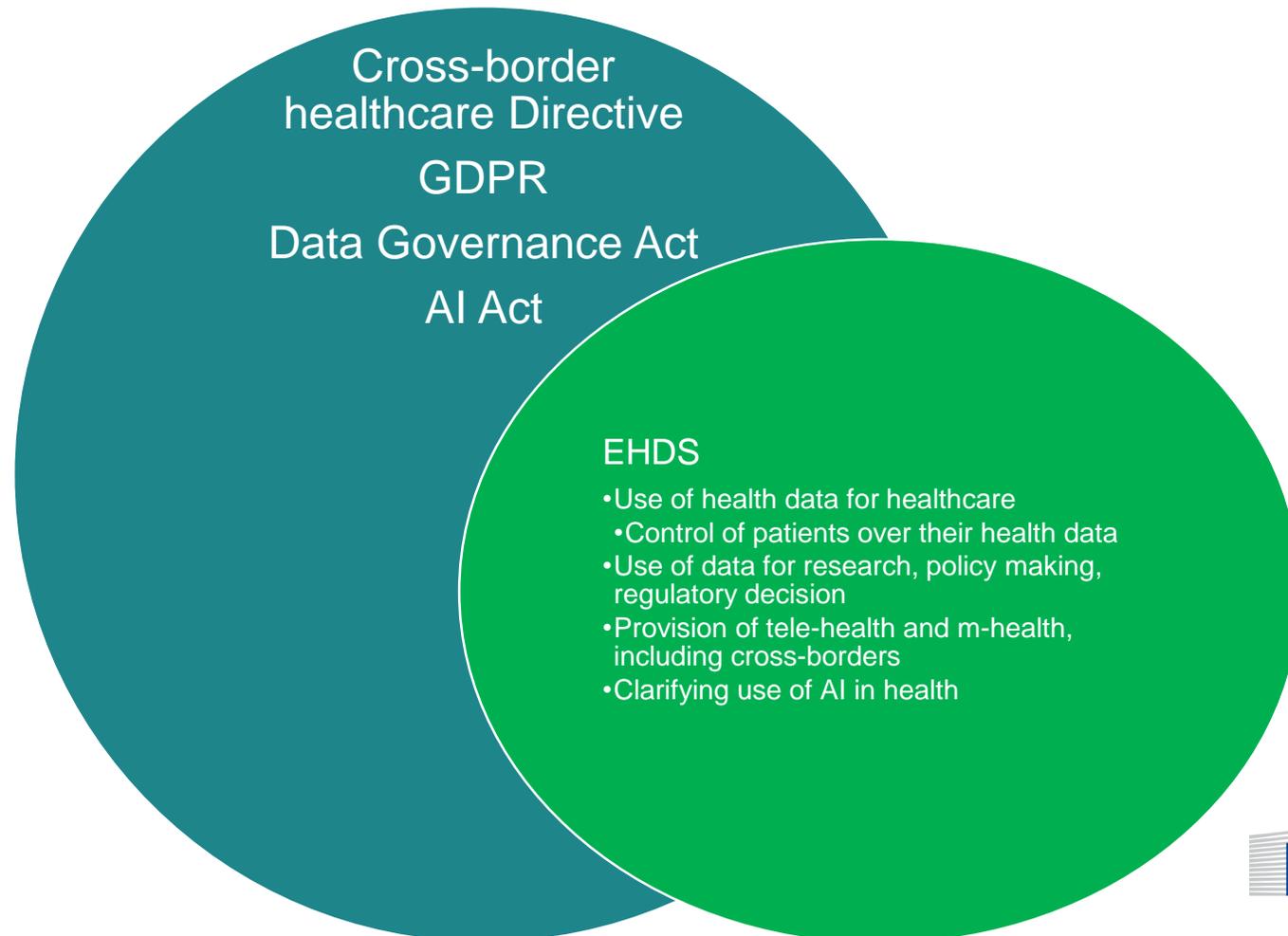
## Problems

- Limited provision of data for training of AI
- Difficulties for regulators to evaluate AI algorithms
- Uncertainty on AI liability in health

## Areas of work

- Support for development and rollout of AI
- Data for AI
- Support for regulators

# EHDS: articulation with EU regulatory framework



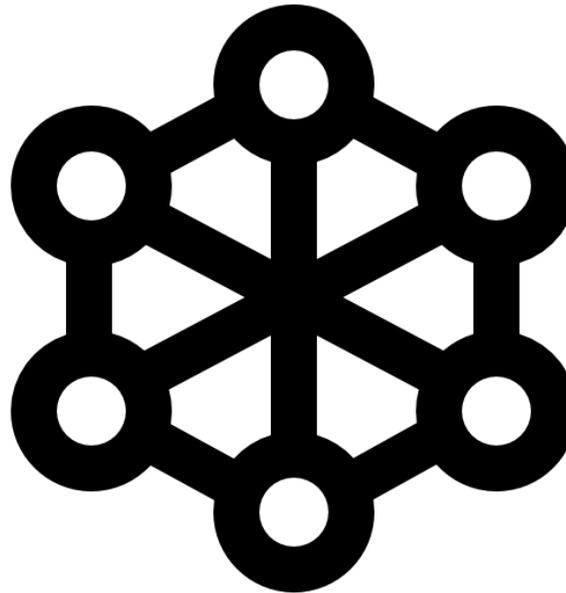


# Re-use of health data for research, innovation, policy making and regulatory decision

# Secondary use in the EHDS



Reuse of health data by researchers, policy-makers and industry



Rules, protocols and governance



Health data from patients and healthcare professionals



Granting researchers, policy-makers and industry access to health data across borders in an interoperable, digital format

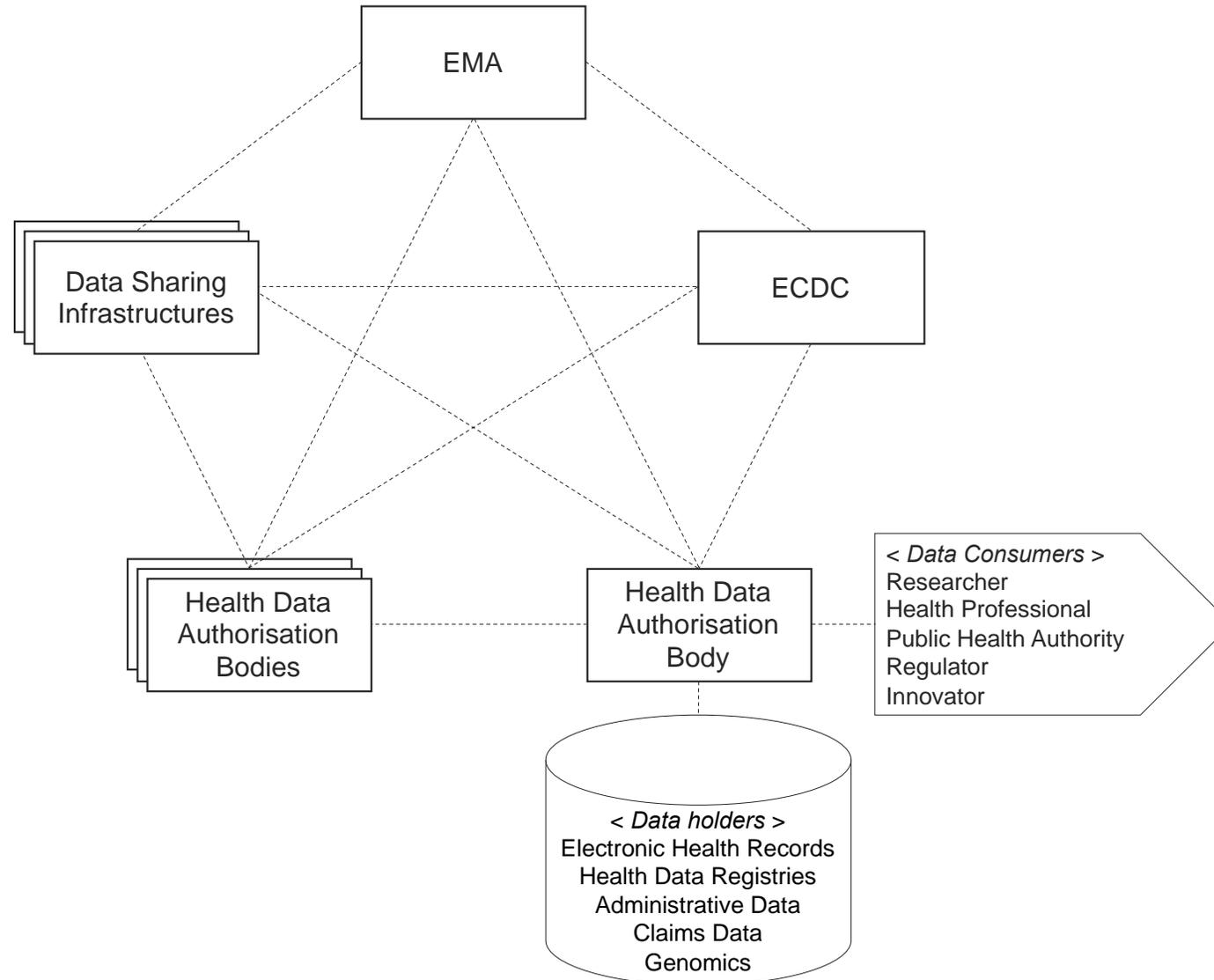
# Secondary use of health data

- The legislative proposal will focus on a number of areas:
- Expanding on the existing **infrastructure** in Member States (Data Permit Authorities)
- Introduce a European **network** with common rules
- Promoting **interoperability** and **data quality** transparency
- Strengthening the **legal base** for the re-use of health data

**Action grants for developing a pilot project for an EU infrastructure ecosystem for the secondary use of health data for research, policy-making and regulatory purposes**

*Code name: EHDS2 Pilot*

# EHDS2 infrastructure (concept)



# EHDS2 Pilot – Expected results

- a) Candidate requirements, architecture and specifications for the technological building blocks for an IT and data infrastructure to enable EU-wide reuse of health data;
- b) Deployment of a working IT infrastructure consisting of, at least, 5 nodes (that can be national authorities empowered by national mandate and legal basis to enable access to health data, ERICs and Research Infrastructures); to these nodes, one could add EU agencies and connection with central services enabling Union-wide reuse of health data;
- c) Report of the assessment performed on the proposed standards and technological building blocks, including findings and lessons learnt on effectiveness and potential to scale towards a Union-wide solution;
- d) Report on candidate legal and governance arrangements for a digital infrastructure for efficient cross border reuse of health data;
- e) Demonstrate the added value of cross-country health data reuse on specific use cases (e.g. scientific research, policy making and regulatory activities).

# Thank you



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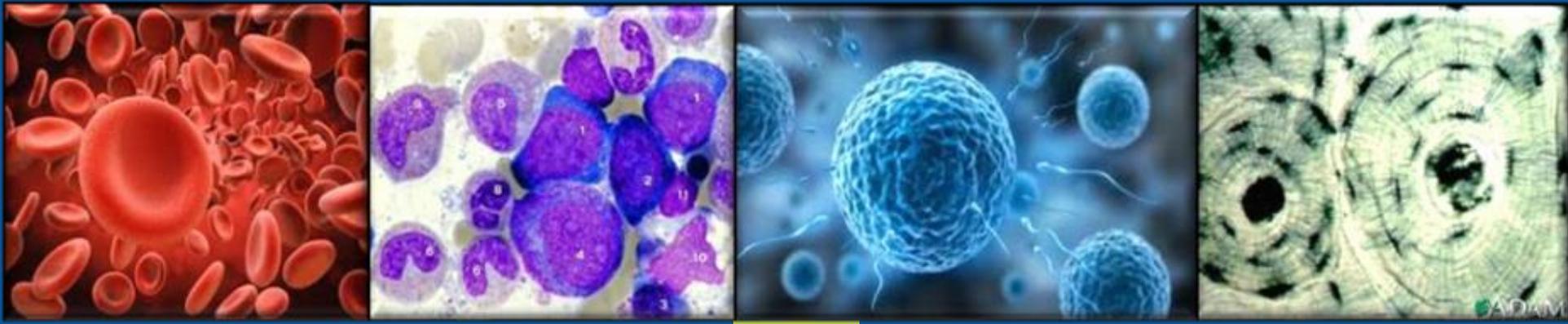
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## HS-g-17.3.1 Call for proposals:

**Action grants to organise and collect data to understand the safety, quality and efficacy of therapies**

- applied in the field of assisted reproduction (ART) and
- based on haematopoietic stem cells (HSC)



# Policy context and objectives

HSC – cancer immunotherapy, blood cancers

ART – fertility (cancer)

## → Political concerns

- Crisis resilience and responsiveness
- Innovation
- Availability, accessibility affordability of therapies

## → Objectives : make best use of data

- Support data use, including collection, aggregation and analyses
- Facilitate design, development and management of sector-specific IT solutions

# Expected results

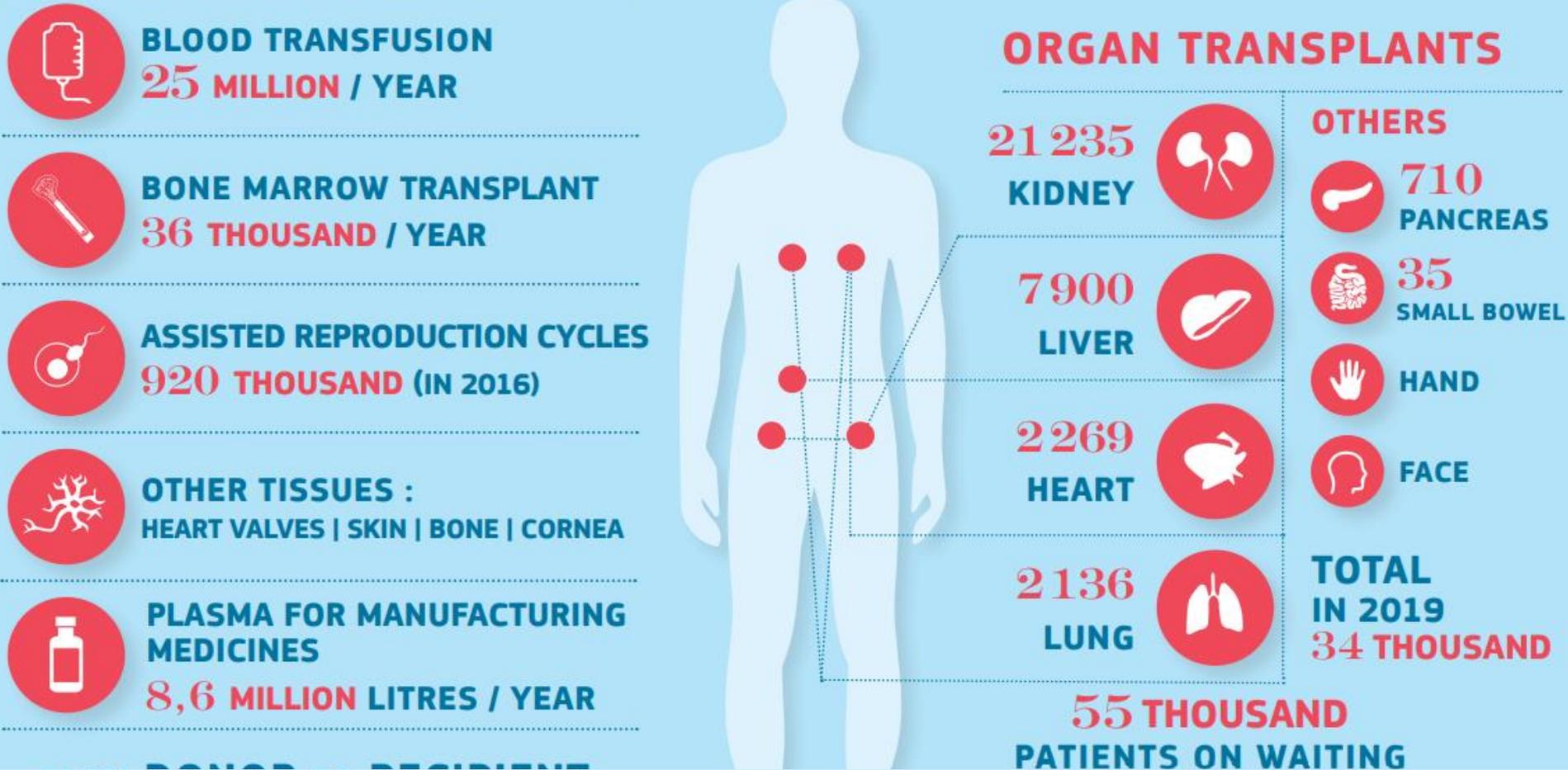
## New/upgraded digital registries

- High quality data
- From and with professionals across EU
- Engaging authorities across EU
- Data sharing (collect once, use often)
  - ➔ Researchers: Science (studies, publications, ...)
  - ➔ Medical professionals: Clinical protocols (assessment, improvement, ...)
  - ➔ Authorities: Oversight (safety monitoring, outcome/efficacy assessment, ... )
  - ➔ EU citizens: Protection (donors, recipients and offspring)
  - ➔ Healthcare systems: Efficiency
  - ➔ Proposed solutions should ensure the findability, accessibility, interoperability, and reuse of digital assets (FAIR principles), use or interoperate with the main European and global data standards and other initiatives (i.e. European Health Data Space, EOSC Life).  
Qualitative data will be available for professionals as well as authorities and other

# Considerations

- FAIR principles (findability, accessibility, interoperability, reuse) of digital data and assets
- Cross-EU dimension
- Fit to EU and global standards (a.o. EHDS) and legal requirements (BTC)
- Sharing data
- Governance (sustainability, funding, right to access, GDPR, publications, ...)
- Procedural
  - Timetable (indicative): Q2-3 2021
  - 2.000.000EUR for HSC, 2.000.000 for ART
  - Open call for proposals (action grant)
  - Type of applicants: professional associations, foundations, NGOs and similar entities and Member States' authorities

# Substances of Human Origin (SoHO) sector



- 1400 Blood establishments
- 3300 Tissue/cell establishments
- Largely public sector, academia and non-profit (Red Cross, ...)

## **EU4H-2021-PJ-07**

Action grants to support implementation of best practices on the ground with direct impact on the effort to tackle mental health challenges during COVID-19

Nicoline TAM SMA, Policy Officer

Unit Health Promotion, Disease Prevention, Financial Instruments, DG SANTE

# Background & policy context

- Mental health problems already considerable challenge prior to pandemic
- New work kicked off in 2021 to support Member States, following prioritisation by Steering Group on Promotion and Prevention:
  - EUR 7 million (3rd Health Programme) for Joint Action and project to implement 3 practices (preventing depression; preventing suicide; community-based system reform)
- COVID-19 exacerbated the situation
- 2020 Commission Communication: support roll-out of practices addressing mental health impact of COVID-19
- Broader policy objective: reducing the burden of NCDs

# Action taken until now on mental health impact of COVID-19

- Health Policy Platform (HPP) network on ‘COVID-19 mental health support’
- Webinars via HPP
- Conference ‘Mental health and the pandemic: living, caring, acting!’
- EU Health Award for community-based initiatives (30 November deadline)

# EU4H-2021-PJ-07 action grants

- To support implementation of best practices on the ground with direct impact on efforts to tackle mental health challenges during pandemic
- More specifically: to strengthen
  - community-based knowledge sharing, awareness, and capacity building
  - the response to the mental health impact of the pandemic, especially at local level.
- Up to 2 proposals to be awarded
- Action to last 12 - 36 months (recommended: 24 months)
- **Total EU contribution available: EUR 750.000**

# Activities to include

- The transfer of practices .....
  - as shared within the Health Policy Platform network on ‘COVID-19 mental health support’.
  - but could also be others...*such as* those (promising practices) presented at May 2021 conference on the mental health impact of the pandemic
- Targeted at one or more specific groups (e.g. children, young people, migrants, people with pre-existing conditions, health workers, older people.....)
- Implemented through pilot projects,
- in consultation *with* representatives from community or target group concerned.

# Activities to include (continued)

- Pilot the transfer of promising practices/approaches
- Report on the results
- Deliver a brief process evaluation of the implementation at pilot sites
- Propose plan for wider implementation (roll-out of practices) in the countries involved
- What would be a plus.....
  - Reflection on wider lessons learned (e.g. on opportunities & relevance for further implementation in other countries)

# Additional requirements?

- Public or private non-profit organisations can apply, but other types of applicants will be also accepted.
- Participation of NGOs active in the field of mental health recommended
- The consortium to include at least one NGO active in the field of mental health, *preferably* at EU level

# Thank you



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# Action grants for the implementation of best practices in community-based services for HIV/AIDS, tuberculosis, viral hepatitis and STIs

EU4HEALTH 2021 WP- INFO SESSION

28 October 2021



POLICY and  
GOALS



STEPPING  
STONES



RESULTS and  
IMPACT



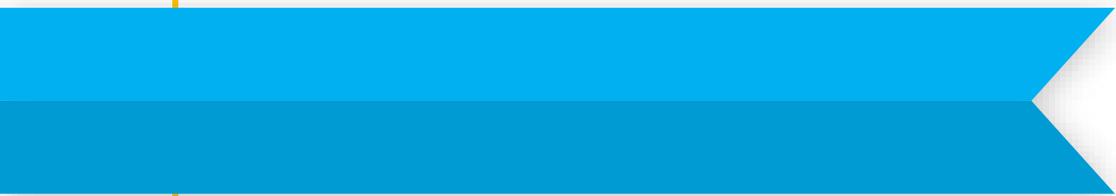
THE WAY

# Commissioner Mission Letter

*“Each Commissioner will ensure the delivery of the United Nations Sustainable Development Goals within their policy area. The College as a whole will be responsible for the overall implementation of the Goals.”*

Mission Letter of **Stella Kyriakides**,  
Commissioner for Health and Food  
Safety





# Policy and Goals

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01  
Sustainable  
Development  
Goals



*Target 3.3: By 2030, to end the epidemics of AIDS, tuberculosis, <...> and combat hepatitis.*

02  
Progress

03  
European  
Health  
Union



04  
Instruments



05  
Actions



2021 EU4Health Work Programme  





# Stepping stones

## Implementation of best practices in community-based services for HIV/AIDS, viral hepatitis, TB and STIs



### Objectives

- Strengthening community-based service organisations
- People-centred, effective and integrated interventions
- Groups at risk



### Activities

- Build on the results of the 3rd Health Programme
- Testing and linkage to care, counselling, harm-reduction, peer support
- Consolidation of networks



### Deliverables

- Choosing Good/Best Practices and/or tools/guides for implementations
- Work across diseases
- Dissemination, implementation and evaluation plan & report



### Eligibility

- Civil society organisations
- Prevention, outreach and awareness raising activities, community services
- Geographical coverage



# Results and impact

- ⚙️ Integrated community-based health services
- ⚙️ Capacity and network building
- ⚙️ Facilitating participation of civil society organisations and networks



# The Way

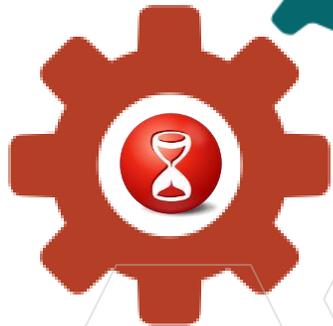
Opening –  
14 October



Call ID –  
EU4H-2021-PJ-13



Budget – EUR 5  
million



**Deadline –  
25 January  
2022 17:00:00  
Brussels time**

1-5 projects of  
max 36 months

Electronic  
Submission  
Service



HaDEA-HP-  
CALLS@ec.euro  
pa.eu

[Funding & tenders \(europea.eu\)](https://europea.eu)

# Thank you

Keep in touch  
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Health Security Unit  
Public Health Directorate  
Directorate-General for Health and Food Safety

EU Commission Public Health: <https://ec.europa.eu/health/>  
Health Policy Platform: <https://webgate.ec.europa.eu/hpf/>  
EU\_Health @ Twitter: [https://twitter.com/eu\\_health](https://twitter.com/eu_health)



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# Call for proposals: Support to the implementation of the EU Action Plan on Antimicrobial Resistance

**Dirk MEUSEL**

European Commission  
DG SANTE

*28 October 2021*  
*EU4HEALTH 2021 WP- INFO SESSION*

# Commissioner Mission Letter

*“Many of today’s epidemics are linked to the rise or return of highly infectious diseases. I want you to focus on the full implementation of the European One Health Action Plan against Antimicrobial Resistance and work with our international partners to advocate for a global agreement on the use of and access to antimicrobials.”*

Mission letter of **Stella Kyriakides**,  
Commissioner for Health and Food  
Safety



# Healthcare-associated infections

- HAIs - a significant part of the AMR burden in the EU
- Health burden high (mortality/morbidity)
- Economic costs high too
- Pivotal importance of infection prevention and control and antimicrobial stewardship in healthcare settings (hospitals, long-term care facilities, primary care, etc.)
- Links to patient safety



Joint [ECDC/OECD technical brief](#)

# Action grants: envisaged activities

- Capacity building
- Various forms of training
- Transfer of good practices in infection prevention and control
- Transfer of good practices in antimicrobial stewardship
- Clinical audit and feedback
- Pilots and demonstration projects

=> Call mainly oriented towards healthcare settings (hospitals, long-term care facilities) but also primary care (e.g. physicians practices and clinics)



# Action grants: overview key details

- Call ID: EU4H-2021-PJ-14
- Opening date: 14 October 2021
- Closing date: 25 January 2022 17:00:00 Brussels time
- Budget: EUR 7 million
- Scope: 1-5 projects of max 36 months
- More information [online](#)

# Thank you

#HealthUnion  
#EUCancerPlan

# Annual Work Programme 2021 Webinar on Action Grants (2nd call)



28 October 2021

Task Force Europe's Beating Cancer Plan

# Action grants to support actions to improve access to human papillomavirus vaccination (EU4H-2021-PJ-8)

- Opening date: 14 October 2021
- Deadline date: 25 January 2022
- Budget: € 1.200.000

**Objectives: to contribute to support Member States' efforts to extend the roll-out of routine HPV vaccination of girls and boys to eliminate cervical cancer and other cancers caused by HPV in the coming decade**

# Action grants for the initiative 'HealthyLifestyle4All': promotion of healthy lifestyles (EU4H-2021-PJ-9)

- Opening date: 14 October 2021
- Deadline date: 25 January 2022
- Budget: € 4.400.000

**Objectives:** to promote healthy lifestyles in the Union, in particular amongst children, and its scope will be widened to involve various Commission services, civil society organisations and the Member States.

# Action grants to reduce liver and gastric cancers caused by infections (EU4H-2021-PJ-10)

- Opening date: 14 October 2021
- Deadline date: 25 January 2022
- Budget: € 2.000.000

**Objectives:** The action aims to reduce the risk of liver cancers associated with infections caused by the Hepatitis B and Hepatitis C viruses and the risk of gastric cancers caused by *Helicobacter pylori*.

# Action grants for 'EU Cancer Treatment Capacity and Capability Mapping' project - Network of Comprehensive Cancer Centres (EU4H-2021-PJ-11)

- Opening date: 14 October 2021
- Deadline date: 25 January 2022
- Budget: € 1.200.000

**Objectives: to map and share the different capabilities and expertise available across the Union.**

# Action grants to create a 'Cancer Survivor Smart Card' (EU4H-2021-PJ-12)

- Opening date: 14 October 2021
- Deadline date: 25 January 2022
- Budget: € 1.800.000

**Objectives: to improve the quality of life and health status of cancer survivors, and to address their potential needs through the development and support for the wide use of new approaches to communication.**

# Action grants for 'Cancer Diagnostic and Treatment for All' including 'Genomic for Public Health' (EU4H-2021-PJ-15)

- Opening date: 14 October 2021
- Deadline date: 25 January 2022
- Budget: € 6.000.000 (first strand + second strand)

**Objectives:** To help Member States improving access for individuals and cancer patients and survivors to prevention, diagnosis and treatment of cancer through personalised medicine, by upscaling available innovation in the field of innovative cancer diagnosis and treatment.

# Action grants for the Computer-aided Drug Repurposing for Cancer Therapy (EU4H-2021-PJ-16)

- Opening date: 14 October 2021
- Deadline date: 25 January 2022
- Budget: € 3.000.000

**Objectives:** to identify potential viable effective anti-cancer drugs by making use and piloting 'in-silico drug repurposing' including by upscaling available innovation using advanced computing and the new big-data technologies and high-performance computing while reducing timeframes and development costs.

# Action grants boosting cancer prevention through the use of the European Code against Cancer and other concerted actions (EU4H-2021-PJ-18)

- Opening date: 14 October 2021
- Deadline date: 25 January 2022
- Budget: € 2.500.000 (first strand + second strand)

**Objectives: to improve access to and understanding of risk factors and health determinants to improve health outcomes for cancer.**