EU4Health Web-InfoDay 2022

Das neue Europäische Gesundheitsprogramm (2021 – 2027) und Arbeitsprogramm 2022

Nationale Kontaktstelle EU4Health

27 April 2022 I 10:00 – 12:40

Online via WebEx

Gesundheit Österreich GmbH

EU4Health InfoDay Agenda

10.00 – 10:10	**Begrüßung und Vorstellung der nationalen Kontaktstelle** *Claudia Habl und Cara Pries, GÖG*
10:10 – 10:20	**Begrüßung durch das Ministerium: Das EU-Aktionsprogramm Gesundheit und sein Stellenwert für Österreich** *Bundesminister für Gesundheit, Soziales, Pflege und Konsumentenschutz Johannes Rauch (Video)*
10:20 – 10:40	**EU4Health: Vision, Priorities and Work Programme 2022** *(presentation in English)* *Giuseppina Luvara, DG SANTE, Europäische Kommission*
10:40 – 10:50	**Q&A**
10:50 – 11:10	**EU4Health: Implementierung, Instrumente und Ausschreibungen** *Maria Merkou, European Health & Digital Executive Agency (HaDEA)*
11:10 – 11:20	**Q&A**
11:20 – 11:40	**EU4Health: Financial and administrative aspects** *(presentation in English)* *Klara Kasnyik, European Health & Digital Executive Agency (HaDEA)*
11:40 – 11:50	**Q&A**

EU4Health InfoDay Agenda

11:50 – 12:20 **Erfolgsgeschichten aus dem EU-Aktionsprogramm für Gesundheit in Österreich**

1. Präsentation EUR-HUMAN (EUropean Refugees-HUman Movement and Advisory Network) – 10 min

   Kathryn Hoffmann, Medizinische Universität Wien

2. Präsentation Localize It! (Local strategies for reducing underage and heavy episodic drinking) – 10 min

   Robert Gruber, Institut Suchtprävention, pro mente Oberösterreich

3. Präsentation COENJA (Joint Action on Instructions for use of re-useable and re-sterilisable medical devices) – 10 min

   Heidrun Eberl, Bundesamt für Sicherheit im Gesundheitswesen (BASG) / AGES Medizinmarktaufsicht

12:20 – 12:35 **Q&A**

12:35 – 12:40 **Verabschiedung**

EU4Health Programme

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

Giuseppina Luvarà
Programme officer-EU4Health Task force
DG SANTE

27.04.2022 AUSTRIA Info Day EU4Health

EU4Health – a vision for a healthier European Union

EU4Health is the Programme for the Union's Action in the Field of Health under the MFF 2021-27

Regulation (EU) 2021/522 – EU4Health Programme

Official Journal of the European Union

L 107

English edition — Legislation — Volume 64 — 26 March 2021

Contents

I *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

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

EUR-Lex
Access to European Union law

European Commission

EU4Health – **4** General objectives

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

IMPROVE & FOSTER HEALTH through disease prevention and health promotion, as well as international health initiatives and cooperation

PROTECT PEOPLE FROM SERIOUS CROSS-BORDER HEALTH THREATS through prevention, preparedness and response to cross-border health threats, complementing national stockpiling of essential crisis-relevant products and establishing a reserve of medical, healthcare and support staff;

IMPROVE ACCESS TO MEDICINAL PRODUCTS, MEDICAL DEVICES & CRISIS-RELEVANT PRODUCTS by encouraging sustainable production and supply chains and innovation in the Union as well as efficient use of medicinal products;

STRENGTHEN THE NATIONAL HEALTH SYSTEMS through improved health data use and re-use, development of digital tools and services, digital transformation of healthcare, enhancing access to healthcare, developing and implementing Union health legislation and evidence-based decision-making and integrated work among MS health systems.

European Commission

EU4Health – **10** Specific objectives

Health is an investment and the EU4Health programme will provide financial support 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

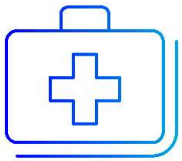
Prevention, preparedness & response to cross-border health threats;

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.

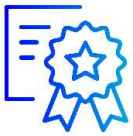
European Commission

EU4Health – annual work programmes : the process

INPUT, CONSULTATION, INFORMATION
on priorities, strategic orientations and needs

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)

European Commission

EU4Health work programmes – 4 strands of action + cancer

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

Possible eligible actions

CANCER

CRISIS PREPAREDNESS

Protect citizens from serious cross-border health threats

Strengthen health systems response;

Enhance coordination among Member States to cope with serious cross-border threats to health

HEALTH PROMOTION & DISEASE PREVENTION

Improve and foster health in the EU

Reduce the burden of communicable and non-communicable diseases

Support health promotion and disease prevention

Reduce health inequalities

Foster healthy lifestyles

HEALTH SYSTEMS & HEALTHCARE WORKFORCE

Improve availability, accessibility and affordability of medicinal products and medical devices

Support their innovation

Strengthen resilience and sustainability of health systems

Reinforce healthcare workforce

DIGITAL TRANSFORMATION

Advance digital transformation of health systems

Strengthen primary & secondary use of health data

European Commission

EU4Health – financial envelope & work programmes

Health is an investment and the EU4Health Programme supports targeted investment to fund the Union health initiatives

24 March 2021

EU4Health 2021-27
EUR 5.3 billion

24 June 2021

Work Programme 2021
EUR 311.8 million

CRISIS PREPAREDNESS (INCLUDING HERA)	**34.0%**
HEALTH PROMOTION & DISEASE PREVENTION	**7.7%**
CANCER	**24.9%**
HEALTH SYSTEMS & HEALTHCARE WORKFORCE	**22.0%**
DIGITAL	**10.4%**
OTHER ACTIONS	**1.1%**

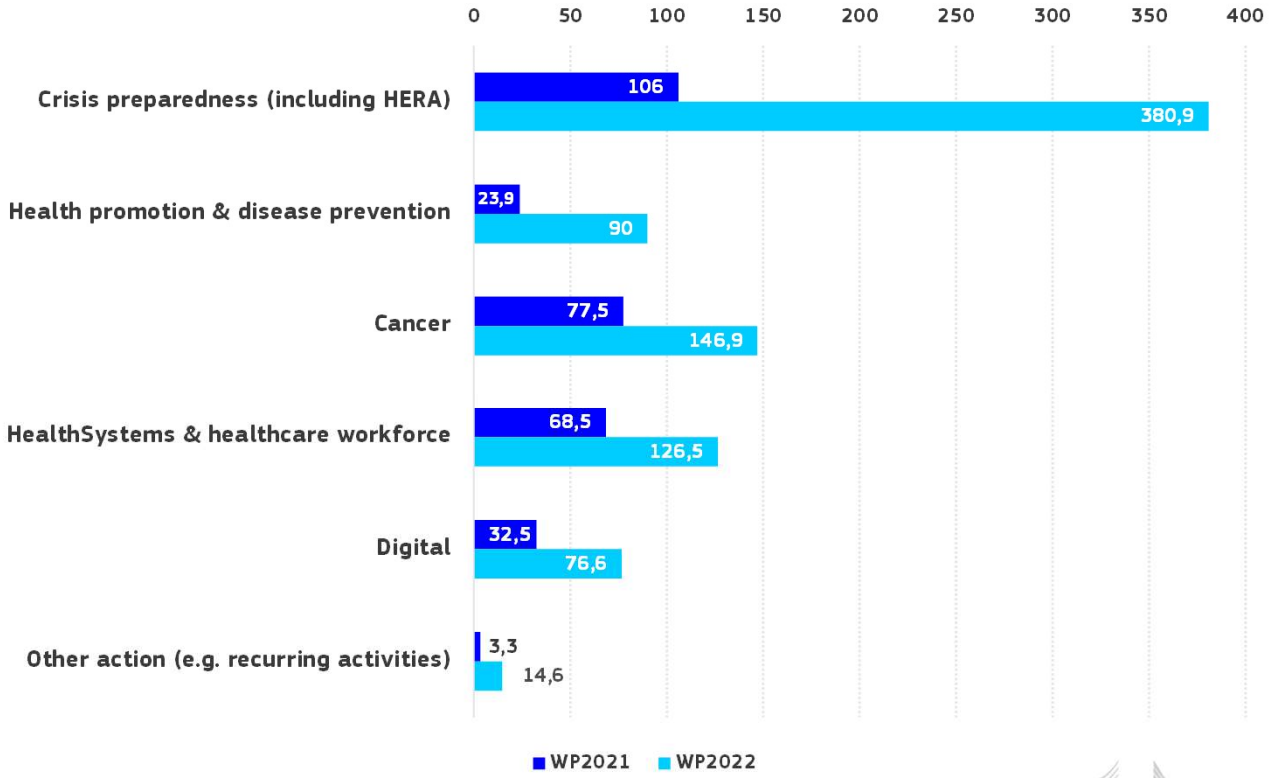
14 January 2022

Work Programme 2022
EUR 835.3 million

CRISIS PREPAREDNESS (INCLUDING HERA):	**45.6%**
HEALTH PROMOTION & DISEASE PREVENTION:	**10.8%**
CANCER:	**17.6%**
HEALTH SYSTEMS & HEALTHCARE WORKFORCE	**15.1%**
DIGITAL	**9.2%**
OTHER ACTIONS:	**1.7%**

EU4Health 2021 & 2022 – Work Programme

10 months after adoption: more than EUR 1 billion invested through the WP2021 and WP2022



European Commission

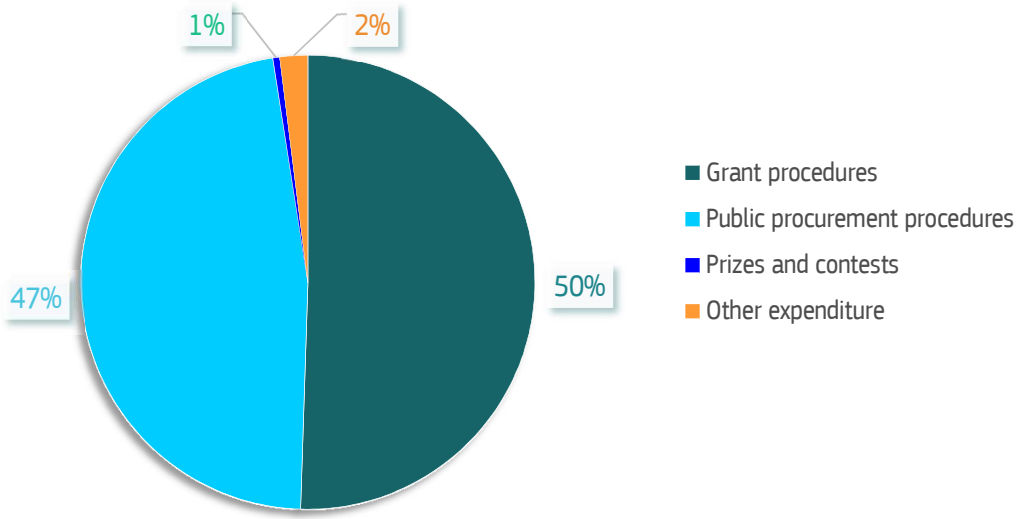
EU4Health – Implementation WP 2021 & 2022

EU4Health is implemented through annual work programmes

WORK PROGRAMME 2021

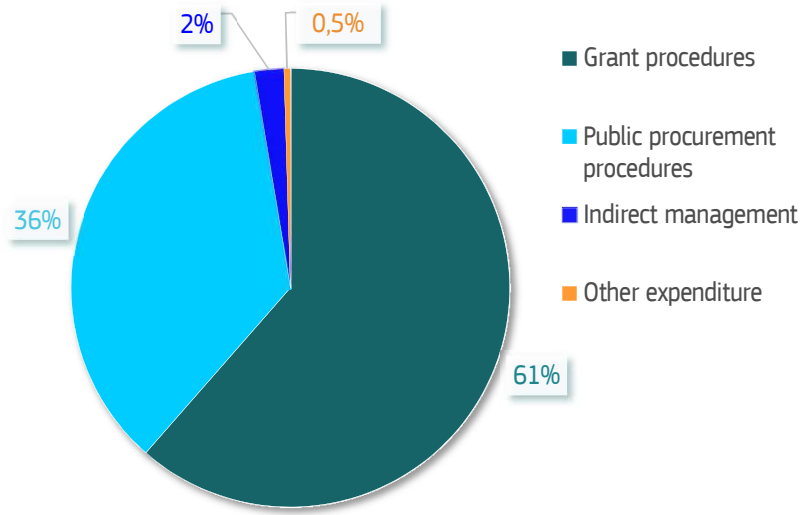
EUR 311.8 million

Almost all actions have been launched with a handful of more complex ones to be launched in Q1/2022



WORK PROGRAMME 2022

EUR 835.5 million



European Commission

EU4Health – Work Programme 2022

Strand 'Crisis preparedness': allocated budget **EUR 380.9 million**

PRIORITIES

- HERA
- Tackling AMR
- Support to large-scale vaccination, including against COVID-19
- One Health approach for cross-border pathogens
- Reinforce Union cooperation with WHO on crisis preparedness

ACTIONS *(non exhaustive list)*

JOINT ACTIONS

- ✓ Implementation of AMR measures in Member States

ACTION GRANTS

- ✓ Implementation of results of innovative public health research in relation to vaccination against COVID-19
- ✓ Public procurement in health sector –HERA

DIRECT GRANTS

- ✓ Enhancing whole genome and RT-PCR national infrastructures and capacities to respond COVID-19 and future health threats –HERA
- ✓ Surveillance system for cross-border pathogens

PROCUREMENT

- ✓ EUFAB for vaccines and therapeutics production –HERA
- ✓ Vaccines against infectious disease threats –HERA
- ✓ IT development –HERA
- ✓ Innovative diagnostics testing -HERA
- ✓ Study on tackling AMR

European Commission

EU4Health – Work Programme 2022

Strand 'Health promotion and Disease prevention': allocated budget **EUR 90.0 million**

PRIORITIES

- Health promotion and prevention of non-communicable diseases (NCDs) and related risk factors
- Addressing mental health challenges

ACTIONS *(non exhaustive list)*

JOINT ACTIONS

- ✓ Cancer and other NCDs prevention - health determinants
- ✓ Prevention NCDs - cardiovascular diseases and diabetes

ACTION GRANTS

- ✓ Cancer and other NCDs prevention - health determinants
- ✓ Prevention NCDs - cardiovascular diseases, diabetes and other NCDs
- ✓ Promoting Mental health (best practices)

PROCUREMENT

- ✓ Evaluation of EU Action plan on childhood obesity

DIRECT GRANTS TO INTERNATIONAL ORGANISATIONS

- ✓ Addressing mental health challenges

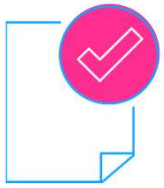
European Commission

EU4Health – Work Programme 2022

Strand 'Cancer': allocated budget **EUR 146.9 million**

PRIORITIES

- Health promotion, cancer prevention and related risk factors
- Innovative approaches to prostate, lung, and gastric cancer screening at EU level
- Reducing inequalities in cancer care
- Quality of life of cancer survivors
- Tobacco control policy
- Evaluation of Europe's beating cancer plan



ACTIONS *(non exhaustive list)*

JOINT ACTIONS

- ✓ Implementation of innovative approaches to prostate, lung, and gastric screening at Union level
- ✓ Second cohort of inter-speciality cancer training programme

ACTION GRANTS

- ✓ Tobacco control policy and legislation
- ✓ Study on effectiveness of health information on alcoholic beverages
- ✓ Obstacles for cancer survivors to return to work
- ✓ Code of conduct on fair access of cancer survivors to financial services

DIRECT GRANTS TO INTERNATIONAL ORGANISATIONS

- ✓ IARC and EU Observatory : cancer inequalities registry
- ✓ WHO – addressing alcohol-related harm

European Commission

EU4Health – Work Programme 2022

Strand 'Health systems': allocated budget **EUR 126.5 million**

PRIORITIES

- Reforming and strengthening health system
- Training for Health workforce, including digital skills
- Enhanced European Reference Networks
- Implementation of the Pharmaceutical legislation and strategy
- Implementation of regulation on Medical devices and in vitro diagnostic medical devices
- Preparation and Implementation of the health technology assessment (HTA) Regulation

JOINT ACTIONS

- ✓ Support ERNs integration to the national healthcare systems
- ✓ Increasing capacity building of EU medicines regulatory network
- ✓ Piloting new model approach for Blood, tissue and Cell preparation process.
- ✓ Reinforcing market surveillance of medical devices and in vitro medical devices

ACTION GRANTS

- ✓ Provide training for health workforce, including digital skills
- ✓ Warning features and guidance in the area of pricing: EURIPID database
- ✓ Supporting increased capacity of notified bodies for medical devices
- ✓ Training of patient and clinical experts contributing to HTA activities

PROCUREMENT

- ✓ Guidelines on access to healthcare of people with disabilities
- ✓ Thematic activites: ERN, Pharma, SoHO, HTA and Medical devices

DIRECT GRANTS TO MS

- ✓ Supporting maintenance of the European Medical Device Nomenclature

DIRECT GRANTS TO INTERNATIONAL ORGANISATIONS

- ✓ Supporting coordinating centres of the 24 ERNs
- ✓ Orphanet: technical assistance and support

European Commission

EU4Health – Work Programme 2022

Strand 'Digital': allocated budget **EUR 76.6 million**

- **Training for Health workforce, including digital skills**
- European Health Data Space – infrastructure & governance; primary use of data
- European Health Data Space – infrastructure & governance; secondary use of data

JOINT ACTIONS

- ✓ Preparatory actions for a European Health Data Space: primary use and reuse of data

PROCUREMENT

- ✓ Expansion of core services to support access of patients to their health data : primary use of data
- ✓ Developing and deploying the basic EHDS2 core services: secondary use of data
- ✓ Operations of Myhealth@EU core services: primary use and support for capacity building
- ✓ Secondary use of health data-infrastructure governance

DIRECT GRANTS TO MS

- ✓ Expansion of Myhealth@EU Digital Service Infrastructure
- ✓ Setting up services by health Data Access Bodies –secondary use of data

European Commission

EU4Health – Work Programme 2022

Funding opportunities for Public Authorities: totally **EUR 472,8 million**

CRISIS PREPAREDNESS

ACTIONS GRANTS

EUR **35 Million**

DIRECT GRANTS

EUR 39 Million

JOINT ACTIONS

EUR **70 Million**

HEALTH PROMOTION & DISEASE PREVENTION

JOINT ACTIONS

EUR **55 Million**

ACTIONS GRANTS

EUR **25 Million**

CANCER

JOINT ACTIONS

EUR **76 Million**

ACTIONS GRANTS

EUR **48 Million**

HEALTH SYSTEMS & HEALTHCARE WORKFORCE

JOINT ACTIONS

EUR **24,7 Million**

ACTIONS GRANTS

EUR **34,3 Million**

DIRECT GRANTS

EUR **1,8 Million**

DIGITAL

JOINT ACTIONS

EUR **4 Million**

DIRECT GRANTS

EUR **60 Million**

European Commission

EU4Health – Work Programme 2022

Funding opportunities for NGOs: totally ***EUR 130 million***

ACTIONS INTENDED FOR NGOS AND OTHER TYPES OF APPLICANTS

CRISIS PREPAREDNESS

Implementation of relevant results of innovative public health research in relation to vaccination against COVID-19

EUR **30 Million**

Support to structured dialogue at national or regional level on public procurement in the health sector – HERA

EUR **5 Million**

HEALTH PROMOTION & DISEASE PREVENTION

Cancer and other NCDs prevention – action on health determinants

EUR **11 Million**

Prevention of NCDs - cardiovascular diseases, diabetes and other NCDs

EUR **10 Million**

Mental health

EUR **15 Million**

CANCER

Monitor and strengthen the implementation of innovative approaches to prostate, lung and gastric cancer screening at Union level

EUR **11 Million**

HEALTH SYSTEMS & HEALTHCARE WORKFORCE

Training for health workforce, including digital skills

EUR **29 Million**

Increase capacity of notified bodies for medical devices

EUR **4 Million**

Implementation of the Regulation on health technology assessment

EUR **1 Million**

ACTIONS INTENDED SOLELY FOR NGOS

DP-g-22-26.01

Open call for proposal for operating grants

Financial contribution to the functioning of health non-governmental bodies implementing one or more specific objectives of Regulation 2021/522EUR

EUR 9 Million

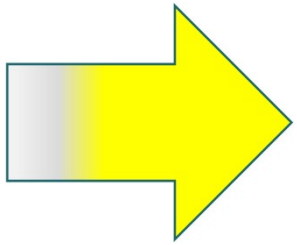
Other: DP-g-22-06.05
EUR 5 million

Total: EUR 14 million

European Commission

EU4Health – Amendment of the 2021 Work Programme

REPLACED FUNDING
CP-p-06.3: Improving access to COVID-19 therapeutics at Union level (EUR 3 mil.)
CP-p-06.2 – Intelligence gathering - Preparation of HERA



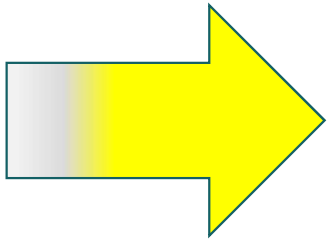
ALLOCATED ACTIONS
✓ CP-g-06.5: Supporting a HERA laboratory network
✓ CP-g-06.6: Strengthening Member States' IT systems ensuring interoperability with HERA's IT platform for intelligence gathering
✓ CP-g-06.7: Strengthening preparedness and response to cross-border health threats at global level (Indirect management - WHO)

European Commission

EU4Health – Amendment of the 2022 Work Programme

REDUCED FUNDING

- ✓ DP-g-22-07.04: Implementing promising best practice(s) to improve mental health and psychosocial wellbeing in migrant and refugee populations
- ✓ DP-g-22-06.03: Direct grant to Member States authorities on prevention of NCDs - cardiovascular disease and diabetes



ALLOCATED ACTION

- ✓ DP-g-22-07.05 ("Mental health and psychosocial support for displaced people coming from Ukraine") Direct grant to the International Federation of Red Cross and Red Crescent Societies to provide mental health and psychosocial support to individuals fleeing Ukraine

European Commission

EU4Health – the way forward

2023 work programme and beyond

Preparatory work: strategic orientations and priorities

- Member States' consultation (EU4Health Steering Group)
- Stakeholder outreach activities
- Synergies and complementarities
- Monitoring and evaluation
- Global Health

European Commission

EU4Health – Synergies & Complementarities

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

Implementation & Deployment
- ERDF
- ESF+
- InvestEU
- RRF
- EU4Health

Research & Innovation
- Horizon Europe
- ERDF
- InvestEU
- EU4Health (*innovation uptake*)

Digital transformation
- EU4Health
- Horizon Europe
- Digital Europe

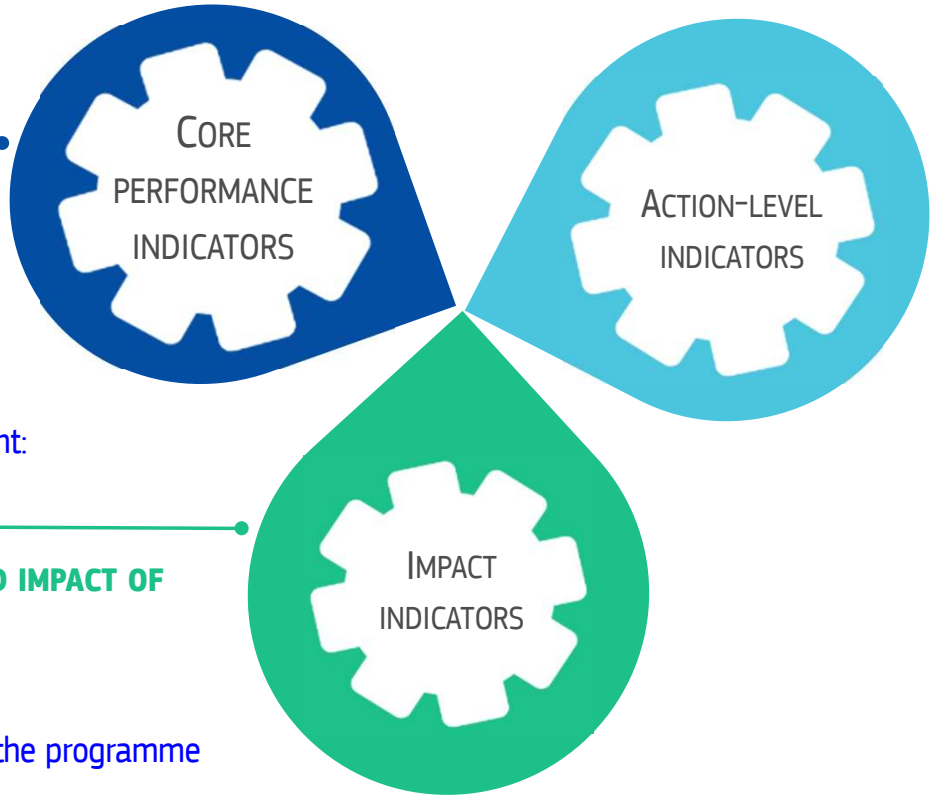
Pilots
- Horizon Europe
- Digital Europe
- EU4Health

Crisis Preparedness & Response
- EU4Health
- UCPM/RescEU
- ERDF
- InvestEU
- RRF

Technical Support & Advisory Services
- Technical Support Instrument
- InvestEU
- EU4Health

European Commission

Performance framework - indicators



INDICATORS LISTED IN ANNEX II OF THE EU4HEALTH PROGRAMME REGULATION

- Reported annually
- Representative of Programme progress and effects
- Precise Information & measurement: metadata, baseline and target

INDICATORS REPORTING ON EXPECTED IMPACT OF THE INTERVENTIONS

- Contribution no attribution
- Representative of the ambitions of the programme
- Linked to SDGs

INDICATORS REPORTING ON INTERVENTIONS

- Outputs and results
- Representative of progress in implementation and effects of interventions
- Aggregated at Programme level for typical actions (capacity building, best practices ...).
- Collected from beneficiaries

European Commission

Thank you

Contact: SANTE-CONSULT-EU4HEALTH@ec.europa.eu

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European Commission

2021-2027

EU4Health Programme

Health and Digital Executive Agency (HaDEA)

27. April 2022

EU4Health Programme (2021-2027)

National Informationstag, Österreich

27 April 2022

Maria Merkou **(EU4Health, HaDEA A1)**

European Commission, Health and Digital Executive Agency (HaDEA) – Brüssel

European Commission

Überblick

- Budget
- Joint Actions – Gemeinsame Maßnahmen
- Action grants – Maßnahmebezogene Finanzhilfen
- Begutachtungskriterien
- Antragsverfahren – Allgemeine Hinweise

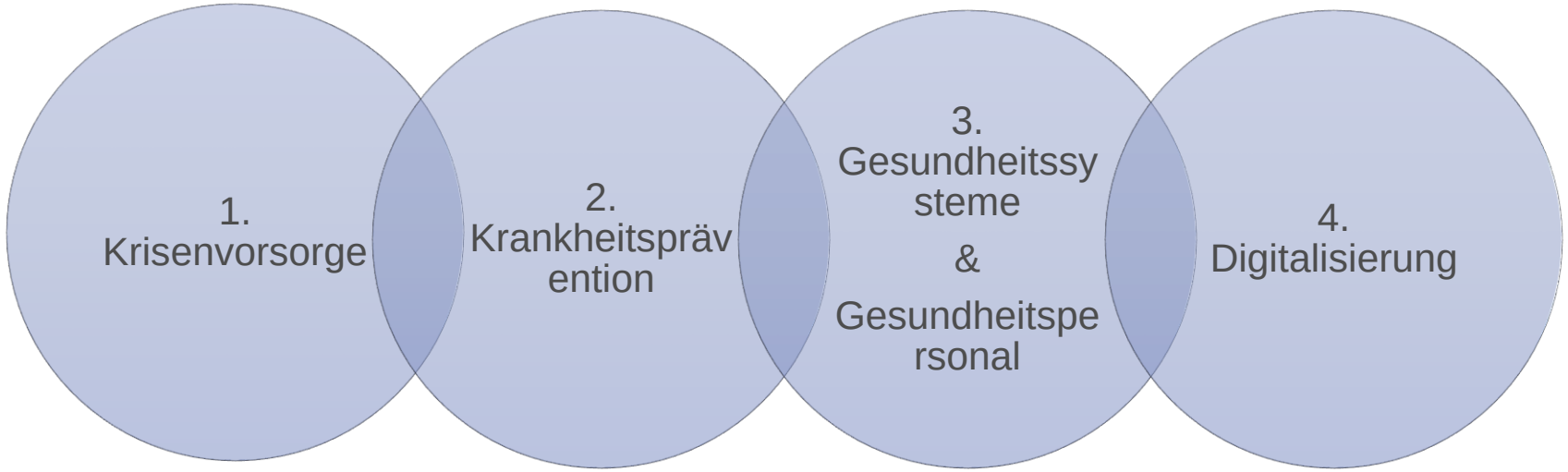
European Commission

BUDGET

European Commission

Die Ziele des Programms

Verordnung (EU) 2021/522, 24 März 2021



Krebs

Budget im Arbeitsprogramm 2022

835 349 555 EUR

European Commission

JOINT ACTIONS

Gemeinsame Maßnahmen

European Commission

Joint Actions – Beteiligungsvoraussetzung

Eine zuständige Behörde je Mitgliedstaat/ teilnehmendem Land

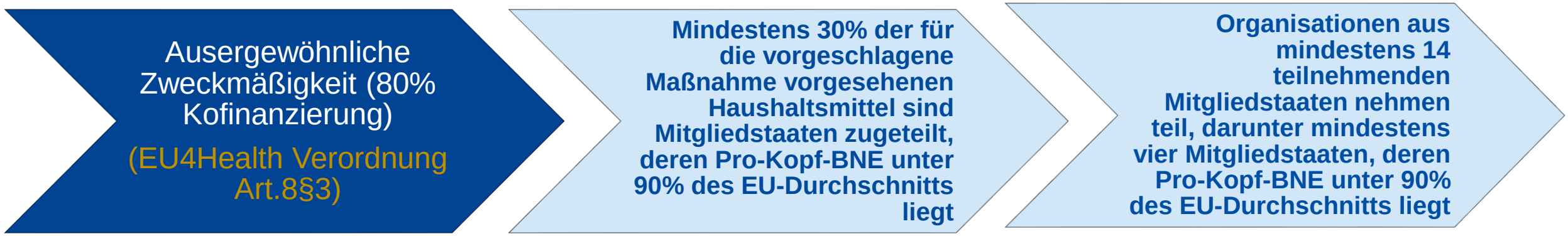
verbundene Unternehmen oder Einrichtungen können vorgeschlagen und nominiert werden

Förderfähige Teilnehmer müssen:

- Ihren Sitz in einem Mitgliedsstaat oder einem mit ihm verbundenen Land oder Gebiet in Übersee haben;
- Ihren Sitz in einem mit dem Programm assoziierten Drittland haben; oder
- Nach EU-Recht geschaffene Rechtsträger oder international Organisationen sein

European Commission

Joint Actions – Zuwendungsvoraussetzung



zusätlich werden **finanzielle- und operative Leistungsfähigkeit** geprüft

European Commission

Joint Actions

Code Topic AWP 2022	Title Topic	Objective EU4Health (Strand)	Amount
CP-g-22-02.01	Implementation of AMR measures in Member States	1	€ 50,000,000.00
CR-g-22-08.01	Cancer and other NCDs prevention – Action on health determinant	2	€ 75,000,000.00
DP-g-22-06.03	Prevention of NCDs – Cardiovascular diseases and diabetes	2	€ 53,000,000.00
CR-g-22-10.03	Direct grant to Member States' authorities for them to contribute to the Cancer Inequalities Registry to monitor national cancer control policies	2	€ 1,000,000.00
HS-g-22-16.02	Support ERNs integration to the national healthcare systems of Member States	3	€ 11,200,000.00
HS-g-22-17.02	Increasing capacity building of the EU medicines regulatory network	3	€ 8,000,000.00
HS-g-22-18.01	Piloting a new model approach for assessing and authorising novel Blood, Tissues and Cells (BTC) preparation processes	3	€ 1,500,000.00
HS-g-22-19.01	Reinforced market surveillance of medical devices and in vitro medical devices	3	€ 4,000,000.00
DI-g-22-22.06	Preparatory actions for a European Health Data Space; primary use of data (for healthcare) and reuse of data	4	€ 4,000,000.00

Joint Actions – Arbeitspakete

European Commission

CALLS FOR PROPOSALS - ACTION GRANTS

Maßnahmenbezogene Finanzhilfen

European Commission

Action Grants – Beteiligungsvoraussetzung

Organisationstyp: Rechtspersönlichkeit nach geltendem nationalen Recht, i.e. privat oder öffentlich, Nichtregierungsorganisationen (NRO), Forschungs- und (öffentliche) Gesundheitseinricchtungen, Universitäten, Hochschulen usw.

Länder, die teilnehmen können:

- **EU Mitgliedstaaten**+ EEA Länder (**Island & Norwegen**)
- **Drittländer die eine spezifische Vereinbarung mit der EU haben** (Art. 6 der Verordnung 2021/522 zum EU4Health Programme)

Minimum Teilnehmerzahl und geographische Abdeckung**: mindestens drei** voneinener unabhängige Organisationen aus mindestends drei Ländern, die zur Teilnahme an EU4Health berechtigt sind.

Jeder Call hat jedoch spezifische Kriterien, die unterschiedlich sein können. Überprüfen sie für jeden Call die Kriterien im Call Dokument!

European Commission

Action Grants – Zuwendungsvoraussetzung

Finanzielle Kapazität: Antragsteller müssen stable, ausreichende Finanzierungsquellen vorweisen, die die Teilnahme während des gesamten Projektzeitraums garantiert*.

Operative Leistungsfähigkeit: Antragssteller müssen für die Durchführung der vorgeschlagenen Maßnahme erforderlichen Ressourcen, Kompetenzen und Qualifikationen bereitstellen.

*EU Kofinanzierung: max 60 % der förderfähigen Kosten. Dieser Betrag kann für Maßnahmen mit einem deutlichen Mehrwert für die Union bis zu 80% betragen. Die außergewöhnliche Zweckmäßigkeit der Maßnahme ist erreicht wenn:

(a) Mindestens 30% der für die vorgeschlagene Maßnahme vorgesehenen Haushaltsmittel sind Mitgliedstaaten zugeteilt, deren Pro-Kopf-BNE unter als 90% des EU-Durchschnitts liegt.

(b) Organisationen aus mindestend 14 teilnehmenden Mitgliedstaaten nehmen teil, darunter mindestens vier Mitgliedstaaten, deren Pro-Kopf-BNE unter 90% des EU-Durchschnitts liegt.

Die Kofinanzierungsrate wird auf Ebene des Konsortiums- sowie einzelner Begünstigter angewendet.

European Commission

1st and 2nd Waves of Open Calls for Proposals

Code Topic AWP 2022	Title Topic	Objective EU4Health (Strand)	Amount	Call ID
CR-g-22-09.01	Monitoring and strengthening the implementation of innovative approaches to prostate, lung and gastric cancer screening at Union level (Subtopic A: Prostate)	2	€ 10,000,000.00	EU4H-2022-PJ-01
CR-g-22-09.02	Monitoring and strengthening the implementation of innovative approaches to prostate, lung and gastric cancer screening at Union level (Subtopic B: Lung)	2	€ 10,000,000.00	EU4H-2022-PJ-01
CR-g-22-09.03	Monitoring and strengthening the implementation of innovative approaches to prostate, lung and gastric cancer screening at Union level (Subtopic C: Gastric)	2	€ 10,000,000.00	EU4H-2022-PJ-01
DP-g-22-06.05	Prevention of NCDs-cardiovascular diseases, diabetes and other NCDs (Subtopic B: NCDs other than the five action strands of the initiative 'Healthier Together – EUNCD Initiative' and cancer; such as chronic kidney diseases and liver diseases, autoimmune diseases, musculo-skeletal conditions, etc.)	2	€ 5,000,000.00	EU4H-2022-PJ-02
DP-g-22-07.01/03	Action Grants to to promote mental health	2	€ 8,000,000.00	EU4H-2022-PJ-03
HS-g-22-20.01/20.01	Implementation of the Regulation on HTA – training of patient and clinical experts contributing to joint HTA activities (Subtopic A)	3	€ 500,000.00	EU4H-2022-PJ-04
HS-g-22-20.01/20.02	Implementation of the Regulation on HTA – training of patient and clinical experts contributing to joint HTA activities (Subtopic B)	3	€ 500,000.00	EU4H-2022-PJ-04
HS-g-22-19.03	Support to increased capacity of notified bodies for medical devices	3	€ 4,000,000.00	EU4H-2022-PJ-05
HS-g-22-15.01	Training for health workforce, including digital skills	3	€ 29,000,000.00	EU4H-2022-PJ-06
CP-g-22-03.01	Support to Member States and other relevant actors to implement relevant results of innovative public health research in relation to vaccination againt COVID-19	1	€ 30,000,000.00	EU4H-2022-PJ-07
HS-g-22-17.01	Development of early warning features and guidance in the area of pricing through the EURIPID database, based on competition cases	3	€ 300,000.00	EU4H-2022-PJ-08
DP-g-22-07.04	Action Grants promoting Mental Health (Subtopic C: implementing promising best practice(s) to improve mental health and psychosocial wellbeing in migrant and refugee populations)	2	€ 2,000,000.00	EU4H-2022-PJ-09

3rd Wave of Open Calls for Proposals

Code Topic AWP 2022	Title Topic	Objective EU4Health (Strand)	Amount	Call ID
CP-g-22-01.05	Support to structured dialogue at national or regional level on public procurement in the health sector - HERA	1	€ 5,000,000.00	EU4H-2022-PJ
DP-g-22-06.04	Prevention of NCDs-cardiovascular diseases, diabetes and other NCDs (Subtopic A: cardiovascular diseases and diabetes, both at an individual and societal level)	2	€ 5,000,000.00	EU4H-2022-PJ
CR-g-22-08.02	Cancer and other NCDs prevention – action on health determinants	2	€11,000,000.00	EU4H-2022-PJ
CR-g-22-08.06	Support for the roll-out of the second cohort of the inter-speciality cancer training programme	2	€ 7,000,000.00	EU4H-2022-PJ

AWARD CRITERIA

Begutachtungskriterien

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Was wird beurteilt? 1/2

- **RELEVANZ:** Klarheit und Konsistenz zwischen Projektzielen und Plannung; entspricht das Projekt den Themen, Prioritäten und Zielen der Aufforderung; Beitrag zum strategischen und gesetzlichen EU Kontext; Europäische und transnationale Dimension; Bedeutung für und Wirkung auf mehrere Länder (EU oder förderfähige nicht-EU Staaten); Möglichkeit die Ergebnisse in anderen Länder zu nutzen; Entwicklung gegenseitigen Vertrauens und Kooperation (30 Punkte)
- **QUALITÄT:**

✓ **Projektdesing and Durchführung:** technische Qualität; logische Verknüpfung der ermittelten Probleme, Bedürfnisse und vorgeschlagene Lösungen (Konzept des logischen Rahmens); Methoden zur Durchführung des Projekts (Konzept und Methodik, Management, Zeitplan, Risiken und Risikomanagement, Evaluierung); Durchführbarkeit des Projekts innerhalb des vorgeschlagenen Zeirahmens; Kosteneffizienz (Preis-Leistungs Verhältnis) (30 Punkte)

✓ **Projektteam- und Kooperationsvereinbarungen:** Qualität des Konsortiums und des Projektteams, Problemlösungmechanismen und Verfahren für die Zusammenarbeit innerhalb des Konsortiums (30 Punkte)

European Commission

Was wird beurteilt? 2/2

- **WIRKUNG:** langfristige Wirkung und Wirkung der Ergebnisse auf die Zielgruppe/allgemeine Öffentlichkeit; Strategie zur Verbreitung der Ergebnisse, Nachhaltigkeit der Ergebnisse nach Auslaufen der EU-Förderung (10 Punkte).

Kriterien	Min. Punkte	Max. Punkte
Relevanz	21	30
Qualität — Projektdesign und Durchführung	21	30
Qualität— Projektteam und Kooperation	21	30
Wirkung	7	10
Gesamtzahl Punkte	**70**	**100**

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Antragsverfahren

Allgemeine Hinweise von der Einreichung bis zur Förderung

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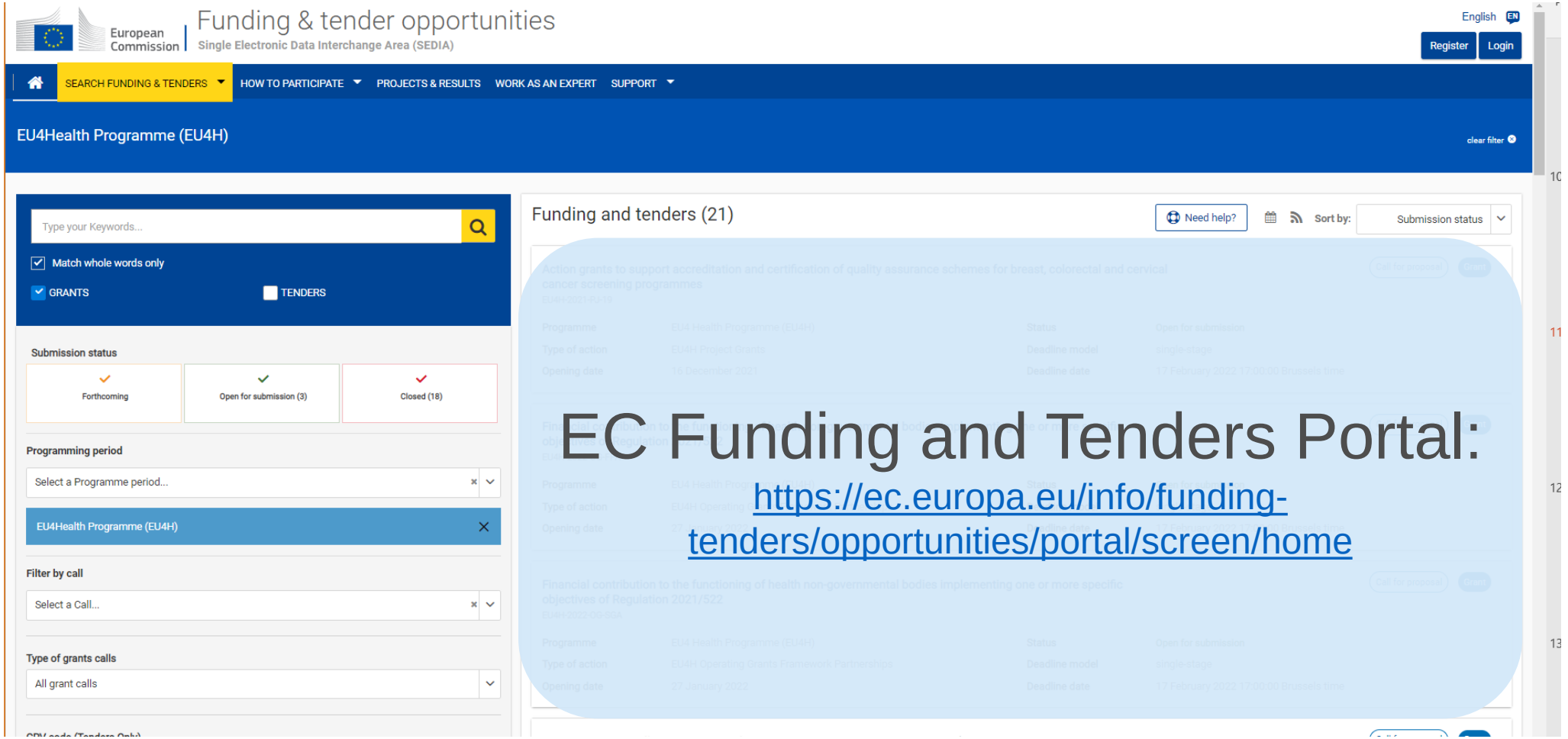


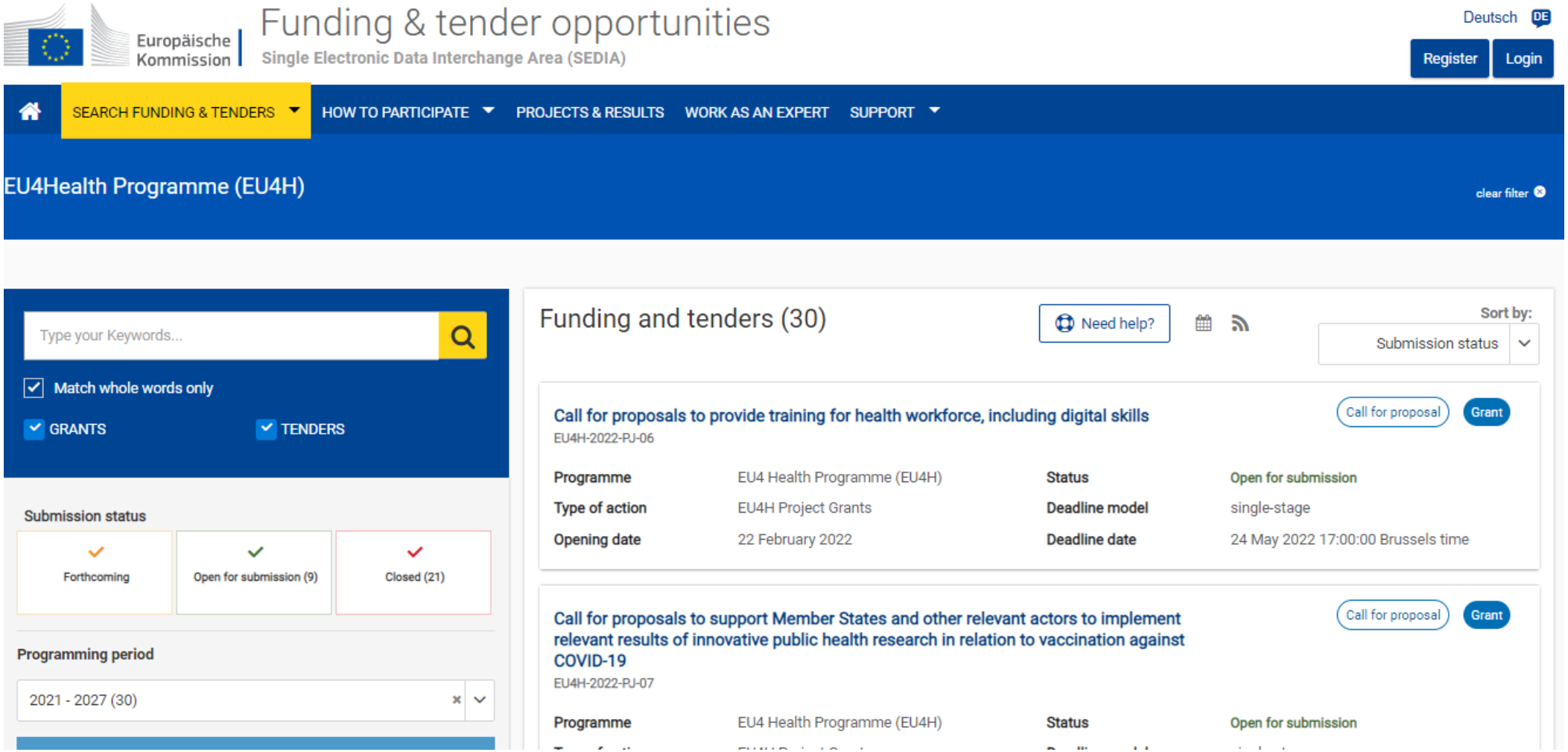
European Commission

Antragsformular

Online Handbuch

Antragsformular

European Commission



EC FUNDING & TENDER OPPORTUNITIES

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

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Teil A – Administratives Formular

- Füllen Sie bitte das Formular online aus (nicht herunterladen)
- Titel, Zeitplan, Zusammenfassung, Schlüsselwörter (Seite 2)
- Erklärungen bestätigen (Seite 3)
- Kontaktdaten der Partner (Teil 2)
- Gesamtbudget (Teil 3)

➢Speichern

➢Überprüfen und Fehler korrigieren

European Commission

Teil B – Technische Beschreibung des Projektes

- Problemanalyse, allgemeine und spezifische Ziele, verbundene Indikatoren (Prozess, Ergebnis/Wirkung)
- Zielgruppe, Politische Relevanz, Methoden und Arbeitsweisen, erweiterte Ergebnisse(!!!)
- Arbeitspakete (einige sind verpflichtend), Aktivitäten, Risikoanalyse, Zeitplan
- Budget: Arbeitsaufwand pro Arbeitpaket, Beiträge Dritter, detaillierte Budgettabelle

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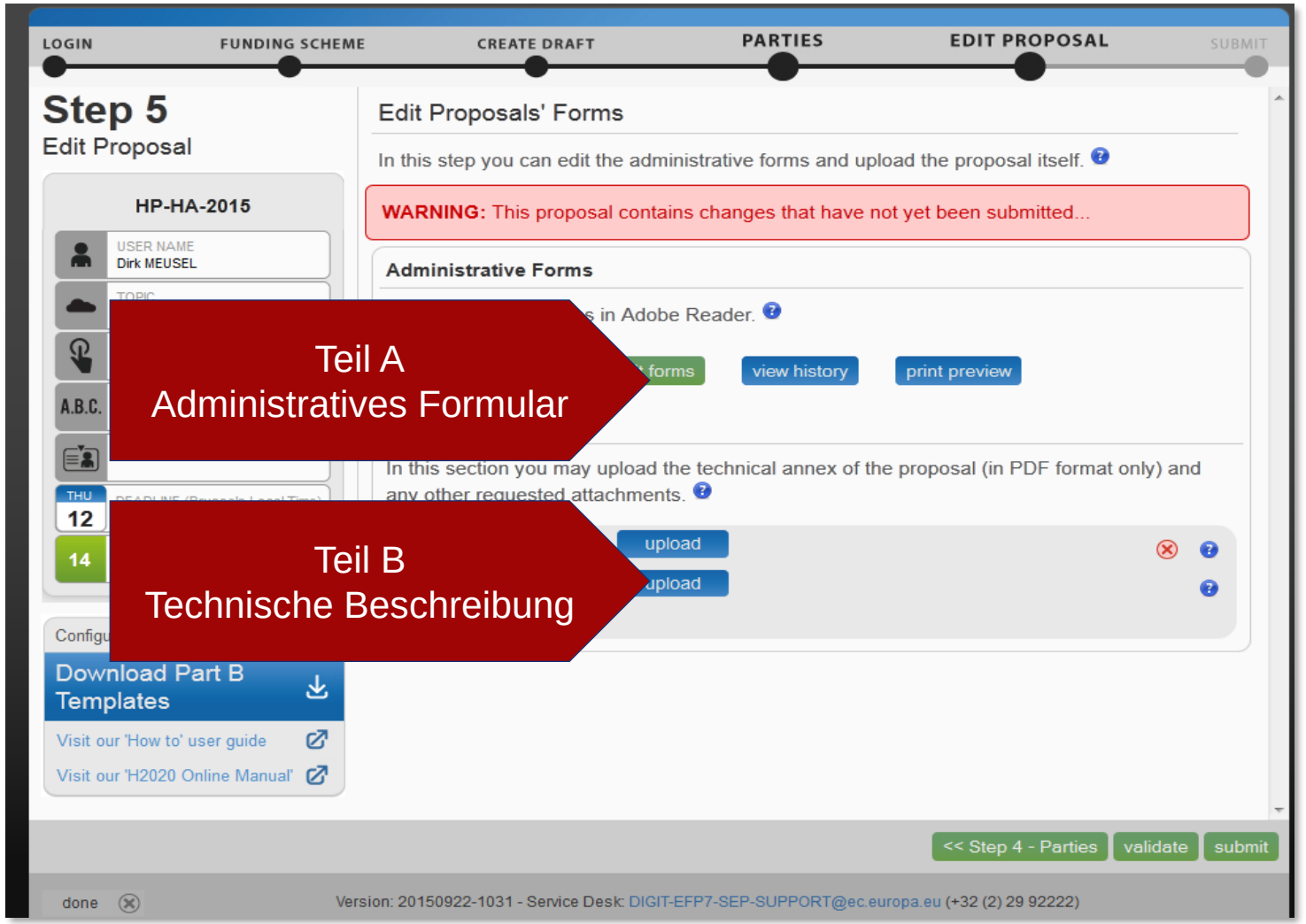

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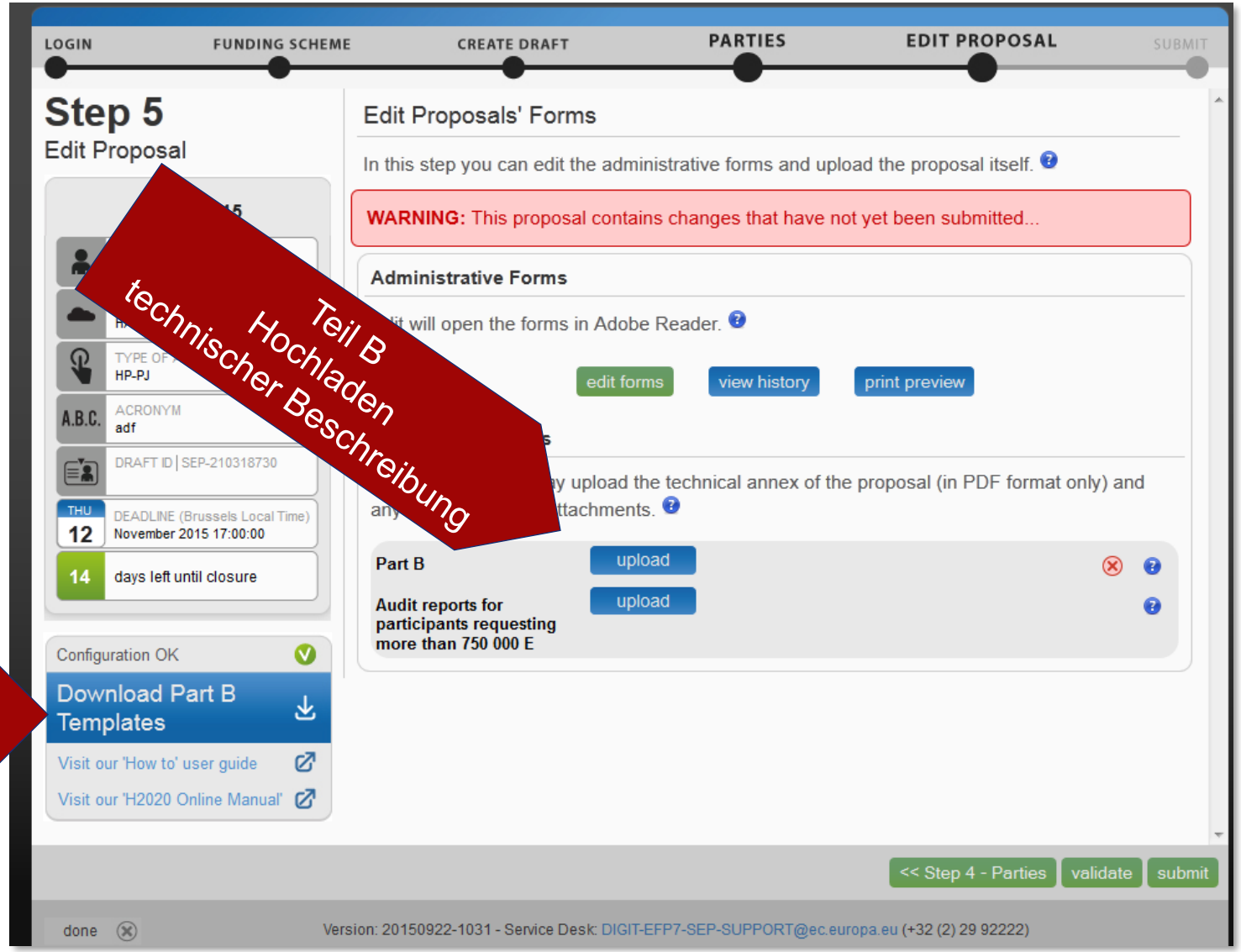

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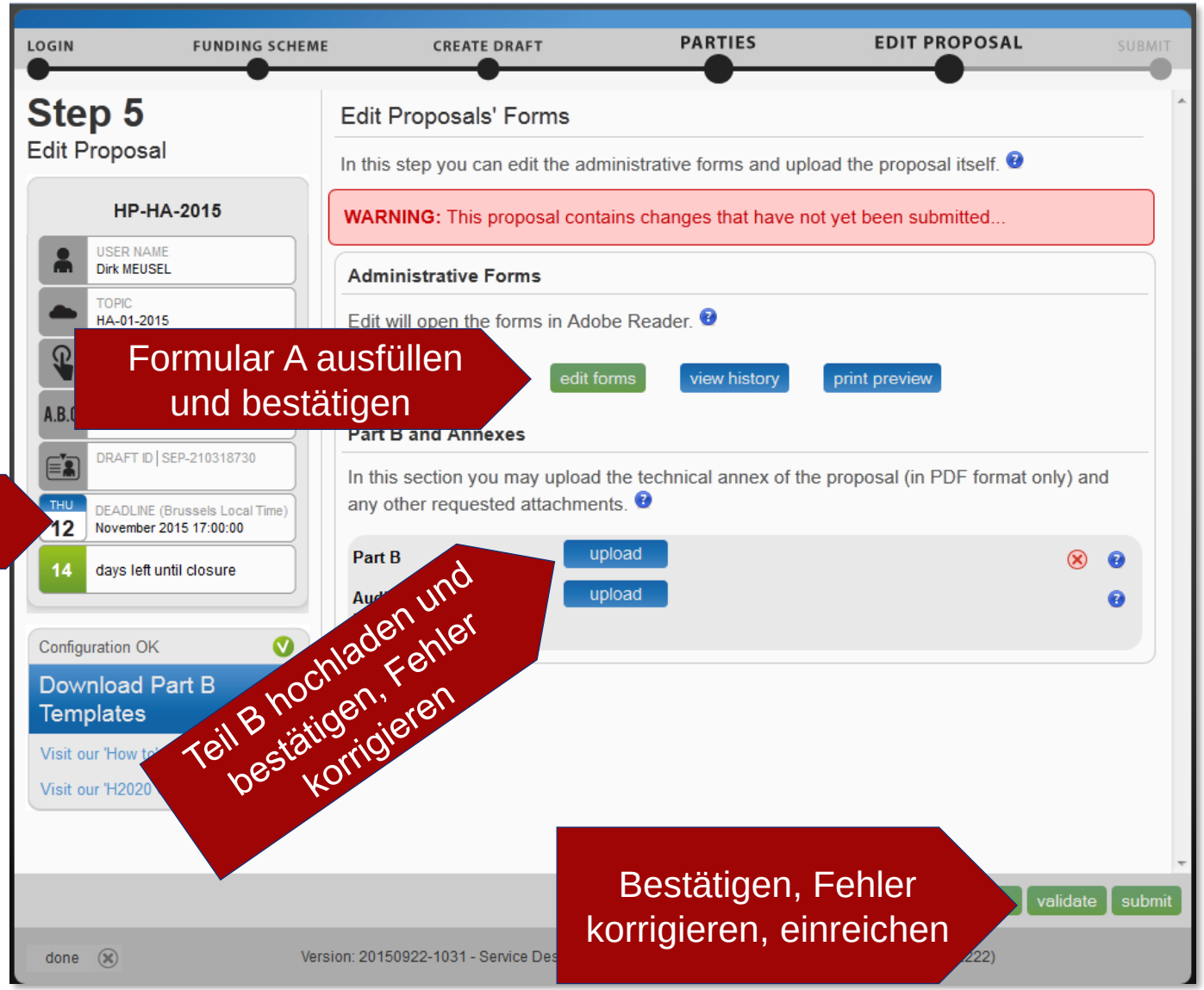

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Förderung – Allgemeine Hinweise

- **HaDEA Website:** https://hadea.ec.europa.eu/index_en
- **HaDEA Functional Mailbox:** HADEA-HP-CALLS@ec.europa.eu

1st Wave of Open Calls AWP 2022: https://hadea.ec.europa.eu/calls- proposals/first-wave-eu4health-calls-2022_en

2nd Wave of Open Calls AWP 2022: https://hadea.ec.europa.eu/calls-proposals/mental-health-assistance-displaced-people-ukraine-open-call-eu4health_en

- **DG SANTE:** https://ec.europa.eu/health/publications/2022-eu4health-work-programme_en
- **Funding and Tender Opportunities Portal (SEDIA):** https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home

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Vielen Dank für ihre Aufmerksamkeit!

European Commission

EU4HEALTH
Annual Work Programme 2022
Info Session - Austria

FINANCIAL MANAGEMENT

27th April, 2022

Procurement: purchase of works, supplies or services

(Financial Regulation, 2018/1046. Title VII – Procurement and Concessions)

- Competitive procedures to select a contractor
- Principles: transparency, equal treatment, non-discrimination, proportionality, sound financial management
- 2022 Annual Work programme for EU4HEALTH: contains the list of activities, topics planned for procurement
- Prior information notice – contains preliminary information on a planned procedure, but creates no obligation, published in the Official Journal "S" series,
- Publication of the call for tender – detailed description of the required service + contractual terms

Procedure and contract management

- Tender documents:
  - Contract notice: official advertisement of the call with key information
  - Tender Specifications: nature and characteristics of the service, deliverables, timeline, application and evaluation procedure, selection, exclusion and award criteria, templates of documents to be submitted, deadlines, budgetary envelope.
  - Draft contract

- Financial capacity check – tenderers must prove sufficient financial capacity as described in the tender specifications under selection criteria

- Contract types:
  - Direct contract – budgetary commitment
  - Framework contract – general contractual terms for specific contracts – no budgetary commitment until the specific contracts are signed under a framework contract

Grant is direct financial contribution to an action

(Financial Regulation, 2018/1046. Title VIII – Grants)

- 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 based on actual costs declared
- Grant = partial reimbursement of eligible costs that are incurred by beneficiaries and affiliated entities listed in the grant agreement at the fixed reimbursement rate.
  - Standard reimbursement rate under the EU4Health programme: 60% of eligible costs
  - Exceptional utility: under certain conditions: 80% of eligible costs
- "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 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.

Eligible costs

General conditions - Cumulative requirements:

- Connected with the action as described in the grant and included in the estimated budget
- Necessary for the implementation of the action;
- Reasonable and justified;
- Incurred within the duration of the grant;
- 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

Cash flow

Beneficiaries / affiliate entities carry out activities, generate costs – e.g. pay salaries, subcontracting, travel, purchases, etc.

Starting date	Interim report(s)	End date
Pre-financing payment upon signature	Approval of reports, Assessment of costs, reimbursement	Approval of reports, Assessment of costs, reimbursement

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Financial capacity assessment

- Beneficiaries must demonstrate that they have necessary financial capacity to carry the burden of the grant.
- Analysis of annual accounts (balance sheet / profit & loss account) before grant signature
- If requested individual grant > 750.000,00 EUR, audit certificate on the annual accounts / declaration on validity of the accounts must also be submitted
- Actions in case of weak financial capacity:
  - Reduced / no pre-financing payment
  - Extended liability of co-beneficiaries
  - Pre-financing guarantee

Grant management

Starting date / Duration

- All activities to carry out, timeframe of eligible costs
- Starting date usually after grant signature, but retroactivity might be allowed – specified in the call text;
- Recommended duration: 12 – 36 months, depends on actions, recommendation on the call

Payment scheme - recommended

- Pre-financing payment after signature of the grant – 30%
- Interim payment(s)
- Balance payment at the end of the duration

Certificates to submit

- At submission of the interim / final report: audit certificate on the financial report submitted – supports the assessment of the financial report to establish the amount of eligible costs.

Thank you

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European Commission

EU Health Info Day 2022

Projektpräsentation: EUR-HUMAN

Assoc.-Prof. Priv.-Doz. Dr. med. Kathryn Hoffmann, MPH

Leiterin Unit Versorgungsforschung und Telemedizin in der Primärversorgung

Abteilung für Sozial- und Präventivmedizin, Zentrum für Public Health,

Medizinische Universität Wien

Funding & Disclaimer

The EUR-HUMAN project is part of the project '717319 /EUR HUMAN' which has received funding from the European Union's Health Programme (2014-2020). "The content of this EUR-HUMAN protocol represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains." them the right to exclusive use.

Eckpunkte EUR-HUMAN

- **EUropean Refugees-HUman Movement and Advisory Network**
- **Acronym: EUR-HUMAN**

- **Ziele:**

Das „EUR-HUMAN“-Projekt war eine länderübergreifende Initiative und zielte darauf ab, die Kapazität, das Wissen und die Expertise von GesundheitsprofessionistInnen im primären Gesundheitssektor in europäischen Mitgliedsstaaten, die Flüchtlinge/Migranten aufnehmen, zu verbessern, besser auf ihre gesundheitlichen Bedürfnisse einzugehen, sie vor Risiken zu schützen und grenzüberschreitende Gesundheitsrisiken zu minimieren.

Eckpunkte EUR-HUMAN

Third Programme for the Union's action in the field of health (2014-2020)

Specific Call HP-HA-2015 – rapid call

Duration: 12 months (01.01.2016 – 31.12.2016)

Grant Amount: 1,320,113 Euros

Coordination by the University of Crete (UoC)

Participating countries:

Austria, Croatia, Greece, Italy, Hungary, the Netherlands, Slovenia, UK

Austrian Team: Elena Jirovsky, E. Sophie Mayrhuber, Kathryn Hoffmann

Team

EUR-HUMAN Project (@eu
Twitter, Inc. [US] https://twitter.com/eur_human
Εφαρμογές Bookmarks
Αρχική Σελίδα Ειδοποιήσεις Μηνύματα
Αναζήτηση στο Twitter
Tweet
EUR-HUMAN
EUR-HUMAN Project
@eur_human
EUROPEAN REFUGEES-HUMAN MOVEMENT AND ADVISORY NETWORK
Heraklion, Greece
eur-human.uoc.gr
Φωτογραφίες και βίντεο
TWEET 21
ΑΚΟΛΟΥΘΕΙ 243
ΑΚΟΛΟΥΘΟΙ 31
"ΜΟΥ ΑΡΕΣΕΙ" 46
Επεξεργασία τ
Tweet
Tweets & απαντήσεις
Φωτογραφίες & βίντεο
EUR-HUMAN Project @eur_human · 24 ώρες
Clinic of Social of Family Medicine, University of Crete @eur_human
fammed.uoc.gr/Joomla/index.p...
EUR-HUMAN Project @eur_human · 4 Φεβ
Η Ιατρική σχολή του Πανεπιστημίου Κρήτης ανέλαβε πανευρωπαϊκό πρόγραμμα στήριξης προσφύγων & μεταναστών @eur_human
shar.es/14mFYb
Προβολή περίληψης
Ο χρήστης EUR-HUMAN Project έκανε Retweet
Ποιους να ακολουθήσετε
Ανανέωση · Προβολή όλων
Evangelos K @ek_videog
Ακολουθήστε
Προωθημένο
Faraz Mughal @farazhmu
Ακολουθείται από Kate O'
Ακολουθήστε
Dr Idris @nausheeriqbal
Ακολουθείται από Tanja P
Ακολουθήστε
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Partners – eur-human
eur-human.uoc.gr/partners/
EUR-HUMAN
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PROJECT INFORMATION:
Funding
This website is part of the project '717319 / EUR-HUMAN' which has received funding from the European Union's Health Programme (2014-2020).
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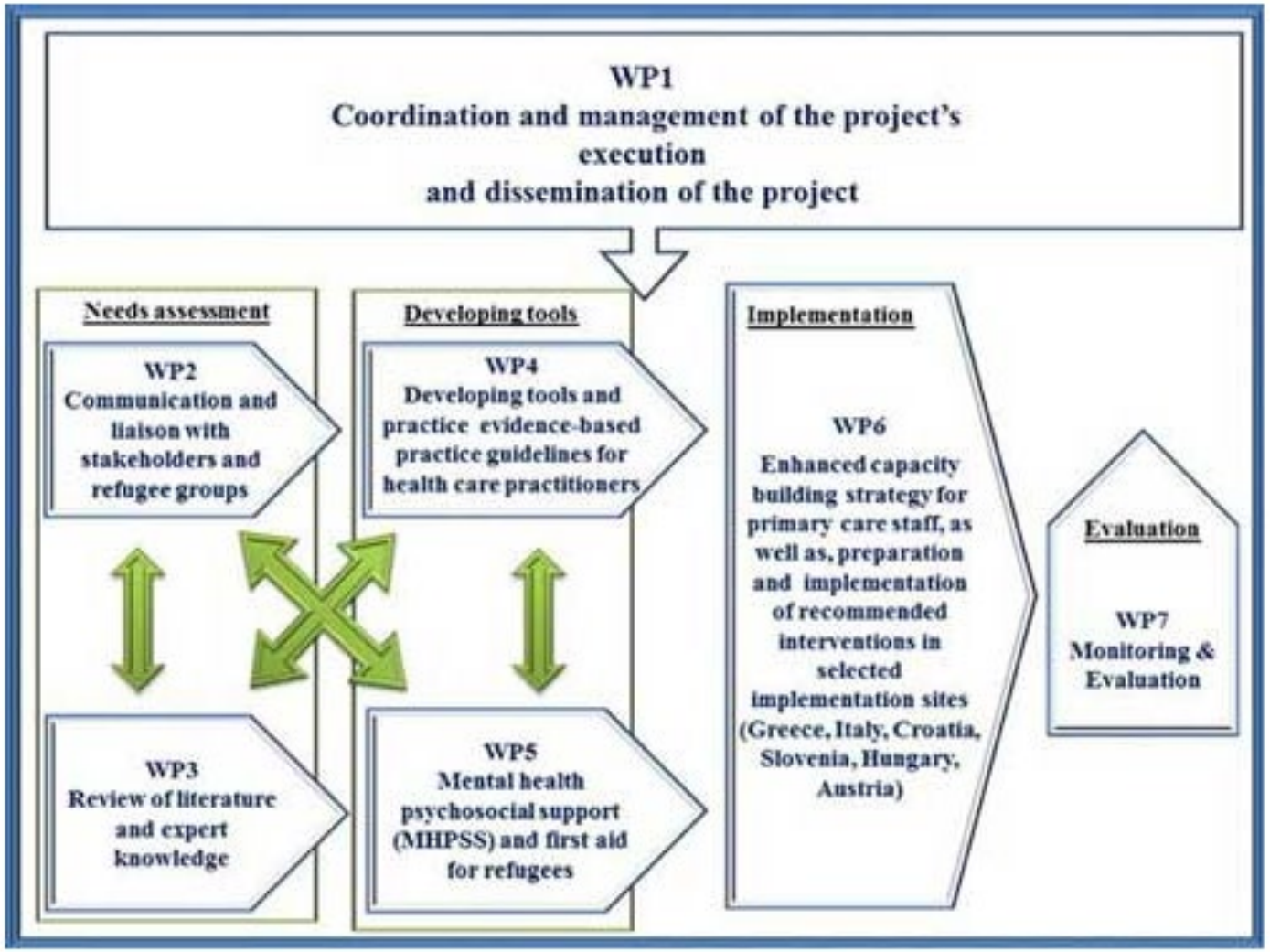
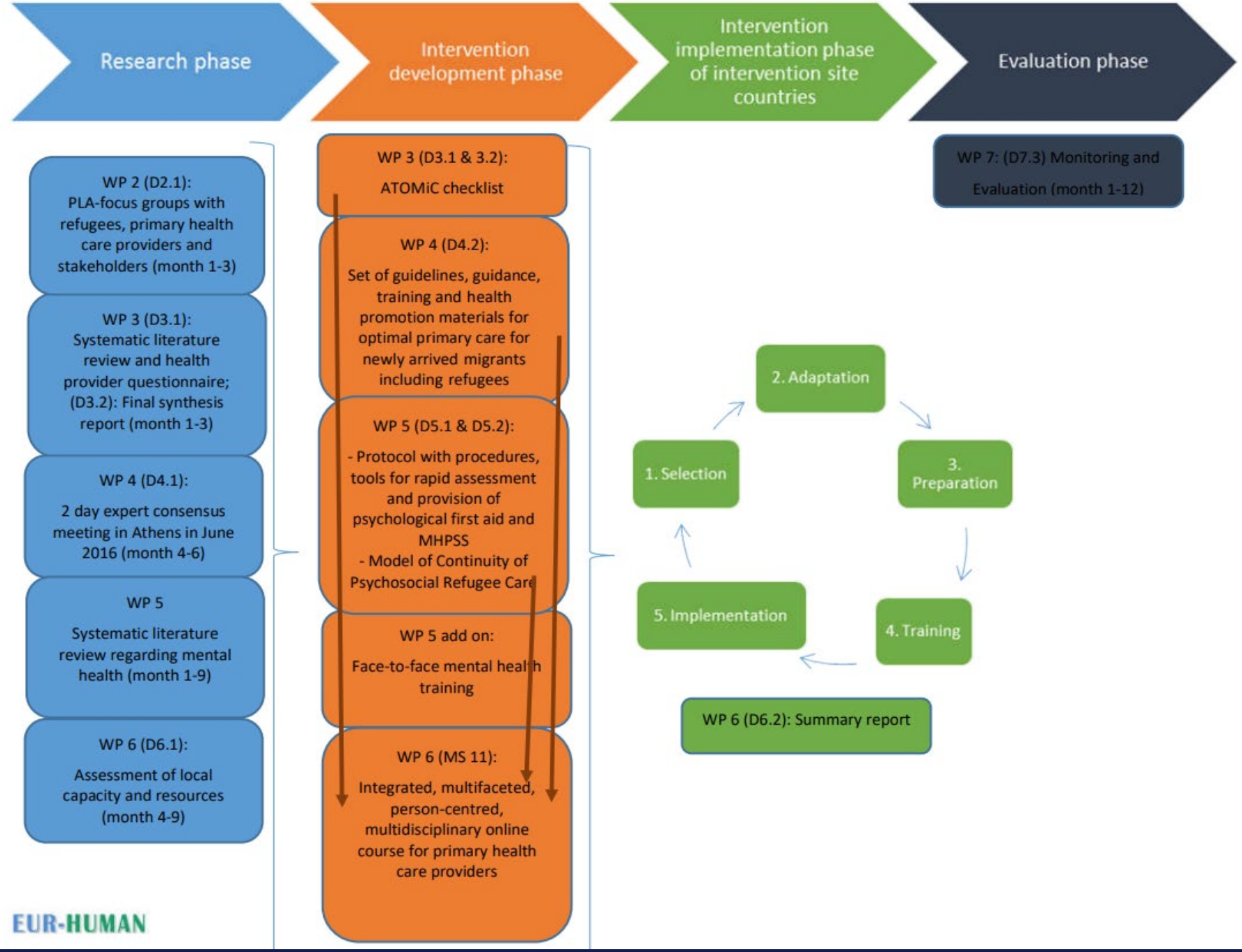
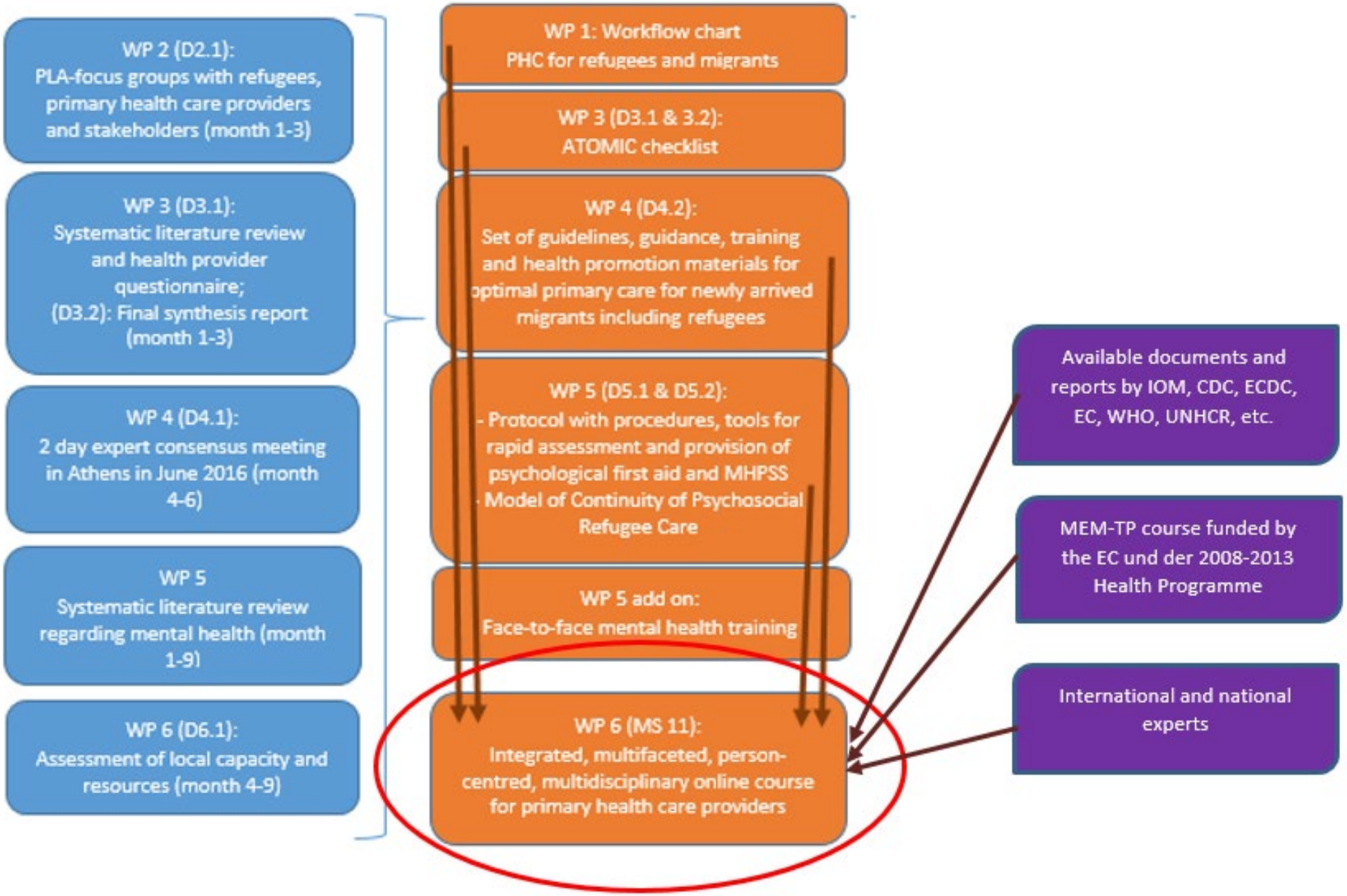
Projektablauf



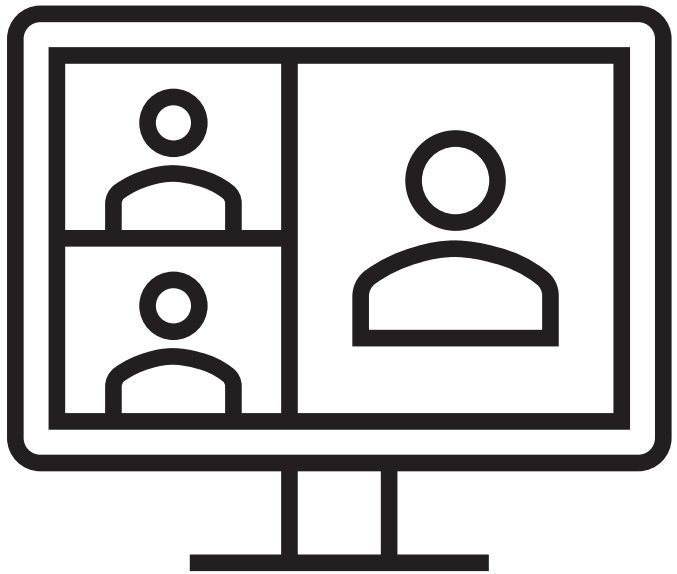
Picture 1: Work process of the EUR-HUMAN project



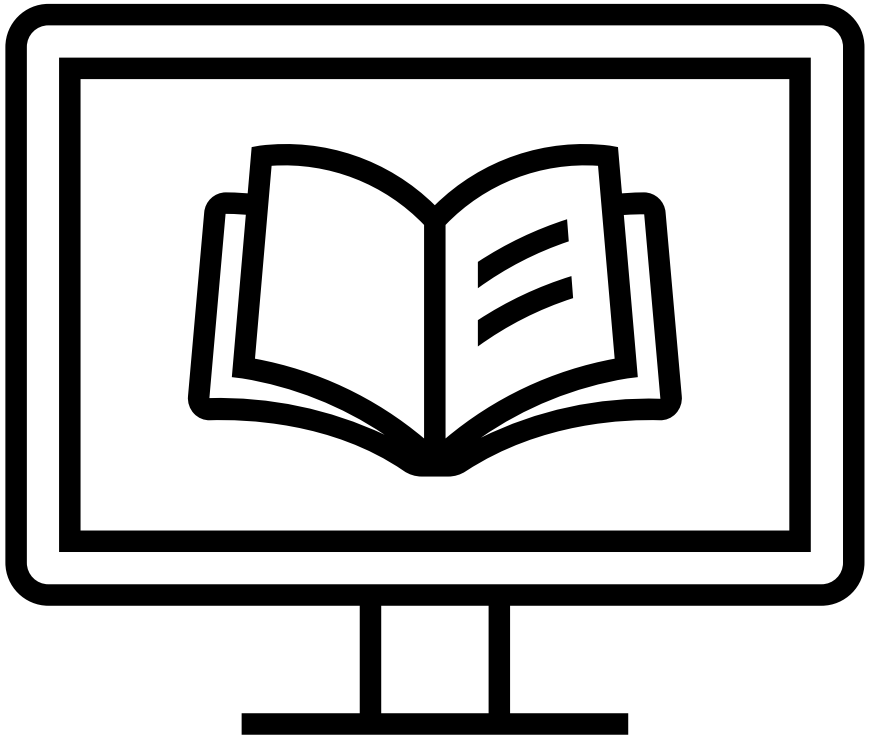

WP 2 (D2.1):
PLA-focus groups with refugees, primary health care providers and stakeholders (month 1-3)
WP 3 (D3.1):
Systematic literature review and health provider questionnaire;
(D3.2): Final synthesis report (month 1-3)
WP 4 (D4.1):
2 day expert consensus meeting in Athens in June 2016 (month 4-6)
WP 5
Systematic literature review regarding mental health (month 1-9)
WP 6 (D6.1):
Assessment of local capacity and resources (month 4-9)
WP 1: Workflow chart
PHC for refugees and migrants
WP 3 (D3.1 & 3.2):
ATOMIC checklist
WP 4 (D4.2):
Set of guidelines, guidance, training and health promotion materials for optimal primary care for newly arrived migrants including refugees
WP 5 (D5.1 & D5.2):
- Protocol with procedures, tools for rapid assessment and provision of psychological first aid and MHPSS
- Model of Continuity of Psychosocial Refugee Care
WP 5 add on:
Face-to-face mental health training
WP 6 (MS 11):
Integrated, multifaceted, person-centred, multidisciplinary online course for primary health care providers
Available documents and reports by IOM, CDC, ECDC, EC, WHO, UNHCR, etc.
MEM-TP course funded by the EC und der 2008-2013 Health Programme
International and national experts

Online-Seminar

- Module 1. About the course
- Module 2. Health monitoring, acute and infectious diseases and vaccination
- Module 3. Legal aspects regarding PHC for refugees and other migrants
- Module 4. Provider – patient interaction (communication, interpreters and the relevance of culture in medical practice)
- Module 5. Mental health and psychological support
- Module 6. Sexual and reproductive health
- Module 7. Child health
- Module 8. Chronic diseases, health promotion and prevention



Lessons Learned



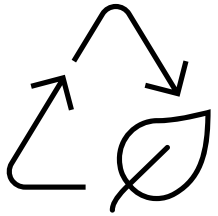
International:

- Bestehendes Netzwerk sehr von Vorteil
- Enge Kommunikation mit EC sehr wichtig
- Nicht zu viel in Projekt hineinpacken wollen
- Immer Zeit für unvorhergesehenes einplanen, passiert sicher!

National:

- Bereits eingearbeitetes Team mit sehr selbstständigen MitarbeiterInnen wichtig
- Administrativer Support sehr wichtig (Personalmanagement, Finanzen, Controlling)

Thema: Nachhaltigkeit



- Website: www.eur-human.uoc.gr
- YouTube channel: https://www.youtube.com/channel/UCvl3kOrEidGv2XA4zAUs01Q (Greece)
- Twitter: https://twitter.com/eur_human (2017)
- The training material of EUR-HUMAN has already been incorporated in the WHO EURO migration knowledge hub: https://www.euro.who.int/en/health-topics/health-determinants/knowledge-hub-on-health-and-migration/knowledge-library?category_code=354709
- Moodle Seminare in Arabisch und Deutsch bis 2020 (aus Eigenmitteln weitergeführt)
- Ab 2020: Keine Finanzierung mehr, kein Interesse der Stakeholder mehr
- 2022: Menschen auf der Flucht aus der Ukraine
- 2022: Submitted für den HORIZON-WIDERA-2022-ImpactPrize, um Finanzierung für Überarbeitung zu haben

Awards & Publikationen

- Assessing refugee healthcare needs in Europe and implementing educational interventions in primary care: a focus on methods. *BMC Int Health Hum Rights* **18,** 11 (2018). https://doi.org/10.1186/s12914-018-0150-x
- Primary care for refugees and newly arrived migrants in Europe: a qualitative study on health needs, barriers and wishes, *European Journal of Public Health*, Volume 28, Issue 1, February 2018, Pages 82–87, https://doi.org/10.1093/eurpub/ckx210
- Development and evaluation of a web-based capacity building course in the EUR-HUMAN project to support primary health care professionals in the provision of high-quality care for refugees and migrants, Global Health Action. 2018. 11:1, DOI: 10.1080/16549716.2018.1547080
- **[Primary care of refugees and migrants. Lesson learnt from the EUR-HUMAN project]. Orvosi Hetilap. 2018 Sep;159(35):1414-1422. DOI: 10.1556/650.2018.31187. PMID: 30146908. → MARKUSOVSZKY AWARD Top10 Hungarian medical papers of 2018**
- Compassionate care provision: an immense need during the refugee crisis: lessons learned from a European capacity-building project. *J of Compassionate Health Care* **5,** 2 (2018). https://doi.org/10.1186/s40639-018-0045-7
- „Das Warten bringt uns wirklich um!‘ Gesundheitliche und psychologische Aspekte von Krieg, Flucht und Leben im Exil “. *Binder, Susanne & Gebhard Fartacek (Hg.). Facetten von Flucht aus dem Nahen und Mittleren Osten. Wien: Facultas*, 228-249
- **Veronika-Fialka-Moser-Diversity Award 2017 for teaching – EUR-HUMAN Seminar**
- **EUR-HUMAN was one of the six cross-border health projects shortlisted for the prestigious European Health Award 2017.**

Vielen Dank für Ihre Aufmerksamkeit!

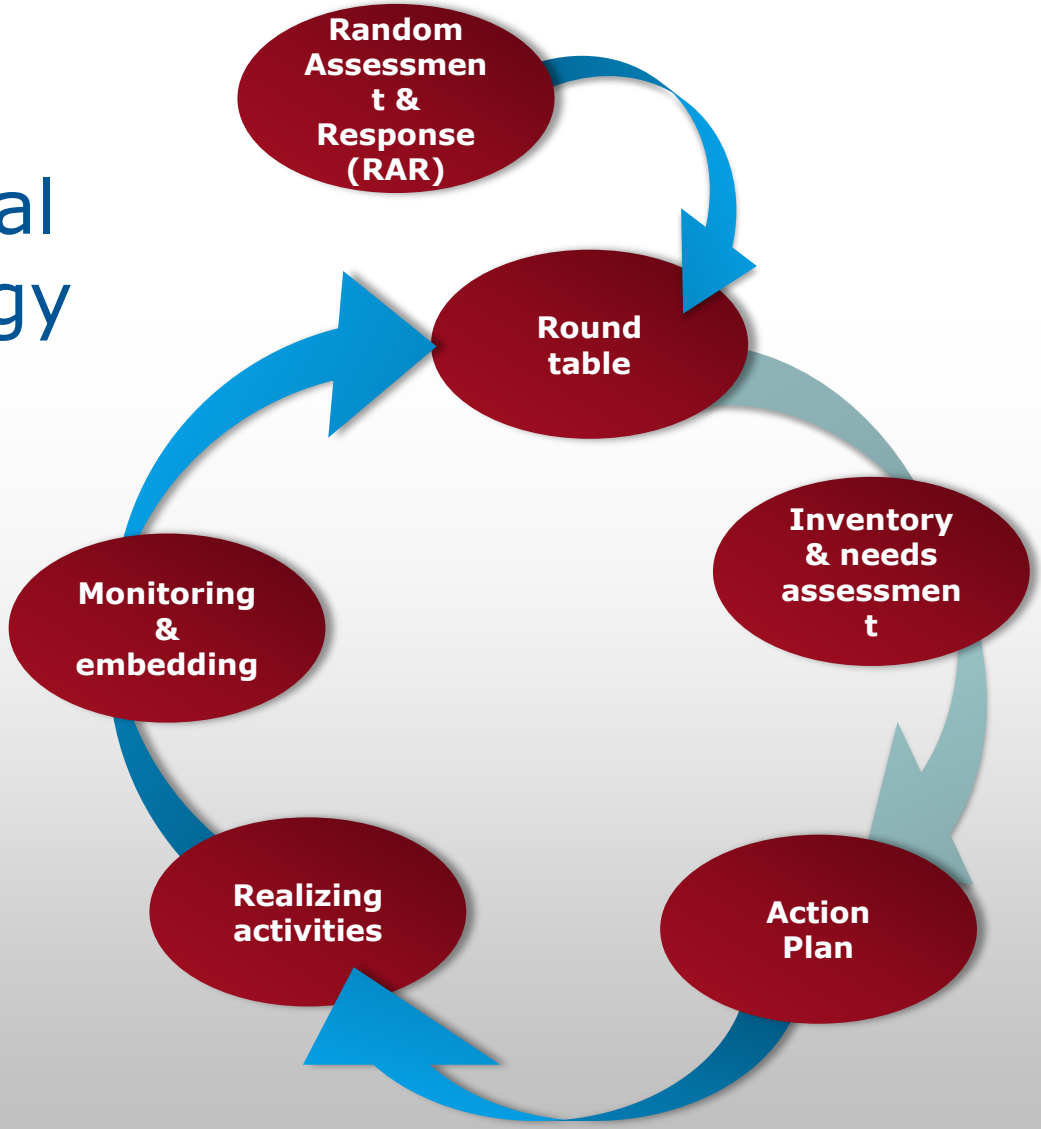
- Kontakt: kathryn.hoffmann@meduniwien.ac.at

Localize It

Local strategies to reduce underage and heavy episodic drinking

Rudolf Gruber (Institut Suchtprävention)

Process of local alcohol strategy



Projektübersicht

1. Auswahl von 2 Gemeinden/Städten pro Land
2. Rapid Assessment and Response (RAR)
3. Sammeln länderbezogener Best Practice Beispiele
4. Settings
5. Trainings zu den Maßnahmen aus der Best Practice Liste
6. Prozesse zur Entwicklung der lokalen Präventionsstrategien
7. Austauschtreffen auf europäischer Ebene
8. Prozess- und Ergebnisbewertung
9. Entwicklung eines Manuals

Praxisbericht aus der Kurstadt Bad Ischl

Rapid Assessment and Response:

- Alkoholkonsumbedingte Ausschreitungen, Lärm, Vandalismus und Gelage in den Parks

- Kurgäste, Innenstadtbewohner, Schüler und Jugendliche haben unterschiedliche Bedürfnisse

Praxisbericht aus der Kurstadt Bad Ischl

Runder Tisch:

- Zusammensetzung des Projektsteuerkreises

- Projektthemen und Zieldefinition

- Auswahl des Settings: Mehrebenenansatz

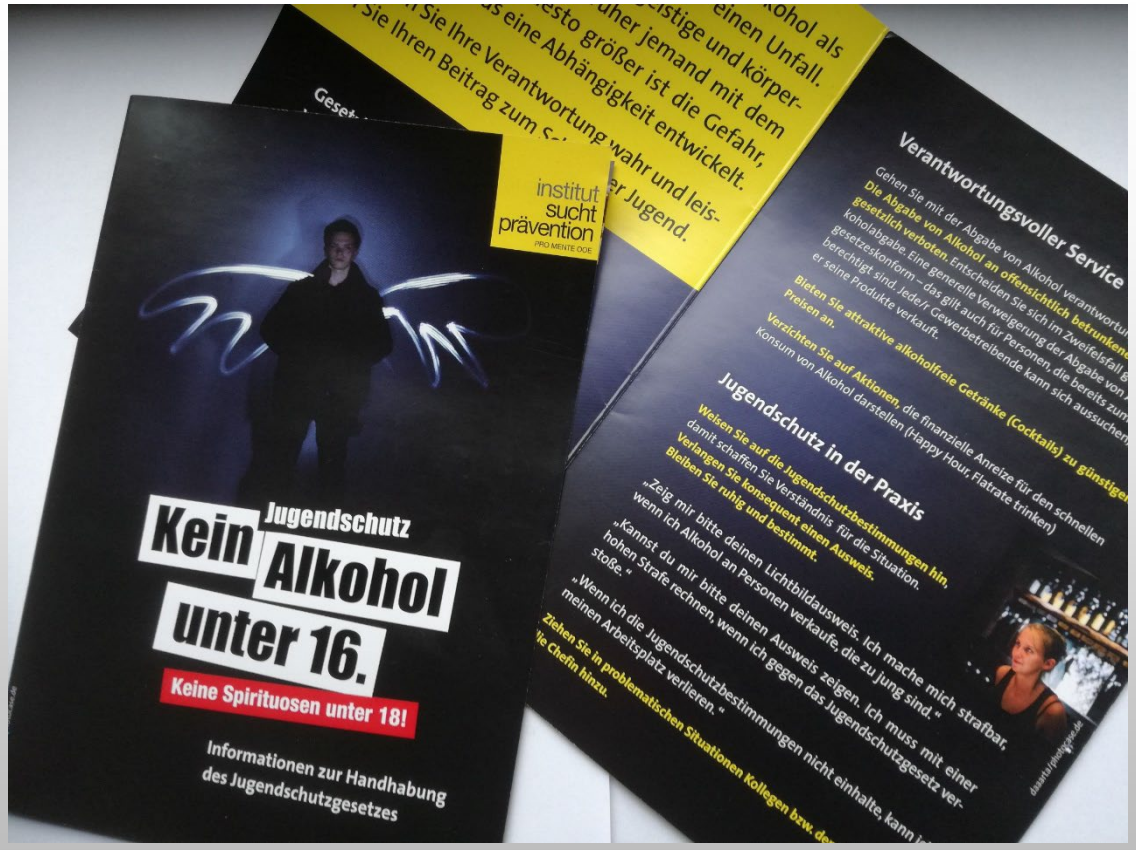
Projektschwerpunkte

a) Öffentlichkeitsarbeit zum Thema „Umgang mit Alkohol“
b) Jugendliche reflektieren ihren Alkoholkonsum
c) Jugendschutz in der Gastronomie
d) Nutzung des öffentlichen Raums

1. Der Workshop Alkohol wurde flächendeckend in sämtlichen Klassen der 9ten Schulstufe in allen Bad Ischler Schulen durchgeführt.
(16 Klassen/5 Schulen)

2. Gastronomie

Infoveranstaltung zur Einhaltung der Jugendschutzbestimmungen + Infoflyer



2. Gastronomie

Produktion und Verteilung von 8000 Getränkeuntersetzern

3. Öffentlicher Raum

Elterninformationsbroschüren „Über Alkohol reden“ und „Alkohol – 10 Tipps für Eltern“

institut sucht prävention
PRO MENTE OOE

4. Öffentliche Veranstaltungen

- Generationen im Zentrum
- Teilnahme an der Jugend- und Familienfachmesse Bad Ischl
- Begegnungstag # Draußen der außerschulischen Jugendarbeit

LOCALIZE IT!

Bundesamt für Sicherheit im Gesundheitswesen

BASG

Bundesamt für Sicherheit im Gesundheitswesen

www.basg.gv.at

EU4Health Web-InfoDay 2022

27. April 2022

Bundesamt für Sicherheit im Gesundheitswesen
BASG

COENJA

Joint Action on Instructions for use of re-useable and re-sterilisable medical devices

COENJA

Projekt Daten

Bundesamt für Sicherheit im Gesundheitswesen
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Dauer
18 Monate

EU co-funding
200.000 €

Teilnehmer
12 Mitgliedsländer

Teilnehmer

12 teilnehmende and 3 mitwirkende Staaten

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Austria	Belgium	Croatia
Hungary	Ireland	Italy
Norway	Portugal	Slovakia
Spain	Sweden	United Kingdom

Germany

Netherlands

Switzerland

Auslöser

Wie kam es zu diesem Projekt

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Auszug der Anwender Meldungen aus dem Feld:

- Keine Informationen zur Wiederaufbereitung erhalten
- Unvollständige/unbrauchbare Informationen
- Sichere Wiederaufbereitung des Produktes nicht möglich (z.B.: Produkt erreicht Sterilisationstemperatur nicht)

Zweck & Ziel

Projektziele

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- Evaluierung, ob im Bereich der Wiederaufbereitung die gesetzlichen Anforderungen von Herstellern eingehalten werden:

  -) Wiederaufbereitungsanleitungen (IFU)

  (RL 93/42, Annex I, Punkt 13.1. + EN 17664)

  -) Validierung der Wiederaufbereitungsprozesse

  (RL 93/42, Annex I + EN 14937)

- Verbesserung der Zusammenarbeit von europäischen Marktaufsichtsbehörden

Aufgaben

Material & Methode

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Was	Wie
Identifizierung geeigneter MP + deren Hersteller	• Festlegung von Kriterien • Suche in nationalen Datenbanken
Erstellung von 2 Fragebögen (IFU + Validierung)	• Excel Checklisten (RL 93/42 Anhang I + EN 17664 / EN 14937)
Vorbereitung für eine einheitliche Bewertung	Organisation von: • Meetings • Trainingkurs

Aufgaben

Material & Methode

Bundesamt für Sicherheit im Gesundheitswesen
BASG

Was	Wie
Auswertung der Fragebögen	• Erstellung eines leicht anwendbaren Bewertungsschemas
Harmonisierung der Auswertung	• IT-tool („Confluence“) • Organisation eines Meetings
Gesamtauswertung aller nationalen Fragebögen	• IT-tool („Quickr“) • Statistische Analyse (Statistikprogramm SAS 9.3)
Joint inspections – Fokus: Validierung der Wiederaufbereitungsprozesse	• Checkliste

Identifizierung geeigneter MP

4 Auswahlkriterien

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- Häufige Anwendung
- Invasiv
- Schwierig zu reinigen, desinfizieren oder sterilisieren
- Dampfsterilisierbar

Identifizierung geeigneter MP

13 Medizinproduktarten

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- Wundhaken
- Chirurgische Nadeln
- Bohraufsätze
- Skalpellgriffe
- Klemmen
- Pinzetten/Zangen
- Nadelhalter
- Chirurgische Sägen
- Sonden
- Scheren
- Trokar
- Kürette
- Endoskopie Zubehör

Sammeln & Bewerten

Bewertung der Wiederaufbereitungsanleitungen

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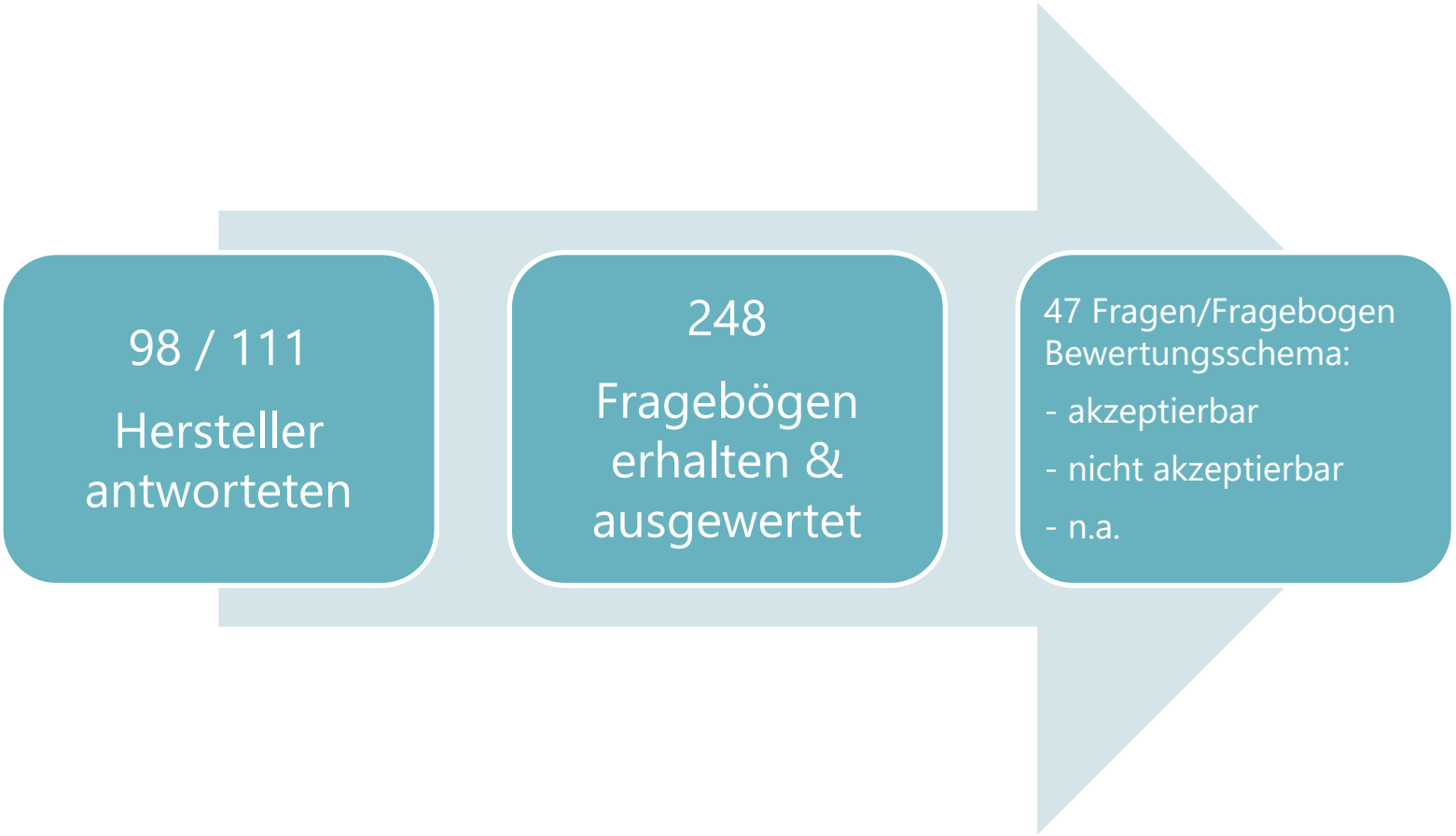

Bewertung

Unterschiedliche Perspektiven

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Betriebsgröße	• Klein (<50 Mitarbeiter) • Mittel (50-250 Mitarbeiter) • Groß (>250 Mitarbeiter)
Medizinproduktart	• 13 unterschiedliche MP-Arten
Risikoklasse	• Risikoklasse I • Risikoklasse höher als I

Ergebnis

Auswertung der Fragebögen

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Betriebsgröße	• Großbetriebe zeigten einen Trend, dass ihre IFUs eher konform waren als Klein- und Mittelbetriebe
Medizinprodukt-arten	• Kein signifikanter Unterschied erkennbar
Risikoklassen	• Es zeigte sich ein Trend, dass IFU von Risikoklasse I Produkten weniger konform sind als bei Produkten mit höherer Risikoklasse

4 Joint Inspections

6 teilnehmende Mitgliedsstaaten

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- Belgien
- Irland
- Norwegen
- Portugal
- Schweden
- Österreich

(Joint) Inspections

Ergebnisse

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- Keiner der inspizierten Hersteller konnte fehlerfreie Validierungsdaten vorlegen

- Wissen über die Validierung von Wiederaufbereitungsprozessen oftmals unterrepräsentiert → Vertrauen auf wenige externe Validierungsfirmen → Fehlerfortpflanzung

Weitere Informationen

Bundesamt für Sicherheit im Gesundheitswesen
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Link:

https://www.camd-europe.eu/joint-action-projects/instructions-for-use-of-medical-devices-coenja2014/

Austrian
Federal Office for
Safety in Health Care

BASG

Dr. Heidrun Eberl

Abteilung Medizinprodukte - Stv. Abteilungsleiterin

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Vielen Dank für Ihre Teilnahme!

Für weitere Fragen oder um sich zu unserem Newsletter anzumelden erreichen Sie die nationale EU4Health Kontaktstelle unter:

NFP.EU4Health@goeg.at

Folien und Aufnahme der Veranstaltung werden ebenfalls bald auf der zukünftigen Website der Kontaktstelle zur Verfügung gestellt.

Gesundheit Österreich GmbH