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Unlocking Success: Insider Insights for Winning Horizon Europe Health Proposals

Sasha Hugentobler, Nicole Wyss |
Euresearch

Project: 101057279 — HNN3.0

12 March 2024
virtual event

www.healthncp.net

Aim

Provide you with information and tips on how to write a successful proposal

We will NOT give general information about Horizon Europe or open calls in Cluster Health

This Webinar

- Will be recorded. Recording available on the HNN3.0 website
- You will get the slides after the event

- Please ask your questions in the Q&A. Use the chat for technical issues

Agenda

Time	Title	Speaker
14:00 – 14:10	Welcome and introduction	Sasha Hugentobler & Nicole Wyss, Health NCPs Euresearch
14:10 – 14:40	Excellence criteria	Nicole Wyss
14:40 – 15:25	Impact criteria	Sasha Hugentobler
	My experience as evaluator	Ariel Beresniak, Datamining International
15:25 – 15:35	*Break*	
15:35 – 16:05	Implementation criteria	Nicole Wyss
16:05 – 16:15	General Q&A session	all
16:15 – 16:25	Clinical Study Template: how and when to fill it in	Sasha Hugentobler
16:25 – 16:30	Conclusion	S. Hugentobler & N. Wyss

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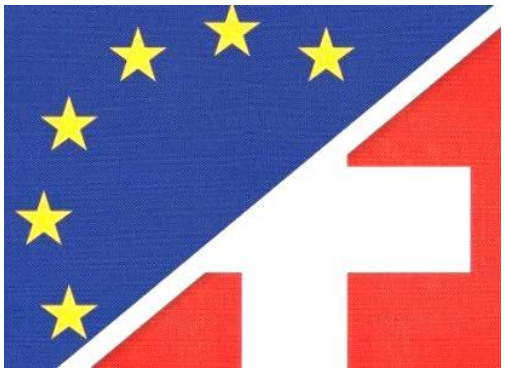
The Status of Switzerland in Horizon Europe

Swiss Status



Regular updates from the Swiss State Secretariat for Education Research Innovation (SERI)

↳ www.horizon-europe.ch

Not associated (yet) to Horizon Europe	Swiss entities can participate as Associated Partners
No signature of the EU Grant Agreement	National funding via SERI (not from the EC)

Financing and Support

Financial Guarantee for eligible calls with deadline in 2024

More details on Euresearch dedicated web page

3 Golden Rules for Proposal Writing

1. Fit to the topic information
2. Address evaluation criteria
3. Follow the proposal template

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Address evaluation criteria

Communication with Evaluators

Horizon Europe Proposal Evaluation Standard Briefing

standard-briefing-slides-for-experts_he_en.pdf

Communication with Evaluators

- Be concise, but comprehensive
- Use culture-neutral language and well-known universal concepts
- Use visuals, when possible
- Make it interesting
- Create a consistent story

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Follow the proposal template

Application Form – Part B

1. EXCELLENCE	2. IMPACT	3. IMPLEMENTATION
What What is the project about?	**Why** Why should we do the project? What evidence do we collect and measure to demonstrate the projects value?	**How** How to achieve the objectives?

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Excellence

Application Form – Part B

1. EXCELLENCE

What

What is the project about?

- The balance: **dazzling** your reviewers WHILE building the **logic** of your proposal
- Show reviewers the overall need for and structure of your project

Read the Topic Information

Basis of proposed project:

objectives and methods/ work packages

Structure of a Topic

TOPIC IDENTIFIER: TOPIC TITLE

Specific Conditions
Expected EU contribution per project
Indicative budget
Type of Action
Eligibility conditions

Expected Outcome
Projects/Activities/Deliverables…

Scope
Description of background/context
EC's motivation for funding
Projects should explore/develop/improve…

Read the Proposal Template

- Definitions
- Excellence sub-sections
  - 1.1 Objectives and Ambition
  - 1.2 Methodology

Read the Evaluation Criteria

- Clarity and pertinence of the project's **objectives**, and the extent to which the proposed work is **ambitious**, and goes **beyond the state-of-the-art**.

- **Soundness of the proposed methodology**, including the underlying concepts, models, assumptions, inter-disciplinary approaches, appropriate consideration of the **gender dimension** in research and innovation content, and the quality of **open science** practices including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.

After Reading, Start Writing

Merge:
the requirements in the topic text with those in the proposal template

TOPIC IDENTIFIER: TOPIC TITLE

Specific Conditions
Expected EU contribution per project
Indicative budget
Type of Action
Eligibility conditions

Expected Outcome
Projects/Activities/Deliverables…

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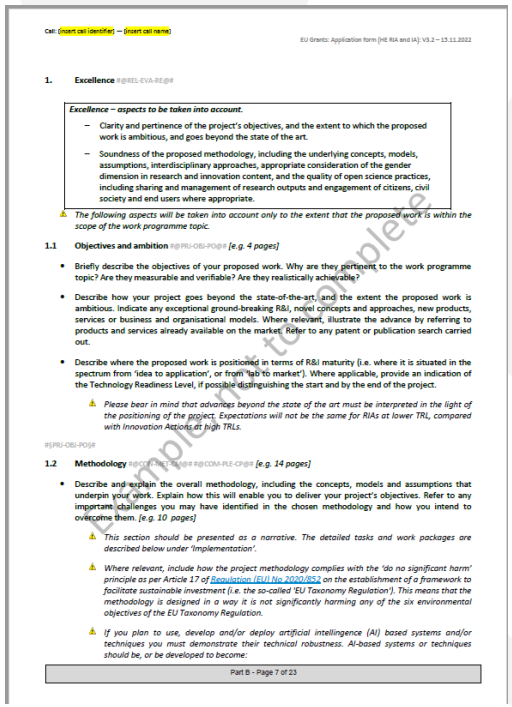
Call: (insert call identifier) – (insert call name)

EU Grants: Application form (HE RIA and IA): V3.2 – 15.11.2022

1. **Excellence** #@REL-EVA-RE@#

Excellence – aspects to be taken into account.

- Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art.
- Soundness of the proposed methodology, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and innovation content, and the quality of open science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.

The following aspects will be taken into account only to the extent that the proposed work is within the scope of the work programme topic.

1.1 **Objectives and ambition** #@PRJ-OBJ-PO@# *[e.g. 4 pages]*

- Briefly describe the objectives of your proposed work. Why are they pertinent to the work programme topic? Are they measurable and verifiable? Are they realistically achievable?
- Describe how your project goes beyond the state-of-the-art, and the extent the proposed work is ambitious. Indicate any exceptional ground-breaking R&I, novel concepts and approaches, new products, services or business and organisational models. Where relevant, illustrate the advance by referring to products and services already available on the market. Refer to any patent or publication search carried out.
- Describe where the proposed work is positioned in terms of R&I maturity (i.e. where it is situated in the spectrum from 'idea to application', or from "lab to market'). Where applicable, provide an indication of the Technology Readiness Level, if possible distinguishing the start and by the end of the project.

Please bear in mind that advances beyond the state of the art must be interpreted in the light of the positioning of the project. Expectations will not be the same for RIAs at lower TRL, compared with Innovation Actions at high TRLs.

#/PRJ-OBJ-PO/#

1.2 **Methodology** #@COM-PLE-CP@# *[e.g. 14 pages]*

- Describe and explain the overall methodology, including the concepts, models and assumptions that underpin your work. Explain how this will enable you to deliver your project's objectives. Refer to any important challenges you may have identified in the chosen methodology and how you intend to overcome them. *[e.g. 10 pages]*

This section should be presented as a narrative. The detailed tasks and work packages are described below under 'Implementation'.

Where relevant, include how the project methodology complies with the 'do no significant harm' principle as per Article 17 of Regulation (EU) No 2020/852 on the establishment of a framework to facilitate sustainable investment (i.e. the so-called 'EU Taxonomy Regulation'). This means that the methodology is designed in a way it is not significantly harming any of the six environmental objectives of the EU Taxonomy Regulation.

If you plan to use, develop and/or deploy artificial intelligence (AI) based systems and/or techniques you must demonstrate their technical robustness. AI-based systems or techniques should be, or be developed to become:

Part B - Page 7 of 23

Example not to complete

1.1 Objectives and Ambition

- Why are the objectives pertinent to the work programme topic?
- Are they measurable and verifiable? Are they realistically achievable (SMART)?
- Describe how your project goes beyond the state of the art.

State of the Art

- Examine existing literature
- Screen existing project landscape (e.g. CORDIS)
- Search in patent databases (e.g. European patent database)

- ✓ **Be systematic in your review**
- ✓ **Highlight the gaps in the state of the art**
- ✓ **Make these gaps clearly linked to the topic information AND your Objectives**

Show how your **objectives** are related to **each gap** in the state of the art you identified

Highlight the **main objectives** in a clear way: easy to find for evaluators (e.g. list, bullet points)

Structure your **project** around your **objectives**

Tips

Structure – clear, logical
Detail – enough to convince reviewers

Include **links and synergies to other EU programmes**, but always highlight the added value of your project compared to those

Social Sciences and Humanities
factsheet on good SSH integration practices – good practices examples

1.2 Methodology

- Open science practices
- Do no significant harm principle (DNSH)
- Gender dimension in R&I content

Open Science

Mandatory

- **OA to research outputs** through deposition in trusted repositories
- **research output management** including data management plan
- measures to ensure **reproducibility of research outputs**

Recommended

- participation in **open peer-review**
- **early and open** sharing of research
- **involving all relevant knowledge actors** in the co-creation of R&I agendas and contents

Data Management Plan

- Project deliverable at month 6
- Regularly updated
- Evaluated in proposal
- EC template available!

Open Science Evaluation

EXCELLENCE

- ✓ How OS practices are implemented as an integral part of the methodology
- ✓ How OS practices are adapted to the nature of the work
- ✓ How OS practices increase the chances of the project delivering on its objectives
- ✓ Evaluation of the research output management and related plan for other outcomes than publications

IMPLEMENTATION

- ✓ Quality and efficiency of the implementation

More information from page 40 of the Horizon Europe Programme Guide

Do No Significant Harm

Explain how the negative impact could be managed if impacting:

Climate change mitigation	Climate change adaptation	Protection and restoration of biodiversity & ecosystems
Sustainable use & protection of water & marine resources	Transition to a circular economy	Pollution prevention & control

To be addressed in **Excellence** AND **Impact** of the project.
Evaluators score DNSH principle only if explicitly stated in the work programme.

Gender Dimension in R & I

This section is **not** about the gender balance in the team carrying out the project!

- Reflect on why sex and/or gender could matter

  (How gender dimension provides added value in terms of creativity, excellence, and return on investment, both from public and private perspectives)
- Consider the production of new knowledge on gender
- Include sex and gender aspects as part of a multidisciplinary approach
- Consider social categories/factors intersecting with sex and gender

Evaluators' Comments

Lack of sufficient in-depth descriptions on individual objectives

Measurable KPIs are missing

Not sufficiently detailed information on number of data sets and patients for some of the clinical sites

Evaluators' Comments

The description of the necessary upscaling of results from pilot areas is vague

Co-creation and other practices to involve citizens, in particular "hard-to-reach" groups, have been described with limited details

The strategy for patient engagement is not sufficiently clear

DOs and DON'Ts

- ✓ Design quantified objectives with clear metrics
- ✓ Address all topic requirements
- ✓ Make the structure logical and clear
- ✓ Describe in detail how to engage with stakeholders

- ○ Don't have too many objectives
- ○ Don't omit reference to relevant publications, patents

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Impact

Application Form – Part B

2. IMPACT

Why

Why should we do the project?

What evidence do we collect and measure to demonstrate the projects value?

1. Project's pathways towards impact
2. Measures to maximise impact - Dissemination, exploitation and communication
3. Summary

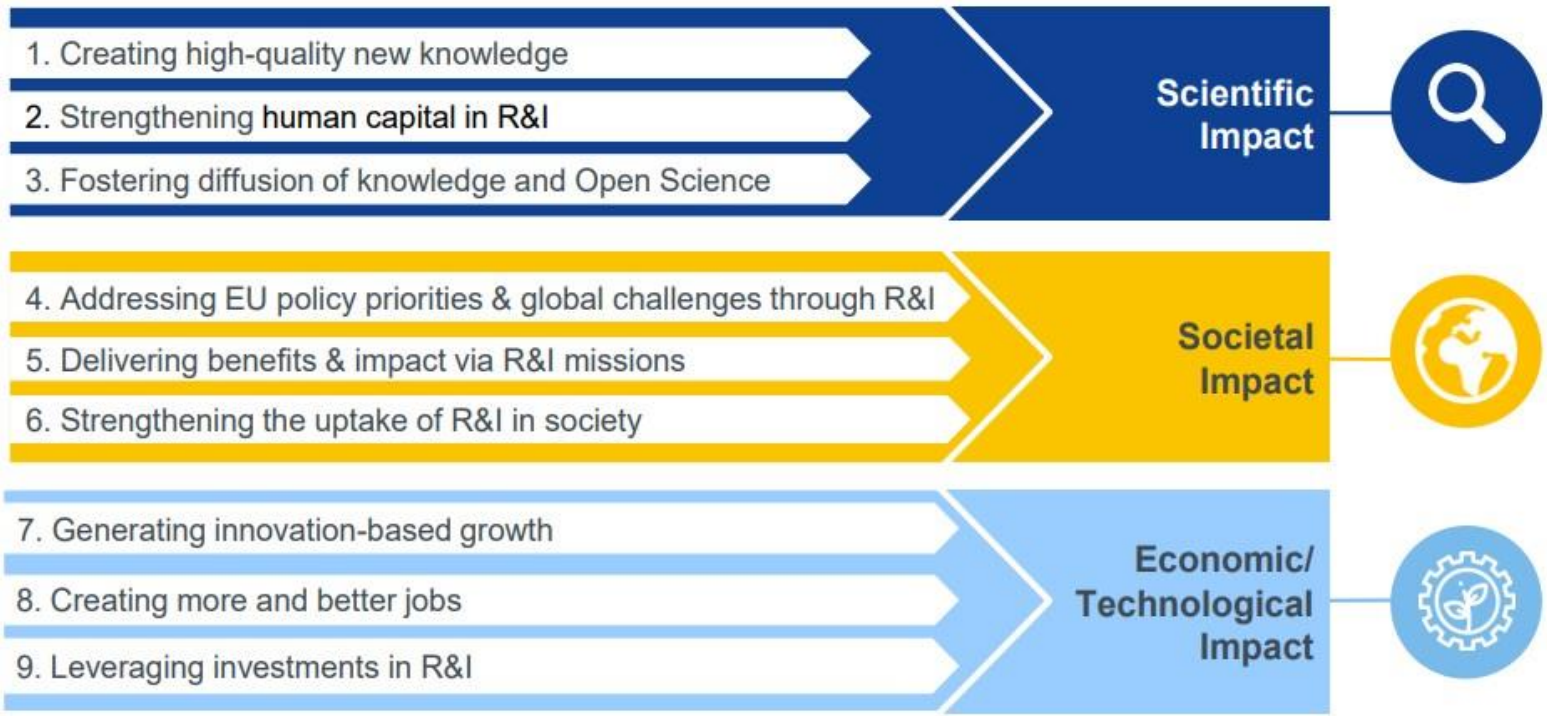
What is Impact?

Wider long-term effects on society, the environment, the economy and science, enabled by the outcomes of R&I investments.

- Impact must be measurable, quantifiable.
- What evidence do you collect and measure in the project to demonstrate impact?
- How do you engage with target groups? What role do you give them? How do you measure their engagement?

Key Impact Pathways

The 9 KIPs in 3 areas of impact



Source: Webinar How to prepare a successful proposal in Horizon Europe, EC, 24 March 2021
A successful proposal for Horizon Europe – part II, EC, 21 April, 2021

The Impact

- Proposals must include a **narrative** explaining how the project's results are expected to contribute towards each of the **outcomes** (→ topic text),
- together with the **target groups** that would benefit if the outcomes were to be achieved.

- Project's contributions to the topic's outcomes must lead, in the longer term, to the **wider impacts** listed in the work programme (→ destination).

Evaluation Criteria

- Credibility of the pathways to achieve the **expected outcomes and impacts** specified in the work programme
- and the likely **scale** and **significance** of the contributions due to the project

- Suitability and quality of the **measures to maximize expected outcomes and impacts**, as set out in the **dissemination and exploitation plan**, including **communication activities**

The Impact Section

- 2.1: Project’s pathways towards impact
- 2.2: Measures to maximise Impact
- 2.3: Summary

2.1: Project's pathways towards impact

Describe the **contribution** of your project results

1. outcomes specified in this topic, and
2. the wider impacts, in the longer term, specified in the respective destinations in the work programme

- Requirements and potential barriers
- Indicate the likely **scale*** and **significance*** of the project's contribution to outcomes and impacts

***Scale** refers to how widespread the outcomes and impacts are likely to be.

***Significance** refers to the importance, or value, of those benefits.

2.2: Measures to Maximise Impact

- A first version of the “plan for the dissemination and exploitation” including communication activities
- **Target groups**
- Strategy for the management of **intellectual property** and **exploitation**

Plan for the DEC

- Plan for the dissemination and exploitation including communication activities. A plan is a strategy, meaning provide a table with info to whom, with which method you provide what and how much of it

- Video how evaluators are briefed

Definitions

- **Results**: Output generated by project (data, prototypes, skills, knowledge, publications, reports, software, prestandards, policy..)
- **Dissemination**: To bring the project results to the attention of targeted communities that can further utilise them
- **Exploitation**: The use of results in further research and innovation activities (eg. Commercialisation for example a product, service, or in standardisation or policy making)
- **Communication**: All activities promoting the actions and its results to various audiences (incl. Media and the public)

Plan for D, E, C

What to disseminate and exploit	To whom	How is the method	Barriers	By whom	How much/achievements	How well
Product 1: Model/ Algorithm/ Material	Innovators technicians, companies	New mathematical model	National Regulations, GDPR...	Partner x, mathematicians	Number of models/ algorithms	
Service 1: Training	Clinicians, Scientists		Resources,language (eg. Online)	Partner y, clinician	Number of downloads/ clicks	Increase in % of clinicians trained

2.3: Summary

- Canvas
  Specific needs, expected results, D & E & C measures, target groups, outcomes, impacts

Provide a summary of this section by presenting a **canvas** with **KIP** (Key Impact Pathways).

The canvas breaks the impact down into its component parts.

SSH-Flagged Topics

How [evaluators are briefed](#)regarding the SSH flagged topics

Evaluators' Comments

Potential barriers to the project outcomes and impacts are not adequately addressed

Concrete activities are not linked to dissemination targets

A more detailed and targeted plan is lacking in order to generate acceptance for this approach and adoption in the specific community

Evaluators' Comments

The exploitation of the produced software is not enough detailed

Target audiences and associated actions have not been identified with sufficient granularity

Not enough measurable indicators to monitor progress

Evaluators' Comments

Project's pathways towards impact

- Provide supporting quantitative detail for the scale and likely timeline to realise the projects outcomes
- The wider impacts (social, scientific, technological) are addressed only at a generic level, and insufficient KPIs or quantitative, measurable indicators are provided to assess the stated impacts

Measures to Maximise Impact

- Elaborate the exploitation plan in detail
- Do not omit explaining in detail the strategy of IP management
- For the regulatory barriers the applicable regulations and mitigation measures are not described in enough detail

DOs and DON'Ts

- ✓ Be as concise and precise as possible
- ✓ Address impact short term (duration of project) and long term (10 years from now)
- ✓ Write an excellent CANVAS

- ○ Don't define impact in qualitative terms only
- ○ Don't omit explaining the means of delivery of end results to users
- ○ Don't be vague regarding targeted stakeholders

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Coffee Time

See you back in 10 min

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Quality & Efficiency of the Implementation

Application Form – Part B

3. IMPLEMENTATION

How?

How to achieve the objectives?

3.1 Work plan and resources

3.2 Capacity of participants and consortium as a whole

Evaluation Criteria

- **Quality** and effectiveness of the **work plan**, assessment of **risks**, and appropriateness of the effort assigned to **work packages**, and the resources overall

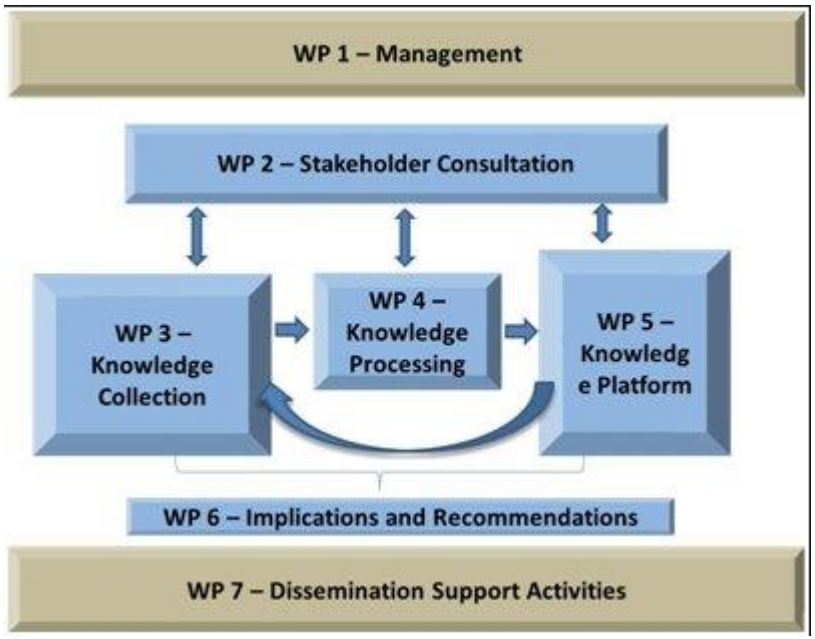
- **Capacity and role of each participant**, and extent to which the consortium as a whole brings together the necessary expertise

Work Plan Structure

PERT Chart

(Project Evaluation and Review Technique)

Links among WPs and to the relevant objective(s) and main methodological aspect(s)



GANTT Chart

- Identify dependencies between tasks;
- assign resources for each task;
- identify task start and end dates;
- work out the overall project duration

Work Packages

Table 3.1a: List of work packages

Work package No	Work Package Title	Lead Participant No	Lead Participant Short Name	Person-Months	Start Month	End month
				Total person-months		

Table 3.1b: Work package description

For each work package:

Work package number	
Work package title	

⚠ *Participants involved in each WP and their efforts are show*
date of each WP are shown in table 3.1a.)

Objectives

Description of work (where appropriate, broken down into
Deliverables linked to each WP are listed in table 3.1c (no nee

Objectives are the **goals** of the work performed within the project, in terms of its research and innovation content.

This will be translated into project **results**.

Deliverables

A deliverable is a **report** that is providing information to ensure effective **monitoring** of the project

You must include deliverables for:

- Data management plan (DMP) (M6)
- Plan for dissemination and exploitation (M6)
- Other compulsory deliverables?

Tips:

- Meaningful and feasible
- At least one deliverable per organisation
- Evenly distribute them during time

Milestones

Milestones are **control points** in the project that help to chart the progress

- May be a critical decision point
- Can be an achievement of a key deliverable
- Become contractual obligation and will be monitored

Tips:

- The achievement of a milestone needs to be **verifiable**
- Not every WP needs a MS, only indicate when necessary

Critical Risks

A critical risk is a plausible event or issue that could have a high adverse impact on the ability of the project to achieve its objectives.

Answer to possible concerns of the evaluators:

- **What harms the project implementation?**

Name an appropriate number of risks and show that you are prepared for these risks:

- **What kind of measures can reduce risks?**
- **Is there a contingency plan?**

Tips:

- Avoid fake risks of low likelihood and low severity
- Pick meaningful ones and show that you are prepared

Risk or Barrier

Risk

A plausible event or issue that could have a high adverse impact on the ability of the project to achieve its objectives

Barrier

Issues arising from factors beyond the scope and duration of the project - that may determine whether the desired outcomes and impacts are achieved

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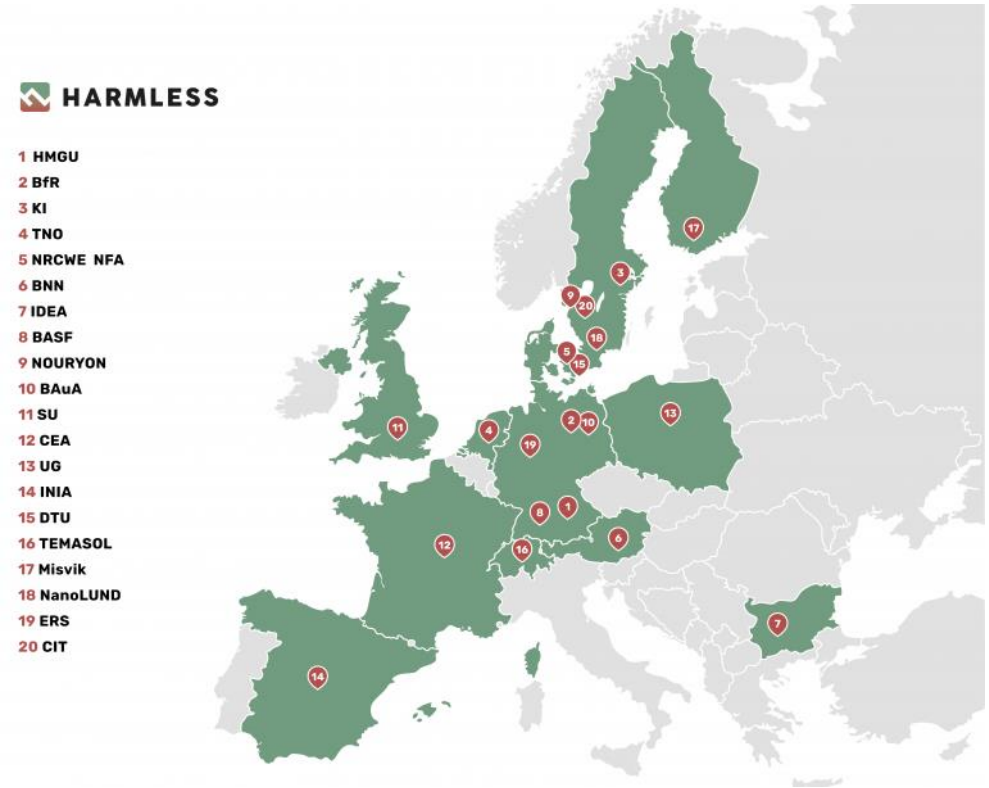
Quizz

3.2 Consortium



Source: www.harmless-project.eu

Role	Partner	Event planinnig and logistics	Training material preparation	Environmental issues assessemnt	Communication	Expertise in SSH	Expertise in Open Science	Exploitation of results
Coordination and C&D	HMGU	•			•		•	•
Pilots	SU		•					
	DTU		•					
	ERS		•					
Knowledge transfer	CEA			•			•	
Quality Assurance	CIT			•		•		
Role X	….					•		
Role Y	….						•	

Evaluators' Comments

Effort distribution among partners is rather imbalanced

Nearly all partners contribute to each work package. This raises concerns on targeted allocation of competences

The risk mitigation plan is not sufficiently described

DOs and DON'Ts

- ✓ Plan work in a concrete and precise way
- ✓ Provide self-explanatory PERT diagram and Gantt chart
- ✓ Demonstrate that the consortium has all the necessary competences
- ✓ Assess the risks and suggest how you will overcome them
- ✓ Speak with a single voice!

- ○ Don't plan too many deliverables and milestones
- ○ Don't be vague when describing the tasks
- ○ Don't include partners with no significant role and tasks
- ○ Don't have an unrealistic timeline in the project and when recruiting patients

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Questions & Answers

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Clinical Study Template: How and When to Fill it in

Clinical Studies – Definition

- Definition: **Clinical study covers clinical studies/trials/investigations/cohorts** and means **any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons** in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition.

  It includes but it is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).

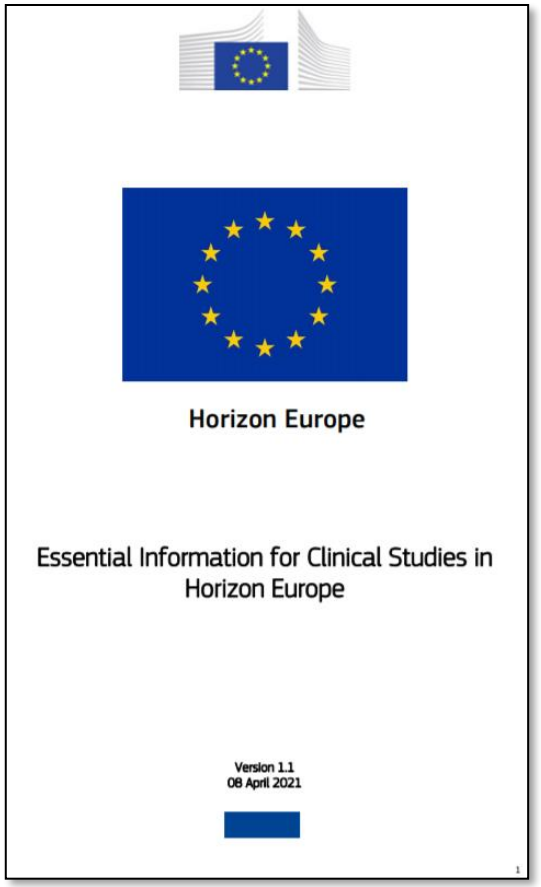
- This includes **interviews, surveys-** all projects that **collect or analyze data of humans (also not linked to any medical studies**)

Fill in this template when

you plan to collect human data or biological samples for

- Phase 1 trial of a vaccination
- New analysis of blood samples of a closed trial
- Clinical investigation of a medical device
- Survey on well-being
- Interviews on specific behaviours/habits
- Retrospective analysis of patient data

Template Essential Information for Clinical Studies



- One template for each study planned
- Stick to the structure and address each section

Why?

- Providing structured information to the evaluators.
- Giving applicants the chance to provide detailed information about clinical studies without page limitations.
- Mandatory for certain topics if a clinical study is included.

Mandatory Deliverables for Each Clinical Study

- Study Initiation Package
  1. Registration number of the study in a registry meeting WHO registry criteria
  2. Final version of study protocol as approved by regulators/ethics committees
  3. All approvals required for the enrolment of the 1st study participant

- Midterm recruitment report
  Is due when 50% of the study population is recruited. Incl. number of recruited participants/site and mention any problems and how to mitigate them to compensate delays

- Report on status of posting results in the study registry(s)
  Irrespective of the successful completion of the clinical study, summary results must be posted in the registry/ies, latest for the last months of the project

Three Parts of the Template

- Description of the clinical study – 7 subheadings
- Prepardness Status – 3 subheadings
- Operational Feasibility - 7 subheadings

How is the Information in the Template Scored?

- It impacts the Excellence score (methodology, objectives..)
- It impacts the Quality and Efficiency of the Implementation score (operational feasibility)
- It impacts the Impact score (barriers, KIP, target groups)

Annotated Template for Information on Clinical Studies

HNN3.0 (The Cluster 1 Health consortium of NCPs for Horizon Europe) has received funding from the European Union's Horizon EUROPE research and innovation programme under Grant Agreement number 101057279

- For more information go to the Health NCP Website.
- You also find a webinar with more information there:
- https://www.healthncp.net/hnn-30-supporting-tools
  https://www.healthncp.net/news-events/hnn30-webinar-annotated-horizon-europe-template-information-clinical-studies

DOs and DON'Ts

- ✓Clearly state the type of intervention as it determines the regulatory and ethical frameworks
- ✓Describe governance of the study. Details of the sponsor of the study are needed.
- ✓Sponsor can have a dedicated WP- then fill in the WP under 3.1 Workplan
- ✓Be aware that country specific information is required
- ✓Regulatory approvals are milestones

- ○ Run into recruitment failure - Have a proper feasibility study
- ○ Omit justifying site feasibility
- ○ Forget end user/patient involvement
- ○ Forget to list the 3 compulsory deliverables under the specific WP description in 3.1
- ○ Forget to list in 3.1 in relevant tables the milestones and risks

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Conclusion

Tools and Links

- Annotated proposal template
- Horizon Europe evaluation form (RIA/IA)
- Cordis
- Factsheet on good SSH integration practices
- HNN3.0 annotated template clinical study
- Information on lump sum

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euresearch
Swiss guide to European research and innovation

Thank you

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