

How to apply to a call for research projects with a grant at the European level?

23rd February 2023

ABOUT US



We believe that multistakeholder collaboration in innovative biomedical research can deliver better health for all

- Barcelona-based SME
- Team of 20 project managers, scientific managers, communication experts and innovation professionals
- Working with more than 100 organisations
- Managing more than 150 million € in projects and studies

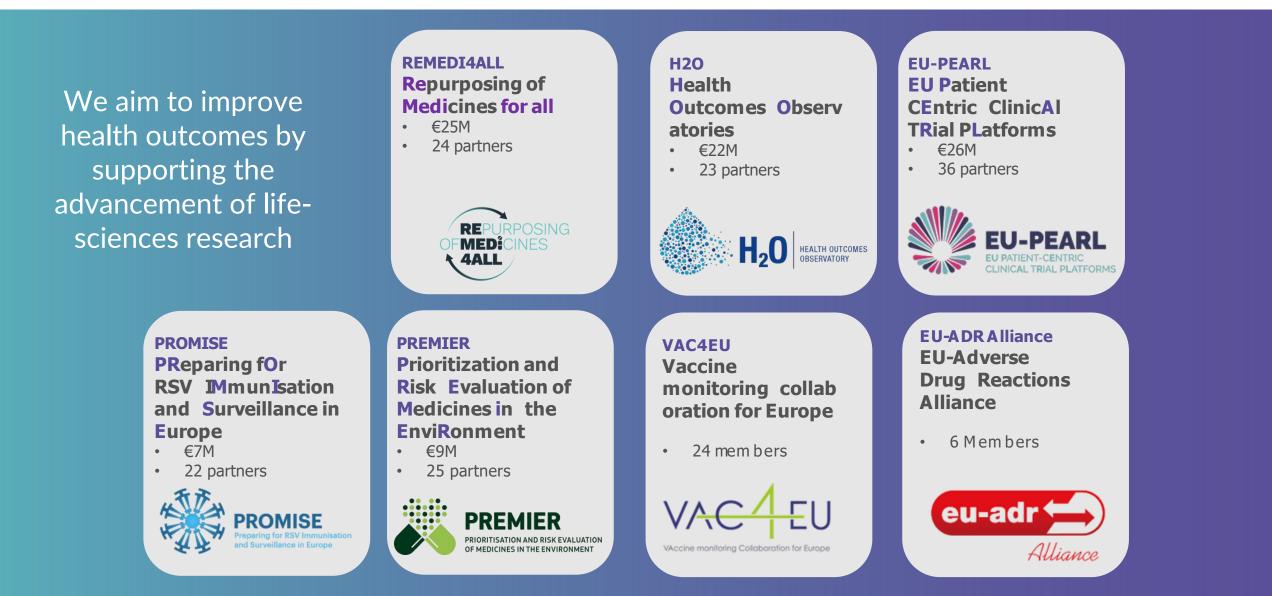




teamit

RESEARCH





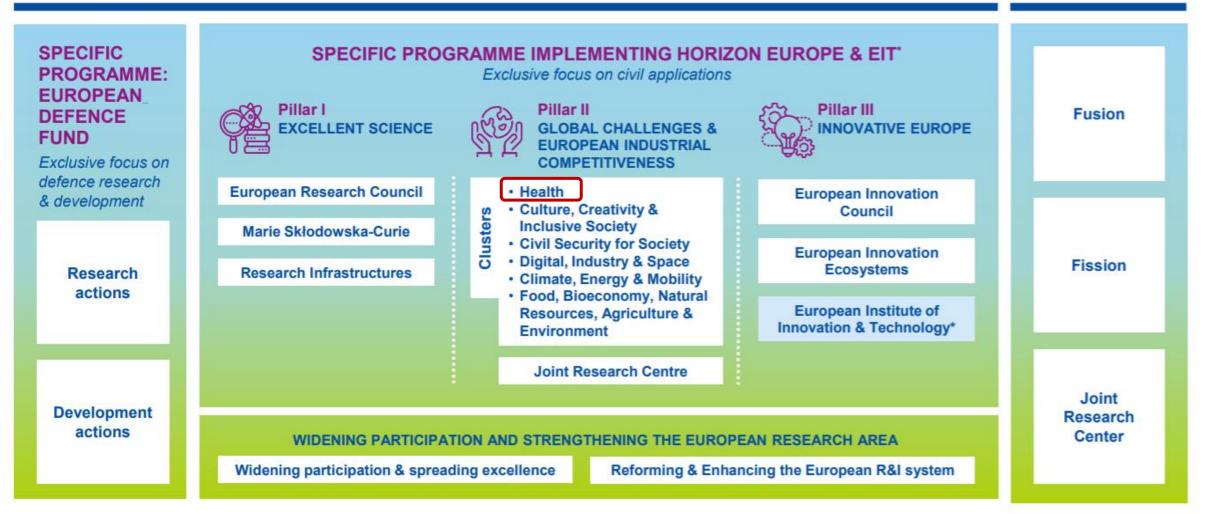






HORIZON EUROPE

EURATOM

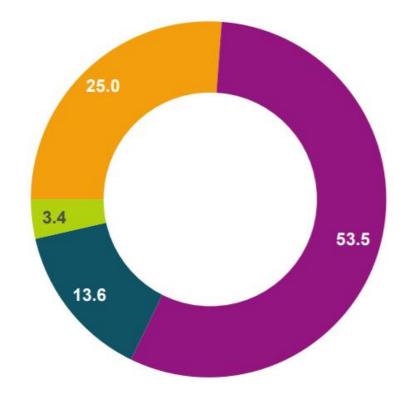


* The European Institute of Innovation & Technology (EIT) is not part of the Specific Programme



Horizon Europe Budget: €95.5 billion (2021-2027)

(including €5.4 billion from NGEU – Next Generation Europe – programme of EU for Recovery from COVID-19 crisis)



Political agreement December 2020 *€ billion in current prices*

- Excellent Science (Pillar I)
- Global challenges and European ind. comp. (Pillar II)
- Innovative Europe (Pillar III)
- Widening Part and ERA



Main type of collaborative projects



1. Research and Innovation Actions (RIA)

Funding for research projects tackling clearly defined challenges, which can lead to the **development of new knowledge or to explore the feasibility of a new or improved technology, product, process, service or solution**. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment.

Who? Consortia of partners from different countries, different stakeholders (academia, industry, patient organisations, SMEs, authorities, etc.)



Main type of collaborative projects



Funding is more focused on **closer-to-the-market activities**. For example, prototyping, testing, demonstrating, piloting, scaling-up etc. if they aim at producing new or improved products or services.

Who? Consortia of partners from different countries, different stakeholders (academia, industry, patient organisations, SMEs, authorities, etc.)



Main type of collaborative projects



3. Coordination and support actions (CSA)

Funding covers the **coordination and networking** of research and innovation projects, programmes and policies. Funding for research and innovation per se is covered elsewhere.

Who? Single entities or consortia of partners from different countries.





Innovative Medicines Initiatives will become the Innovative Health Initiatives

A new public-private partnership (PPP) for health under Horizon Europe building on the successes and lessons learnt from IMI.

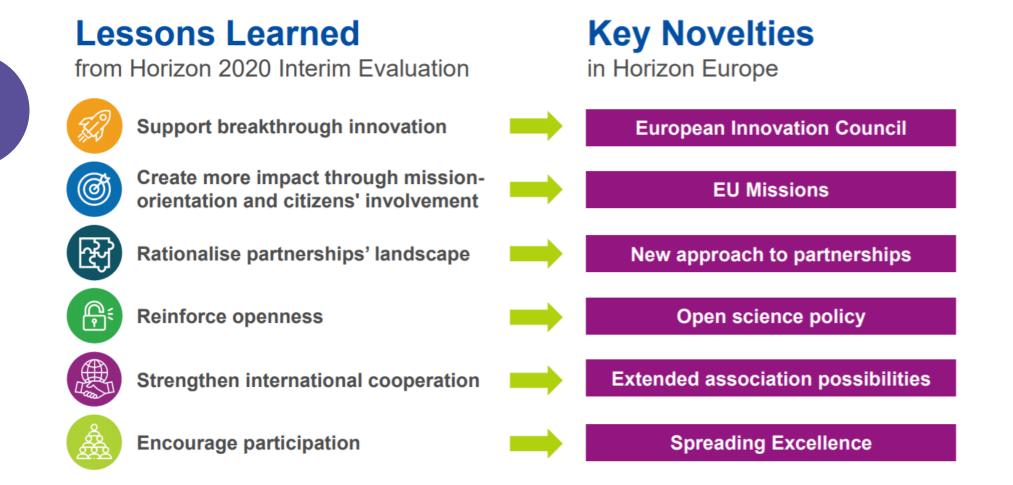
This initiative will help create an EU-wide health research and innovation ecosystem that facilitates the translation of scientific knowledge into tangible innovations. It will cover **prevention**, **diagnostics**, **treatment and disease management**.

This cross-sectoral Partnership brings together all stakeholders including <u>5 key health industry sectors</u> involved in the patient's journey and aims to make significant progress towards addressing unmet health needs.



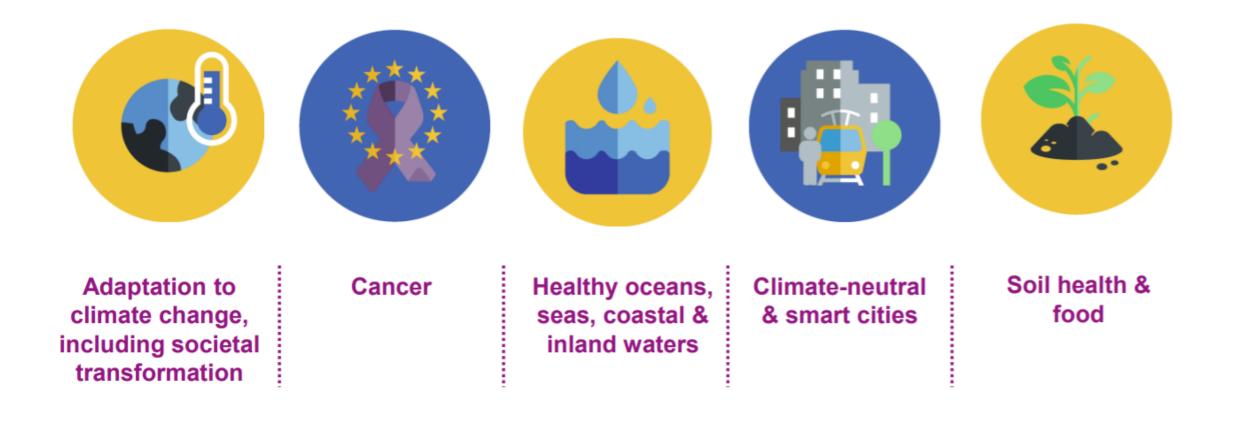


HE: Evolution, not revolution





Five Missions Areas

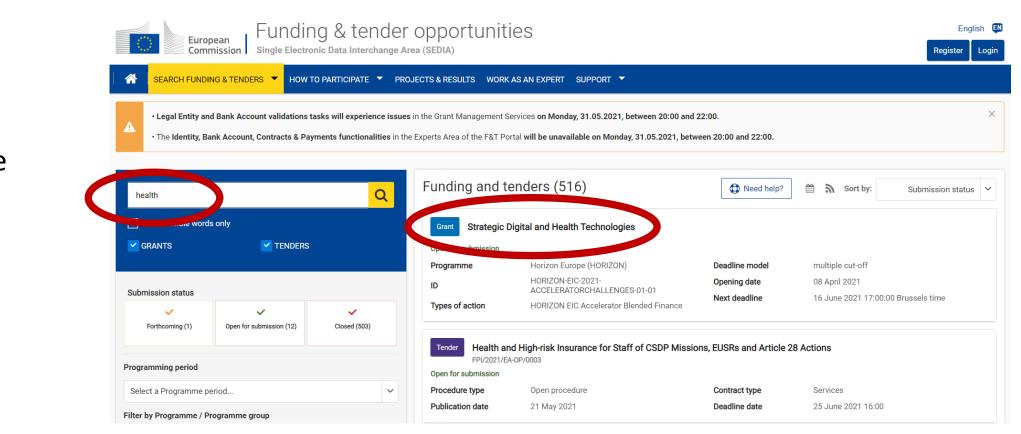


Where to start? Find a call topic





The Call topic



Find and understand the call topic



From the idea to the proposal

Proposal preparation phase

Grant				
General information	General information			
Topic description	Programme	Work programme part		
Conditions and documents	Horizon 2020	Health, demographic change and we	ell-being	
Submission service	Call Personalised Medicine (H2020-SC1-	<u>2016-2017)</u>	Work programme year H2020-2016-2017	See budget overview
Topic related FAQ	Type of action			Closed
Get support	Deadline model	Opening date	Deadline date	
Call information	single-stage	20 October 2015	16 February 2016 17:00:00 Brussels time	
Call updates				
Funded project list	Topic description			
Go back to search results	applies also to healthcare. Big Data is gen systemic level to develop personalised me more generic and commercial instruments the analysis of health and well-being scen	erated from an increasing plurality of source edicine, prevent diseases and support healt s, like mobile apps for health and well-being arios. It is important to assure ethical aspe I interpretation, in order to avoid misinterpre	sing and analysis of immense amounts of dat es and offers possibilities for new insights, fo hy life. Primary sources are new eHealth perso I. In addition, social networks can be consider cts of data, confidentiality, anonymity of data t etation and inappropriate conclusions. Greater	r understanding human systems at the onal solutions, but can be extended also to ed for integrating the social dimension in transfer and engagement of those who



	Horizon Europe - Work Programme 2021-2022 Health
Horizon Europe - Work Programme 2021-2022	HORIZON-HLTH-2021-ENVHLTH-03-01: European partnership for the assessment of risks from chemicals (PARC)
Health	Call - Environment and health (Single Stage - 2022)
	Conditions for the Call 57
	HORIZON-HLTH-2022-ENVHLTH-04-01: Methods for assessing health-related costs of
	environmental stressors
EN	
Horizon Europe	Destination 3. Tackling diseases and reducing disease burden62
	Call - Tackling diseases (2021)
Work Programme 2021-2022	Conditions for the Call
	HORIZON-HLTH-2021-DISEASE-04-01: Improved supportive, palliative, survivorship
	and end-of-life care of cancer patients
4. Health	HORIZON-HLTH-2021-DISEASE-04-02: Building a European innovation platform for
7. 120410	the repurposing of medicinal products
	HORIZON-HLTH-2021-DISEASE-04-03: Innovative approaches to enhance poverty-
	related diseases research in sub-Saharan Africa
DISCLAIMER	HORIZON-HLTH-2021-DISEASE-04-04: Clinical validation of artificial intelligence (AI)
This draft has not been adopted or endorsed by the European Commission. Any views	solutions for treatment and care
expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information	HORIZON-HLTH-2021-DISEASE-04-07: Personalised medicine and infectious diseases:
transmitted is intended only for the Member State or entity to which it is addressed for	understanding the individual host response to viruses (e.g. SARS-CoV-2)
discussions and may contain confidential and/or privileged material.	HORIZON-HLTH-2021-DISEASE-04-05: A roadmap towards the creation of the
	European partnership on One Health antimicrobial resistance (OH AMR)
	preparedness
	Call - Tackling diseases (Two Stage - 2022)
	Conditions for the Call
	HORIZON-HLTH-2022-DISEASE-06-02-two-stage: Pre-clinical development of the next
	generation of immunotherapies for diseases or disorders with unmet medical needs
	HORIZON-HI TH 2022 District of the second se
	seneration of vaccines
	HORIZON-HLTH-2022-DISEASE-06-04-two-stage: Development of new effective
	therapies for rare diseases
	Vice diseases (Single Stage - 2022)
	Conditions for the Call
	HORIZON-HLTH-2022-DISEASE-07-02: Pandemic preparedness
	HORIZON-HLTH-2022-DISEASE-07-03: Non-communicable diseases risk reduction in
	adolescence and youth (Global Alliance for Chronic Diseases - GACD)
	HORIZON-HLTH-2022-DISEASE-07-01: Support for the functioning of the Global
	Research Collaboration for Infectious Disease Preparedness (GloPID-R)
Part 4 - Page 1 of 181	Call - Partnerships in Health (2022)
	Can - Farmersups in realin (2022)
	Part 4 - Page 3 of 181



General Topic structure: Specific conditions / \rightarrow Expected outcomes / \rightarrow Scope /

Topic example: HORIZON-HLTH-2022-DISEASE-06-04-two-stage: Development of new effective therapies for rare diseases

Specific conditions

Expected EU contribution per project	The Commission estimates that an EU contribution of around EUR 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 60.00 million.
Type of Action	Research and Innovation Actions
Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply: The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.



Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 *"Tackling diseases and reducing disease burden"*. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Researchers and developers make the best use of the state-of-the-art knowledge and resources for a fast and effective development of new therapies for rare diseases.
- Researchers and developers increase the development success rate of therapies for rare diseases by employing robust preclinical models, methods, technologies, validated biomarkers, reliable patient reported outcomes and/or innovative clinical trials designs.
- Developers and regulators move faster towards market approval of new therapies for rare diseases (with currently no approved treatment option) due to an increased number of interventions successfully tested in late stages of clinical development.
- Healthcare professionals and people living with a rare disease get access to new therapeutic interventions and/or orphan medicinal products.



Scope: Despite the considerable amount of knowledge that has been accumulated and the new orphan medicines developed in recent years, the number of available therapies for rare diseases remains low, as fewer than 6% of rare diseases have an approved treatment option.

The joint evaluation of the regulations on orphan medicinal products and paediatric medicines concluded that those regulations have boosted the development for new therapies for rare diseases but have not yet adequately managed to direct research and innovation in areas of greatest unmet medical need. Actually, there is an urgent unmet medical need for the development of therapies for rare diseases, where there is still no approved therapeutic option available.

Therefore, proposals should aim to develop therapies for rare diseases with no approved therapeutic option. Proposals should focus on group(s) of rare diseases with commonalities, such as shared biological features, possibly within the same and/or across different medical areas within the rare diseases landscape. Thus, proposals should not address a single disease only (for example with an Orphacode representing a single disease).



The therapies to be developed may include a broad family of therapeutic interventions such as small molecule(s), advanced therapy medicinal products, repurposing of existing medicinal products, including non-pharmacological interventions and/or their combinations, as relevant. Sex and gender aspects should be considered, where relevant. To ensure that the needs of people living with a rare disease are adequately addressed, the involvement of patient representatives in all phases of the research and development process is strongly encouraged. Rare infectious diseases and rare cancers are excluded from this topic and will not be considered.

The topic will support proposals covering several different stages in the continuum of the innovation pathway (i.e. translational, preclinical, clinical research, validation in the clinical and/or real-world setting etc.), as relevant. SME(s) participation is encouraged with the aim to strengthen the scientific and technological basis of SME(s) and valorise their innovations for the benefit of people living with a rare disease.



The proposals should address most of the following research activities:

- Establish multidisciplinary collaborations between all relevant stakeholders by integrating disciplines, technological developments and existing knowledge. Integrate harmonised data from multiple sources (i.e. natural history studies/clinical trials, multi-omics, medical imaging, registries etc.) by utilising data analytics and/or other suitable methods, with the aim to understand the pathophysiology/heterogeneity of the rare diseases concerned and to identify therapeutically actionable mechanisms.
- Develop and utilise relevant preclinical models and/or innovative tools/technologies to: verify molecular/cellular pathways/genes that can be therapeutically targeted, increase the confidence in the targets selection and/or perform toxicity studies. When using disease models the applicants should describe how well the model replicates the pathology or the human condition.



- Develop and/or execute innovative clinical trials designs for small populations and novel approaches to assess and monitor the safety and efficacy of the proposed interventions. Such approaches may include but are not limited to: biomarkers defining robust surrogate and clinical endpoints; artificial intelligence tools/medical devices/biosensors/ companion/ complementary diagnostics for defining reliable patient reported outcomes; modelling and simulation and in-silico trials methodologies.
- Carry out preclinical proof-of-concept (PoC) studies and/or multinational interventional clinical studies to demonstrate the safety and efficacy of the therapeutic interventions under study. Preclinical PoC studies should include latestage preclinical studies (i.e. toxicological properties, adverse effects etc.). Clinical studies may cover all necessary development stages. Applicants should propose a clear exploitation pathway through the different necessary steps (research, manufacturing, regulatory approvals and licensing, IP management etc.) in order to accelerate marketing authorisation and uptake by the health systems.



Proposals should involve group(s) of rare diseases (i.e. a rare disease being individually defined in the European Union as affecting not more than five in 10.000 persons). Proposals that plan to run clinical trials should demonstrate that they have already taken into account scientific advice or protocol assistance from EMA. In particular, proposals planning the clinical development of orphan medicinal products should demonstrate that they have been granted approval for an orphan designation at the latest on the date of the call deadline.

Proposals should adhere to the FAIR data principles and take stock, wherever relevant, of data standards, harmonisation guidelines and good practices for data sharing/access developed by existing European health research infrastructures (i.e. ESFRI infrastructures). Proposals should take stock, where relevant, of the FAIR guidance, of good practices for analytical methods and preclinical models and of good exploitation strategies for the translation of research results into high impact interventions, developed by the European Joint Programme on Rare Diseases (EJP RD) and other relevant EU-funded projects.



Whenever the proposed data sources or fields of application include genomics, the proposals should take into account, where relevant, the data standards, and legal, ethical and technical interoperability requirements and guidelines agreed within the 1+ Million Genomes initiative. Data-intensive proposals, particularly those using data from patient registries, could consider the involvement of the European Commission's Joint Research Centre (JRC) and take stock of the tools and services provided by the European Platform on Rare Disease Registration (EU RD Platform), including the adoption, where relevant, of the European standards such as the "set of common data elements". In addition, synergies should be sought with the European Reference Networks, where relevant.

Projects funded under this topic will contribute towards the goals of the International Rare Diseases Research Consortium (IRDiRC) that supports the development of 1000 new therapies for rare diseases by 2027 and may take stock of the IRDiRC Orphan Drug Development Guidebook, where relevant.

Questions



- Do you think this topic is interesting for you?
- Is it aligned with your strategy?
- Could you highlight a few sentences that resonate with you?
- Can you identify the main challenges?
- Do you have a network of core partners that can contribute to this topic?
- What is missing? A) in the topic; B) in your project idea



TEN TIPS FOR THE WRITING A COMPETITIVE PROPOSAL



1. Without ideas, there is nothing

- Project proposals are complete documents that define the project characteristics in a detailed manner. An excellent proposal must be based on an **excellent idea**.
- There should be a previous phase of **project conception**, which is based on the **project idea**. The project idea is essential and will be the **key driver** of a good proposal and a subsequently solid project.





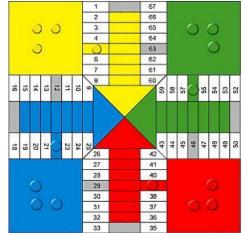
1. Without ideas, there is nothing

- The lack of an **inspiring project idea** is very difficult to overcome when writing the proposal.
- It is therefore **not** advisable to **artificially** adapt the project idea to the call priorities.



teamit 2. Learn by heart the rules of the game

- Once we have a project idea and want to develop a project proposal, we should devote some time to KNOW the **call characteristics.**
- We can find this in the *Call Documents* that are published at the time of the call opening. There are two essential documents:
 - Work Programme
 - Proposal template



teamit 2. Learn by heart the rules of the game

• When looking at the Workprogramme, we should make sure that our project idea **matches the topic** (not only the title, but the **'spirit**' of the topic text).

• In the Proposal Template we will learn about the **formal process** to prepare and submit a proposal (sections, expected content, format, etc), plus how proposals will be **evaluated**.

tease 3. What we will do in the project / what we will NOT do in the project

• The project idea will be developed and specified in the proposal. The **scope** of the project defines **what we will do and what we will not do** in the project.

• It is important to be clear about the scope and **avoid ambiguities** that can result in false expectations and endanger the project viability.

• A balance should be found between **being ambitious** and **being realistic.**



teasing 3. What we will do in the project / what we will NOT do in the project

When the scope is defined, we should derive the:

- General objective
- Specific objectives

Easy to

- Work Breakdown Structure
- Deliverables
 Project outcomes
- Milestones
 Kill-points

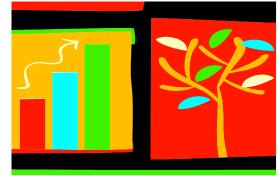
teasit 4. The first impression really makes a difference

- The first section in the proposal typically refers to project **objectives, concept, rationale** of the project. It has a clear impact on the opinion of the evaluators about our project.
- Sufficient time should be devoted to writing this section in a **convincing and organized** manner.
- In order to catch the reader's attention, we should balance rationality and passion, ambition and realism, originality and rigor.



teasit 4. The first impression really makes a difference

- The text should **link smoothly** one idea with the next one and convey the problem we want to address in the project.
 - Avoid excessive detail
 - Facilitate reading
 - Organize information efficiently
 - Go to the point (what do you want to do in the project)
- The text should grab you like a (good) novel!





5. Choose the right partners

- **Building a consortium** is typically a source of anxiety for project coordinators.
- It is a critical aspect, since most of the **issues encountered during the project implementation** will have to do with the consortium.
- A consortium should be formed **by all partners needed** to satisfactorily execute the project (no more, no less).





6. Being good is not enough, proposals have to "look" good

• Do not disregard the **formal aspects** of the proposal. Evaluators examine many proposals in little time.

• Facilitating the reading, exposing ideas in order, using short sentences, being consistent, etc. all contribute to make a **good impression** of the project. Use graphical elements when possible. Check the language, typos.

• (Un)Surprisingly, proposals tend to contain a high number of formal errors. This could be easily avoided.



teamit 7. The right information in the right place

• Typically, European proposals follow a pre-defined structure. Doubts may arise on which information should be included in each section.

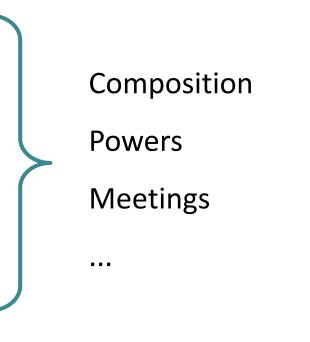
• We should make an initial effort to **segment the project information** in order to avoid duplicities and inconsistencies across the proposal.

Proposal writing strategy:
 centralized / de-centralized?





- The governance structure will enable the decision-making process in the project, which should be agile but ensuring enough consensus among partners.
 - General Assembly
 - Executive Committee
 - Advisory Board
 - Scientific Coordinator
 - Project Manager
 - Work Package Leaders
 - Activity Leaders...





9. Transparent budgeting

- Always **relate budget to work** (effort persons/month). Avoid "political" distribution of budget.
- **Be transparent** and share the budget information with the consortium.
- Explain the **rationale** behind the figures in the proposal.





- "Expert advice" cannot substitute preparing a solid proposal. **Do not overestimate the political component** of European projects.
- "Recommendations" should only be included in your project if they **fit naturally.**



HE FORCE BE WITH YOU

Thank you for your attention!

