Fit for Health 2.0

Support to SMEs & Researchers in FP7 and Horizon 2020 health-oriented projects

Scientific and/or Technical Excellence – including Ethics

www.fitforhealth.eu

23.06.2015 | Madrid

Astrid Hoebertz | FFG

Fit for Health is funded by the European Commission

SEVENTH FRAMEWORK PROGRAMME

Structure of Horizon 2020

I. Excellent Science

- ERC
- FET
- Marie-Skłodowska-Curie
- Infrastructures

II. Industrial Leadership

- **LEIT**
  Leadership in Enabling and Industrial Technologies:
  ICT, Nanotechnology, Advanced Materials, Biotechnology, Production Technology, Space
- Access to Risk Finance
- Innovation in SMEs

III. Societal Challenges

- Health, Demographic Change and Wellbeing
- Challenges in the European Bioeconomy…
- Secure, clean and efficient Energy
- Smart, green and integrated transport
- Climate, environment, resource efficiency & raw materials
- Integrative, innovative and reflective societies
- Secure societies

Spreading Excellence Widening Participation

Science with and for Society

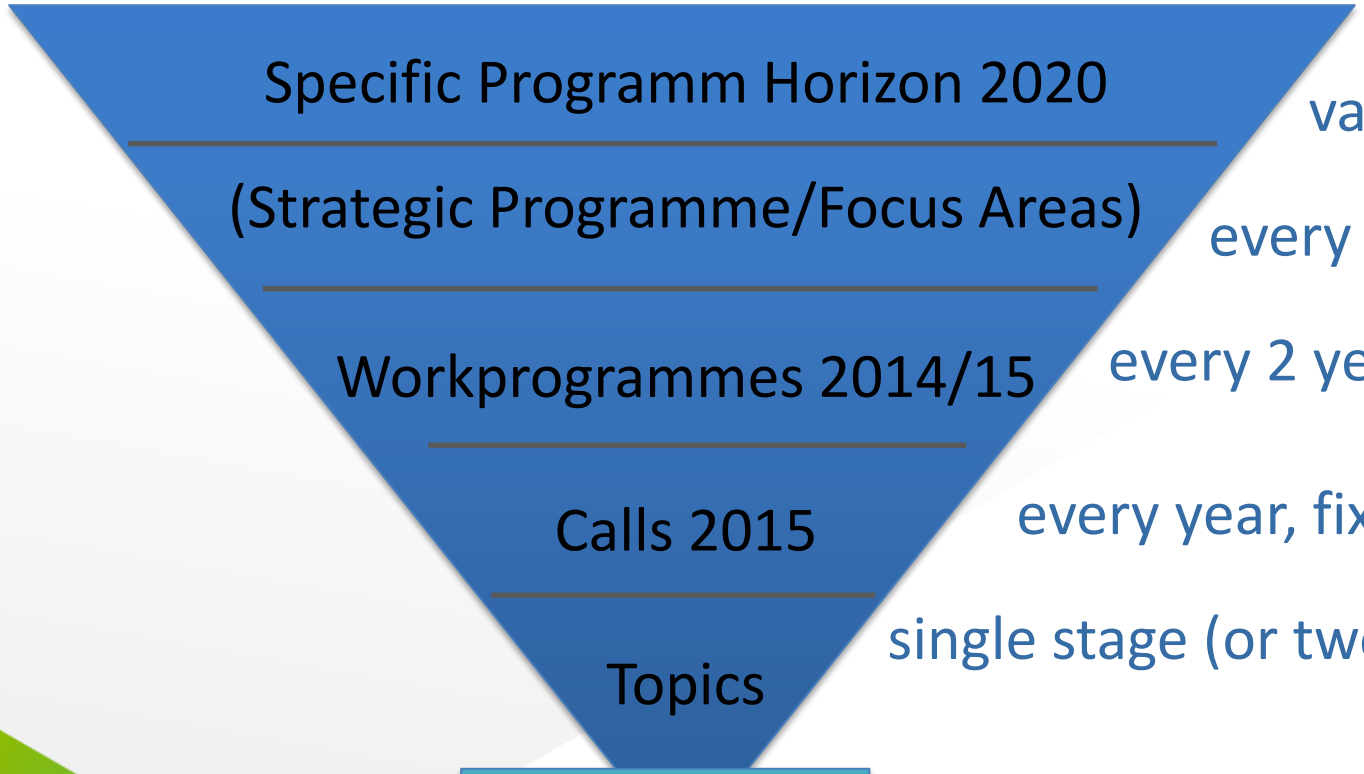
JRC

EIT

SC 1 - Health, Demographic Change And Wellbeing

- Personalised Medicine
- Broad topics
- Less prescriptive topic texts
- Two-year work programme
- Stronger focus on end users
- Clinical trials

HORIZON 2020: from programm…..to the project!



valid for 7 years

every 2 years

every 2 years, update year 2

every year, fixed deadlines

single stage (or two stage)

Project idea → **Submission**

Orientation – Where to start?

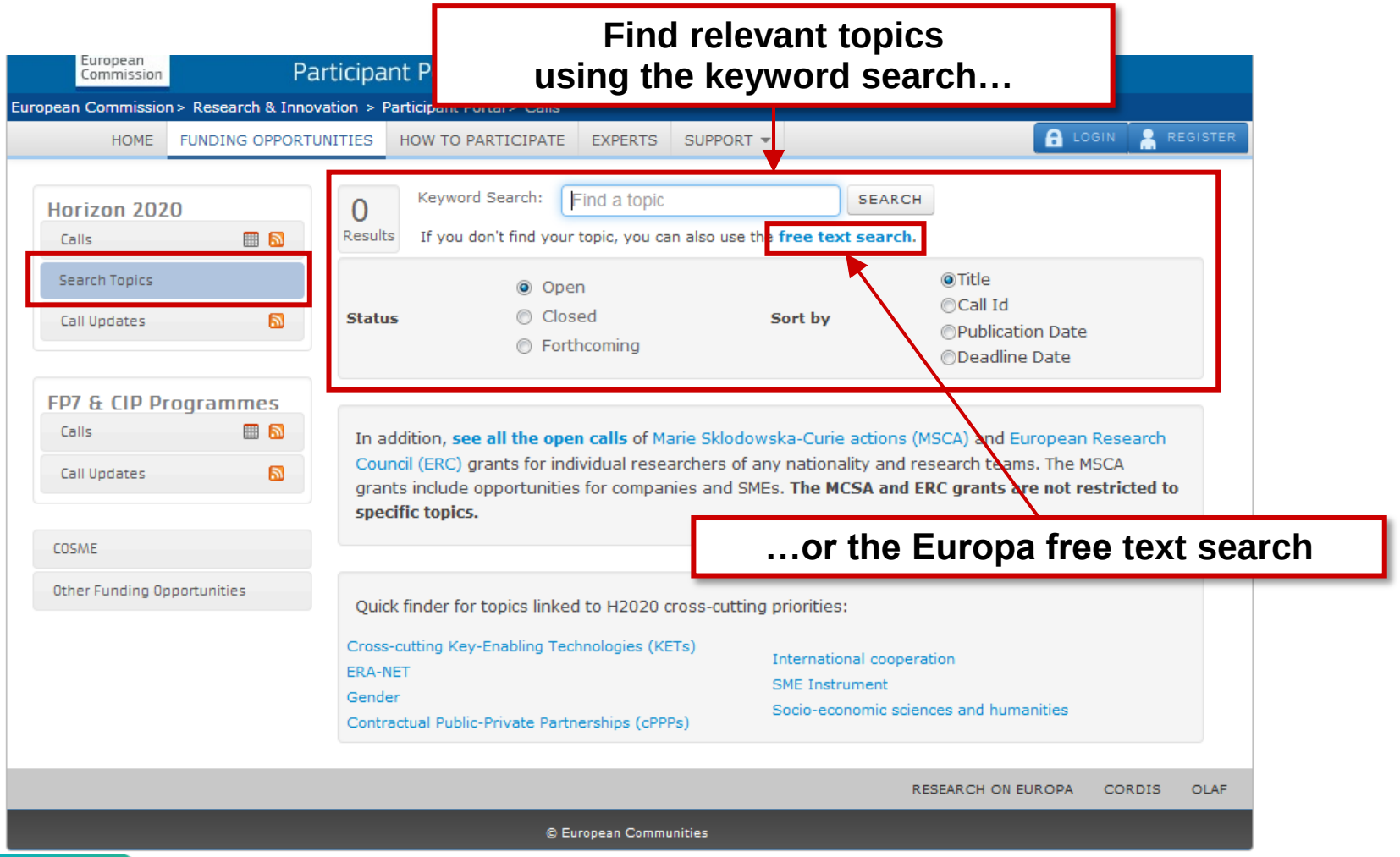
Important:

- Please check carefully in the participant portal: several calls are published at the same time!
- As soon as the calls are published you can register a project for your specific topic and download the **Proposal Templates**

PARTICIPANT PORTAL: ONE-STOP SHOP

http://ec.europa.eu/research/participants/portal

Searching topics in the Participant Portal



Topic example (former call – topic now closed!)

PERSONALISING HEALTH AND CARE (PHC)

PHC 3 - 2015: Understanding common mechanisms of diseases and their relevance in co-morbidities

Specific challenge: The development of new treatments will rely heavily on an improved understanding of the pathophysiology of diseases. There is therefore a need to address the current knowledge gaps in disease aetiology in order to support innovation in the development of evidence-based treatments. In this context, a better understanding of the mechanisms that are common to several diseases, in particular of those leading to co-morbidities, constitutes an important challenge.

Scope: Proposals should focus on the integration of pre-clinical and clinical studies for the identification of mechanisms common to several diseases. Proposals should assess and validate the relevance of these common mechanisms and of their biomarkers (where relevant) on the development of disease-specific pathophysiology, as well as their role in the development of co-morbidities in both males and females.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact: This will provide:
- A better understanding of disease pathways and / or mechanisms common to a number of diseases
- New directions for clinical research for better disease prevention, health promotion, therapy development, and the management of co-morbidities

Type of action: Research and Innovation actions

What's next? WP 2016-2017 (under discussion)

6 Areas => for specific topics see final call text!

1.1. Understanding health, well-being and disease
1.2. Preventing disease
1.3. Treating and managing disease
1.4. Active ageing and self-management of health
1.5. Methods and data
1.6. Health care provision and integrated care

Publication September/October 2015
Deadlines February – April 2016
=> contact your NCP!

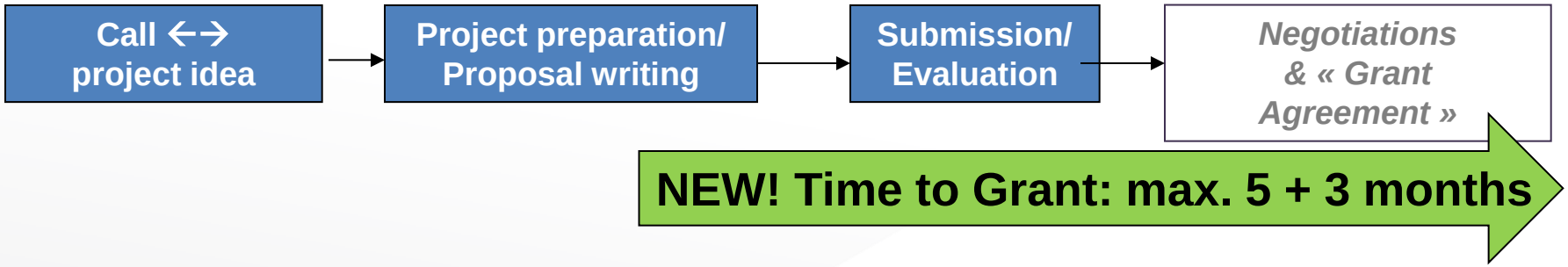
From the proposal template…

1. Excellence

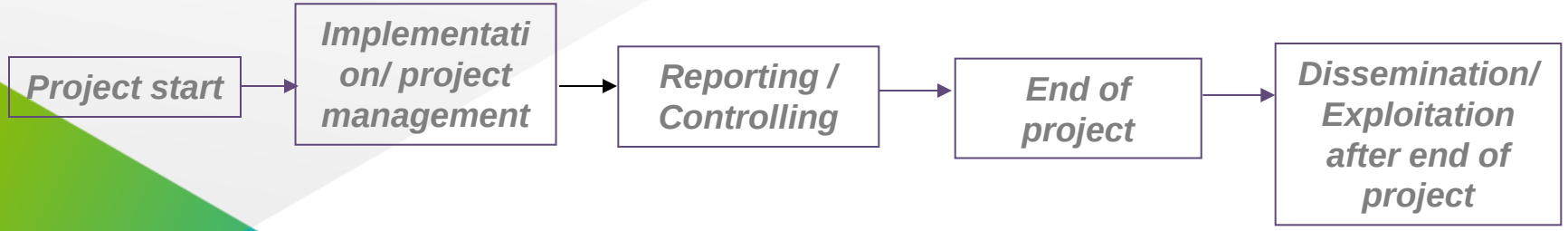
"Your proposal must address a work programme topic for this call for proposals."

Project Cycle

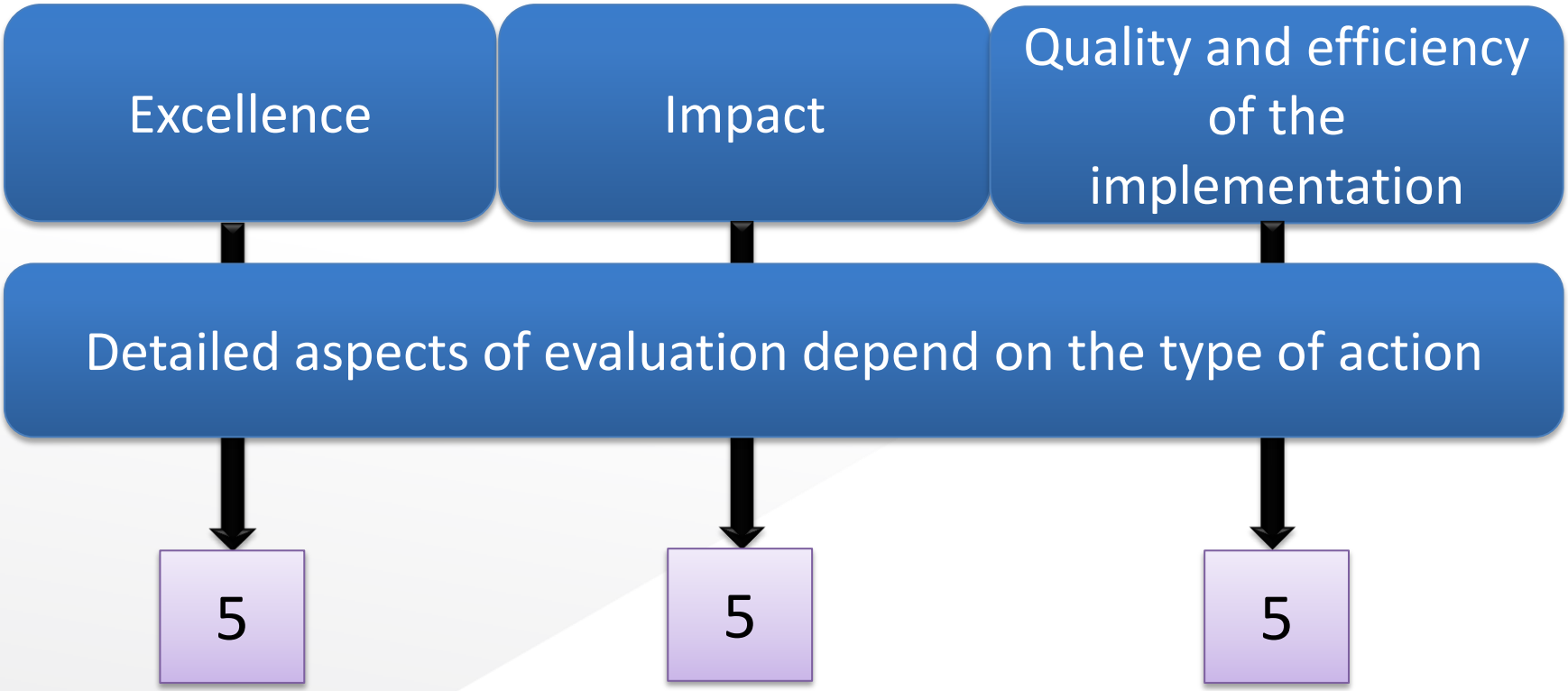
Project Preparation



Project Implementation and Monitoring



Evaluation criteria



Evaluation process

- Pre-Phase: experts register in database, EC puts together experts/evaluator teams, experts get briefed by EC on topics and evaluation procedure
- Phase 1 — Individual remote evaluation 
- Phase 2 — Consensus group  + 
- Phase 3 — Panel review  + 

Orientation – Where to start?

Important:

- Please check carefully in the participant portal: several calls are published at the same time!
- As soon as the calls are published you can register a project for your specific topic and download the **Proposal Templates**

Proposal writing

Proposal contains at least 2 parts – more in Health!

- **“Part A”: administrative information – only online forms!**
  ...including abstract!
- **“Part B”: technical information - upload pdf in a predetermined structure**
- **Template for essential information to be provided for proposals including clinical trials / studies / investigations**
- **Optional supporting documents on Ethics**

Template Structure –
Research and Innovation Action

1. Excellence
   - 1.1 Objectives
   - 1.2 Relation to the work programme
   - 1.3 Concept and approach
   - 1.4 Ambition
2. Impact
   - 2.1 Expected impacts
   - 2.2 Measures to maximise impact
     - Dissemination and exploitation of results
     - Communication activities
3. Implementation
   - 3.1 Work plan - Work packages, deliverables and milestones
   - 3.2 Management structure and procedures
   - 3.3 Consortium as a whole
   - 3.4 Resources to be committed
4. Members of the consortium
   - 4.1. Participants (applicants)
   - 4.2. Third parties involved in the project (includi… party resources)
5. Ethics and Security
   - 5.1 Ethics
   - 5.2 Security

Page limit

Careful – template might slightly change for next calls!

"BIG PROJECT PICTURE" – One Pager

- Planned Title of the project:
- Objectives/Aim of the project:
- Project background:
- Expected results and lead users of these results:
- How do you want to achieve these objectives? Work phases of the project:
- Which partner expertise is necessary to achieve these objectives? Consortium in brief:
- Planned duration of the project:
- Expected budget:

1. Excellence

1.1 Objectives

1.2 Relation to the work programme

1.3 Concept and approach

1.4 Ambition

1.1 Objectives

Describe the specific objectives for the project, which should be **clear, measurable, realistic and achievable** within the duration of the project.

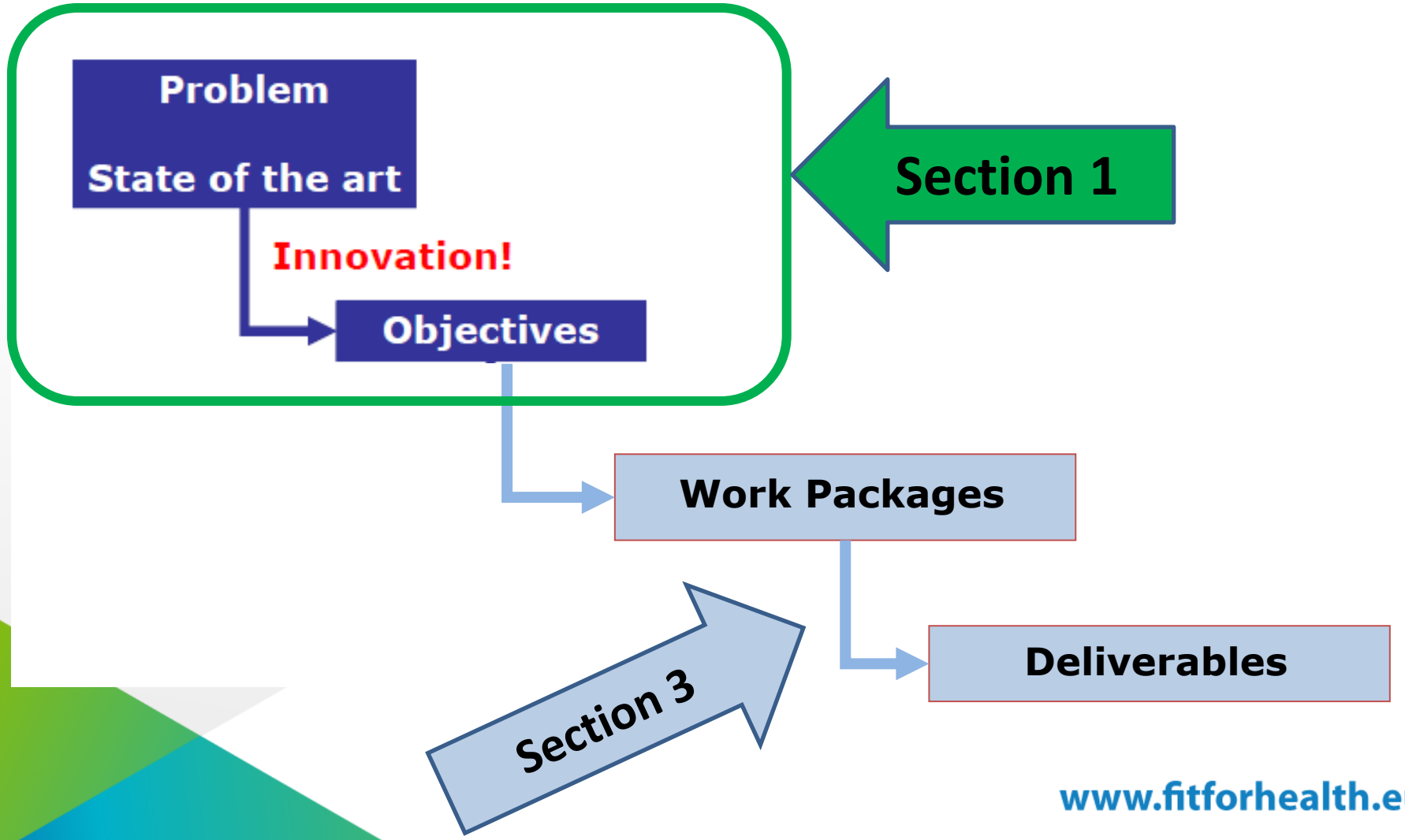
Objectives should be consistent with the expected exploitation and impact of the project
(see section 2)

Objectives ≠ activities!

- The right question:
  - **What do I plan to achieve?**

- The wrong question:
  - **What am I going to do?**

Line of reasoning



Objectives are S M A R T

S specific, concrete

- What **exactly** are you going to achieve?
- Is the objective written in a clear and **comprehensible** way?

M measurable

- How can you tell if the objective is reached?
- Are there clear **indicators** or **parameters** to measure the objective?
- How many, how large, how fast?

Objectives are S M A R T

A acceptable

- Will the stakeholders be **happy** with the results?
- Do the objectives provide an **acceptable solution** to the problem?

R realistic

- Is the objective **achievable**, given the time and resources committed?
- Is the objecitve a **challenge or an excessive demand?**

T timely?

- **When** will the objectives be achieved?

~~Obesity causes death in millions of Europeans. The objective of this research project is to study the role of nutritional signals causing bad food habits as a starting point for a possible new therapy~~

The objective is to develop a new therapy for obesity based on bioactive compounds.

Examples - Objectives

- Addressing of 5000 different SMEs in the area of Health research in Europe
- Organisation of 4 trans-regional partnering days, 1 international brokerage event and 2 virtual match-making events
- Identification and dealing with 220 partner searches
- Establishment of a “Helpdesk”

Fit for Health 2.0

In the best case….section 1.1 „Objectives“ is only 1 page long!

- **Short introductory paragraph answering 5 KEY QUESTIONS**
  - Why bother? What problem are you trying to solve?
  - Is it a European priority or could it be solved at national level?
  - Is the solution already available?
  - Why now? What would happen if we did not do this now?
  - Why you? Are you the best people to do this work?
- **Overall aim**
- **Specific objectives listed with bullet points**

It is possible and very reader friendly!!

1.2 Relation to the work programme

Indicate the work programme topic to which your proposal relates, and explain how your proposal addresses the specific challenge and scope of that topic, as set out in the work programme.

Keep it simple…

Make a **table** of **all** relevant elements of the **topic text** and the way you deal with them in the project.

The scope of call PHC-11 is:	Our project (Acronym) will provide
„……“	….
„……“	….

1.3 Concept and approach – 1

Describe and explain the **overall concept** underpinning the project. Describe the **main ideas, models or assumptions** involved. Identify any trans-disciplinary considerations;

Describe the **positioning** of the project e.g. where it is situated in the spectrum from 'idea to application', or from 'lab to market'. Refer to **Technology Readiness Levels** where relevant.

Concept and approach…

- The right question:
  - **How am I going to reach my goals?**

- The wrong question:
  - **What exactly am I going to do when?**

1.3 Concept and approach – 1 - TIPPS

- the concept should be based on a certain model/ hypothesis/ assumption that should be clearly stated and elaborated….(best if the hypothesis is based on findings of consortium members!)
- …some facts/figures/numbers to the current situation
- this section is still quite general, not too much methodological detail with regards to the „how“

Show that you build on existing knowledge!!

Fit for Health 2.0

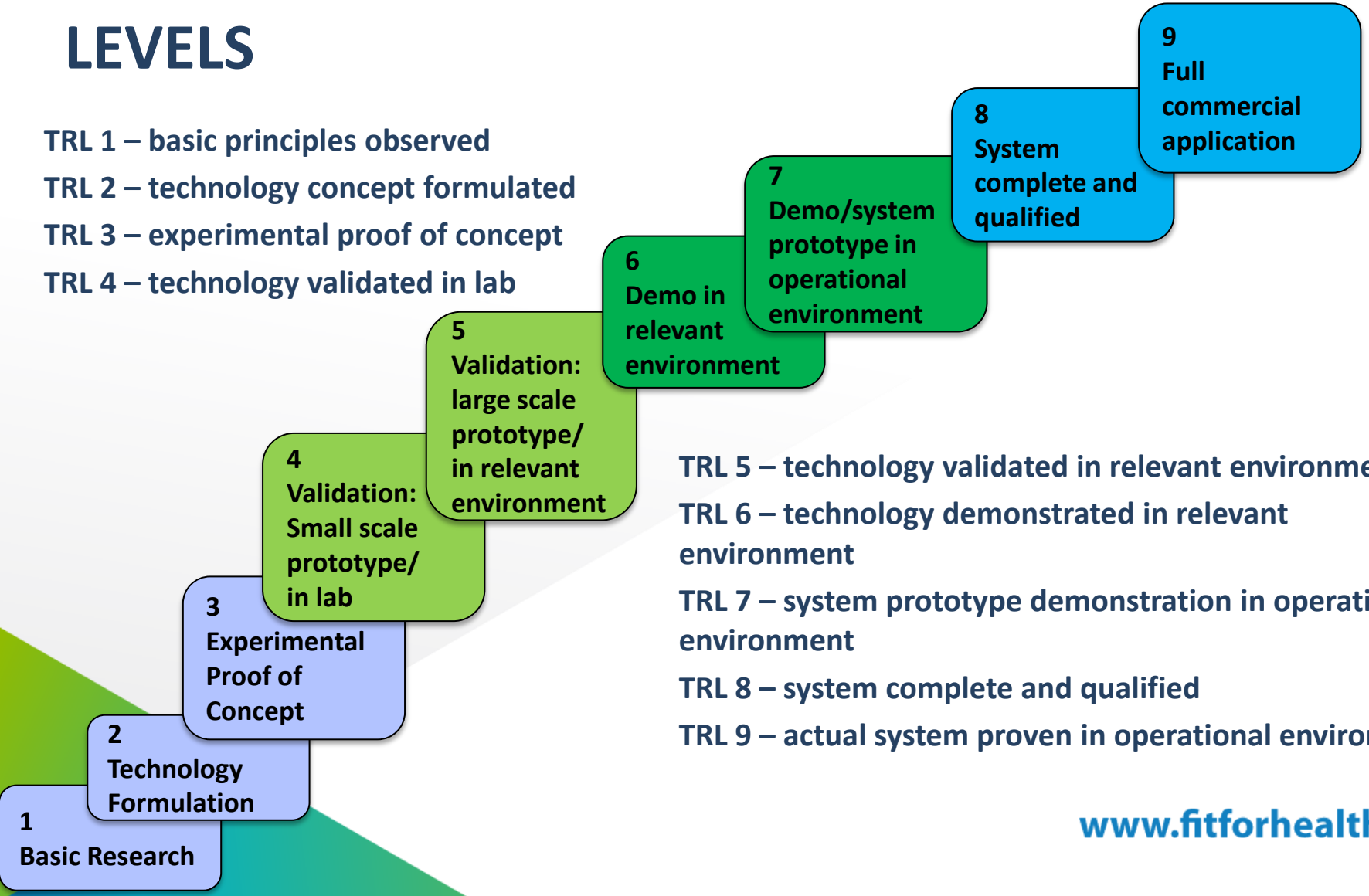
NEW: TECHNOLOGY READINESS LEVELS

TRL 1 – basic principles observed

TRL 2 – technology concept formulated

TRL 3 – experimental proof of concept

TRL 4 – technology validated in lab



TRL 5 – technology validated in relevant environment

TRL 6 – technology demonstrated in relevant environment

TRL 7 – system prototype demonstration in operational environment

TRL 8 – system complete and qualified

TRL 9 – actual system proven in operational environment

Technological Readiness Levels

When relevant it can be very illustrative to make a table of key elements of the project and the TRLs before and after the work

Element	Before	After
Handheld Ultrasound technology	TRL3	TRL8
Hyperspectral Imaging	TRL3	TRL5
Acoustic Imaging	TRL2	TRL5

1.3 Concept and approach - 2

Describe any **national or international research and innovation activities** which will be linked with the project, especially where the outputs from these will feed into the project;

Describe and explain the **overall approach and methodology**, distinguishing, as appropriate, activities indicated in the relevant section of the work programme, e.g. for research, demonstration, piloting, first market replication, etc;

1.3 Concept and approach – 2 - TIPPS

Describe any **national or international research and innovation activities** which will be linked with the project, especially where the outputs from these will feed into the project;

⇒ Simply show the evaluators how your project connects to the rest of the world, and that you are aware of ongoing projects in the same field

⇒ Don't overdo it, don't write 7-10 pages full of references or links

1.3 Concept and approach – 2 - TIPPS

Describe and explain the **overall approach and methodology**, distinguishing, as appropriate, activities indicated in the relevant section of the work programme**, e.g. for research, demonstration, piloting, first market replication, etc;**

⇒ this is the chance to demonstrate the **excellence of the consortium…**list all excellent/ ground breaking technologies you will be applying …and why you have composed it this way

⇒ also briefly describe your clinical trials and make reference for all details to the Template on clinical trials!

avoid too much redundancy with WP descriptions in Section 3!

Clinical Trials

Webinar on clinical trials for Horizon 2020 projects

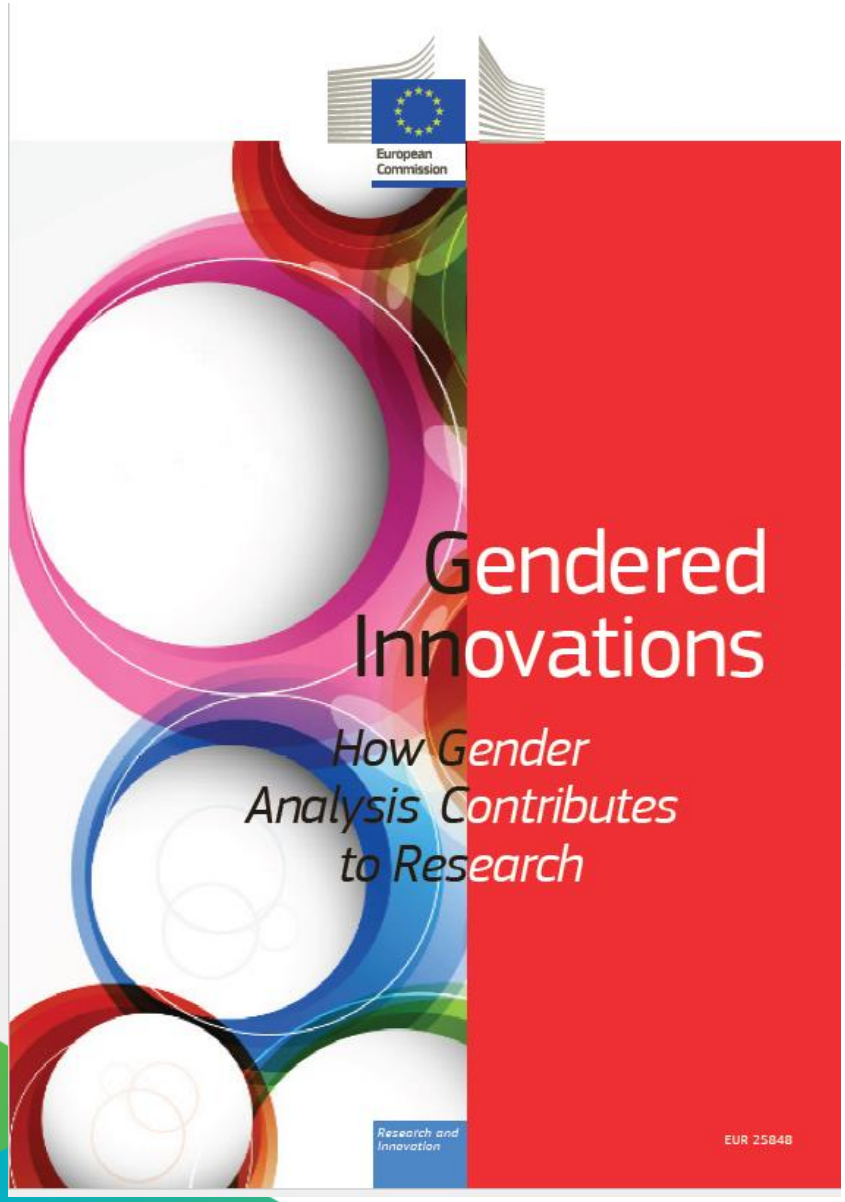
http://www.fitforhealth.eu/event-created/webinar-clinical-trials-horizon-2020-projects

http://www.fitforhealth.eu/sites/default/files/factsheet_clinical_trials_for_web.pdf

1.3 Concept and approach - 3

Where relevant, describe how **sex and/or gender analysis** is taken into account in the project's content.

- *NOT: how many women and men work in your project*
- **BUT:** Differences in your research area between female and males, and how do you adress these differences in your project design?



http://ec.europa.eu/research/science-society/document_library/pdf_06/gendered_innovations.pdf

1.4 Ambition - 1

Describe the **advance** your proposal would provide **beyond the state-of-the-art**, and the extent to which the proposed work is **ambitious**. Your answer could refer to the ground-breaking nature of the objectives, concepts involved, issues and problems to be addressed, and approaches and methods to be used.

1.4 Ambition – 1 - TIPPS

- Possibly break down into several subareas:
  - What is the state of the art in this field?
  - How does your project go **beyond** this state of the art?
- Don't write endless pages on the state of the art – stay reader friendly! Stay focused on YOUR project
- Stress the AMBITION of the project!
- But: don't be overambitious and unrealistic!

1.4 Ambition - 2

Describe the **innovation potential** which the proposal represents. Where relevant, refer to **products and services** already available on the market. Please refer to the results of any patent search carried out.

1.4 Ambition – 2 - TIPPS

- Where/What is your innovation? *(sometimes difficult ….overlaps with ambition in previous subchapter…)*
- Prove your “freedom to operate” and that you know the market
- Are there existing similar patents in this field?
- Would this hinder your project freedom?
- Or do you own the patents yourself?

Practical example

Topic: New avenues for treatment and prevention of cancer

Challenge:

- Incidence rate of cancer is still raising
- early diagnosis is either too expensive, not applicable or not existing

Scope:

- improvement of early diagnosis
- use of „big-data“ approach
- focus on common cancer
- transdisciplinary approach

Expected Impact:

- fast and easy diagnosis of cancer in early stages
- impact on health care systems

Your Project: development of early diagnosis program for skin cancer

1.1 Objectives:

Overall objective:

Reduction of incidence of skin cancer in Europe

Specific Objectives:

- 3 new validated and easy to measure biomarkers for skin cancer
- Draft program for early diagnosis of skin cancer which could be applied all over Europe

1.3 Concept und approach - CONCEPT:

- Skin cancer has risen dramatically over the last decade, yet an affordable early diagnosis is lacking
- Recent findings indicate that early diagnosis is possible via biomarkers
- 1 biomarker may not be sufficient, but combining 3 markers will enhance sensitivity and diagnostic value
- Our consortium has therefore gathered expertises in the areas of x, y, z
- and is outstanding with regards to …
- Members of the consortium have access to … (infrastructure) and are also members in project A, B, C, and in the steering board of initiative X and editorial board of (journal)
- As skin cancer has a 20% higher incidence rate in women, we will take this into account …

1.3 Concept und approach - APPROACH

- biomarker will be identified using –omics approach
- 3 biomarkers will be investigated and validated each on ist own and in combination within a clinical study
- Based on these findings, a new program for early diagnosis of skin cancer will be developed, in collaboration with health care providers and policy makers

Methodology used:

-omics, MRT, ….. (groundbreaking)

Fit for Health 2.0

1.4 Ambition:

- A combination of 3 easy measurable biomarkers is new and has never been applied so far (for skin cancer/ cancer/ etc.).
- The chance to diagnose skin cancer in a very early stage will dramatically change the treatment of skin cancer
- The test kit combining 3 validated markers will be highly innovative and has so far not been patented (we have freedom to operate); opportunity for own patent application (develop patent strategy)
- High market volume envisaged.

Ethics…

Whenever your project deals with:

- Human embryos or foetusses
- Humans (patients, children, vulnerable groups)
- Human cells or tissues
- Personal data
- Animals
- Non-EU countries
- Environment protection

…you have an ethical issue!

Ethics…

Activity	Who?	When?	How?
Ethics Self-assessment	**Applicant**	**Application phase**	Consideration of ethical issues of the proposal
Ethics Pre-screening/Screening	Ethics experts	Evaluation phase	Review of application material
Ethics Assessment (for proposals involving hESC or raising serious ethical issues: severe intervention on humans)	Ethics experts	Evaluation/ Grant preparation phase	Review of application material
Ethics Check/Audit	Ethics experts	Implementation phase	Review of project deliverables/interview with applicants

Ethics Issues Table (1)

1. Human embryos/foetuses

- Does your research involve the use human embryos/human embryonic stem cells/human foetal tissues/cells?

2. Humans

- Does your research involve human participants/physical interventions on the study participants?

3. Human cells/tissues

- Does your research involve human cells or tissues?

4. Protection of personal data

- Does your research involve personal data collection and/or processing/further processing of previously collected personal data (secondary use)?

5. Animals

- Does your research involve animals?

Ethics Issues Table (2)

6. Non-EU Countries

- Does your research involve non-EU countries?
- Do you plan to use local resources?
- If your research involves low and/or lower middle income countries, are benefits-sharing measures foreseen?
- ….

7. Environment Protection

- Does your research involve the use of elements that may cause harm to the environment, to animals or plants/deal with endangered fauna and/or flora and/or protected areas?

8. Dual Use

- Does your research have the potential for military applications?

9. Misuse

- Does your research have the potential for malevolent/criminal/terrorist abuse

10. Other ethics issues

Short on Ethics

- Show that you fully understand all ethical issues in the application
- Describe all interventional procedures and the ethical implications
- Include, if appropriate, an independent ethics advisor or advisory board, or in case of major potential ethical challenges, a work package on ethics
- Address informed consent, data protection and privacy issues in a comprehensive manner
- Clearly state where what research will be carried out and what authorities will approve the studies

Evaluators' comments – Section 1

- "The objectives are very clearly and coherently described and pertinent to the call"

- "The objectives are well stated and the proposal gives an excellent overview of the state-of-the-art and expected progress beyond."

- "The proposed methodology is coherent and includes indicators for success in order to reach the objectives"

Evaluators' comments – Section 1

- **Very often:** detailed criticism on specific scientific, technological and methodological details, or badly designed clinical trials!
- "The proposal fails to convince that any new insight can be achieved, and that real new innovation for this process can be developed."

- "The proposal work is not ambitious and has limited innovation potential, which is not to be considered to be beyond state of the art"
- "The concept is not sound, since it is not sufficiently based on evidences."
- "The research program is ambitious and well-presented but the main concept is highly speculative"

Take home messages

- Remember for whom you're writing
- Take the reader by the hand and guide them
- Create a logical link between objectives, workpackages and deliverables – very important!
- Do not work to fill the 70 pages! Work to get your ideas across!

Thank you!

Dr. Astrid Hoebertz | Austrian Research Promotion Agency

astrid.hoebertz@ffg.at | **www.ffg.at**