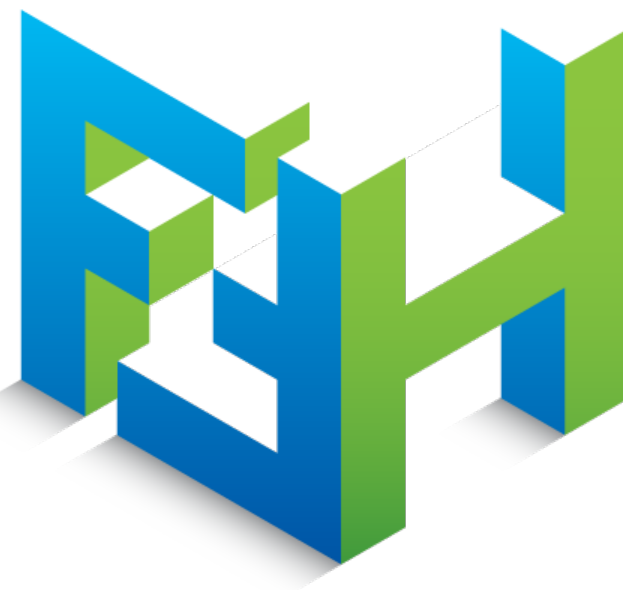


# Fit for Health 2.0

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

## The new SME Instrument in Horizon 2020



[www.fitforhealth.eu](http://www.fitforhealth.eu)

14.03.2014 | Webinar

Ines Haberl | Austrian Research Promotion Agency

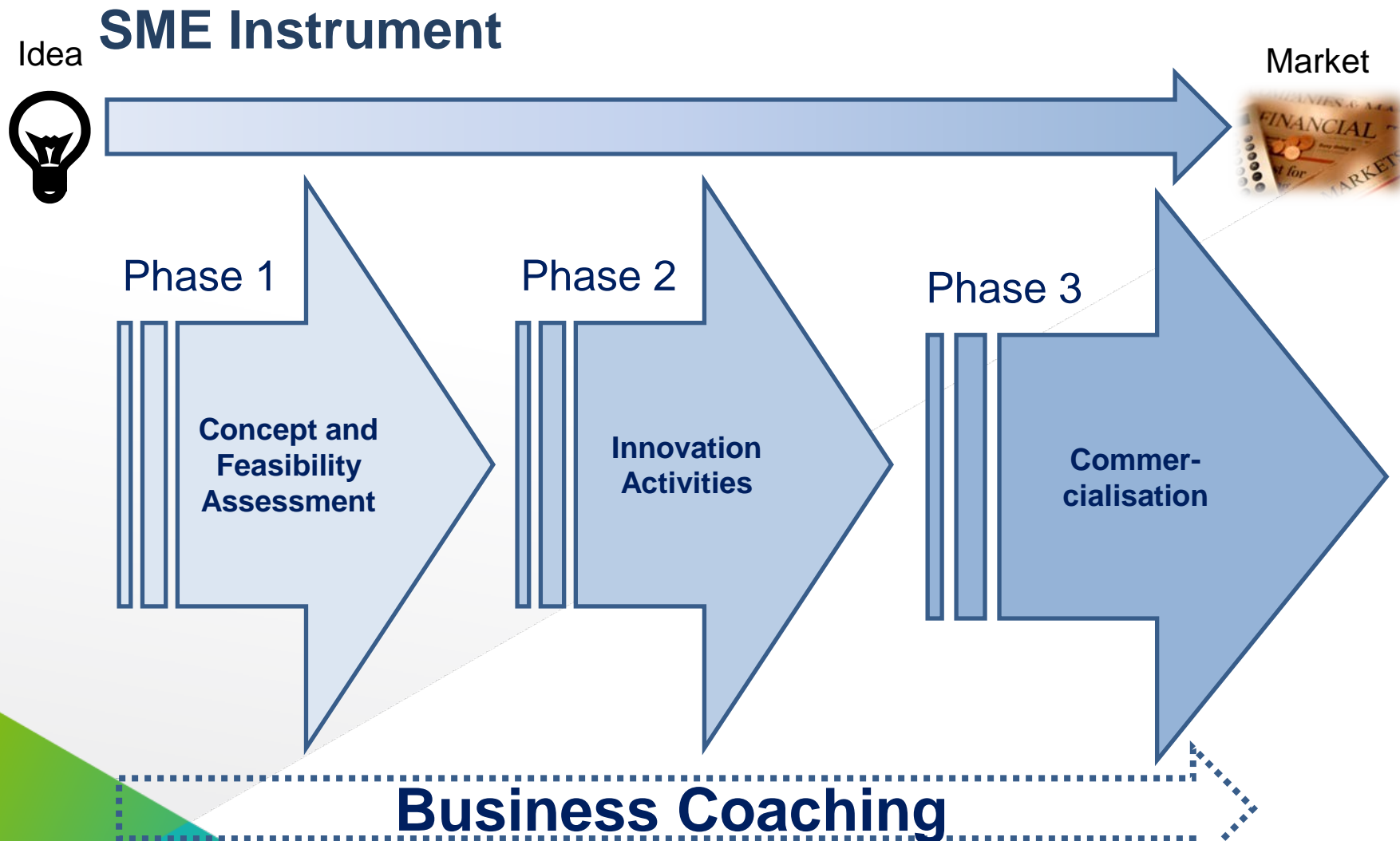


Fit for Health is funded by  
the European Commission

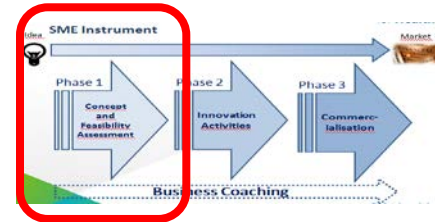


# Content

1. What is the concept?
2. Who should apply?
3. Which topics are available?
4. How to prepare an application for phase 1?
5. Submission and evaluation procedure
6. Accompanying support, further information and final recommendations



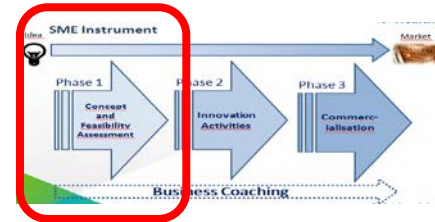
# Phase 1: Concept and Feasibility Assessment



## ■ Objectives:

- Exploration and assessment of the technical and technological feasibility, the commercial potential, the economic viability of a breakthrough idea
- Considerable novelty to the industrial sector
- → new products, processes, services, technologies or new market applications

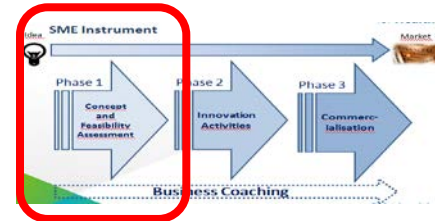
# Phase 1: Concept and Feasibility Assessment



## ■ Activities:

- Risk assessment
- Description of bottlenecks
- Market study
- User involvement
- IP regime
- Partner search
- Initial business plan based on proposed idea / concept

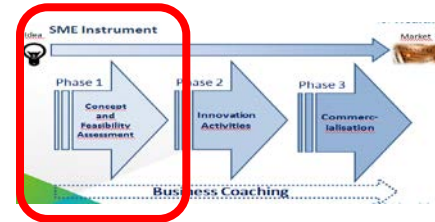
# Phase 1: Concept and Feasibility Assessment



## ■ Results:

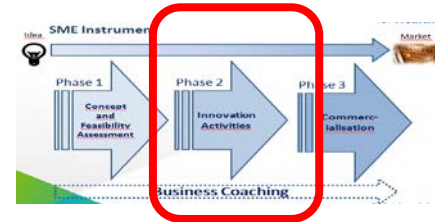
- Report: business innovation plan
- Recommendations for additional innovation activities
- Private financing needs
  
- Solution exists on the market
- Buying existing know-how or IPR as an option  
→ no further funding!

# Phase 1: Concept and Feasibility Assessment



- **Duration:**  
6 months (could also be shorter, could be longer if desired and justified)
- **Time to grant:**  
About 3 months
- **Success rate:**  
About 10% (estimation!)
- **Funding:**  
Lump sum: 50.000€

## Phase 2: Innovation Activities

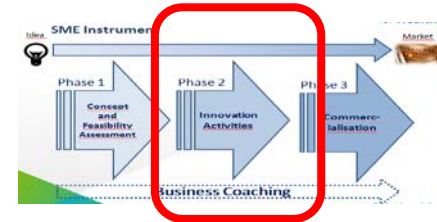


### ■ Objectives:

- Projects need to address a specific challenge and demonstrate high potential for competitiveness and growth



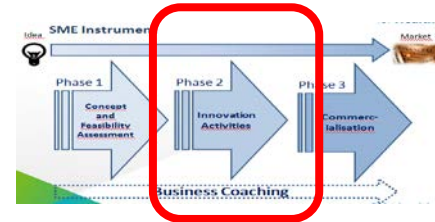
## Phase 2: Innovation Activities



### ■ Activities:

- Demonstration
- Testing
- Prototyping
- Clinical studies
- Piloting
- Scaling-Up
- Miniaturisation
- Design
- Market replication

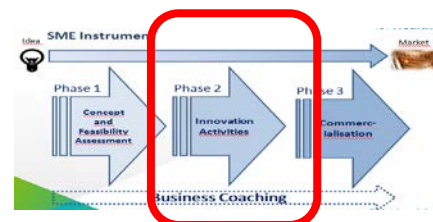
## Phase 2: Innovation Activities



### ■ Results:

- Development of new product, process, service that can be deployed and launched on the market
- Business plan containing detailed commercialisation strategy, financing plan explaining the investment of private investors

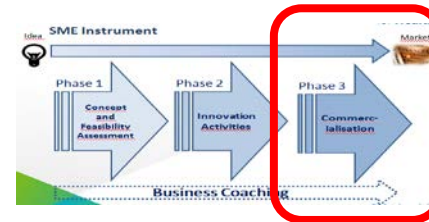
## Phase 2: Innovation Activities



- **Duration:**  
1-2 years (could be longer if desired and justified)
- **Time to grant:**  
About 6 months
- **Success rate:**  
About 30-50% (estimation!)
- **Funding:**  
70 % funding rate: 0.5-2.5 Mio €

**ATTENTION:** exception for 1 topic in “Health, demographic change and wellbeing: **100% funding rate**, funding up to 5 Mio €

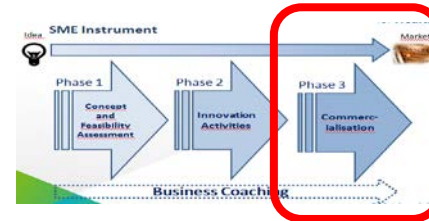
## Phase 3: Commercialisation



### ■ Objectives:

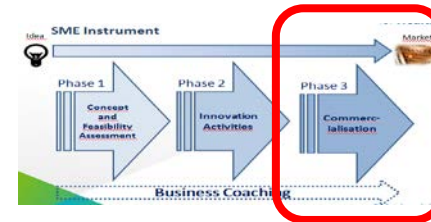
- Promote the implementation and successful commercialisation of the new innovative solutions
- Facilitated access to private capital and first customers
- SME instrument as quality label for successful projects

## Phase 3: Commercialisation

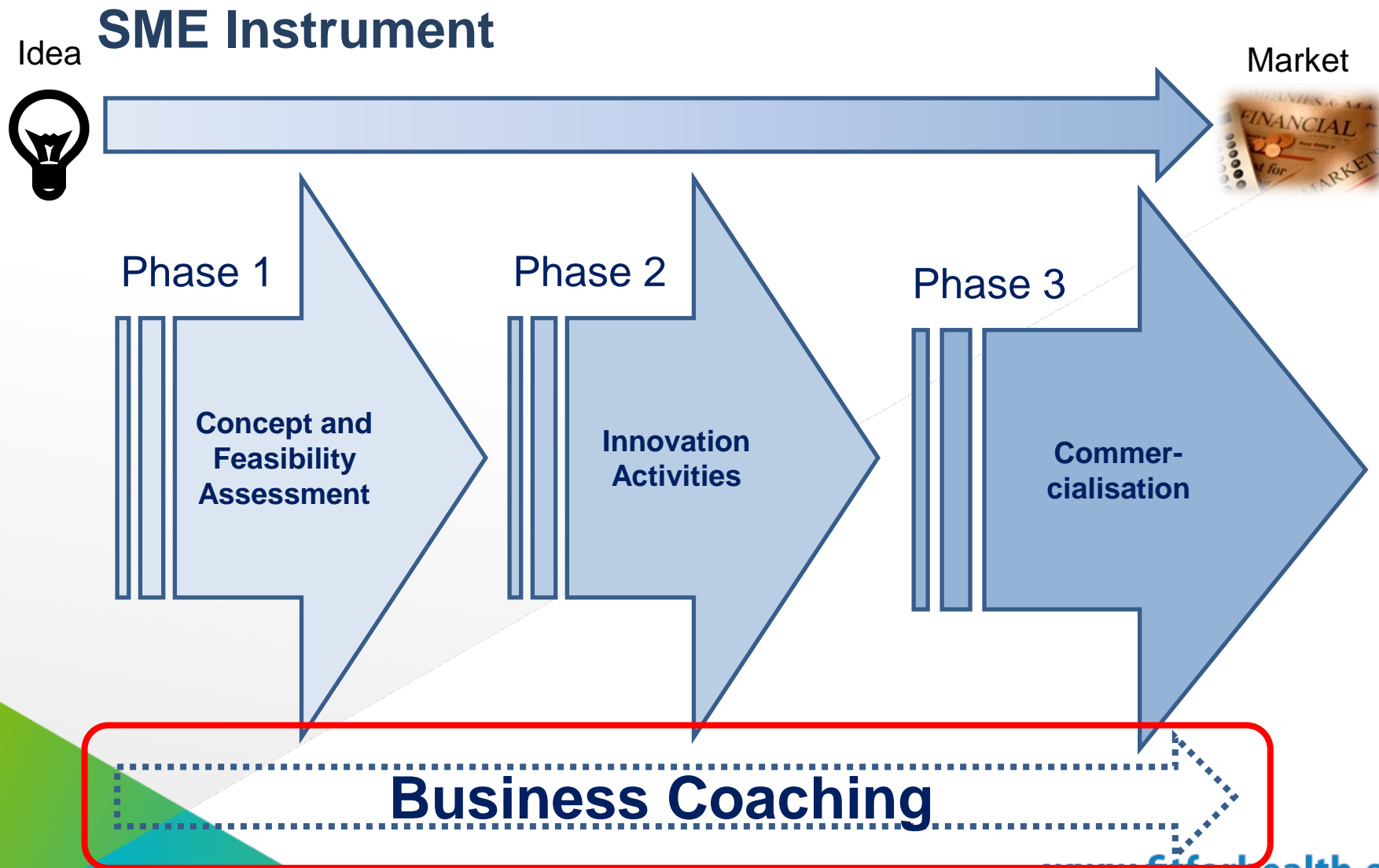


- **Activities:**  
Support via
  - networking
  - training
  - information
  - addressing i.a. IP management
  - knowledge sharing
  - dissemination
- SME window in the EU financial facilities (debt facility and equity facility)
- Possible connection to Procurement

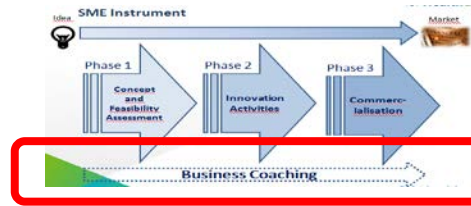
## Phase 3: Commercialisation



- **Results:**
  - No direct funding, but benefit from indirect support measures
- **Funding:**
  - Place new product, service, process on the market



# Business Coaching



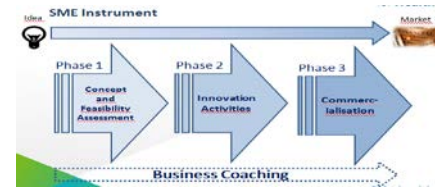
- **Voluntary business coaching** offered in Phase 1 and Phase 2:
  - Phase 1: 3 coaching days
  - Phase 2: 12 coaching days
- Business coaches will drive the performance of the organization by working with the senior management team
- Coach selection from a pool offered by the EC
- Coach and SME to decide a coaching plan in Phase 1. A summary of coaching foreseen for Phase 2 will form part of the application to Phase 2
- Coaching paid in addition to Phase 1 and Phase 2 contribution



# SME Instrument



## Additional Considerations



- No obligation to sequentially cover all the phases
- Linear process is strongly recommended
- Number of applications / projects: no concurrent submission or implementation with another phase 1 or phase 2 project (neither as lead (single) applicant nor as partner in a consortium)

# Content

1. What is the concept?
- 2. Who should apply?**
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## Who should apply – the target group

- Innovative for-profit SMEs showing a **strong ambition to develop, grow and internationalise**
- **Single company** support is possible or **consortium of for-profit SMEs**
- Highly competitive, market-oriented, EU dimension
- **Other partners** (research providers like universities and research institutes, large companies etc.) can be involved as third parties (**subcontractors**)
- SMEs need to be **established** in the EU-member states or associated countries

## ***The SME definition from the European Commission since 01/01/2005:***

- enterprise with interest in business and commerce
- employs fewer than 250 persons
- annual turnover does not exceed EUR 50 million or annual balance-sheet total does not exceed EUR 43 million
- autonomous



### ***Complete definition:***

***<http://europa.eu/scadplus/leg/en/lvb/n26026.htm>***

### ***Guide:***

***[http://ec.europa.eu/enterprise/policies/sme/files/sme\\_definition/sme\\_user\\_guide\\_en.pdf](http://ec.europa.eu/enterprise/policies/sme/files/sme_definition/sme_user_guide_en.pdf)***

## Who should apply – the target group

- **Start-ups:**

Companies without a balance sheet are legally not excluded, but the SME Instrument is not foreseen as support to create and bring up a company but to increase the growth potential from already established ones

→ ***Not the project as such but the project implemented by the company will be evaluated!***

# Content

1. What is the concept?
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# Structure of Horizon 2020



Source: [www.eubuero.de](http://www.eubuero.de). Simplified nomenclature

# SME instrument topics

## Participant Portal

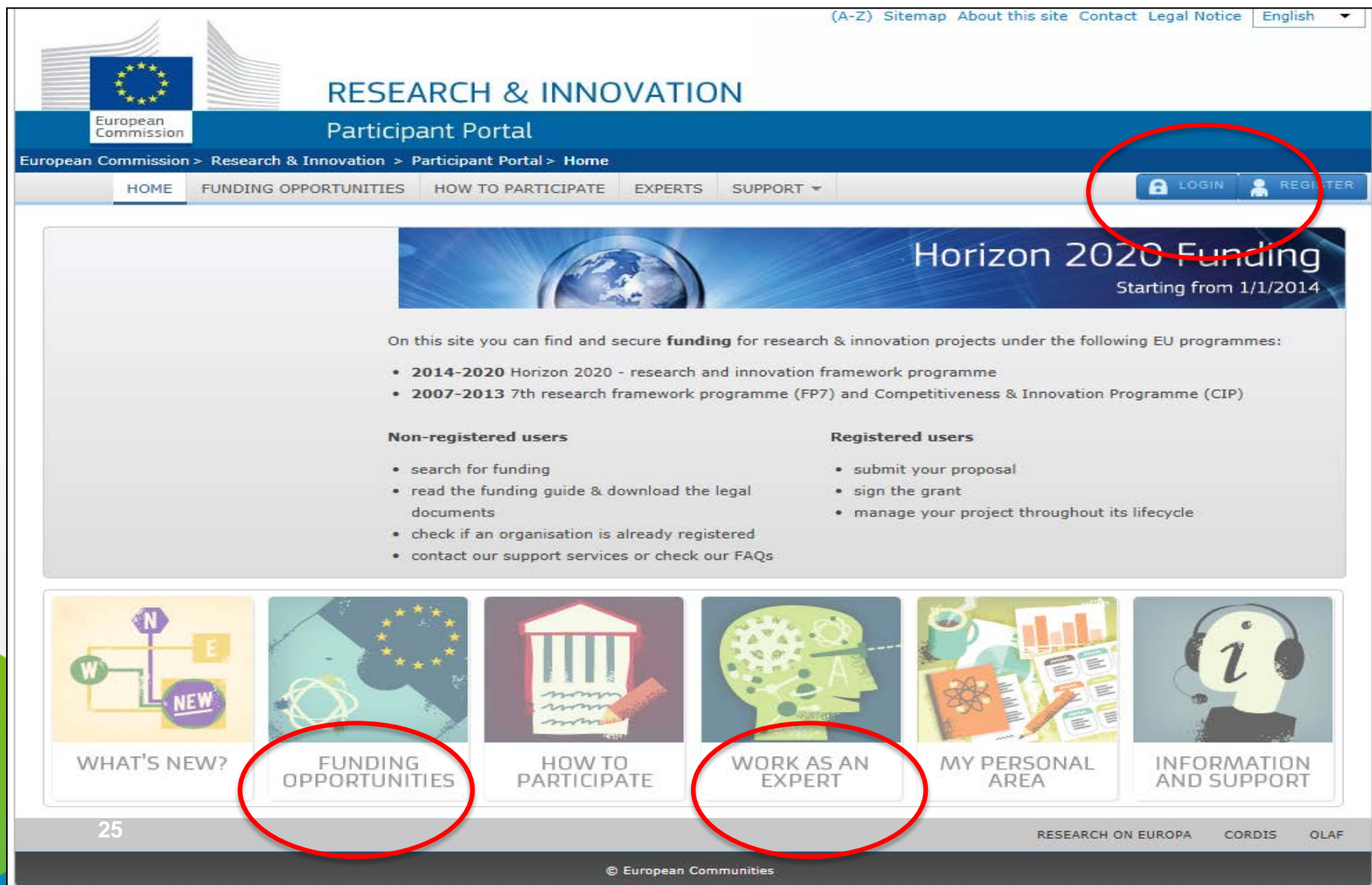
- Communication with the EC starting from your submission until the implementation
- Whole life cycle of a project is shown
- **Services:**
  - Overview about funding opportunities
  - Guidelines and documents
  - Services how to manage your projects
  - Register as an expert



<http://ec.europa.eu/research/participants/portal/desktop/en/home.html>

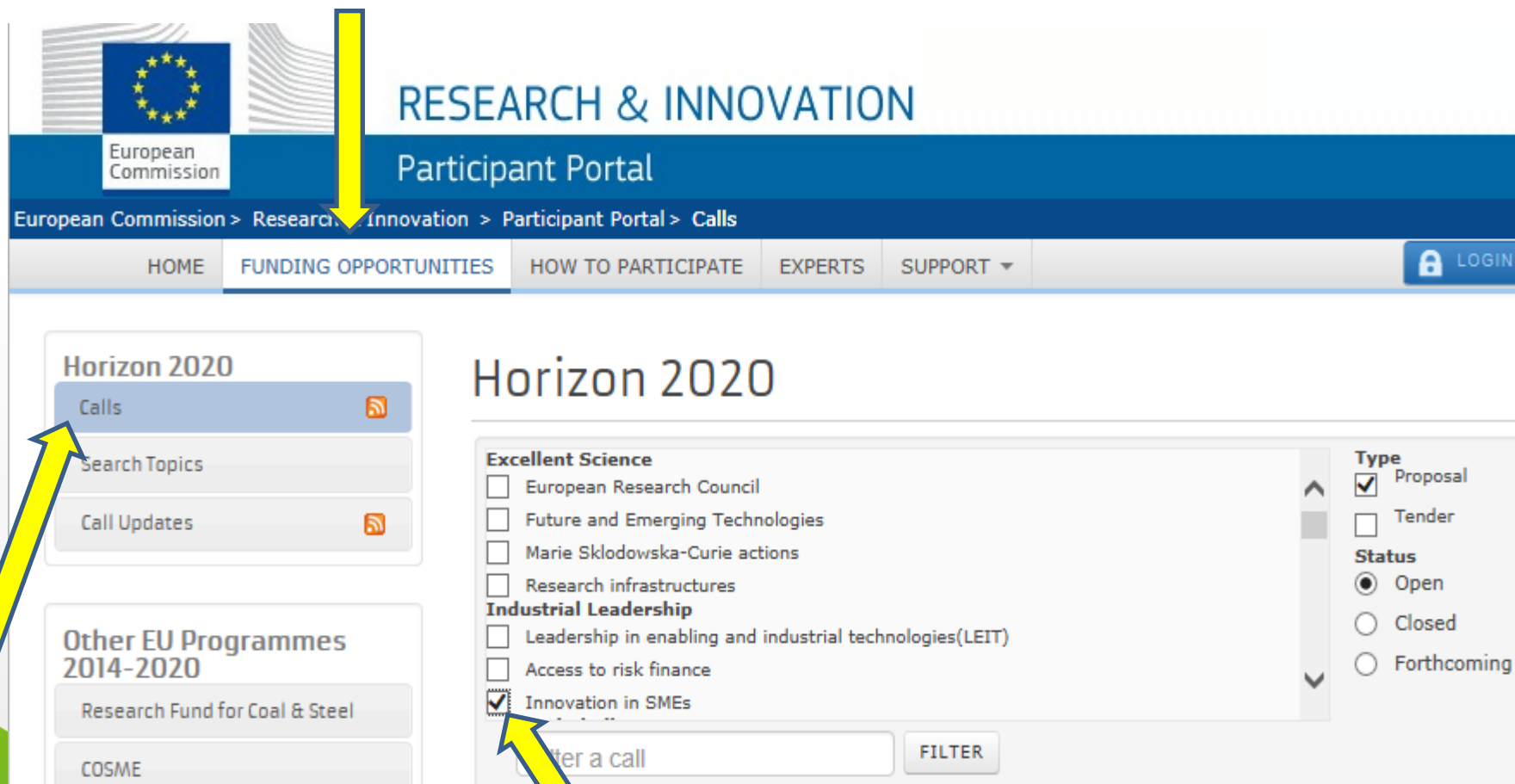


# Participant Portal: One - Stop Shop



The screenshot shows the Participant Portal website interface. At the top right, there are links for (A-Z) Sitemap, About this site, Contact, Legal Notice, and a language dropdown set to English. The main header features the European Commission logo and the text "RESEARCH & INNOVATION Participant Portal". Below this is a breadcrumb trail: "European Commission > Research & Innovation > Participant Portal > Home". A navigation menu includes "HOME", "FUNDING OPPORTUNITIES", "HOW TO PARTICIPATE", "EXPERTS", and "SUPPORT". On the right side of the navigation menu, there are "LOGIN" and "REGISTER" buttons, both of which are circled in red. The main content area has a banner for "Horizon 2020 Funding Starting from 1/1/2014". Below the banner, it states: "On this site you can find and secure **funding** for research & innovation projects under the following EU programmes:" followed by a list: "• 2014-2020 Horizon 2020 - research and innovation framework programme" and "• 2007-2013 7th research framework programme (FP7) and Competitiveness & Innovation Programme (CIP)". There are two columns of user instructions: "Non-registered users" (search for funding, read the funding guide, check registration, contact support) and "Registered users" (submit proposal, sign grant, manage project lifecycle). At the bottom, there is a row of six icons with labels: "WHAT'S NEW?", "FUNDING OPPORTUNITIES", "HOW TO PARTICIPATE", "WORK AS AN EXPERT", "MY PERSONAL AREA", and "INFORMATION AND SUPPORT". The "FUNDING OPPORTUNITIES" and "WORK AS AN EXPERT" icons are circled in red. The footer contains the number "25", the text "RESEARCH ON EUROPA CORDIS OLAF", and the copyright notice "© European Communities".

# SME instrument topics



The screenshot shows the 'Participant Portal' for 'RESEARCH & INNOVATION'. The breadcrumb trail is 'European Commission > Research & Innovation > Participant Portal > Calls'. The navigation menu includes 'HOME', 'FUNDING OPPORTUNITIES', 'HOW TO PARTICIPATE', 'EXPERTS', and 'SUPPORT'. A 'LOGIN' button is in the top right.

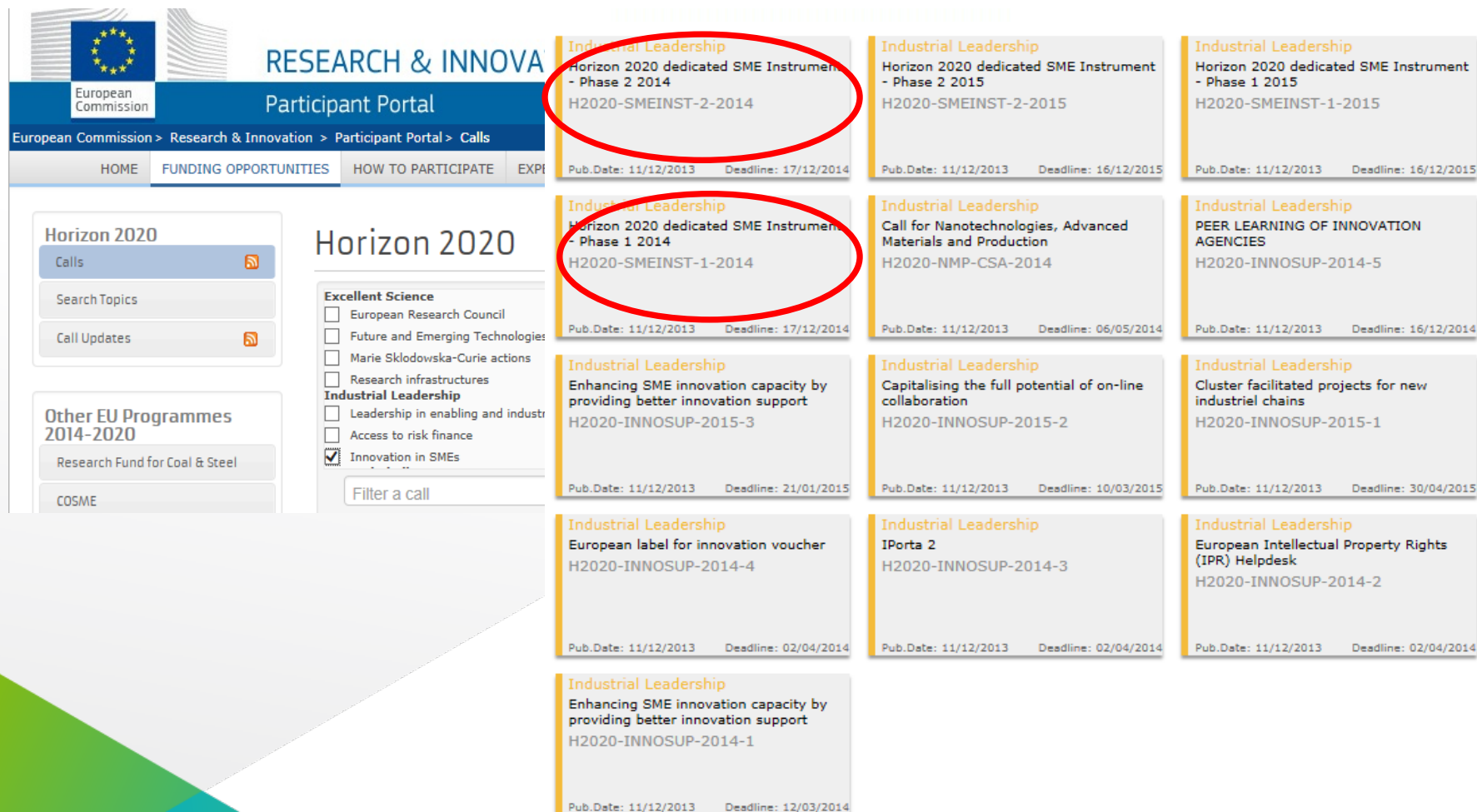
On the left sidebar, under 'Horizon 2020', the 'Calls' link is highlighted with a yellow arrow. Below it are 'Search Topics' and 'Call Updates'. Under 'Other EU Programmes 2014-2020', 'Research Fund for Coal & Steel' and 'COSME' are listed.

The main content area is titled 'Horizon 2020' and contains a list of funding topics. A yellow arrow points to the 'Innovation in SMEs' option, which is checked. The list includes:

- Excellent Science**
  - European Research Council
  - Future and Emerging Technologies
  - Marie Skłodowska-Curie actions
  - Research infrastructures
- Industrial Leadership**
  - Leadership in enabling and industrial technologies (LEIT)
  - Access to risk finance
  - Innovation in SMEs

On the right, there are filters for 'Type' (Proposal checked, Tender unchecked) and 'Status' (Open selected, Closed and Forthcoming unselected). A 'FILTER' button is at the bottom right of the list.

# SME instrument topics



The screenshot displays the Horizon 2020 Participant Portal interface. The top navigation bar includes 'HOME', 'FUNDING OPPORTUNITIES', 'HOW TO PARTICIPATE', and 'EXPLORE'. The main content area is titled 'Horizon 2020' and features a sidebar with filters for 'Excellent Science' and 'Industrial Leadership'. The 'Industrial Leadership' section is expanded, showing a list of calls. Two calls are circled in red:

- Industrial Leadership**  
Horizon 2020 dedicated SME Instrument - Phase 2 2014  
H2020-SMEINST-2-2014  
Pub.Date: 11/12/2013 Deadline: 17/12/2014
- Industrial Leadership**  
Horizon 2020 dedicated SME Instrument - Phase 1 2014  
H2020-SMEINST-1-2014  
Pub.Date: 11/12/2013 Deadline: 17/12/2014

Other visible calls include:

- Industrial Leadership**  
Horizon 2020 dedicated SME Instrument - Phase 2 2015  
H2020-SMEINST-2-2015  
Pub.Date: 11/12/2013 Deadline: 16/12/2015
- Industrial Leadership**  
Horizon 2020 dedicated SME Instrument - Phase 1 2015  
H2020-SMEINST-1-2015  
Pub.Date: 11/12/2013 Deadline: 16/12/2015
- Industrial Leadership**  
Call for Nanotechnologies, Advanced Materials and Production  
H2020-NMP-CSA-2014  
Pub.Date: 11/12/2013 Deadline: 06/05/2014
- Industrial Leadership**  
PEER LEARNING OF INNOVATION AGENCIES  
H2020-INNOSUP-2014-5  
Pub.Date: 11/12/2013 Deadline: 16/12/2014
- Industrial Leadership**  
Enhancing SME innovation capacity by providing better innovation support  
H2020-INNOSUP-2015-3  
Pub.Date: 11/12/2013 Deadline: 21/01/2015
- Industrial Leadership**  
Capitalising the full potential of on-line collaboration  
H2020-INNOSUP-2015-2  
Pub.Date: 11/12/2013 Deadline: 10/03/2015
- Industrial Leadership**  
Cluster facilitated projects for new industrial chains  
H2020-INNOSUP-2015-1  
Pub.Date: 11/12/2013 Deadline: 30/04/2015
- Industrial Leadership**  
European label for innovation voucher  
H2020-INNOSUP-2014-4  
Pub.Date: 11/12/2013 Deadline: 02/04/2014
- Industrial Leadership**  
IPorta 2  
H2020-INNOSUP-2014-3  
Pub.Date: 11/12/2013 Deadline: 02/04/2014
- Industrial Leadership**  
European Intellectual Property Rights (IPR) Helpdesk  
H2020-INNOSUP-2014-2  
Pub.Date: 11/12/2013 Deadline: 02/04/2014
- Industrial Leadership**  
Enhancing SME innovation capacity by providing better innovation support  
H2020-INNOSUP-2014-1  
Pub.Date: 11/12/2013 Deadline: 12/03/2014

## SME Instrument Life Sciences Themes

### *Health:*

- PHC 12 – 2014/2015: Clinical research for the validation of biomarkers and/or diagnostic medical devices

100% funding

### *Food:*

- SFS-8-2014/2015: Resource-efficient eco-innovative food production and processing
- BG-12-2014/2015: Supporting SMEs efforts for the development - deployment and market replication of innovative solutions for blue growth

70% funding

### *Biotech:*

- BIOTEC 5 – 2014/2015: SME-boosting biotechnology-based industrial processes driving competitiveness and sustainability

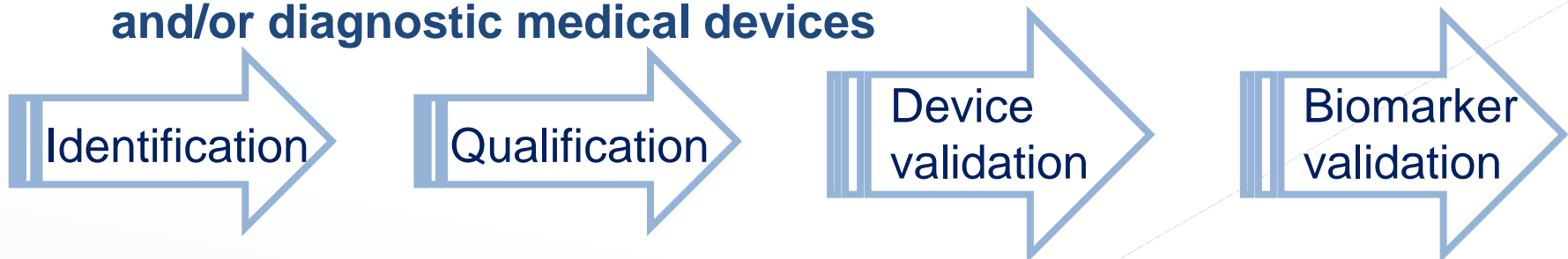
70% funding

# SME instrument topics

- **ICT 37 – 2014-15:** Open disruptive innovative scheme
- **NMP 25 – 2014-15:** Accelerating the uptake of nanotechnologies, advanced materials or advanced manufacturing and processing technologies by SMEs
- **H2020-SME-SPACE-2014-15**
- **SIE 1 – 2014-15:** Stimulating the innovation potential of SMEs for a low carbon and efficient energy system
- **IT.1-2014-15:** Small business innovation research for transport
- **DRS-17-2014-15:** Protection of urban soft targets and urban critical infrastructures
- **SC5-20-2014-15:** Boosting the potential of small businesses for eco-innovation and a sustainable supply of raw materials

# SME instrument topics

## PHC 12 – 2014-15: Clinical research for the validation of biomarkers and/or diagnostic medical devices



- All **existing potential biomarkers** (prediction, diagnostic, prognostic, monitoring, toxicity, end-point, etc.).
- Both **in vivo and in vitro** potential biomarkers are eligible.
- Preference will be given to the validation of **disease-related biomarkers** (i.e. diagnostic, susceptibility/risk, monitoring and prognostic biomarkers), but drug biomarkers are not excluded.
- Validation of the performance of **new diagnostic devices** (either in combination with the biomarker validation, or against existing standards).



# SME instrument topics

## PHC 12 – 2014-15: Clinical research for the validation of biomarkers and/or diagnostic medical devices – **BACKGROUND**

- Global market for diagnostics is in expansion, in particular for biomarkers
- 90% of the companies in the sector are SMEs
- **R&D bottleneck:** around 25.000 biomarkers identified each year that are in most cases not validated -> market failure with insufficient investments
- The Commission has published a **proposal for a regulation on in vitro diagnostic medical devices** -> this will change substantially the regulatory environment and it will request further clinical evidence.

# SME instrument topics

## PHC 12 – 2014-15: Clinical research for the validation of biomarkers and/or diagnostic medical devices – DEFINITIONS

- A **biomarker** is a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention (*NHI Biomarkers Definitions Working Group; 2001*)
- A **valid biomarker** is defined as “a biomarker that is measured in an analytical test system with well-established performance characteristics and for which there is an established scientific framework or body of evidence that elucidates the physiologic, toxicological, pharmacologic, or clinical significance of the test results (*FDA. Guidance for industry - pharmacogenomic data submissions. 2005*)



# SME instrument topics

## PHC 12 – 2014-15: Clinical research for the validation of biomarkers and/or diagnostic medical devices – **REGULATION PROCESS**

- **"Performance of a device"** means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting the intended purpose of the device. *(IVD & medical device regulation proposals)*
- **"Analytical performance"** means the ability of a device to correctly detect or measure a particular analyte. *(IVD regulation proposal)*
- **"Clinical performance"** means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological state in accordance with the target population and intended user. *(IVD regulation proposal)*

# SME instrument topics

## PHC 12 – 2014-15: Clinical research for the validation of biomarkers and/or diagnostic medical devices – **EXPECTED IMPACT**

- Increased clinical availability and exploitation of biomarkers
- New diagnostic devices
- Facilitation of entry of improved diagnostics in the clinic and the market
- Support for the implementation of the EC proposal for a revised in vitro diagnostic devices regulation
- Enhancing profitability and/or growth performance of SMEs
- Contribution to the sustainability of health care systems
- Increased likelihood of market uptake
- Leveraging of private investment

# Content

1. What is the concept?
2. Who should apply?
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# Applications for phase 1

Your proposal consists of 2 parts:

- On-line administrative forms – **Part A**
- Upload descriptive part – **Part B** (2 pdf files)

# Applications for phase 1 – Part B

## Templates for the applications in phase 1 and 2

- Specific templates are available on the participant portal:



[http://ec.europa.eu/research/participants/data/ref/h2020/call\\_ptef/pt/h2020-call-pt-sme-1\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/call_ptef/pt/h2020-call-pt-sme-1_en.pdf)

- As soon as you are registered with a project you will be able to download the word documents to insert your text

# Applications for phase 1 – Part B

1. EXCELLENCE

2. IMPACT

3. IMPLEMENTATION

**Attention:**

Page limit: cover page, sections 1, 2 & 3, together **not longer than 10 pages!** The 2 tables in these sections must be included within this limit!

4. MEMBERS OF THE CONSORTIUM

5. ETHICS AND SECURITY

not covered by the page limit!

# Applications for phase 1

## Cover page

### COVER PAGE

**Title of Proposal**

**List of participants**

<b>Participant No *</b>	<b>Participant organisation name</b>	<b>Country</b>
1 (Coordinator)		
2		
3		

\* Please use the same participant numbering as that used in the administrative proposal forms.

**Table of Contents**

# Applications for phase 1

## 1. EXCELLENCE

- 1.1 Objectives
- 1.2 Relation to the work programme
- 1.3 Concept and approach
- 1.4 Ambition



# Applications for phase 1

## 1. EXCELLENCE

- 1.1 Objectives
  - Objectives of your project: what is the expected outcome?
  - Objectives of your feasibility study:

**Business  
plan**

clear

measurable

realistic

achievable within the duration of the  
project

# Applications for phase 1

## 1. EXCELLENCE

- 1.2 Relation to the work programme
  - You are referring to the topic related to your proposal  
*e.g. PHC 12 – 2014/2015: Clinical research for the validation of biomarkers and /or diagnostic medical devices*

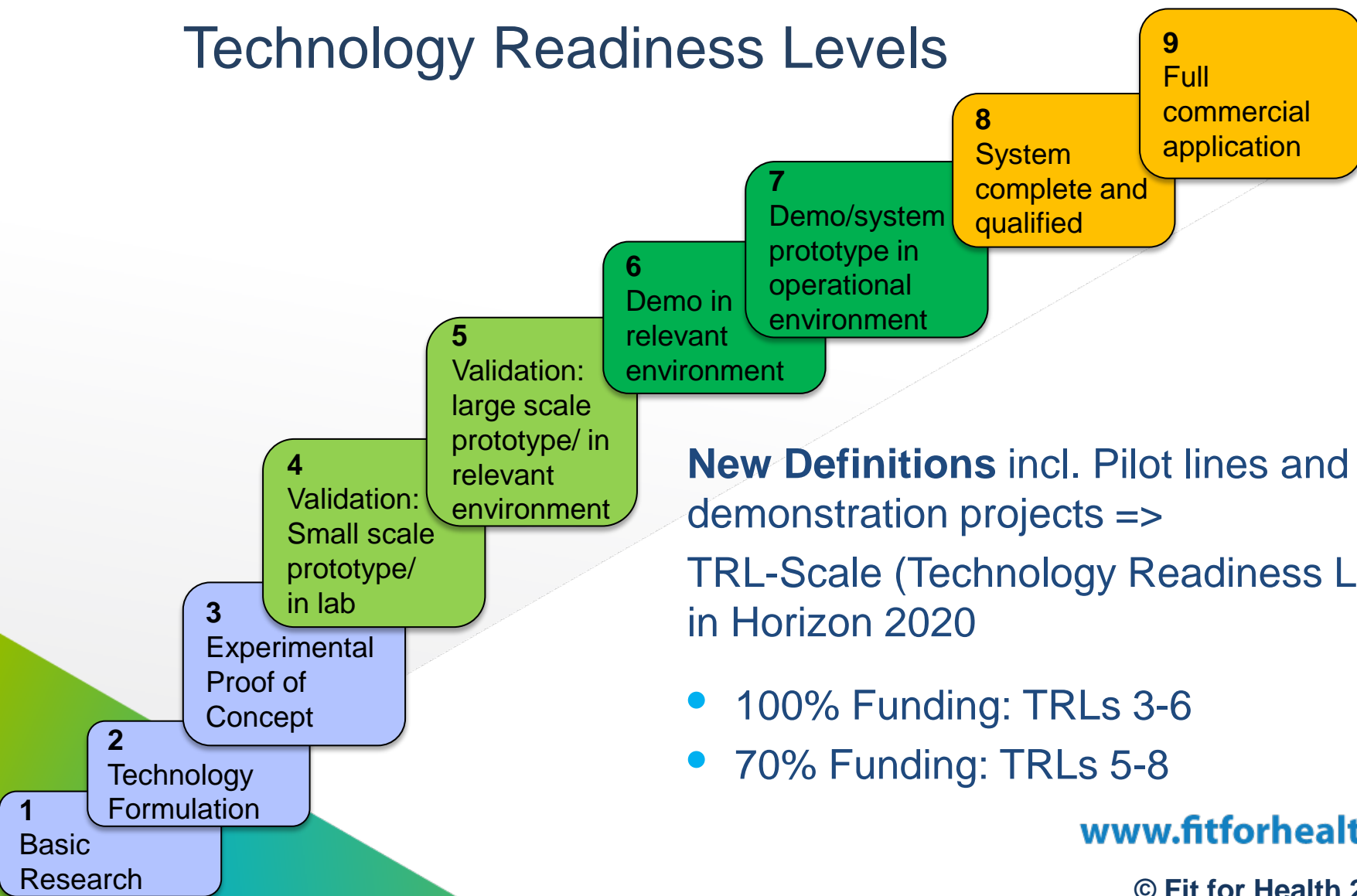
# Applications for phase 1

## 1. EXCELLENCE

- 1.3 Concept and approach
- How will your innovative solution solve the problem and/or use the business opportunity?
- What is the current stage of development of the innovation? What are key milestones that led to the current stage?
- Describe the positioning of the business innovation 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 (please see also in the General Annex G of the work programme)

# Applications for phase 1

## Technology Readiness Levels



**New Definitions** incl. Pilot lines and demonstration projects =>

TRL-Scale (Technology Readiness Levels) in Horizon 2020

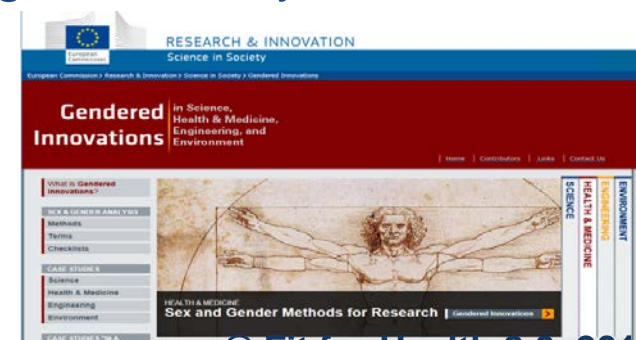
- 100% Funding: TRLs 3-6
- 70% Funding: TRLs 5-8

# Applications for phase 1

## 1. EXCELLENCE

- 1.3 Concept and approach
- What would you like to achieve in the feasibility assessment?
  - Explain the **approach and methodology**
  - Assessment of the **technological/technical/practical feasibility**
  - Assessment of the **economic viability**
- Describe how your project intends to **develop something new to Europe** that addresses EU-wide/global challenges
- Where relevant, describe how sex and/or gender analysis is taken into account in the project's content
  - e.g. for PHC12 important!

[http://ec.europa.eu/research/science-society/gendered-innovations/index\\_en.cfm](http://ec.europa.eu/research/science-society/gendered-innovations/index_en.cfm)



# Applications for phase 1

## 1. EXCELLENCE

- 1.4 Ambition
- Novelty of your innovation business project - what do you envisage as **key market application** of the innovation project result?
- What is the **advantage** of your (expected) solution with respect to competing solutions?
- Describe intended improvement potential over time - **why is it worth to develop / or to invest in it?**

# Applications for phase 1

## 2. IMPACT

- 2.1 Expected Impacts
  - a) Users/Market
  - b) Company
- 2.2 Measures to maximise impact
  - a) Dissemination and exploitation of results
  - b) Intellectual property, knowledge protection and regulatory issues

# Applications for phase 1

## 2. IMPACT

### ■ 2.1 Expected Impacts

#### ■ a) Users/Market:

- Who are the users of your product, service, etc?
- Main economic benefits for the users
- What are your unique selling points?
- Type of market: total available market size and growth rate (mature or growing market)? What are the market trends?
- List main competitors and competitive solutions



# Applications for phase 1

## 2. IMPACT

### ■ 2.1 Expected Impacts

#### ■ a) Users/Market:

- Most relevant market segments for initial introduction of the new solution
- Most important market barriers
- Targeted users of the final solution
- List key stakeholders to get involved for making a successful commercial exploitation

# Applications for phase 1

## 2. IMPACT

- 2.1 Expected Impacts

- b) Company:

- How does the innovation project fit with the ***strategy of the participating SME(s)***
- What is the relevance and rationale of the innovation project for the management team of the SME (or lead SME(s) in a consortium)
- Expected growth potential in terms of turnover, employment, market size, IP management, sales, return on investment and profit etc.

# Applications for phase 1

## 2. IMPACT

- 2.2 Measures to maximise impact

- *a) Dissemination and exploitation of results*

- Initial plan for full commercialisation of the project results, i.e. ***own commercialisation or licensing?***
- Need of ***cooperation with third parties*** for own commercialisation?
- Estimate of the ***total funding requirements?*** Approximate time to first sales/employment?
- How does the proposed work in Phase 1 of the SME instrument fit into the ***overall plan to reach the market?***

# Applications for phase 1

## 2. IMPACT

- 2.2 Measures to maximise impact
  - b) Intellectual property, knowledge protection and regulatory issues
- Explain key knowledge (*IPR*) items and who owns them
- Status and ***strategy for knowledge protection***: e.g. has a patent application already been filed or is there potential for patent application?
- ***Regulatory and/or standard requirements*** are to be fulfilled for the exploitation of the innovation

***IMPORTANT for PHC12!***

# Applications for phase 1

## 3. IMPLEMENTATION

- 3.1 Work plan – Work Package and deliverable
- 3.2 Management structure and procedures
- 3.3 Consortium as a whole
- 3.4 Resources to be committed

# Applications for phase 1

## 3. IMPLEMENTATION

### ■ 3.1 Work plan – Work Package and deliverable

Table 3.1 a: Work package description	
Work Package Title	Feasibility Study
Objectives	
Description of work (where appropriate, broken down into tasks), lead partner and role of participants	
Deliverable: Feasibility report, including a business plan (brief description and month of delivery)	

Table 3.1a:  
Work Package description

# Applications for phase 1

## 3. IMPLEMENTATION

- 3.2 Management structure and procedures
  - Organisational structure & the decision-making
  
- 3.3 Consortium as a whole (if applicable)
  - Describe the consortium: matching project's objectives, complementing each other (cover the value chain), contribution to the project, effectively work together

# Applications for phase 1

## 3. IMPLEMENTATION

- 3.4 Resources to be committed

	A. Costs of the feasibility study/Direct and indirect costs of the action	Total costs	Reimbursement rate %	Maximum EU contribution	Maximum grant amount
Form of costs	Lump sum				
	50 000	71 429	70 %	50 000	50 000

**Attention:** No modification is possible!



# Applications for phase 1

## 4. MEMBERS OF THE CONSORTIUM

- Description of the legal entity
- For consortia: main tasks of the project partner (how will his / her profile match the tasks in the proposal)
- **Curriculum vitae** or description of the profile of the persons, who will be primarily responsible for carrying out the proposed activities
- List of up to **5 relevant publications, and/or products, services**
- List of up to **5 relevant previous projects** or activities
- Description of any **significant infrastructure** and/or any major items of technical equipment
- In case of a newly created company, explain the purpose of the company creation

# Applications for phase 1

## 4. MEMBERS OF THE CONSORTIUM

- 4.2 Third parties involved in the project

Please complete, for each participant, the following table (or simply state "No third parties involved", if applicable)

Does the participant plan to subcontract certain tasks	Y/N
<i>If yes, describe and justify the tasks to be subcontracted</i>	

# Applications for phase 1

## 5. ETHICS AND SECURITY

### 5.1 ETHICS

Ethics issues have to be entered in the ethical issue table in the administrative proposal forms:

- submit an ***ethics self-assessment***
- provide the documents that you need ***under national law*** (if you already have them) e.g.
  - an ethics committee opinion
  - the document notifying activities raising ethical issues or authorising such activities

# Applications for phase 1

## 5. ETHICS AND SECURITY

### 5.2 SECURITY

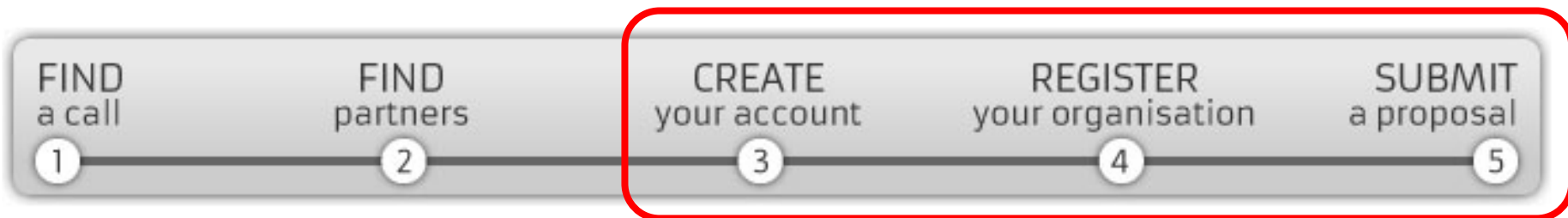
Please indicate if your project will involve:

- activities or results raising security issues: (YES/NO)
- 'EU-classified information' as background or results: (YES/NO)

# Content

1. What is the concept?
2. Who should apply?
3. Which topics are available?
4. How to prepare an application for phase 1?
- 5. Submission and evaluation procedure**
6. Accompanying support, further information and final recommendations

# Submission and Evaluation Procedure



## How to submit your proposal?



<https://ec.europa.eu/research/participants/portal/desktop/en/funding/index.html>

# Submission and Evaluation Procedure

## PARTICIPANT PORTAL

- Generate your proposal under “Submission Service”

Horizon 2020 dedicated SME Instrument - Phase 1 2014

H2020-SMEINST-1-2014 Sub call of: H2020-SMEInst-2014-2015

<b>Publication date</b>	2013-12-11	<b>Deadline Date</b>	2014-12-17 17:00:00 (Brussels local time)
		<b>Intermediate deadlines(s)</b>	2014-06-18 +17:00:00 (Brussels local time)
			2014-09-24 +17:00:00 (Brussels local time)
<b>Total Call Budget</b>	€25,102,000	<b>Main Pillar</b>	Industrial Leadership
<b>Status</b>	Open	<b>OJ reference</b>	OJ C361/9 of 11 December 2013
<b>Topic: Clinical validation of biomarkers and/or diagnostic medical devices</b>		<b>PHC-12-2014-1</b>	

Topic Description    Topic Conditions & Documents    **Submission Service**

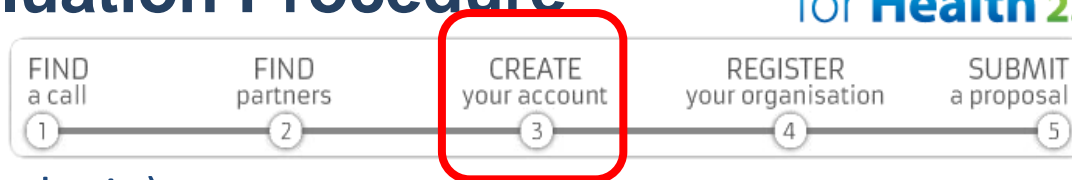
To access the Electronic Submission Service of the call, please select the **type of action** that is most relevant to your proposal from the list below. You will then be linked to the correct entry point.

To access existing draft proposals for this call, please login to the Participant Portal and select the My Proposals page of the My Area section

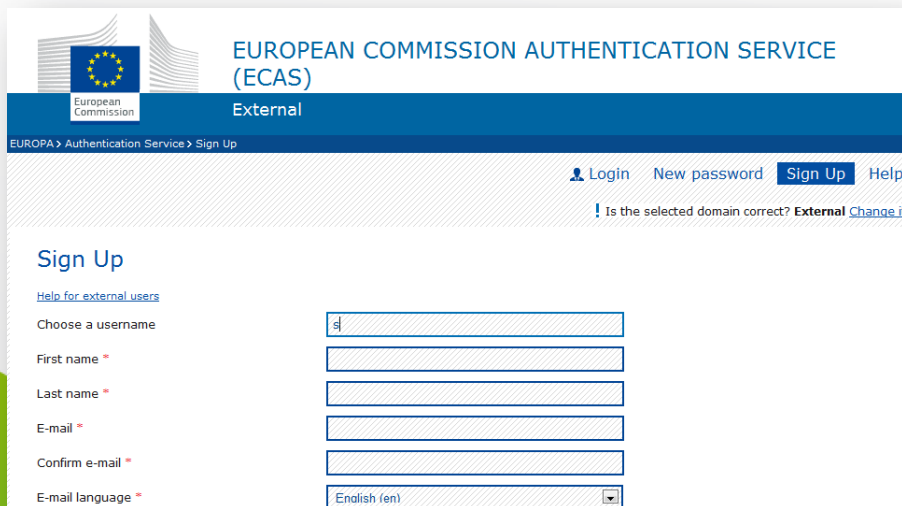
SME instrument phase 1 [SM]

<http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/index.html>

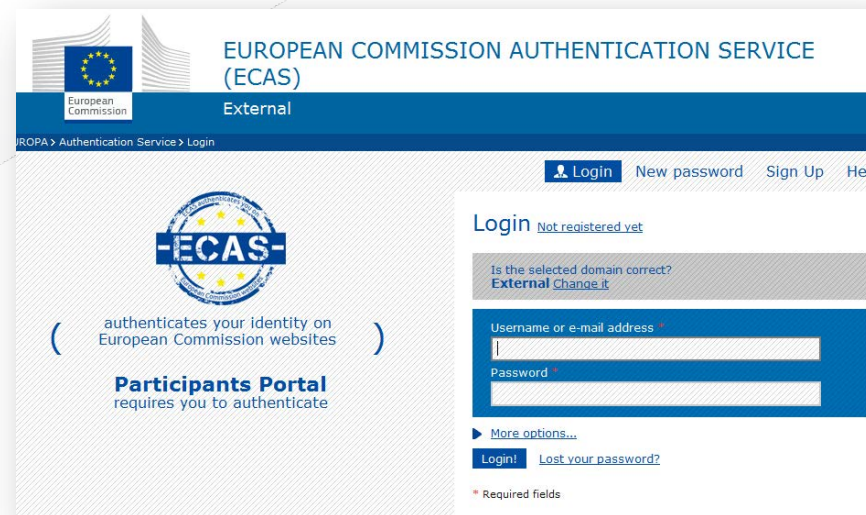
# Submission and Evaluation Procedure



- Create your account (or login)
- Registration via **ECAS** (European Commission Authentication Service)
- Authentication Service of the European Commission
- Single Sign in for all services on the Participant Portal



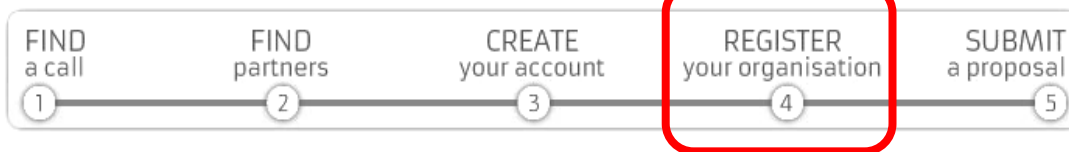
Sign up



Log in



# Submission and Evaluation Procedure



## Registration procedure

**RESEARCH & INNOVATION**  
Participant Portal H2020 Online Manual

- H2020 Online Manual
  - Your user account & roles
    - Login with ECAS
    - Roles & access rights
  - Grants
    - Applying for funding
      - Find a call
        - Horizon 2020 structure and budget
        - What you need to know about Horizon 2020 calls
      - Find partners or apply as individual
      - Register an organisation
        - Registration of organisation**
        - LEAR appointment
        - Validation of organisation
        - Financial viability self-check

**REGISTER AN ORGANISATION**

Registration of organisation → Validation of organisation → LEAR appointment / Financial viability self-check → Data update

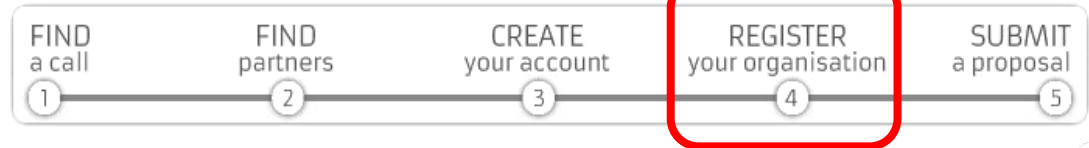
### Registration of organisation HOW TO

Before applying for research funding (by submitting a project proposal), all organisations (partners) involved in the project must first be registered with the Commission.

When an organisation **does not have legal personality**, his/her representatives must prove they have the capacity to undertake legal obligations on behalf of the organisation and that the organisation has financial and operational capacity equivalent to that of legal persons.

You can **check if your organisation is already registered** on the [Beneficiary Register](#) page.

# Submission and Evaluation Procedure



- An organisation that is registered and validated receives a Participant Identification Code (**PIC**)

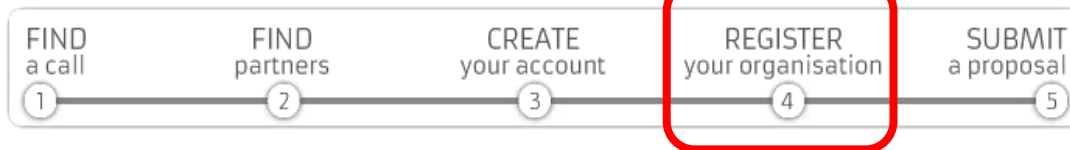
- Legal Entity Appointed Representative (**LEAR**):

- they are nominated from the organisation
- they can change data from their organisation and they have an overview about all proposals and projects of an organisation

**Attention:** Organisations who participated already in FP7 have a PIC!

**Attention:** Your PIC from FP7 will remain in Horizon 2020 but you need to be **validated as SME** to be able to submit a proposal!

# Submission and Evaluation Procedure



## Participant Identification Code (PIC)

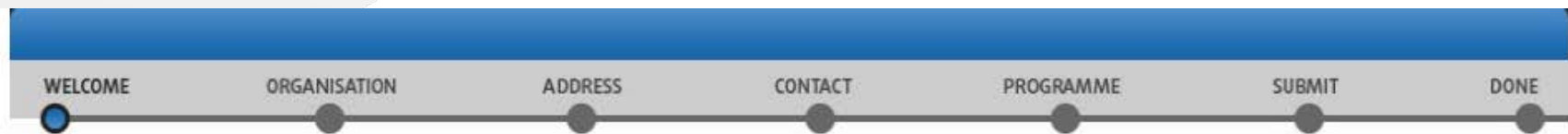
1. You are already registered in Horizon 2020 or you have participated in FP7 ? →

- Search for your organisation on the Participant Portal: Beneficiary Register

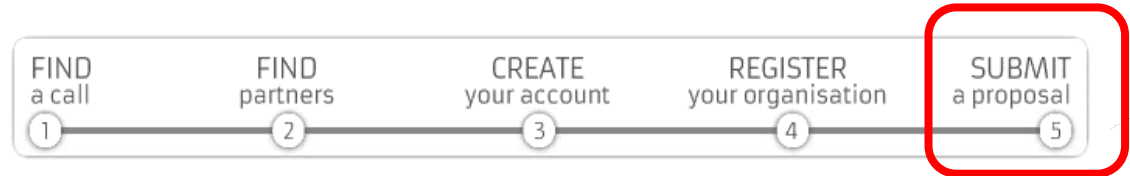


- <https://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html>

2. Your organisation is not yet registered? -



# The submission process



## Electronic Submission System

- Prepare the proposal:
  - On-line administrative forms – **Part A**
  - Upload descriptive part – **Part B** (2 pdf files)

# The submission process

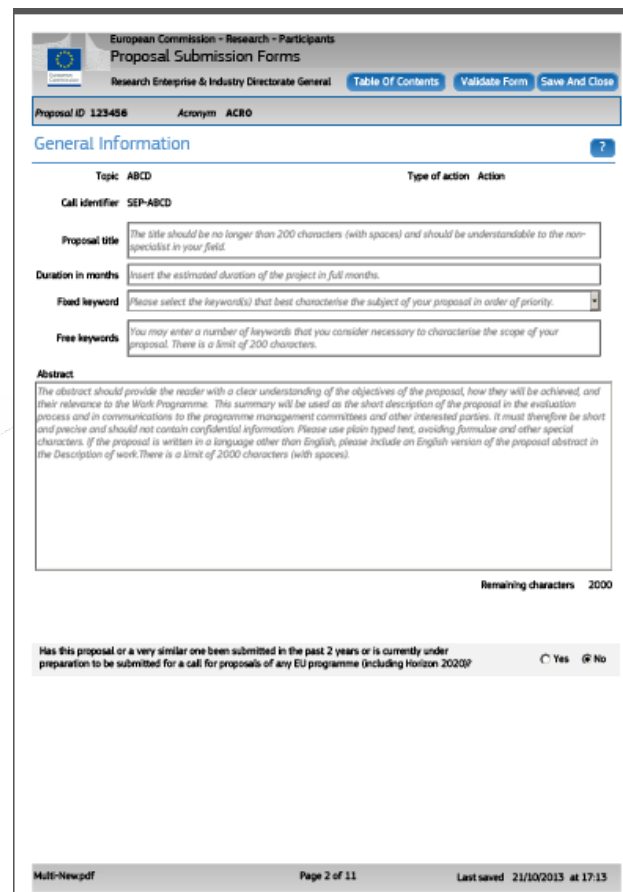
## ■ Part A – online

### Section 1

- Title, acronym, objective etc.
- Keywords
- 2000 character proposal abstract
- Previous/current submission
- Declarations

### Section 2 (one form per partner)

- Participant Identification Code (PIC)
- Department
- Dependences
- Contact information
- Other contact information



European Commission - Research - Participants  
Proposal Submission Forms

Research Enterprise & Industry Directorate General [Table Of Contents](#) [Validate Form](#) [Save And Close](#)

Proposal ID 123456 Acronym ACRO

#### General Information

Topic: ABCD Type of action: Action

Call identifier: SEP-ABCD

Proposal title:   
The title should be no longer than 200 characters (with spaces) and should be understandable to the non-specialist in your field.

Duration in months:   
Insert the estimated duration of the project in full months.

Fixed keyword:   
Please select the keyword(s) that best characterise the subject of your proposal in order of priority.

Free keywords:   
You may enter a number of keywords that you consider necessary to characterise the scope of your proposal. There is a limit of 200 characters.

Abstract

The abstract should provide the reader with a clear understanding of the objectives of the proposal, how they will be achieved, and their relevance to the Work Programme. This summary will be used as the short description of the proposal in the evaluation process and in communications to the programme management committees and other interested parties. It must therefore be short and precise and should not contain confidential information. Please use plain typed text, avoiding formulae and other special characters. If the proposal is written in a language other than English, please include an English version of the proposal abstract in the Description of work. There is a limit of 2000 characters (with spaces).

Remaining characters: 2000

Has this proposal or a very similar one been submitted in the past 2 years or is currently under preparation to be submitted for a call for proposals of any EU programme (including Horizon 2020)?  Yes  No

Multi-Newpdf Page 2 of 11 Last saved 21/10/2013 at 17:13

# The submission process

## Part A – online 2/2

### Section 3

- Cost and requested grant details

A. Costs of the feasibility study/Direct and indirect costs of the action		Total costs	Reimbursement rate %	Maximum EU contribution	Maximum grant amount
Form of costs	Lump sum				
	50 000	71 429	70 %	50 000	50 000

### Section 4

- Questionnaire on ethical issues & societal impact

### Section 5

- Call specific questions: clinical trial, Stage 2, SME Instrument, Open Data Pilot, etc.

# Applications for phase 1 – Part B

1. EXCELLENCE

2. IMPACT

3. IMPLEMENTATION

**Attention:**

Page limit: cover page, sections 1, 2 & 3, together **not longer than 10 pages!** The 2 tables in these sections must be included within this limit!

4. MEMBERS OF THE CONSORTIUM

5. ETHICS AND SECURITY

not covered by the page limit!

# The submission process

## What to consider?

- Don't wait until the Cut Off date with your submission
- Make your submission in due time
- Submission failure rate = + 1%
- Typical reason for failure when waiting till the last minute:
  - Technical problems
  - Panic-induced errors (uploading the wrong proposal)
  - Too late starting upload, run out of time

**IMPORTANT:** you can submit your proposal only ONCE!  
(big difference to other Calls!)



## Evaluation Procedure

- Open Call with **Cut Off Dates** -> proposals can be submitted at any time since 3 March 2014
- **Cut Off Dates:** 4 are planned / year (March, June, September, December) BUT in 2014 only 3!
- Evaluation starts on **1st April 2014**

2014		2015	
<u>Phase 1</u>	<u>Phase 2</u>	<u>Phase 1</u>	<u>Phase 2</u>
18/06/2014	09/10/2014	18/03/2015	18/03/2015
24/09/2014	17/12/2014	17/06/2015	17/06/2015
17/12/2014		17/09/2015	17/09/2015
		16/12/2015	16/12/2015

## Evaluation Procedure

- Evaluation is done **remotely**
- Evaluators with background on financing and business development (not necessarily THE experts in your thematic area!)
- No consensus meetings are foreseen
- Feedback to applicants: short & standardised
- Negotiations are not foreseen

# Evaluation Procedure - Criteria

## Excellence

Clarity of objectives

Soundness of the concept, Ambition

Progress beyond the state of the art

## Impact

Impacts listed in work programme

Enhancing innovation capacity

Strengthening the competitiveness

Dissemination & Exploitation

## Implementation

Coherence of work plan, Ressources

Complementarity of the consortium

Appropriateness of the management

## Evaluation criteria SME Instrument – Phase 1

Type of action	Excellence	Impact	Quality and efficiency of the implementation
	<i>The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the work programme.</i>	<i>The extent to which the outputs of the project should contribute at the European and/or International level to:</i>	<i>The following aspects will be taken into account:</i>
	4/5	4/5	4/5
Threshold: 13/15			

### SME Instrument Phase 2:

The threshold for Impact will be 4/5

The overall threshold will be 12/15

## Evaluation Procedure - Criteria

- **Ranking:** for Impact 1.5 weighting
- Identical „Scores“ -> higher score for impact is decisive
- The criterion Impact will be evaluated first, then Excellence and then Implementation

**IMPORTANT:** evaluation can be stopped if proposals fail to achieve a threshold for the ‚impact‘ criterion

# Evaluation Procedure

## SELF-EVALUATION FORMS

- Self-evaluation of your proposals by „independent experts“
- Criteria and forms are similar the documents of the evaluators



<p><b>1. Excellence</b></p> <p><i>Note: The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the work programme:</i></p> <ul style="list-style-type: none"><li>• Clarity and pertinence of the objectives;</li><li>• Credibility of the proposed approach;</li><li>• Soundness of the concept, including trans-disciplinary considerations, where relevant;</li><li>• Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art (e.g. ground-breaking objectives, novel concepts and approaches).</li></ul> <p><u>Comments:</u></p>	<p>Score 1: Threshold 3/5</p>
--	-----------------------------------

# Evaluation Procedure

## WHERE TO FIND IMPORTANT DOCUMENTS?

- Informationen about the evaluation process
- H2020 Grants Manual – Section „proposal submission & evaluation“
- Horizon 2020 Work Programme – General Annex Section H - Evaluation



[http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference\\_docs.html](http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html)

# Content

1. What is the concept?
2. Who should apply?
3. Which topics are available?
4. How to prepare an application for phase 1?
5. Submission and evaluation procedure
6. **Accompanying support, further information and final recommendations**



## Take home messages & recommendations

- Applications for the SME instrument only **for a minority of SMEs** ("Champions league" ) -> think about alternatives! (e.g. key word search in the Participant Portal)
- Check your SME-status in case of doubts!
- Will such a project fit into your long term strategy? Where do you see your company in 5 years?
- Why is it worth to invest in it?
- Who are your strategic partners?
- What are your unique selling points?
- Are you really visible to the scientific community? -> use portals like "Fit for Health 2.0" to increase your visibility and register with an expertise profile!

## Take home messages & recommendations

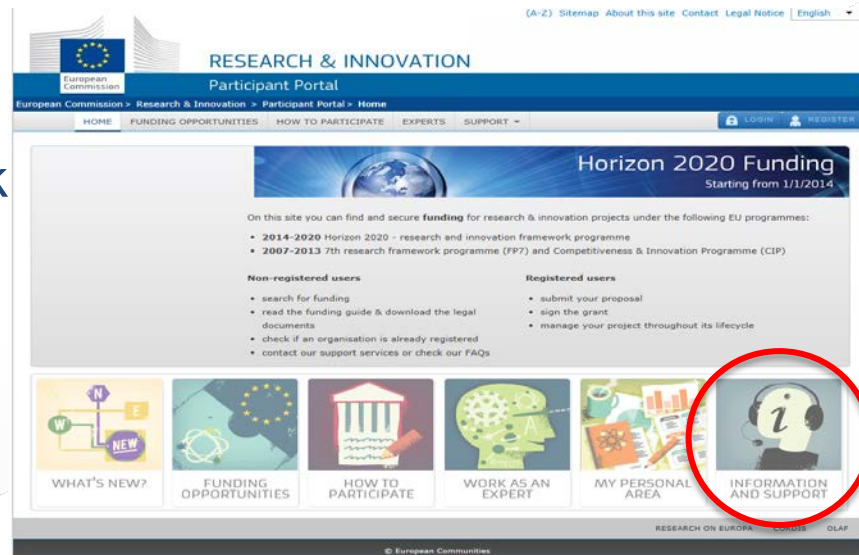
- Get familiar with the participant portal in time – it offers a lot of information!
- Start with your application in due time: keep within the page limits and don't wait until the Cut-off date with your submission
- In case that you are submitting a proposal as a consortium: think about the protection of your IP BEFORE starting to design the project
- Don't forget about ethical issues in case that this is of importance for your project
- Check if you need (again) to be validated as SME (your PIC from FP7 will remain in Horizon 2020 but might need to be validated)
- Use the documents available that help you to improve your application like the self-evaluation forms

# Take home messages & recommendations




- Use the advice offered by *support networks*:

- National Contact Points
- Enterprise Europe Network
- Horizon 2020 Helpdesk
- IT Helpdesk
- FAQ sections
- Initiatives like “Fit for Health 2.0”



## TAKE HOME MESSAGE

The best training is to become an expert evaluator yourself !



**Experts**

Join the database of independent experts

The European Commission appoints independent experts for research and innovation assignments including projects, and evaluation of programmes

<http://ec.europa.eu/research/participants/portal/desktop/en/experts/index.html>

## Further information

### Participant Portal

<http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/calls/h2020-smeinst-1-2014.html#tab1>

### EASME

[http://ec.europa.eu/easme/sme\\_en.htm](http://ec.europa.eu/easme/sme_en.htm)

### Intellectual Property Rights (IPR) Helpdesk

<http://www.iprhelpdesk.eu/>

## Further information

Health Directorate of DG RTD

[http://ec.europa.eu/research/health/index\\_en.html](http://ec.europa.eu/research/health/index_en.html)

In Vitro Diagnostic Regulation

[http://ec.europa.eu/health/medical-devices/documents/revision/index\\_en.htm](http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm)

Medical Device Regulation

[http://ec.europa.eu/health/medical-devices/documents/revision/index\\_en.htm](http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm)



FFG

Thank you!

Dr. Ines Haberl | Austrian Research Promotion Agency

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