

# HORIZON 2020

LE PROGRAMME DE RECHERCHE ET  
D'INNOVATION DE L'UNION EUROPÉENNE

**Réunion H2020 Santé, Toulouse – Midi-Pyrénées, Vendredi 17 juin 2016**

**« Les financements européens en sciences de la vie »**



MINISTÈRE  
DE L'ENSEIGNEMENT SUPÉRIEUR  
ET DE LA RECHERCHE

# Le système Horizon 2020

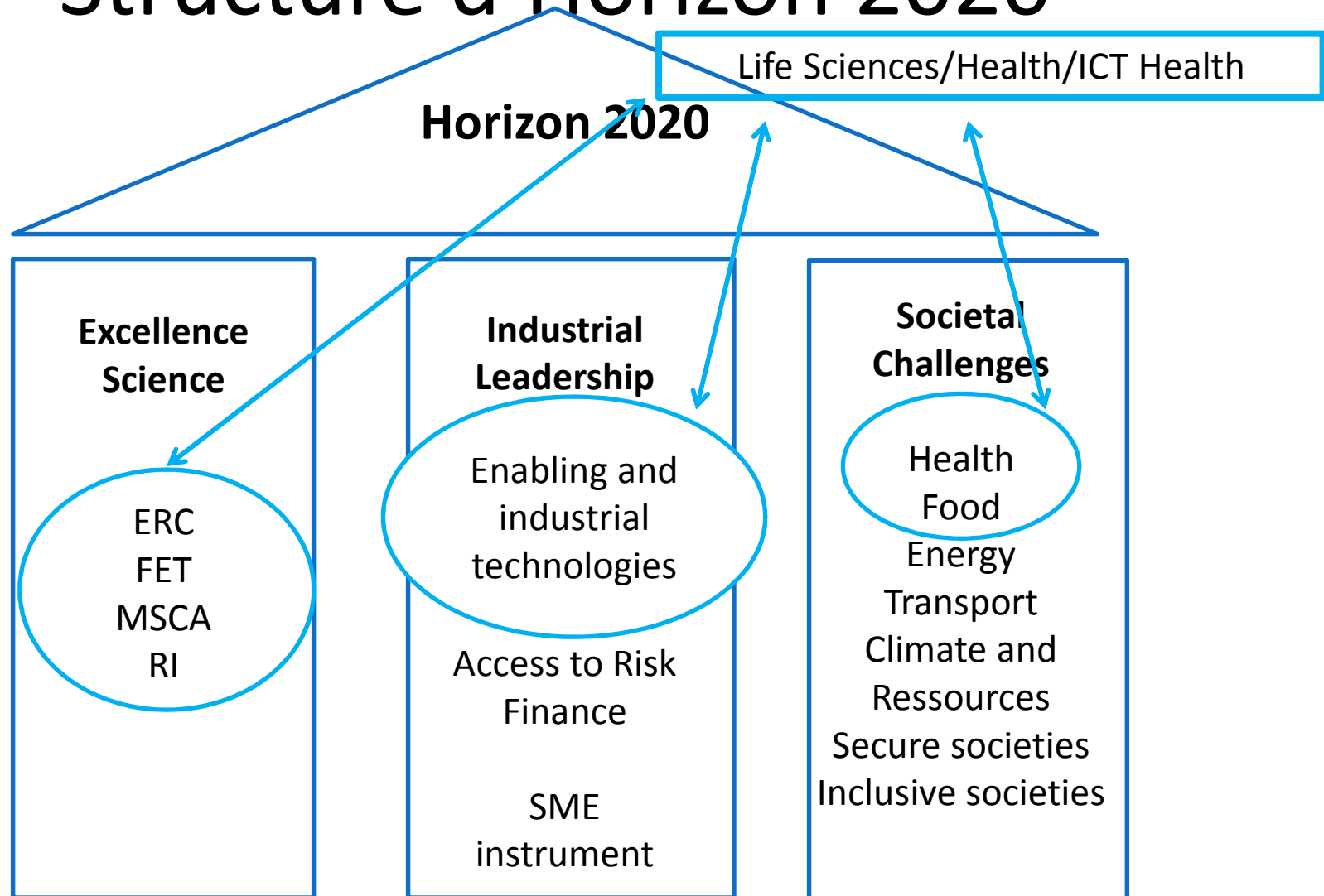




# Horizon 2020, c'est quoi ?

- Le programme principal pour le financement de la recherche & de l'innovation à l'échelle européenne ;
- Un budget de 80 milliards d'euros pour la période 2014-2020 ;
- Une contribution majeure à la stratégie "Europe 2020", à l'initiative "l'Union de l'Innovation" et à l' "Espace Européen de la Recherche" pour :
  - Répondre à la crise économique par un investissement dans les métiers futurs et la croissance ;
  - Prendre en compte les inquiétudes des citoyens concernant leur niveau de vie, leur sécurité et l'environnement ;
  - Renforcer la position de l'UE dans le monde dans les domaines de la recherche, de l'innovation et des technologies.

# Structure d'Horizon 2020



# Règles de participation

- Toute entité légale peut participer
- Consortium: 3 entités légales de 3 Etats-membres ou Etats associés différents (exception pour outils PME - mono bénéficiaire et action de coordination)
- Entités légales financées établies dans les Etats-membres ou Etats associés (pour les Etats tiers : participation certains pays cf liste ci-dessous –ou expressément prévu dans le programme de travail)

Exception santé: USA financés

[http://ec.europa.eu/research/participants/data/ref/h2020/grants\\_manual/hi/3cpart/h2020-hi-3cpart\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-3cpart_en.pdf)




# Règles de financement

- **Taux de financement des coûts directs éligibles**  
(Coûts de personnels (y compris statutaires),  
Consommables (HT si TVA récupérable)  
Amortissement (HT si TVA récupérable), Frais de mission,  
Frais de dissémination, Frais de parties tierces,  
Frais de sous-traitance..)  
TVA déductible éligible

**Taux de financement des coûts indirects éligibles**

**Forfait de 25% des coûts directs éligibles**

Topic ouvert	« Non-profit » organisations	Entreprises
Recherche et Innovation (RIA)	100%	100%
Innovation (IA)	100%	70%







## Excellence

- la clarté et la pertinence des objectifs
- la crédibilité de l'approche proposée
- le bien-fondé du concept, incluant la multidisciplinarité, si c'est pertinent
- le degré d'ambition du projet, le potentiel d'innovation, et jusqu'à quel point le projet va au de la de l'état de l'art

## Impact

- réaliser les impacts listés dans le programme de travail et sous le "topic" pertinent ;
- renforcer la compétitivité et la croissance des entreprises en développant des innovations répondant aux besoins des marchés européens et globaux
- prendre en compte les autres impacts environnementaux et sociétaux importants.
- mesure de dissémination convaincantes, en incluant la gestion des droits de propriétés intellectuelles et l'exploitation des résultats

## Qualité et efficacité de la mise en œuvre

- la cohérence et l'efficacité du plan de travail ("**workplan**"), incluant l'adéquation de la répartition des tâches et des ressources ;
- les compétences et expériences des participants et la complémentarité des participants individuellement, ainsi que du consortium dans son ensemble ;
- l'adéquation des structures de management et des procédures, en incluant la gestion des

# Mise en œuvre du Programme de travail

- Des appels basés sur des défis de société
  - Des topics plus larges, moins prescriptifs
  - Un accent accru sur l'interdisciplinarité
  - Un accent sur l'impact socio-économique du topic
- Étendre le spectre des participants, newcomers






# Un programme de travail pluriannuel

2014	2015	2016	2017	2018	2019	2020
Strategic Programme						
Work Programme 1		Strategic programme				
		Work Programme 2	Strategic Programme			
				Work Programme 3		
Call for proposal	Call for proposal	Call for proposal	Call for proposal	Call for proposal	Call for proposal	Call for proposal



## Contexte du défi Santé

- Changement démographique
-  Accroissement du fardeau des maladies non-transmissibles
- Augmentation du coût de la santé & de la pression sur les systèmes de santé
- Augmentation des coûts du développement des médicaments et vaccins
- Insuffisance de preuves des avantages et efficacité, des approches et pratiques actuelles

→ Favoriser l'innovation

→ Soutenir la recherche translationnelle

→ Volonté d'amplifier les réseaux de recherche existants

→ Réduire les inégalités dans le domaine de la santé

→ Promouvoir le vieillissement actif et en bonne santé



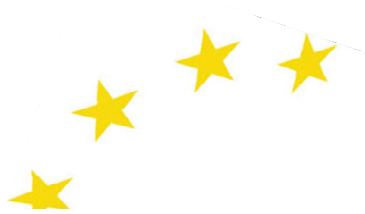


## Understanding health, well-being and disease

# Défi SANTE – WP 2016-2017 *Personalized Medicine (PM)*

Budg  
projet      Budget  
total      Type

PM	Year	Project Title	Budget projet	Budget total	Type
PM01	2016	<b><i>Multi omics for personalised therapies</i></b>	12-15	30	RIA
<div data-bbox="235 367 470 510" style="border: 2px solid red; padding: 5px; display: inline-block; transform: rotate(-2deg); color: red; font-weight: bold;">Closed</div> <p>Integrate and use high quality genome-epigenome-metabolome-microbiome data from large international initiative with innovative imaging, structural, lifestyle/environmental data + disease oriented analysis&gt;&gt;understanding health&amp;disease</p> <ul style="list-style-type: none"> <li>- Relevant biomarkers for clinical validation → targeted therapies for complex diseases.</li> <li>- International cooperation</li> </ul>					
PM02	2017	<b><i>New concepts in patient stratification</i></b>	4-6	40	RIA
<p>A majority of drugs effective in a limited n. of patients = New concepts for disease based PS for personalised interventions Integrate –omics, modelling, longitudinal data</p> <ul style="list-style-type: none"> <li>- to be validated in pre-clinical/clinical studies</li> <li>- Any disease (with high economic impact), except rare disease.</li> <li>- SMEs, patient associations, regulators</li> </ul>					
PM03	2017	<b><i>Diagnostic characterisation of rare diseases</i></b>	10-15	15	RIA
<p>Apply genomics or other-omics to molecular characterisation of undiagnosed RD. Lien IRDiRC. &gt;&gt;molecular diagnosis of large n. of RD</p> <ul style="list-style-type: none"> <li>- Genetic variability</li> <li>- Classification of RD: common standards &amp; terminologies , classif. Bioinfo tools (large scale project)</li> </ul> <p>Molecular/functional characterization to confirm diagnosis</p>					
PM04	2016	<b><i>Networking and optimising the use of population and patient cohorts at EU level</i></b>	8-10	30	RIA
<div data-bbox="235 1372 470 1516" style="border: 2px solid red; padding: 5px; display: inline-block; transform: rotate(-2deg); color: red; font-weight: bold;">Closed</div> <ul style="list-style-type: none"> <li>- Maximize exploitation of Population cohorts . Use ICT, new type of data &gt;&gt; provide knowledge on health disease determinants, course of disease etc</li> <li>- Link with INFRA, international initiatives- facilitate hypothesis-driven research</li> <li>- Support to Health policv</li> </ul>					



**Preventing disease**

Budget projet    Budg total    Type

PM06	2016	<i>Vaccine development for malaria and/or neglected infectious diseases</i>	3 à 5 15 à 20	40	RIA
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**preclinical and early clinical development of new vaccine candidates (antigens/adjuvants)**

**A) large platforms >>advances in vaccinology** (e.g. in silico analysis and novel in vitro and in vivo immunoscreens) or new approaches for the discovery and selection of novel, appropriately immunogenic antigens, and/or novel formulations/combinations for the generation of new vaccine candidates.

**B)** Include a systematic approach and define key gate-criteria for selection across each step of the research and development pipeline

**C) SMALLER PROPOSALS = focus on one disease or one vaccine candidate (similar innovative/comprehensive approach).**

- *Eligible: Malaria + 17 Neglected Tropical Diseases (WHO) + childhood diarrhoeal diseases and neglected viral emerging epidemic diseases. **Filoviral diseases EXCLUDED.***

- Utilization in poor resource settings (field logistics, high temp., costs, population behaviour)

- Link with mapping exercises on vaccine candidates + vaccine development roadmaps

- Link with EDCTP2 (clinical trials, Africa)

**Closed**

PM07	2017	<i>Promoting mental well-being in the young</i>	2-4	20	RIA
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- Population-oriented primary prevention interventions to promote mental well-b. Target group: up to 25 years.





- Build on biological, psychological and social determinant of mental well being such as cultural, work life, lifestyle, epidemio, economic, environmental

- Aim at increasing resilience and mitigating the impact of risk factors

- Multi-disciplinary approach.

- Includes the young themselves (empowerment) + relevant stakeholders

**Treating and managing diseases**

PM08	2017	<i>New therapies for rare diseases</i>	4-6	60	RIA
		<ul style="list-style-type: none"> <li>- Support will be provided to clinical trials on substances where orphan designation has been given by the European Commission (at the submission deadline)</li> <li>- from small molecule to gene or cell therapy, may include novel interventions and/or repurposing of existing and known interventions.</li> </ul>			
PM09	2016	<i>New therapies for chronic diseases</i>	4-6	60	RIA
 		<p>clinical trial(s), for chronic <b>non-communicable or chronic infectious diseases</b>                  &gt;&gt;supporting proof of concept of clinical safety and efficacy in humans <b>of novel therapies</b> (pharmacological as well as non-pharmacological) or the optimisation of available therapies (e.g. <b>repurposing</b>)</p> <ul style="list-style-type: none"> <li>- Preclinical research should be completed before the start</li> <li>- Rare diseases, regenerative medicine excluded</li> </ul>			
PM10	2017	<i>Comparing the effectiveness of existing healthcare interventions in the adult population</i>	4-6	40	RIA
		<p>Compare the use of currently <b>available preventative or therapeutic</b> (pharmacological as well as non-pharmacological) healthcare interventions in adults (elderly not excluded)</p> <ul style="list-style-type: none"> <li>- Address conditions that are : frequent, may lead to co-morbidities, have a high negative impact on the quality of life of the individual, high costs&gt;&gt; make recommendations</li> </ul> <p>Assessment of health and socio-economic outcomes (e.g. quality of life, patient mortality, morbidity, costs, and performance of the health systems)</p> <ul style="list-style-type: none"> <li>- costs-effectiveness analysis to be done</li> </ul>			
PM11	2016+2017	<i>Clinical research on regenerative medicine</i>	4-6	30	RIA
		<ul style="list-style-type: none"> <li>- Test NEW regenerative medicine therapies which are ready for clinical (in-patient) research focus on one specific clinical phase of work.</li> <li>- Any disease eligible if justified</li> <li>- include authorization to conduct clinical trials and ethical approvals or provide evidence of regulatory engagement and that such approval is close</li> </ul>			

**Active and healthy ageing**

PM12	2016	<b>PCP-eHealth innovation in empowering the hospitalised patient</b>	4	18	PCP
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PCP for R&D of new services / integration of existing services

Increasing the level of interactions between the user and the health professional, enabling users to control their health conditions and adhere to prescribed medical plans.

*Ex: telemedicines for follow-up of patient (chronic and rare diseases), e-mental health for patient empowerment, domestic rehabilitation (physical and cognitive) under remote professional supervision;*

Key documents: eHealth action plan 2012-2020 + mHealth green paper.



PM13	2016	<b>PPI for deployment and scaling up of ICT solutions for active and healthy ageing</b>	2-5	9	PPI
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= specify, purchase and deploy ICT-based solutions for active and healthy ageing

Key document: scaling-up road map of the EIP. Co-fund up to 40% of total costs



PM14	2016	<b>EU-JAPAN cooperation on novel ICT Robotics based solutions for active and healthy ageing at home or in care facilities.</b>	2-3	5	RIA
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Developing and demonstrating ICT robotics based solutions for extending active and healthy ageing

- multidisciplinary research (including behaviour/SSH)
- Modularity, cost-effectiveness, reliability, flexibility (=adaptation to needs & lifestyle of older people)
- Safety and acceptability
- Test site in EU and Japan, with sufficient users (for validating)
- Notion of spreading services (use of generalized infrastructure cloud systems, open source) + interoperability, standardization, open platforms, Internet of things approach
- Max 36 months, no other third country partner, consortium agreement



PM15	2017	<b>Personalised coaching for well-being and care of people as they age</b>	3-4	26	RIA
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= dvppt of radically new concept for a virtual coach (ex diet, physical activity, risk avoidance, leisure from a physical, mental and cognitive, and social point of view)

- Take into account gender and ethics aspects.
- User-centred. Cost-effectiveness.

## Methods and data

# Défi SANTE – WP 2016-2017 *Personalized Medicine (PM)*

PM16	2017	<u>In-silico trials</u> for developing and assessing <u>biomedical products</u>	4-6	19	RIA
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To simulate human physiology and physiopathology at the relevant biological level (ex cell, tissue, organism) and the interaction with the product

To take into account the variability between individuals (genetics, gender, microbiota etc)

To build virtual patients or populations for predicting tratments outcomes >>Personalised medicine

Multidisciplinary approach: computational modelling, systems biology, tissue mechanismes, biology, pharmaceutics, medicine

- To be included: simulated trials; measures for validation (human trials, animal studies, validation in the cell cutture)
- Contact with regulators
- Key document: Research and technological road map for in-silico trials.

PM17	2016	<b>Increasing digital security of health related data on a systemic level</b>	4-6	11	RIA
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= security related to storage and exchange (including cross-border) of health/personal data protection of personal data and data collected via mobiles

Based on existing projects: DECIPHER, open NCP, EPSOS, STORK.

- Legal & societal aspects (for deployment)
- Respect national regulation regarding data protection + standards
- To be at least tested in 3 EU MS. Anticipate the technological deployment in other countries

**Closed**

PM18	2017	Personalised computer models and in-silico systems for well-being	4-6	19	RIA
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= dvppt of computer models and simulations systems able to aggregate various informations (biochemical, imaging, medical, lifestyle, ...etc) into robust predictors for resilience and recovery

- Multiscale (time and spatial scales) approach; patient-specific
- Multidisciplinary : medicine, SSH and ICT
- Based on existing large database (clinical medicine, biomedical/ocupational research, environmental sciences and SSH

## Methods and data

# Défi SANTE – WP 2016-2017 Personalized Medicine (PM)

PM19	2016	Big Data supporting Public Health policies [CNECT]	3-5	10	RIA
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= Acquisition, management, sharing, modelling, processing and exploiting big data into integrated solutions to support to health policy (decision marking): ex combined effect of environment, lifestyle and genetics on public health

- Big data governance
- Security and privacy issues

Closed

PM20	2017	PPI for uptake of standards for the exchange of digitalised healthcare records [CNECT]		8,26	PPI
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EHealth interoperability

PM21	2017	Development of new methods and measures for improved economic evaluation and efficiency measures in the health sector		9	RIA
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To be developed in a future WS

## Health care provision and integrated care

PM22	2016	Implementation research for scaling-up of evidence based innovations and good practice	4-6	40	RIA
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- Based on implementation research concept = « *scientific study of methods to promote the uptake of research findings* ».
- Selected intervention to be scale up: to make health systems and services more responsive, person-centred, safe, effective and efficient. Large scope (in terms of content + geographical coverage)
- Gender issues & Multidisciplinary research
- Socio-eco-political analysis to be done + organization and business model of the interventions
- Include stakeholders and end-users into the project

Closed



# SME Instrument



## Phase 1

### Concept & Feasibility Assessment

- Feasibility of concept
- Risk assessment
- IP regime
- Partner search
- Design study

**Lump sum:**  
~ 50.000 €  
~ 6 months

## Phase 2

### Innovation R&D activities

- Development, prototype, testing
- Miniaturisation/design
- Clinical trials
- Etc.

**EU funding:**  
1 to 5 million EUR  
12 to 36 months

## Phase 3

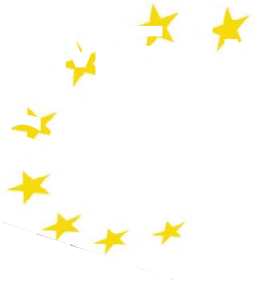
### Commercialization

- Facilitate access to private finance
- Support via networking, training, knowledge sharing, dissemination

**No direct funding**

## Market





- SMEInst – Supporting innovative SMEs in the healthcare biotechnology sector
  - Cell technologies in medical applications
  - Clinical research for the validation of biomarkers and/or diagnostic medical devices
- SMEInst – Accelerating market introduction of ICT solutions for Health, Well- Being and Ageing Well

# Fast Track to Innovation

- Objectif : réduire les délais entre l'idée et le marché, stimuler la participation des primo-proposants et accroître les investissements privés en R&I
- Participants : consortia comprenant entre 3 et 5 entités légales, établies dans 3 pays différents de l'UE
- Min 3 industriels
- Forte implication des industriels
- Allocation d'au moins 60% du budget aux participants industriels
- Appel en continu et sans thématique,
- Aide : 70% couts éligibles, entre 1 et 2M€ par projet (voir 3M€)
- Poids de l'impact sera prépondérant

# Projets collaboratifs en Santé

## EXCELLENCE SCIENTIFIQUE

ERC

European Research Council

FET

*Future Emerging Technologies*

Actions Sklodowska Marie Curie

Infrastructures

## PRIMAUTE INDUSTRIELLE

### Technologies clefs génériques (KET)

- TIC
- Nanotechnologies,
- Matériaux avancés,
- Systèmes de production, Biotechnologies
- Espace

Accès au financement à risque

Innovation dans les PME

## DEFIS SOCIETAUX

Heal

**Bioéconomie**

Energie

Transport

Changement climatique

Sociétés inclusives

Sécurité



## Défi 2 - WP 2016-2017

<i>Healthy and safe foods and diets for all</i>			Budget call	Type
SFS-38	2016	Encouraging healthy dietary choices in childhood and measuring its impact on health	9M	RIA

**Closed**

- = Provide evidence-based support for innovative EU policy on food education programmes/tools
- Take into account geographical, behavioural, cultural, socio-economic factors.
- Identify societal-risk groups.
- Multi/Trans/Interdisciplinary research: natural SSH
- Link with industry/market actors + schools

SFS-39	2017	The impact of consumer practices in biological and chemical food safety risks and mitigation strategies	10M	RIA
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- = scientific characterization of in- & post-retail private consumer practises & relation to exposure to food-borne hazards and related-risks
- Identify consumer-risk groups
- Take into account gender, socio-economic and cultural aspects (consumer profile).
- Multi-disciplinary research (include SSH to engage consumer)

SFS-40	2016	<u>Impulsivity and compulsivity</u> and the link to nutrition, lifestyle and the socio-economic environment	12M	RIA
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**Closed**

- = understanding influences of nutrition, lifestyle and the socio-economic environment and their interdependencies on the occurrence of these disorders
- To nurture public policy / propose list of remedial actions. *Pharmaceutical treatment not covered.*
- On various populations: youngs, teenagers, elderly
- Take into account gender.
- Multidisciplinary approach

### *Healthy and safe foods and diets for all*

**Budget  
call**

**Type**

SFS-41

2017

How to tackle the obesity epidemic?

13M

RIA

= better understanding of the factors leading to obesity and their complex interactions

- Based on analysis of existing initiatives (motivational programmes at national level, new dietary and lifestyle interventions, environmental factors)
- Based on existing research
- Multidisciplinary approach: health and life science, SSH
- Include policy makers & industries
- Gender aspect to be taken into account.
- Link with international partners (esp. USA, AU, Canada, NZ)
- To be translated into new lifestyle and dietary tools

Etudes  
interventionnelles

SFS-42

2017

Sweeteners and sweetness enhancers

9M

RIA

- Focus on health, obesity and safety issues (combined/prolonged use, metabolic effects, gut-brain signalling, neurobehaviour, microbiota)
- Sustainability of the whole value chain
- Consumer perceptions and preferences and link to physiological, psychological and socio-economic drivers
- Nurture public policy (health, environment, safety)
- Disseminate to food-related SMEs

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# Echelle TRL

## (*Technology Readiness Level*)



**TRL 2 – technology concept formulated**

**TRL 3 – experimental proof of concept**

**TRL 4 – technology validated in lab**

**TRL 5 – technology validated in relevant environment (industrial environment in the case of KETs)**

**TRL 6 – technology demonstrated in relevant environment (industrial environment in the case of KETs)**

**TRL 7 – system prototype demonstration in operational environment**

**TRL 8 – system complete and qualified**


**TRL 9 – actual system proven in operational environment (competitive manufacturing in the case of KETs; or in space)**



## Pilier 2 -LEIT : WP 2016-2017

Key enabling technologies for societal challenges - Advanced materials and nanotechnologies for healthcare			Budget projet	Type
NMBP9	2016	Biomaterials for diagnosis and treatment of multiple sclerosis . TRL3-5	5-8	RIA
NMBP10	2016	Nanoformulation of biologicals TRL 3 /4 to 5 / 6.	5-6	RIA
NMBP12	2017	Development of a reliable methodology for better risk management of engineered Biomaterials in Advanced Therapy Medicinal Products and/or Medical Devices . TRL 4-6	5-8	RIA
NMBP13	2017	Cross-KET for Health	5	RIA
NMPB14	2017	Regulatory Science Framework for assessment of risk-benefit ratio of Nanomedicines and Biomaterials. TRL3-7	3-7	RIA
NMBP15	2017	Nanotechnologies for imaging cellular transplants and regenerative processes in viv.o TRL 3-4 to 5-6	5-7	RIA
NMBP16	2017	Mobilising the European nano-biomedical ecosystem 55	1-2	CSA

### Two-stages 2016:


 - 1st stage: 08/12/2016  
 - 2<sup>nd</sup> stage: 24/05/2016

### Two-stages 2017:

- 1st stage: 10/11/2016  
 - 2<sup>nd</sup> stage: 25/04/2017





# Trouver des partenaires

Utilisez d'abord **VOTRE** réseau

- **Utilisez les réseaux de spécialistes des projets européens**
  - Le service de fitforhealth: [www.fitforhealth.eu](http://www.fitforhealth.eu)
  - Rapprochez vous des organismes/universités/CHU
  - Si vous cherchez des PME utilisez les réseaux régionaux : EEN, ARI, Pôles de compétitivités CCI, Régions et via le PCN PME
  - Cordis portal: <http://cordis.europa.eu/> Trouver ce qui a été financé
- **Participez aux évènements autour de Horizon2020 ou internationaux**
  - **Brokerage event 7 juillet 2016 à Bruxelles**  
<http://www.fitforhealth.eu/event-created/horizon-2020-health-partnering-day-2016>
  - **Infoday 8 juillet 2016**  
<http://ec.europa.eu/research/index.cfm?pg=events&lg=en&filter=ec&theme=0&period=2016&selectmonth=07>
  - Devenez évaluateurs  
<http://ec.europa.eu/research/participants/portal/page/experts>



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- la crédibilité de l'approche proposée
- le bien-fondé du concept, incluant la multidisciplinarité, si c'est pertinent
- le degré d'ambition du projet, le potentiel d'innovation, et jusqu'à quel point le projet va au de la de l'état de l'art

## Impact

- réaliser les impacts listés dans le programme de travail et sous le "topic" pertinent ;
- renforcer la compétitivité et la croissance des entreprises en développant des innovations répondant aux besoins des marchés européens et globaux
- prendre en compte les autres impacts environnementaux et sociétaux importants.
- mesure de dissémination convaincantes, en incluant la gestion des droits de propriétés intellectuelles et l'exploitation des résultats

## Qualité et efficacité de la mise en œuvre

- la cohérence et l'efficacité du plan de travail ("**workplan**"), incluant l'adéquation de la répartition des tâches et des ressources ;
- les compétences et expériences des participants et la complémentarité des participants individuellement, ainsi que du consortium dans son ensemble ;
- l'adéquation des structures de management et des procédures, en incluant la gestion des

# Excellence:

## *Points positifs*

- **Clarity/Cohrence:** objectives clear, pertinent, well described, methodology convincing, large number of subjects, using a good model, Design and methodology are clearly laid out
- **Novelty:** Beyond the state of the art, potential to create a paradigm shift, several novel concepts ambitious, original and innovative
- **Preliminary data:** data from existing cohorts, based on previous FP projects, biobanks, well-supported by cited literature, building on robust preliminary work, build on preclinical data
- **Challenge driven:** high unmet medical or clinical need, diseases with high prevalence and high, socio-economic impact, Cost effective, EU added value, knowledge can be applied to different EU policies
- **Interdisciplinarity**
- **Intersectorial:** SMEs, Hospitals, patients organisations
- **Gender**

## *Points négatifs*

- **Lack of novelty:** state of the art not clear, no real breakthrough, not well aligned with current treatment guidelines
- **Over ambitious** within the time frame, not credible, risk management not sufficiently described, going into clinical trials is premature
- **Clinical trials:** number of patients in trial small/not sufficient/ no statistical power, safety issues not sufficiently detailed
- Lack description on **ethics**
- **Lack of preliminary data:** lack of validation on animal models/lack of longitudinal studies
- **Consortium** do not have the expertise (or not proved)

# Impact:

## *Points positifs*

- **Dissemination and exploitation of the results for the benefit of**
  - ❖ **The scientific community:** Data management plan, open-innovation platform
  - ❖ **The economy:** business plan , active participation of SMEs, EU competitiveness, clearly end user driven, clear target application , cost-effective, reducing healthcare costs, regulatory registration and commercialization is appropriate
  - ❖ **The decision makers:** lead to prevention strategies, connection with standardization agencies
  - ❖ **The people:** improvement of public health, lead to prevention strategies, communication plan impressive, broad potential application, multiple therapeutic areas-other diseases, Great impact at EU and international level, strong engagement from the end user community
- **Effective IP management plan**
- **Connection with relevant national and international initiatives**

## *Points négatifs*

- **Low impact on**
  - ❖ **the society:** disease not that frequent/only bring a change to a relatively small patient population, impact care, public care recommendation and health policy are missing, lack of communication towards the final user, impact for the patient is not sufficiently substantiated
  - ❖ **The economy:** market analysis is unconvincing, potential exploitation by the partner SMEs is not sufficiently considered, commercialization impact is difficult to trust, no Work Package on data management
- **Intellectual property rights not detailed**
- **Synergies with previous EU funded project expected**

# Implementation:

## *Points positifs*

- **Clarity of the description:** management structures, risk management plan, tasks allocations: clear, well described and well balanced
- **Balance of powers (tasks, budget) between partners:** good balances between SME and academic partners/cross-disciplinary expertise, scientific and ethic board /advisory board with clinicians, reseachers and ethical experts
- **Expertise of partners:** reknown scientists complementarity of partners, pre-existing links, partners already involved in other EU projects,

## *Points négatifs*

- **Clinical trials:** not enough explanation about the role of partners (from different countries) involved in clinical trial, Low recruitment rate per centre/not considered standard practice
- **Lack of clarity/description:** validation of results not enough described, management structure not convincing, proposed business plan insufficient, models should be better described, IP description insufficient
- **Risk** not well evaluated
- **Consortium** needs more expertise, some partners are assigned to too many tasks( coordinator



Innovative Medicines Initiative

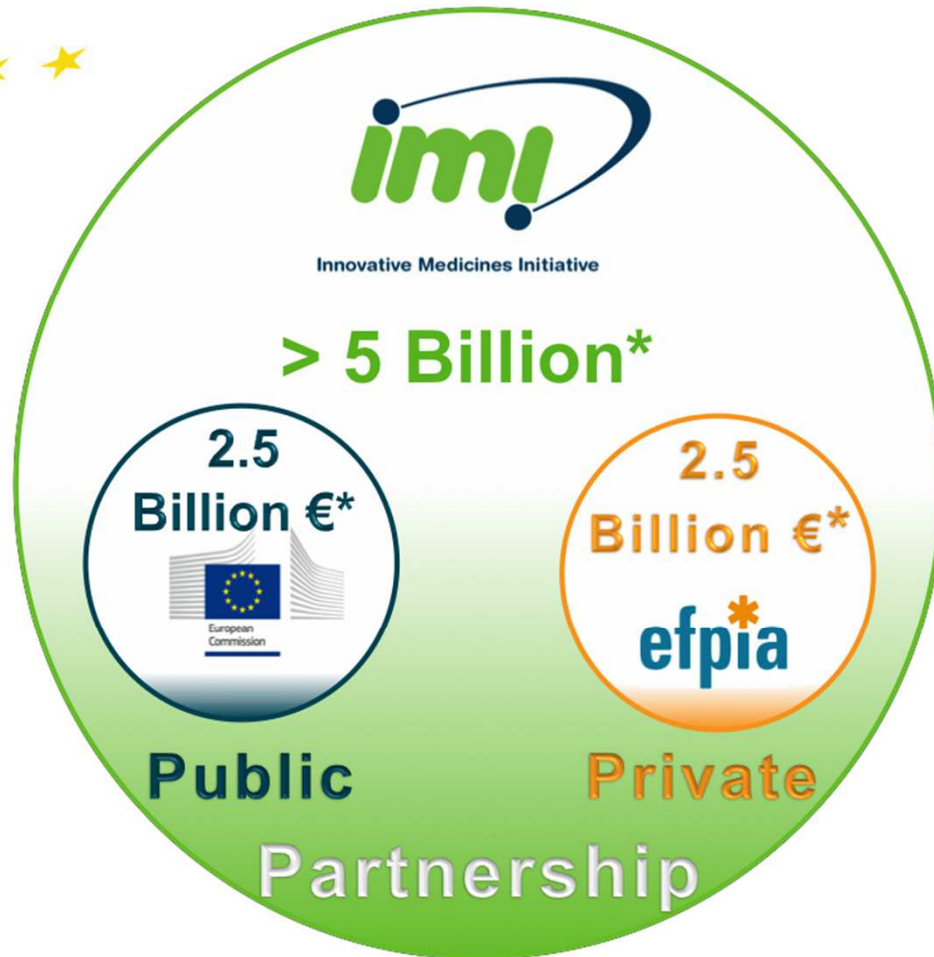


# IMI 2

[www.imi.europa.eu](http://www.imi.europa.eu)

## Partenariat Public-Privé avec l'industrie

# Joining forces from public and private bodies



\* IMI 1+2  
2008-2020

IMI2 =  
€1.5 billion Public  
+  
€1.5 billion Private



# A typical IMI consortium

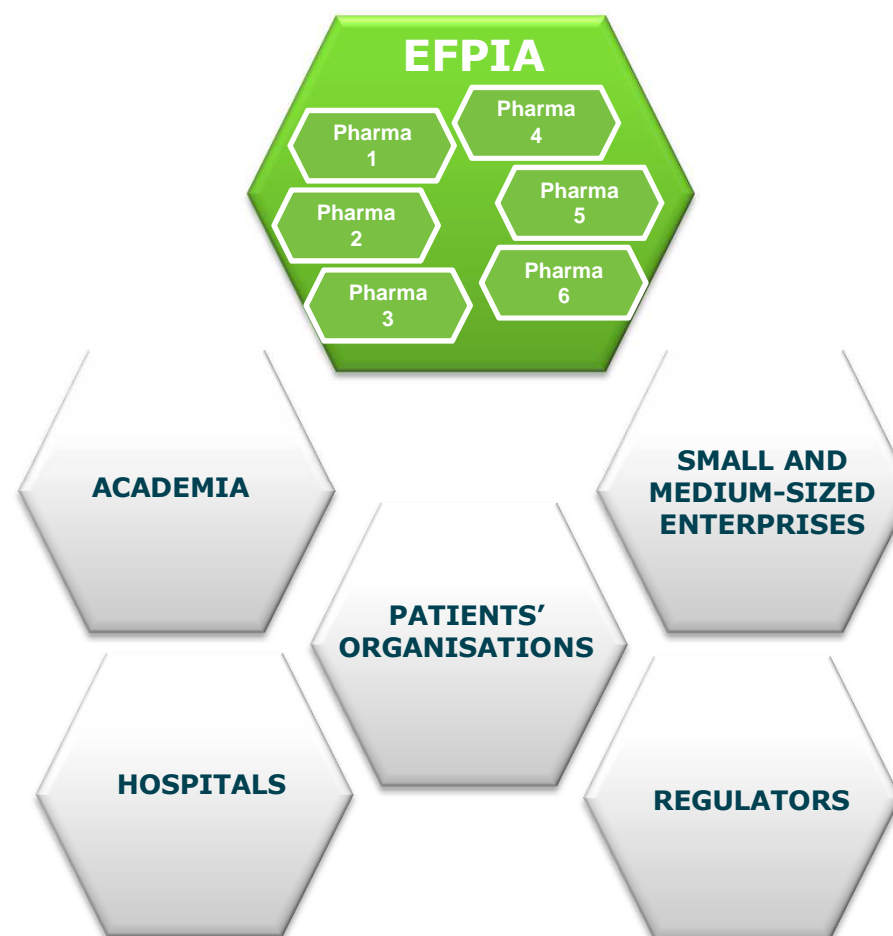


Appels



2 stages :

- 1<sup>er</sup> stage: 15 pages review panel expert
- ranking
- 1<sup>er</sup> classé invité au 2<sup>nd</sup> stage
- Full proposal public+ privé
- Contractualisation



# IMI2: Next Call



Innovative Medicines Initiative

- Addressing the **clinical burden of *Clostridium difficile* infection (CDI)**: Evaluation of the burden, current practices and set-up of a **European research platform** (part of the IMI **New Drugs for Bad Bugs (ND4BB)** programme)
- Development of **immune tolerance therapies** for the treatment of **rheumatic diseases**
- Data quality** in preclinical research and development
- Next generation of **electronic translational safety**
- Identification and validation of biomarkers for **non-alcoholic steatohepatitis (NASH)** and across the spectrum of **non-alcoholic fatty liver disease (NAFLD)**
- Joint **influenza vaccine effectiveness** studies

Publication date: 27 April 2016

Stage 1 submission deadline: **26 July 2016** – 17:00:00 Brussels time



efpia

30 juin 2015 : lancement de l'appel

29 septembre 2015, 17 heures : date limite de soumission



efpia

# Submit an idea:

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**Directement à l'EFPIA:**

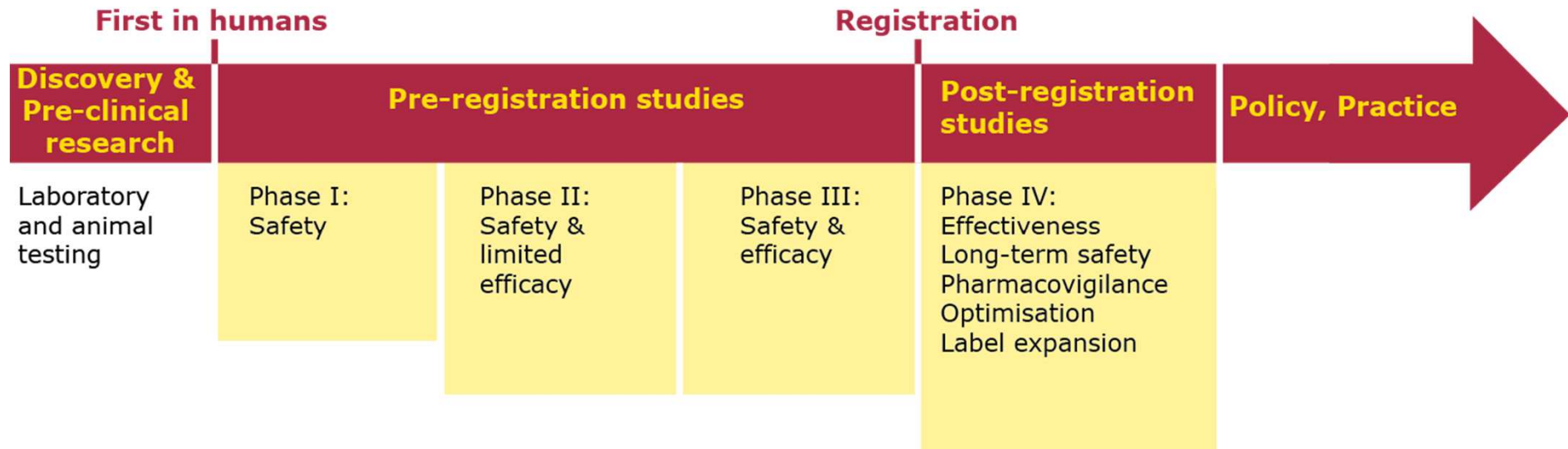
- **En ligne avec l'agenda stratégique:  
The right prevention and treatment, to the right patient at the right time**
- **Template**
- **Réponse sous 2 mois de la possibilité de créer un call**
- **<http://imi.efpia.eu/imi2/create-your-imi2>**







# EDCTP2' Scope



## ■ Pathologies éligibles :

- ✓ VIH/SIDA, Tuberculose, Paludisme
- ✓ Les 17 maladies tropicales négligées reconnues par l'OMS + les filovirus



# Les différentes familles d'appel

- **Clinical Research Activities (drugs, diagnostics, vaccines, microbicides)**
- **Capacity Development Activities**
  - **Fellowships**
  - **Ethics and Regulatory grants**
  - **Regional Networks of Excellence**



# Règles de participation

- **Pour être éligible, un consortium doit être au minimum composé de :**
  - ✓ Deux institutions de deux pays européens membres de l'association + une institution d'un pays africain
- **Les institutions des autres pays européens peuvent participer au consortium et sont éligibles au financement**
- **Un consortium peut être coordonné par une institution africaine**
- **Les institutions d'autres pays (or Afrique) peut participer mais ne sont pas éligibles au financement**

# ERA-nets en santé (participation FR)



Maladies rares (**renouvelé**)

Cancer (**renouvelé**)

Nanomédecine (renouvellement à venir)

Neurosciences (**renouvelé**)

Maladies infectieuses Humaines  
*Exclusion : VIH, hépatites, malaria et tuberculose*

Médecine systémique (**nouveau – lancé en 2015**)

Biologie de Synthèse





# Initiative de Programmation Conjointe



## INITIATIVE CONJOINTE DANS LE DOMAINE DES MALADIES NEURODÉGÉNÉRATIVES

→ *Mettre en commun de manière plus efficace les forces de recherche sur les **maladies neuro dégénératives***



## RÉSISTANCE ANTI-MICROBIENNE

Appel à projets transnational sur les approches novatrices pour lutter contre la **résistance antibactérienne**



## NUTRITION





**Merci de votre attention**

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