

Innovative partnerships for innovative medicines

23/11/2012



Marta Gómez Quintanilla
Health & IMI Spanish Representative
IMI States Representatives Group vice-Chair
Joint Programming on Neurodegeneration Research MB Member
EU's R&D Framework Programme Department

NO DISTRIBUIR

(26/11/2012)



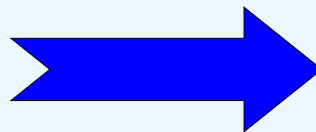
Centro para el Desarrollo
Tecnológico Industrial



OBJETIVO

Posicionamiento

- IMI
- PPP Health research (IMI2)

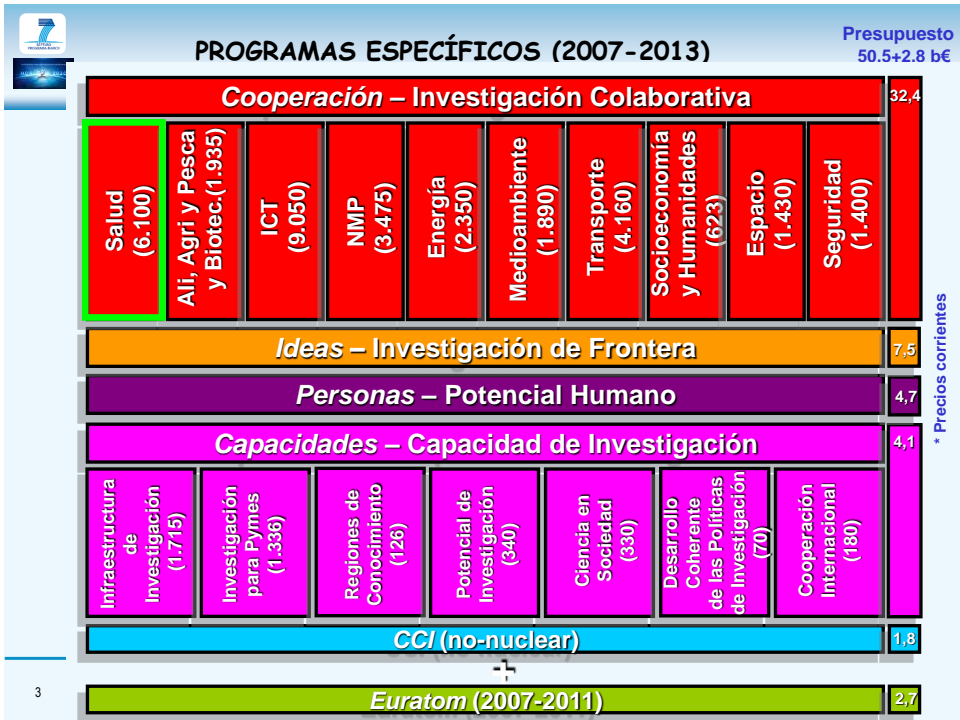


2

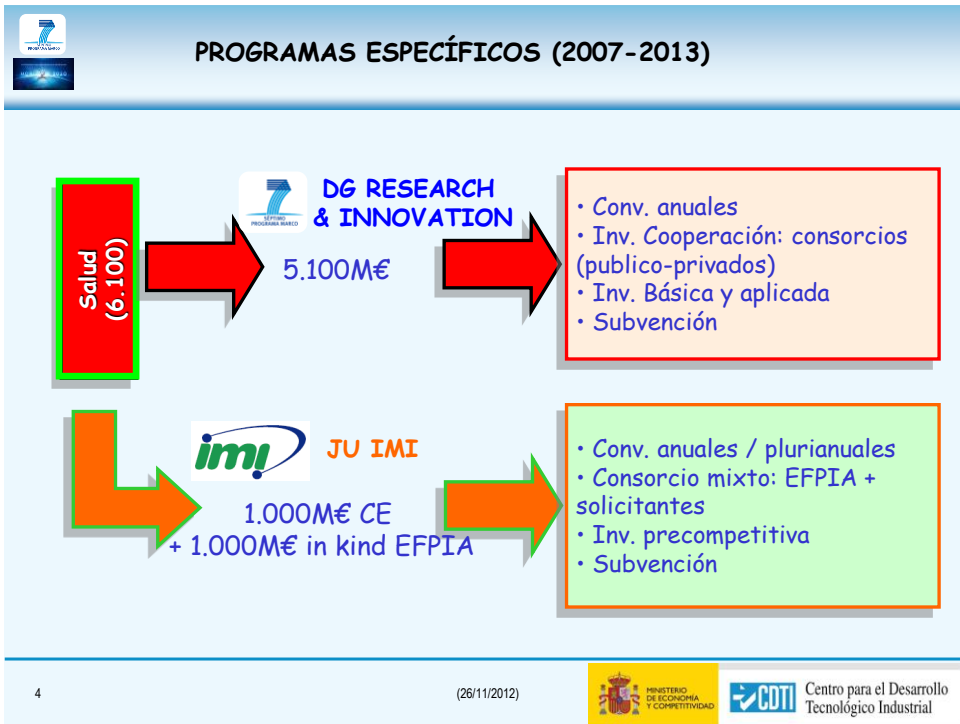
(26/11/2012)



Centro para el Desarrollo
Tecnológico Industrial



3



4

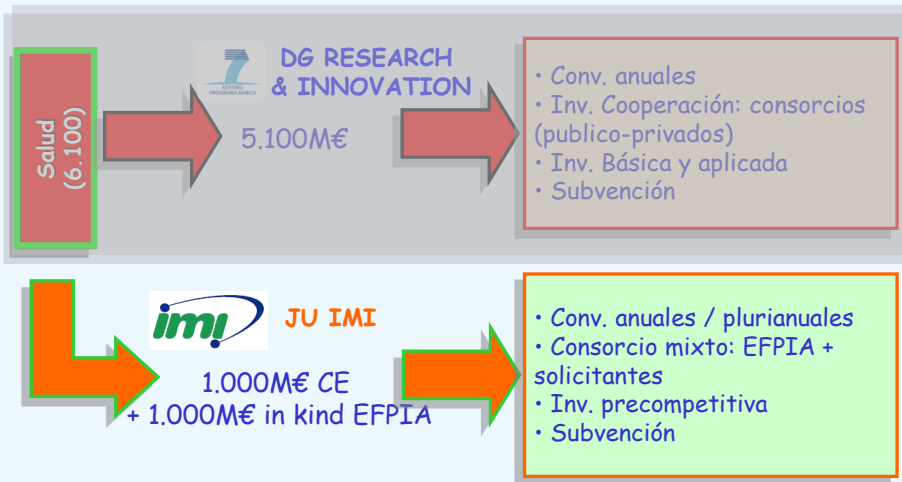
(26/11/2012)



Centro para el Desarrollo
Tecnológico Industrial



PROGRAMAS ESPECÍFICOS (2007-2013)



5

(26/11/2012)

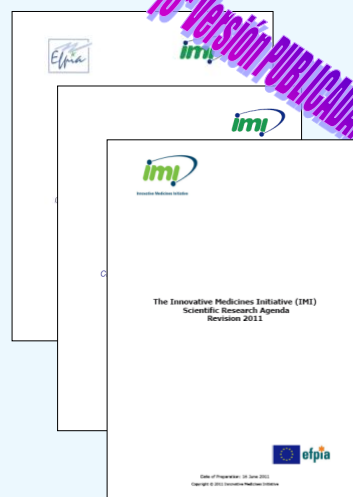


Centro para el Desarrollo Tecnológico Industrial



Objetivo y definición

• Desarrollar **nuevas metodologías y herramientas** para acelerar el desarrollo de nuevos **medicamentos** de uso humano **más seguros y eficaces**, superando los **“cuellos de botella”** de la inv. precompetitiva.



6

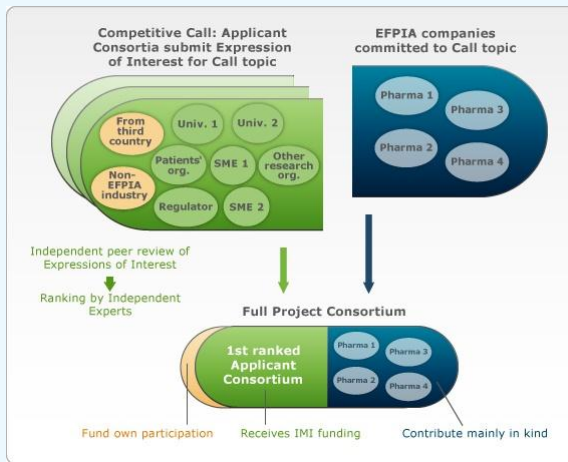
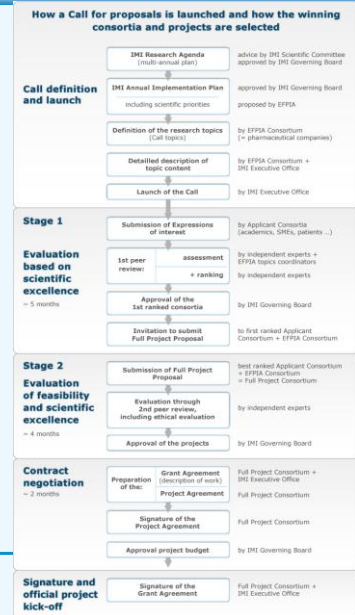
(26/11/2012)



Centro para el Desarrollo Tecnológico Industrial



IMI now



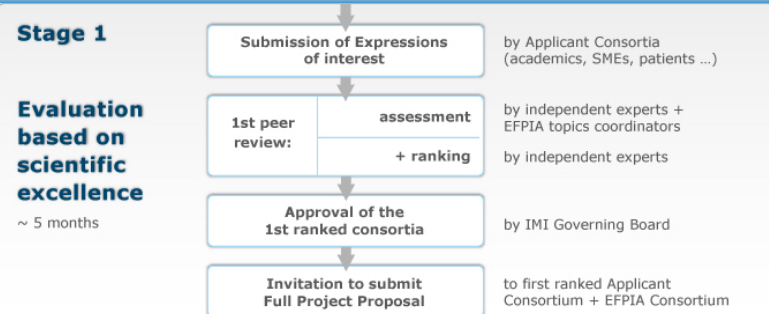
(26/11/2012)



Centro para el Desarrollo Tecnológico Industrial

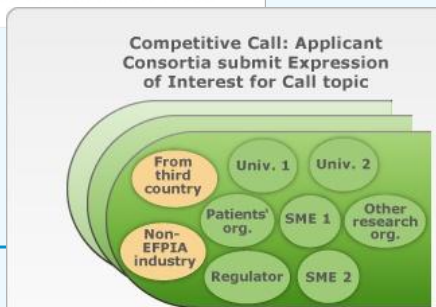


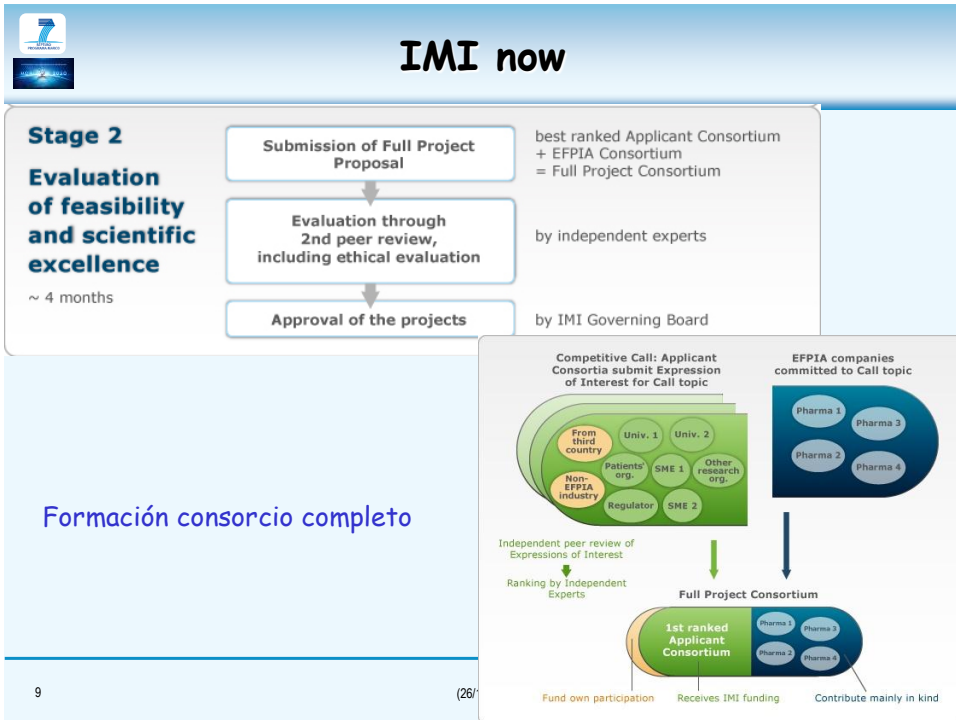
IMI now



Formación consorcio solicitante.

Financiación posible para:
- PYMEs
- Entidades sin ánimo de lucro

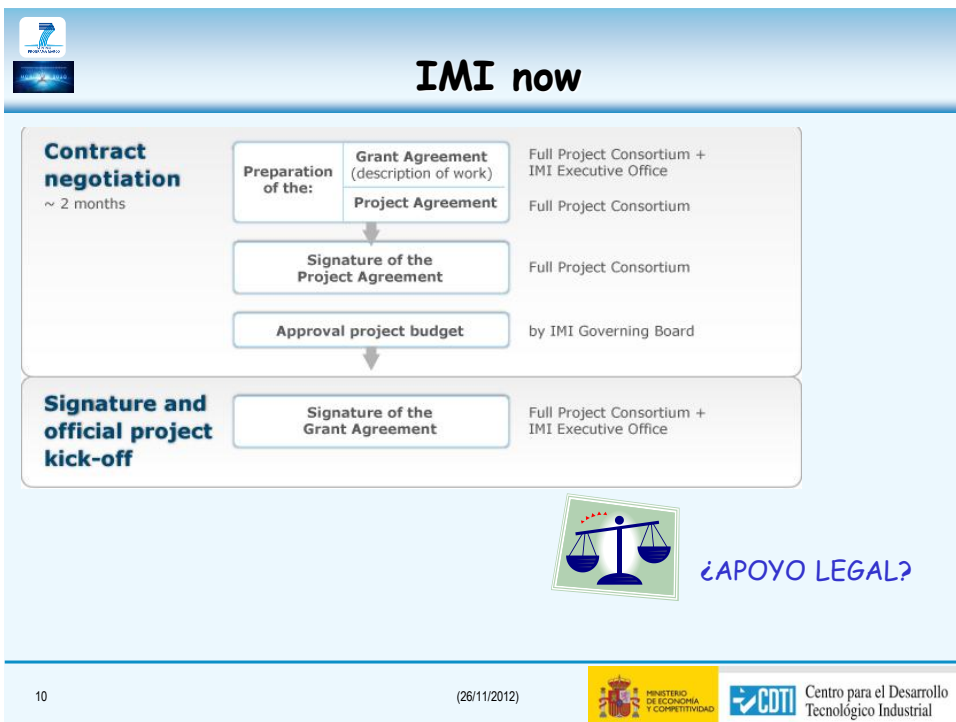




best ranked Applicant Consortium + EFPIA Consortium = Full Project Consortium

by independent experts

by IMI Governing Board



Full Project Consortium + IMI Executive Office

Full Project Consortium

Full Project Consortium

by IMI Governing Board

Full Project Consortium + IMI Executive Office

¿APOYO LEGAL?



ÍNDICE

- Situación actual en IMI: desde la gestión a la participación
- Definición IMI2 en H2020: Tendencias y fechas

11

(26/11/2012)



Centro para el Desarrollo
Tecnológico Industrial



ÍNDICE

- Situación actual en IMI: desde la gestión a la participación
- Definición IMI2 en H2020: Tendencias y fechas

12

(26/11/2012)



Centro para el Desarrollo
Tecnológico Industrial



Available online



GENERAL
2007-2010



SALUD & IMI
2011



SALUD & IMI
2012

Source: www.cdti.es

13

(26/11/2012)

<http://www.cdti.es/index.asp?MP=7&MS=51&MN=4&TR=C&IDR=416&IDP=133&IDS=6>



Centro para el Desarrollo Tecnológico Industrial



Resultados provisionales SALUD & IMI 2007-2012

RESULTADOS PARTICIPACIÓN ESPAÑOLA EN EL TEMA 1: SALUD e IMI Acumulado 2007- 2012. Datos provisionales.

Participación en propuestas**	Presentadas España, nº Coordinadas España, nº Financiación solicitada España, M€	1.323 280 1.124,7
Financiación actividades	Financiadas España, nº (% del total) Coordinadas España, nº (% del total)	326 (38,2%) 55 (6,4%)
Resultados entidades	Entidades españolas con proyectos aprobados (Empresas / % PYME*)	229 (82, 82,9%)
Tasa de éxito España**	% proyectos financiados/ propuestas presentadas	24,6%
Retorno económico	Millones de € % UE-27 (% del total)	219,3 6,1% (5,3%)
Posición de España por retorno		7ª

* PYME: empresas < 250 empleados

** En las convocatorias en dos fases sólo se considera la segunda fase de la evaluación

14

(26/11/2012)

Source: CDTI - Provisional data, subject to changes



Centro para el Desarrollo Tecnológico Industrial



Resultados provisionales SALUD & IMI 2007-2012

RESULTADOS PARTICIPACIÓN ESPAÑOLA EN EL TEMA 1: SALUD e IMI Acumulado 2007- 2012. Datos provisionales.

Participación en propuestas**	Presentadas España, nº Coordinadas España, nº Financiación solicitada España, M€	1.323 280 124,7
Financiación actividades	Financiadas España, nº (%) Coordinadas España, nº (%)	125 (38,2%) 55 (6,4%)
Resultados entidades	Entidades con proyectos aprobados	229 (82, 82,9%)
Tasa de financiación	Proyectos financiados/ Propuestas presentadas	24,6%
Retorno económico	Millones de € % UE-27 (% del total)	219,3 6,1 (5,3%)
Posición de España por retorno		7ª

* PYME: empresas < 250 empleados

** En las convocatorias en dos fases sólo se considera la segunda fase de la evaluación

15

(26/11/2012)



Centro para el Desarrollo
Tecnológico Industrial

Source: CDTI - Provisional data, subject to changes



Provisional ES - IMI 2008-2010

RESULTADOS PARTICIPACIÓN ESPAÑOLA EN IMI Acumulado 2007- 2012. Datos provisionales.

ES Proposal participation (2nd stage)	# ES # Coordinated ES Funding ES, M€	19 1 10,5
ES Results	Financed ES, # (%) Coordinated ES, # (%)	19 (63,3%) 1 (3,3%)
ES Entities	Entities with funded projects (Companies / % SME*)	25 (6, 66,7%)
ES Funding	M€ % UE-27 (% del total)	10,5 3,7% (3,5%)
ES Ranking		8ª

* PYME: empresas < 250 empleados

** En las convocatorias en dos fases sólo se considera la segunda fase de la evaluación

16

(26/11/2012)

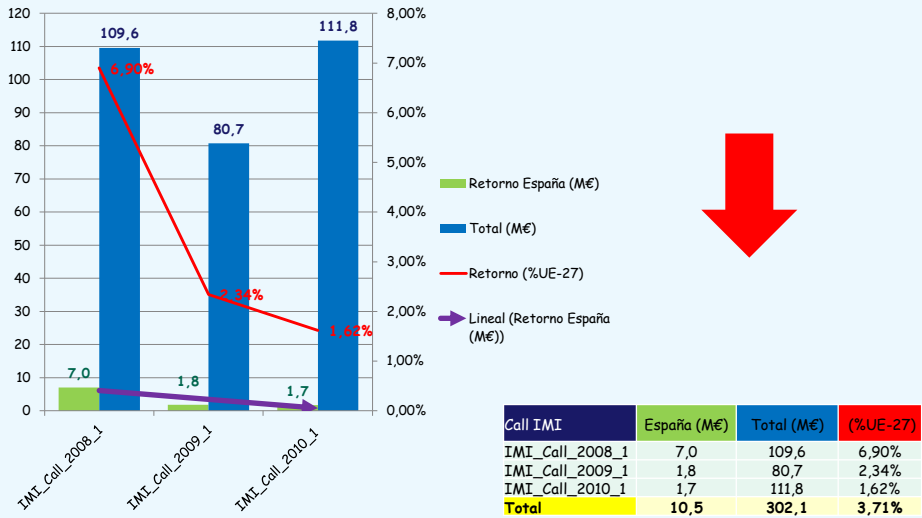


Centro para el Desarrollo
Tecnológico Industrial

Source: CDTI - Provisional data, subject to changes



IMI Results



17
Source: CDTI - Provisional data, subject to changes

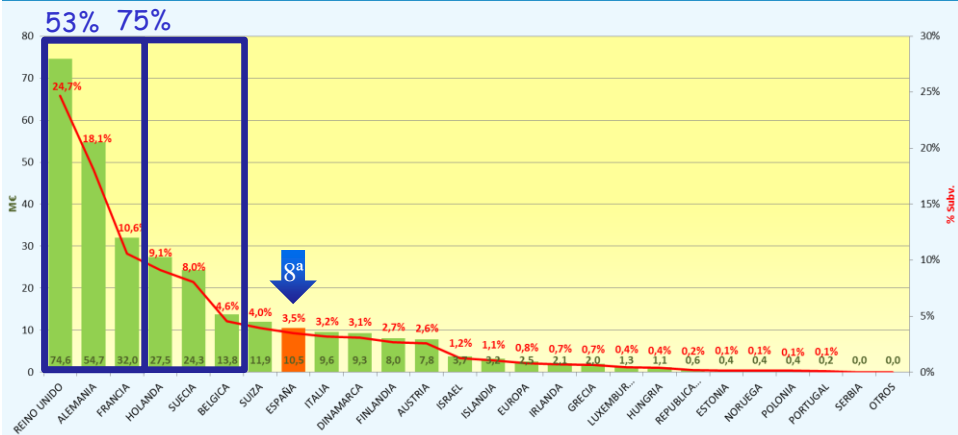
(26/11/2012)



Centro para el Desarrollo Tecnológico Industrial



Statistics



* ES 8 position
* UK, DE & FR = 53% Funding

18

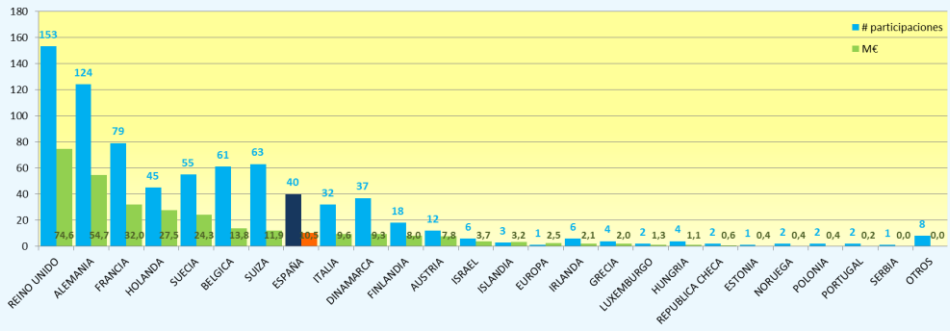
(26/11/2012)



Centro para el Desarrollo Tecnológico Industrial



Statistics



19

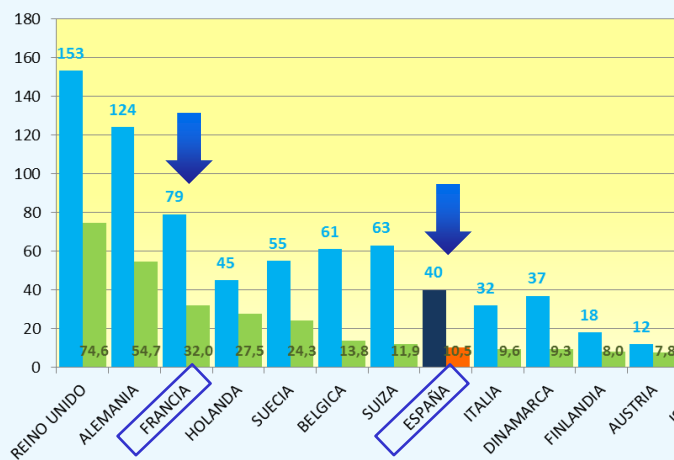
(26/11/2012)



CDTI Centro para el Desarrollo Tecnológico Industrial



Statistics



participations ≠ Funding

20

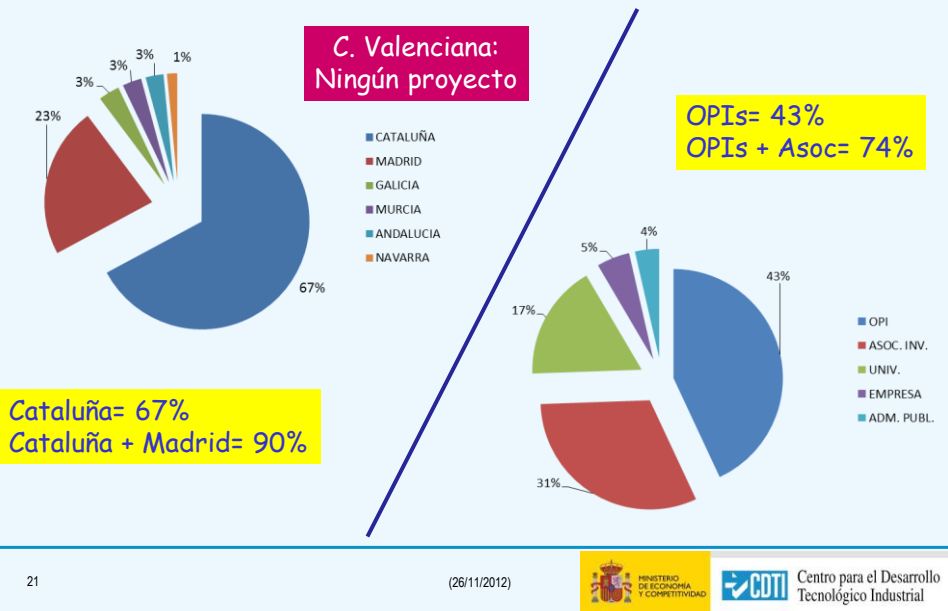
(26/11/2012)



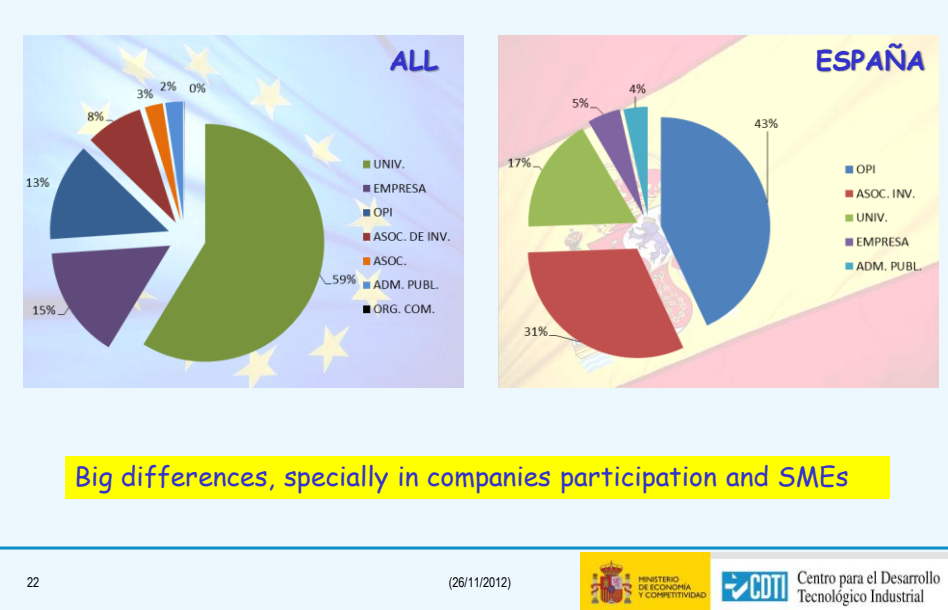
CDTI Centro para el Desarrollo Tecnológico Industrial



ES Funding



ES Funding

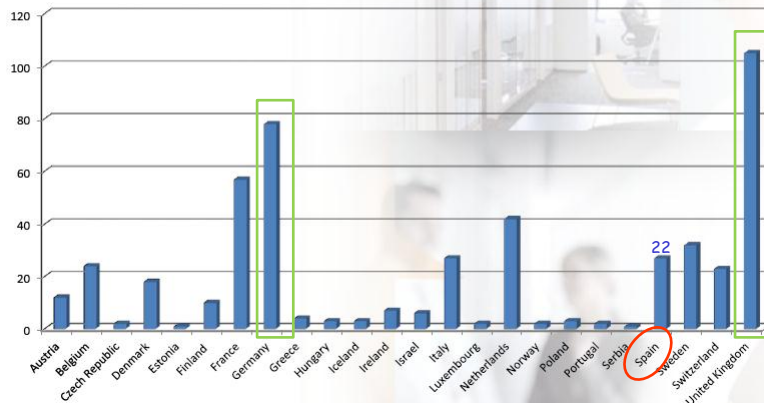




Calls 1st to 3rd



1st to 3rd Call Projects IMI JU beneficiaries (per country)



23

(26/11/2012)



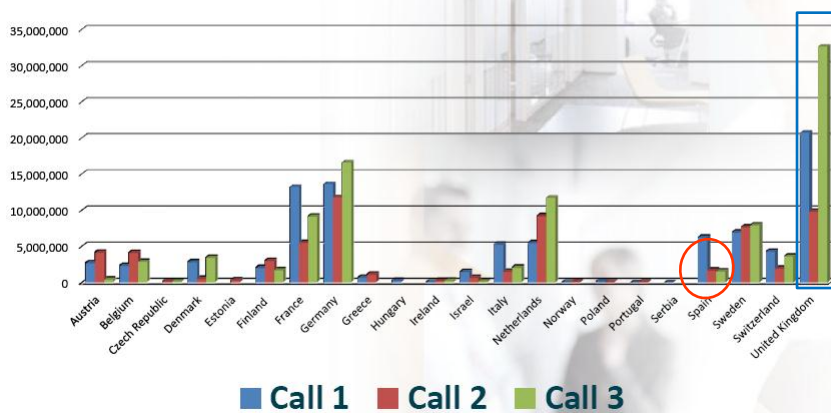
Centro para el Desarrollo Tecnológico Industrial



Calls 1st to 3rd



1st to 3rd Call Projects IMI JU contribution to academics (in EUR)



24

■ Call 1 ■ Call 2 ■ Call 3

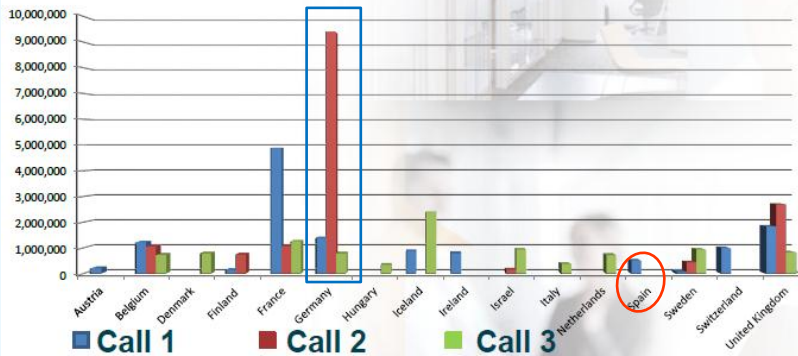
ollo al



Calls 1st to 3rd



1st to 3rd Call Projects IMI JU contribution to SMEs (in EUR)



25

(26/11/2012)



Centro para el Desarrollo Tecnológico Industrial



Statistics

		30/08/2012			CLOSED		
Call #		1st Call	2nd Call	3rd Call	Partial results		
Data*		Official data					
Call text	Publication date	30/04/2008	27/11/2009	22/10/2010			
	Closing date (2nd)	20/01/2009	28/06/2010	15/06/2011			
	IMI funding (M€)	122,7	75,0	114,0	311,7		
	EFPIA in kind (M€)	172,5	75,0	114,0	361,5		
	TOTAL	295,2	150,0	228,0	673,2		
1st stage	Call topics	18	9	7	34		
	Expressions of interest	134	124	32	290		
	Participants	1.294	1.118	433	2.845		
	EoIs/topic	7,4	13,7	4,6	8,5		
	Funded Projects	15***	8****	7	30		
Results after 2nd stage**	Project Total Cost	287,6	169,5	220,1	677,2		
	Project Total funding	109,6	80,7	111,8	302,1		
	Success rate	11,2%	7,3%	21,9%	10,3%		
	ES in projects (%)	12 (80%)	3 (38%)	4 (57%)	19 (63%)		
	ES entities: EFPIA + no EFPIA (SME)	2 + 15 (3)	1 + 5 (0)	3 + 3 (0)	3 + 22 (3)		
	ES participations	28	6	6	40		
	ES M€ (% UE27)	7,0 (6,9%)	1,8 (2,3%)	1,7 (1,6%)	10,5 (3,7%)		
	ES position (funding)	5°	10°	12°	8°		

* Data based on information provided by IMI-JU office

** Unless otherwise specified, ES data includes EFPIA and non EFPIA entities

*** 3 proposals failed in 2nd stage

**** 2 proposals merged in 2nd stage

(26/11/2012)



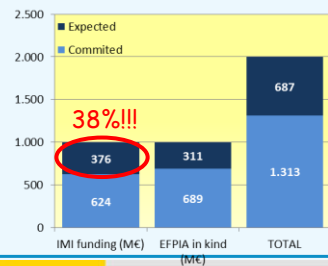
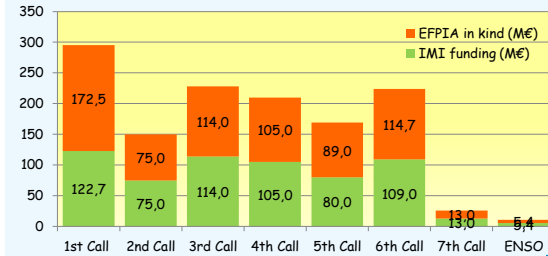
Centro para el Desarrollo Tecnológico Industrial



Statistics: Calls

30/08/2012		CLOSED				OPEN				TOTAL	
Call #	1st Call	2nd Call	3rd Call	Partial results	4th Call	5th Call	6th Call	7th Call	ENSO		
Data*	Official data				Estimations						
Call text	Publication date	30/04/2008	27/11/2009	22/10/2010	18/07/2011	06/03/2012	24/05/2012	17/07/2012	21/08/2012		
	Closing date (EoI)	15/07/2008	08/01/2010	11/01/2011	18/10/2011	16/05/2012	09/07/2012	09/10/2012			
	Closing date (Full)	20/01/2009	28/06/2010	15/06/2011	13/03/2012	13/09/2012	10/10/2012	xx/03/2013	30/9 & 15/12		
	IMI funding (M€)	122,7	75,0	114,0	311,7	105,0	80,0	109,0	13,0	5,4	624
	EFPIA in kind (M€)	172,5	75,0	114,0	361,5	105,0	89,0	114,7	13,0	5,4	689
	TOTAL	295,2	150,0	228,0	673,2	210,0	169,0	223,7	26,0	10,8	1.313
Call topics	18	9	7	34	7 (9)	2	2 (3)	2	-	38	

* Data based on information provided by IMI-JU office



27

(26/11/2012)



Centro para el Desarrollo Tecnológico Industrial



Statistics: Participation

30/08/2012		CLOSED			
Call #	1st Call	2nd Call	3rd Call	Partial results	
Data*	Official data				
Call text	Publication date	30/04/2008	27/11/2009	22/10/2010	
	Closing date (2nd)	20/01/2009	28/06/2010	15/06/2011	
	IMI funding (M€)	122,7	75,0	114,0	311,7
	EFPIA in kind (M€)	172,5	75,0	114,0	361,5
	TOTAL	295,2	150,0	228,0	673,2
Call topics	18	9	7	34	
1st stage	Expressions of interest	134	124	32	290
	Participants	1.294	1.118	433	2.845
	EoIs/topic	7,4	13,7	4,6	8,5



* Data based on information provided by IMI-JU office

** Unless otherwise specified, ES data includes EFPIA and non EFPIA entities

*** 3 proposals failed in 2nd stage

**** 2 proposals merged in 2nd stage

(26/11/2012)

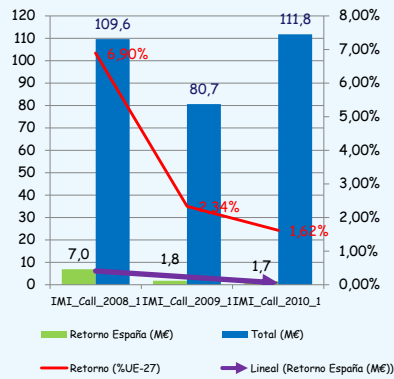


Centro para el Desarrollo Tecnológico Industrial



Statistics: Results

30/08/2012		CLOSED			Partial results
Call #	1st Call	2nd Call	3rd Call		
Data*	Official data				
Call text	Publication date	30/04/2008	27/11/2009	22/10/2010	
	Closing date (2nd)	20/01/2009	28/06/2010	15/06/2011	
	IMI funding (M€)	122,7	75,0	114,0	311,7
	EFPIA in kind (M€)	172,5	75,0	114,0	361,5
	TOTAL	295,2	150,0	228,0	673,2
	Call topics	18	9	7	34



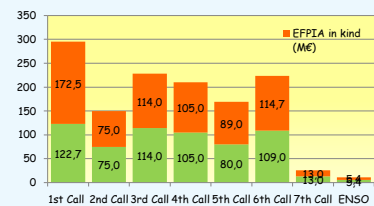
30/08/2012		CLOSED			Partial results
Call #	1st Call	2nd Call	3rd Call		
Data*	Official data				
Results after 2nd stage**	Funded Projects	15***	8****	7	30
	Project Total Cost	287,6	169,5	220,1	677,2
	Project Total funding	109,6	80,7	111,8	302,1
	Success rate	11,2%	7,3%	21,9%	10,3%
	ES in projects (%)	12 (80%)	3 (38%)	4 (57%)	19 (63%)
	ES entities: EFPIA + no EFPIA (SME)	2 + 15 (3)	1 + 5 (0)	3 + 3 (0)	3 + 22 (3)
	ES participations	28	6	6	40
	ES M€ (% UE27)	7,0 (6,9%)	1,8 (2,3%)	1,7 (1,6%)	10,5 (3,7%)
	ES position (funding)	5°	10°	12°	8°

* Data based on information provided by IMI-JU office
 ** Unless otherwise specified, ES data includes EFPIA and non EFPIA entities (26/11/2012)
 *** 3 proposals failed in 2nd stage
 **** 2 proposals merged in 2nd stage

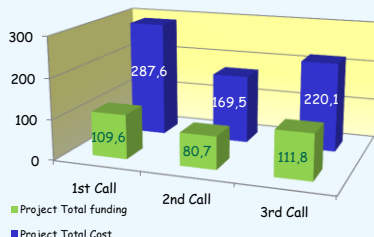


Statistics: Results

30/08/2012		CLOSED			Partial results
Call #	1st Call	2nd Call	3rd Call		
Data*	Official data				
Call text	Publication date	30/04/2008	27/11/2009	22/10/2010	
	Closing date (2nd)	20/01/2009	28/06/2010	15/06/2011	
	IMI funding (M€)	122,7	75,0	114,0	311,7
	EFPIA in kind (M€)	172,5	75,0	114,0	361,5
	TOTAL	295,2	150,0	228,0	673,2
	Call topics	18	9	7	34



30/08/2012		CLOSED			Partial results
Call #	1st Call	2nd Call	3rd Call		
Data*	Official data				
Results after 2nd stage**	Funded Projects	15***	8****	7	30
	Project Total Cost	287,6	169,5	220,1	677,2
	Project Total funding	109,6	80,7	111,8	302,1
	Success rate	11,2%	7,3%	21,9%	10,3%
	ES in projects (%)	12 (80%)	3 (38%)	4 (57%)	19 (63%)
	ES entities: EFPIA + no EFPIA (SME)	2 + 15 (3)	1 + 5 (0)	3 + 3 (0)	3 + 22 (3)
	ES participations	28	6	6	40
	ES M€ (% UE27)	7,0 (6,9%)	1,8 (2,3%)	1,7 (1,6%)	10,5 (3,7%)
	ES position (funding)	5°	10°	12°	8°

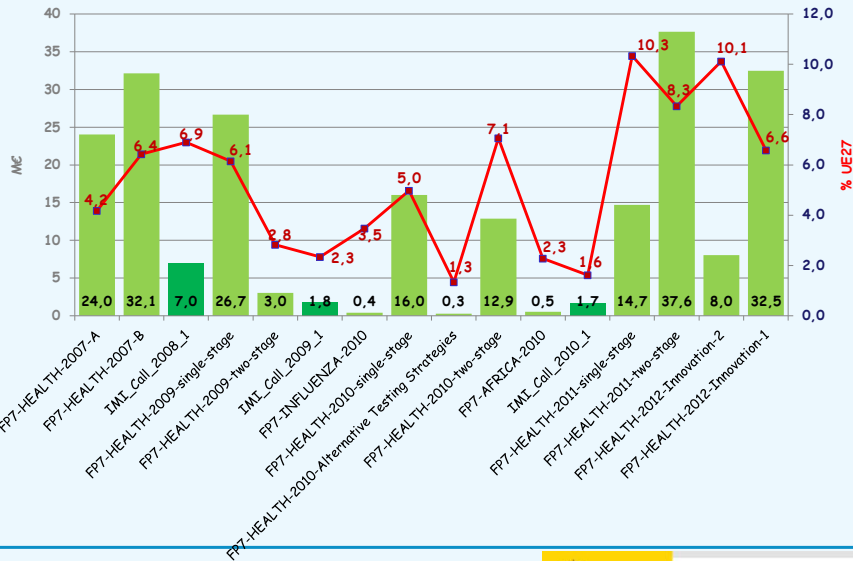


* Data based on information provided by IMI-JU office
 ** Unless otherwise specified, ES data includes EFPIA and non EFPIA entities (26/11/2012)
 *** 3 proposals failed in 2nd stage
 **** 2 proposals merged in 2nd stage





ES Results (compared with health calls)



31

Source: CDTI - Provisional data, subject to changes

CONVOCATORIAS

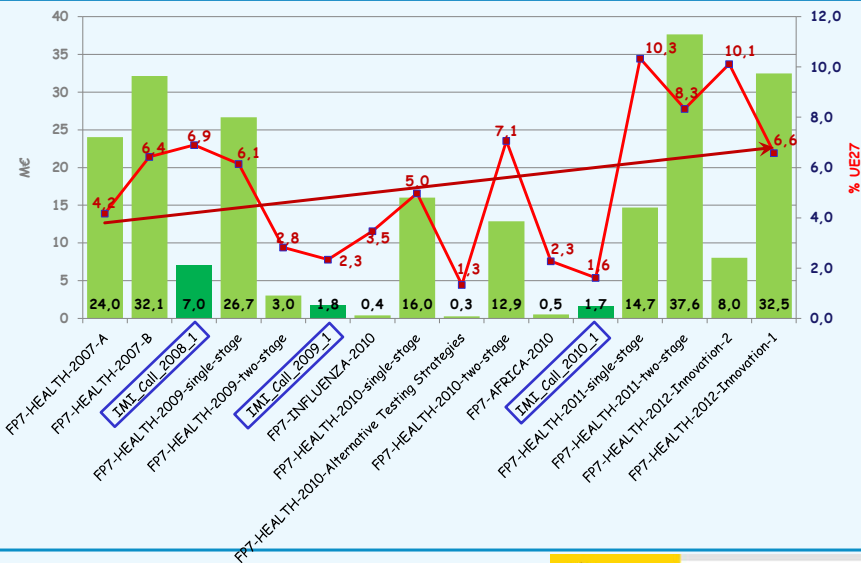


CDTI

Centro para el Desarrollo Tecnológico Industrial



ES Results (compared with health calls)



32

Source: CDTI - Provisional data, subject to changes

CONVOCATORIAS

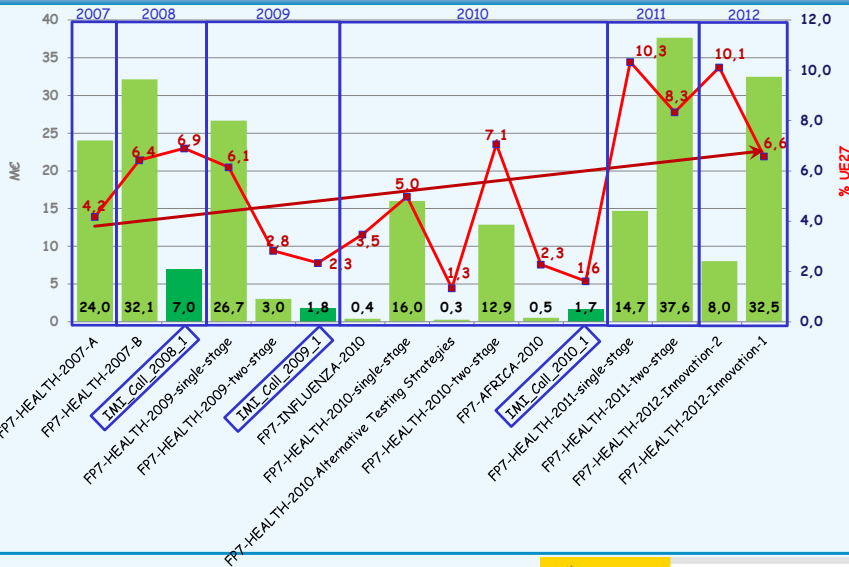


CDTI

Centro para el Desarrollo Tecnológico Industrial



ES Results (compared with health calls)



33

Source: CDTI - Provisional data, subject to changes

Cooperación



Centro para el Desarrollo Tecnológico Industrial



Tendency

		30/08/2012							TOTAL		
Call #		CLOSED				OPEN					
Data*		1st Call	2nd Call	3rd Call	4th Call	5th Call	6th Call	7th Call		ENSO	
Call text	Publication date	30/04/2008	27/11/2009	22/10/2010	Partial results	18/07/2011	06/03/2012	24/05/2012	17/07/2012	21/08/2012	
	Closing date (EoI)	15/07/2008	08/01/2010	11/01/2011		18/10/2011	16/05/2012	09/07/2012	09/10/2012		
	Closing date (Full)	20/01/2009	28/06/2010	15/06/2011		13/03/2012	13/09/2012	10/10/2012	xx/03/2013	30/9 & 15/12	
	IMI funding (M€)	122,7	75,0	114,0	311,7	105,0	80,0	109,0	13,0	5,4	624
	EFPIA in kind (M€)	172,5	75,0	114,0	361,5	105,0	89,0	114,7	13,0	5,4	689
	TOTAL	295,2	150,0	228,0	673,2	210,0	169,0	223,7	26,0	10,8	1.313
Call topics	18	9	7	34	7 (9)	2	2 (3)	2	-	38	
M€/topic	16	17	33	20	30	85	112	13		41	

* Data based on information provided by IMI-JU office

- Project budget gets bigger
- ≈34% funding to be committed
- Non EU (EFPIA) participation increasing (new rules).
- From annual calls (2008-2011) to monthly calls (2012-2013) -> overlapping in opening and deadlines, management gets complicated.

Data: IMI-JU, CDTI
Elaboración propia

(26/11/2012)



Centro para el Desarrollo Tecnológico Industrial



IMI Calls: Publication & Deadlines

July

17 - Publication IMI-Call 7

August

21 - Publication IMI-Call-ENSO

September

13 - Deadline IMI-Call 5 (2nd stage)

30 - Deadline IMI-Call-ENSO (1st cut-off day)

October

9 - Deadline IMI-Call 7 (1st stage)

10 - Deadline IMI-Call 6 (2nd stage)

November

December

¿7? - Publication IMI-Call 8

15 - Deadline IMI-Call-ENSO (2nd cut-off day)

At least 5 IMI calls
OPEN
in 6 months



35

(26/11/2012)



Centro para el Desarrollo
Tecnológico Industrial



IMI & Health Calls: Publication & Deadlines

July

10 - Publication HEALTH-2013-INNO1

10 - Publication HEALTH-2013-INNO2

17 - Publication IMI-Call 7

August

21 - Publication IMI-Call-ENSO

September

13 - Deadline IMI-Call 5 (2nd stage)

25 - Deadline HEALTH-2013-INNO2
(1st stage)

30 - Deadline IMI-Call-ENSO (1st cut-off day)

October

2 - Deadline HEALTH-2013-INNO1
(1st stage)

9 - Deadline IMI-Call 7 (1st stage)

10 - Deadline IMI-Call 6 (2nd stage)

November

23 - TODAY

December

¿7? - Publication IMI-Call 8

11 - Deadline HEALTH-2013-INNO2
(2nd stage)

15 - Deadline IMI-Call-ENSO (2nd cut-off day)



36

(26/11/2012)



Centro para el Desarrollo
Tecnológico Industrial



IMI - 2012 Calls

ENSO - IMI Call for proposals to explore new scientific opportunities in ongoing IMI JU collaborative projects 2012/2013

Launch date: 21 August 2012

8th Call for proposals

Indicative CALL TEXT PUBLISHED!!

- **Combating Antibiotic Resistance: New Drugs for Bad Bugs (ND4BB)***
 - Topic 1C: Innovative Trial Design & Clinical Development (work package 6 of Topic 1)
 - Topic 3: Discovery and development of new drugs combating Gram - negative infections
- Developing an aetiology-based taxonomy of human disease
- European induced pluripotent stem cell bank

<http://www.imi.europa.eu/content/8th-call-2012>

All information regarding future IMI Call topics is indicative and subject to change. Final information about the IMI's future Calls will be communicated after approval by the IMI Governing Board.



Centro para el Desarrollo Tecnológico Industrial



Info available web IMI

The screenshot shows the IMI website interface. On the left, a navigation menu includes 'Home', 'About IMI', 'Ongoing projects', 'Call for proposals', and 'New opportunities'. The 'Call for proposals' section is expanded, showing 'IMI 8th Call 2012' with a red circle around it. The main content area features a banner for 'IMI 8th Call 2012' and a section for 'Future Topics 8th Call for proposals', also circled in red. A red box highlights a disclaimer: 'All information regarding future IMI Call topics is indicative and subject to change. Final information about the IMI's future Calls will be communicated after approval by the IMI Governing Board.'



Areas covered



- Alzheimer
- Schizophrenia
- Depression
- Autism
- Chronic Pain
- Diabetes
- Cancer
- Infectious diseases
- Asthma
- COPD
- Tuberculosis
- RA

- Integrated drug development & safety
- Pharmacovigilance & pharmacoepidemiology
- Pan-European course catalog
- Patient education



- Kidney, liver and vascular system toxicity
- Non genotoxic carcinogens
- In silico tox prediction
- Adverse drug reaction detection and monitoring
- Biopharmaceutical safety
- Vaccine safety

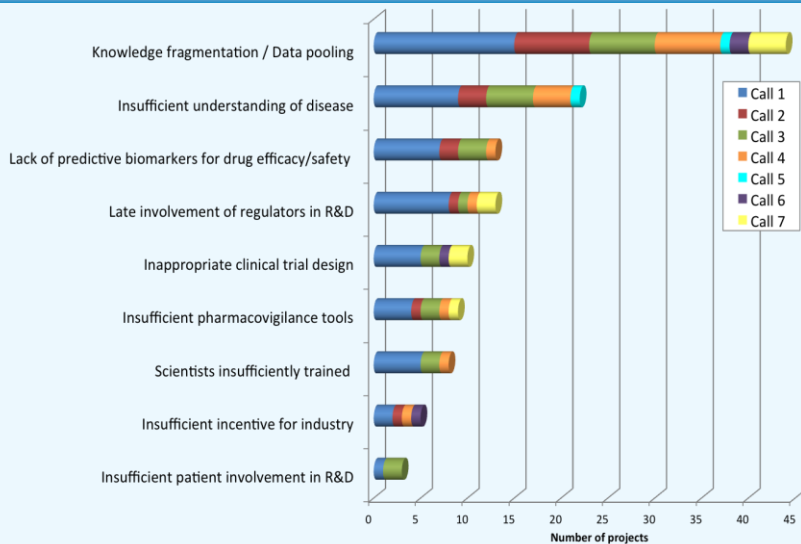
- Model based drug development
- EHR in medical research
- Open access innovation platform
- Patient Health Information Framework
- Translational research informatics and analytics platform

Desarrollo Industrial

39 Source: IMI JU



Projects Address Hurdles in R&D



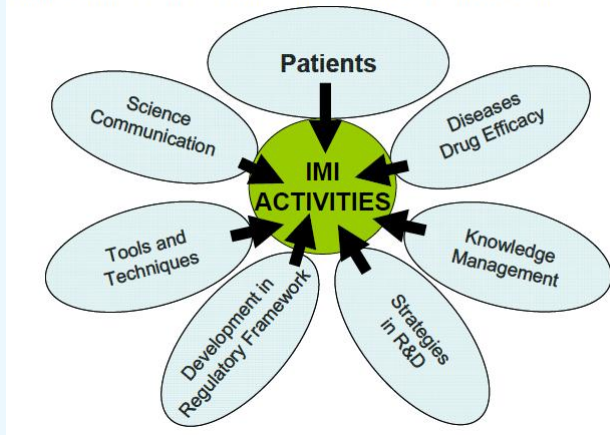
40

(26/11/2012)



Centro para el Desarrollo Tecnológico Industrial

Figure 3: Areas of Research Interest of the revised IMI SRA



<http://www.imi.europa.eu/content/research-agenda>



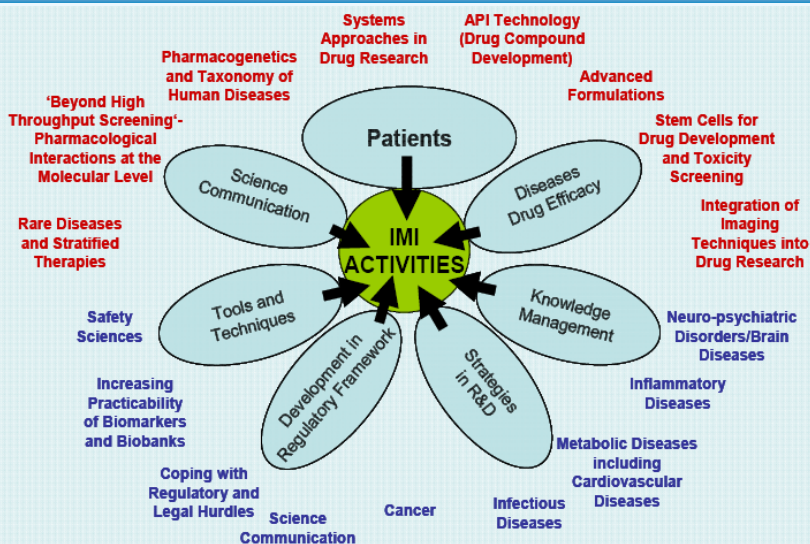
Old priorities, still there (2008):

- Safety Sciences
- Increasing Practicability of Biomarkers and Biobanks
- Coping with Regulatory and Legal Hurdles
- Knowledge Management
- Science Communication
- Neuro-psychiatric Disorders/Brain Disease
- Inflammatory Diseases
- Cancer
- Metabolic Diseases including cardiovascular diseases
- Infectious Diseases

New priorities (2011):

- Pharmacogenetics and taxonomy of human diseases;
- Rare diseases and stratified therapies;
- Systems approaches in drug research;
- Beyond high throughput screening - pharmacological interactions at the molecular level;
- Active Pharmaceutical Ingredient (API) technology (drug compound development);
- Advanced formulations;
- Stem cells for drug development and toxicity screening;
- Integration of imaging techniques into drug research.

Summary existing and new priorities



Call definition -> SRG

Governance



IMI 4th Call for Proposals, June 2011



Call definition -> SRG

Building an IMI project (1)

Call definition and launch



IMI 4th Call for Proposals, June 2011



A potential **Topic** of key interest is represented by 'Studies on disease heterogeneity leading to a new taxonomy of human disease'. Selected diseases, preferably chosen from the list of priority diseases (cf. Research Priorities) and where there is a priori

Scientific Research Agenda
Revision 2011

Page 18/43

THE INNOVATIVE MEDICINES INITIATIVE

evidence for heterogeneity, should be studied in sub-projects. The research should lead to identifying patterns of genes, as well as downstream biological phenomena and molecular changes closer to disease, for example, epigenetic changes, alternative splicing and post-translational modification of proteins that both predispose and protect against the selected diseases.

The **Topic** of 'Genetic mapping of extreme phenotypes' is of high relevance for the progress of the understanding in the variation of drug response and risk of adverse drug effects.

An IMI **Topic** on 'Co-ordinating R&D and enrolling studies on rare and neglected diseases' would be of value in reviewing potential bottlenecks in R&D on rare and neglected diseases that could be addressed through IMI. The European Medical Information System could facilitate enrolling in trials for rare diseases and obtaining samples to further disease understanding. It will be necessary to ensure that such work does not duplicate activities already being coordinated through other European R&D programmes. Projects and results of the FP7 Health theme, especially Activity 2.4.4 'Rare diseases' should be considered and engaged.

An IMI **Topic** on 'Paediatric medicines research' fostering the provision of multi-national, multi-source, pharmaco-epidemiological data covering all subsets of the paediatric population, would have a positive impact on the quality and the feasibility of clinical studies in children driven by the pharmaceutical industry. An active involvement of the corresponding authorities (EMA) will be requested. Investigations in other European initiatives should be considered (e.g. ECRIN), avoiding overlaps with ongoing projects in FP7 addressing paediatric research, and taking into account results from other European projects, or example TEDDY.

4.3 Systems Approaches in Drug Research

(Area of Interests: Strategies, Diseases)

Systems biology is presently a leading paradigm of life science research. IMI has the opportunity to play an active role in integrating systems biology paradigm into drug research. In light of the significant ongoing developments within systems biology the revision of the SRA will provide opportunities for future IMI calls in this field.

Systems approaches in drug research are by no means limited to the molecular or cellular level. An IMI **Topic** on 'Integrative organ-systems pharmacology' addressing tissue systems, organ systems and whole body systems and their integration into a comprehensive view on disease and potential therapies from 'molecule to patient' is recommended. Organ-systems modelling is of critical importance due to the fact that many 'classical definitions' of disease are based at the organ level. Synergies with existing European initiatives in the area (projects of Area 2.1.2 in the Health Theme, and FP7 topic 'Preparing for the future research and innovation activities in systems biology') should be considered.

An IMI **Topic** addressing 'New tools for hit and lead generation' could foster the set up of a joint European compound library and potentially a screening centre. Basic compound profiling should be run in a blinded way including minimal ADME and toxicology (*in silico*, *in vitro*, *in vivo*). Co-operation with existing IMI initiatives, for example E-TOX and other European initiatives (ESFRI EU-OPENSREEN, FP7 projects of Area 1.1 'High-throughput research' and Area 2.1 'Integrating Biological Data and Processes: Large Scale data gathering, Systems Biology' of the HEALTH theme) should be sought.

An IMI **topic** 'Towards a greater understanding of optimisation of kinetics of binding in drug discovery' would address this knowledge gap. Methods should be developed to allow information to be generated within project time scales so it could have a greater impact on compound design leading to more successful selection of drug candidates. Methodologies for the large-scale investigation and prediction of binding thermodynamics are also needed. New techniques designing compounds with specific thermodynamic and kinetic characteristic should be developed.



SRA - topics

platforms, inhibitor chemotypes and target associated biology. An IMI **Topic** addressing the challenges of understanding 'protein/protein interaction', and protein modifications such as 'ubiquitin ligation', to generate new methods and tools for this emerging area of drug R&D would be of value. Results from ongoing European projects, like Predict-IV 'Profiling the toxicity of new drugs: a non animal-based approach integrating toxicodynamics and biokinetics' should be considered.

development. An IMI **Topic** on 'In vivo predictive biopharmaceutics tools for oral drug delivery' is recommended in order to foster the development of new methods and validation of existing biopharmaceutics modelling/prediction tools for medicine performance in practice. 'Delivery and targeting mechanisms for biological macromolecules' is a topic of high interest in this Research Priority.

It is a relevant IMI **topic** to address the clear needs for the development of robust and practical functional imaging schemes that are appropriately translatable from preclinical models to the clinical area, validated and standardized across laboratories and hospitals and the public and private sector. Furthermore the use of a multimodal approach would allow validation of MRI-results based on BOLD or CBV imaging, with high test-retest variability, with alternative methods such as PET using FDG-PET or H2O15-PET, with excellent test-retest variability, an important point in longitudinal studies, including challenge studies. Close cooperation between IMI projects and other European imaging projects and, for example, Joint Programming Initiative on Neurodegeneration, ESFRI European Biomedical Imaging Infrastructure from molecule to patient (EuroBioImaging) should be aspired to and overlaps should be avoided.

51

10



Algunos puntos para el debate

- ¿Cómo mejorar la participación española en consorcios ganadores?
- ¿No se tienen buenos retornos por falta de capacidad o de medios?
- ¿Debemos mejorar el contacto con las farmas europeas?
- ¿Cómo hacer más visibles las capacidades españolas?
- ¿Deben las instituciones reforzar sus estructuras de apoyo?
- ¿Cómo mejorar la preparación?
- ¿Qué incentivos deben darse para favorecer la participación?
- ¿Qué herramientas de apoyo deberían darse desde la administración?
- ¿Debemos ser menos humildes y participar de una manera más relevante o no tenemos capacidades para ello?

52

(26/11/2012)



Centro para el Desarrollo Tecnológico Industrial



ÍNDICE

- Situación actual en IMI: desde la gestión a la participación
- Definición IMI2 en H2020: Tendencias y fechas



53

(26/11/2012)



Centro para el Desarrollo
Tecnológico Industrial





PROCESO DE DEFINICIÓN Y APROBACIÓN

La **propuesta** presentada por la CE el 30 de noviembre de 2011 se compone de los siguientes documentos (en discusión, públicos):

- **Comunicación** de la Comisión al Parlamento Europeo, al Consejo, al Comité Económico y Social Europeo y al Comité de las Regiones - Horizonte 2020 - Programa Marco de Investigación e Innovación (2014-2020) [COM(2011) 808 final]
- Propuesta de **Reglamento** del Parlamento Europeo y del Consejo por el que se **establece Horizonte 2020**, Programa Marco de Investigación e Innovación (2014-2020) [COM(2011) 809 final]
- Propuesta de **Reglamento** del Parlamento Europeo y del Consejo por el que se establecen las **normas de participación y difusión** aplicables a Horizonte 2020, Programa Marco de Investigación e Innovación (2014-2020) [COM(2011) 810 final]
- Propuesta de **Decisión del Consejo** por la que se establece el **Programa Específico** por el que se ejecuta Horizonte 2020, Programa Marco de Investigación e Innovación (2014 - 2020) [COM(2011) 811 final]

Los Reglamentos siguen el procedimiento legislativo ordinario.
El Programa Específico requiere de una decisión del Consejo.



PROCESO DE DEFINICIÓN Y APROBACIÓN

NOVEDADES:

El **Consejo** ha alcanzado un "acuerdo general parcial" sobre la propuesta de la CE sobre el Horizonte 2020.

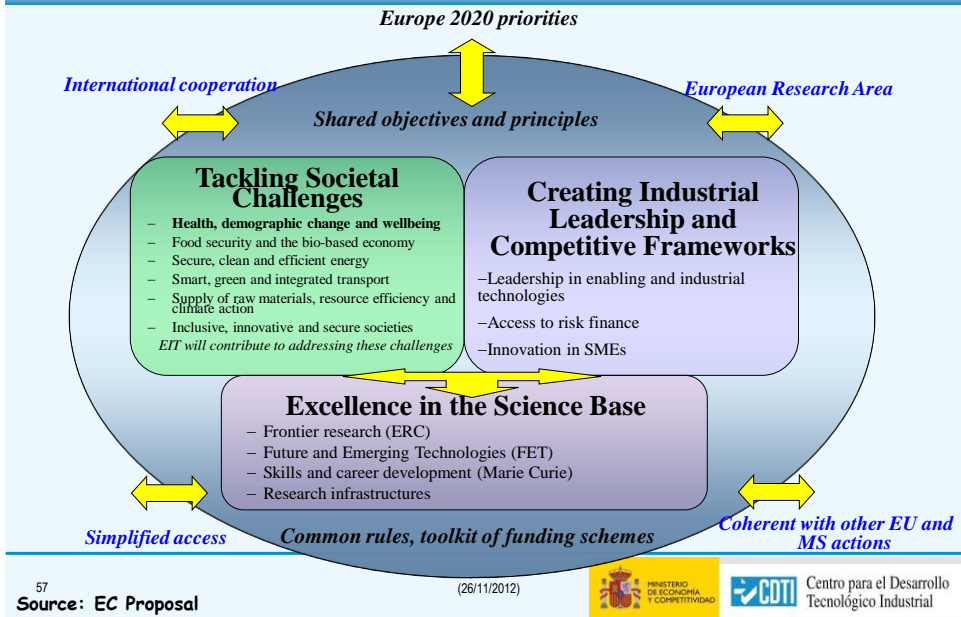
El **Parlamento Europeo** ha presentado los informes al respecto de la propuesta CE

- Propuesta de Reglamento por el que se establece Horizonte 2020
Rapporteur: Teresa RIERA MADURELL
- Propuesta de Reglamento Normas de Participación y Difusión:
Rapporteur: Christian EHLER
- Propuesta de Decisión sobre el Programa Específico:
Rapporteur: Maria Da Graça CARVALHO

Disponibles



Horizon 2020 – Objetivos y estructura



Estructura y Presupuesto

Propuesta CE

HORIZONTE 2020		79.271
I. Prioridad «Ciencia excelente»		24.598
1. El Consejo Europeo de Investigación (CEI)		13.268
2. Las Tecnologías Futuras y Emergentes (FET)		3.100
3. Las acciones Marie Curie		5.752
4. Las infraestructuras de investigación		2.478
II. Prioridad «Liderazgo industrial»		17.938
1. Liderazgo en tecnologías industriales y de capacitación:		13.781
1.1 Tecnologías de la información y la comunicación (TIC)		7.939
1.2 Nanotecnologías, 1.3 Materiales avanzados y 1.5 Fabricación y transformación avanzadas		3.797
1.4 Biotecnología		509
1.6 Espacio		1.536
2. Acceso a la financiación de riesgo		3.538
3. Innovación en las PYME		619
III. Prioridad «Retos sociales»		31.748
1. Salud, cambio demográfico y bienestar		8.033
2. Seguridad alimentaria, agricultura sostenible, investigación marina y marítima y bioeconomía		4.152
3. Energía segura, limpia y eficiente		5.782
4. Transporte inteligente, ecológico e integrado		6.802
5. Acción por el clima, eficiencia de los recursos y materias primas		3.160
6. Sociedades inclusivas, innovadoras y seguras		3.819
Instituto Europeo de Innovación y Tecnología (EIT)		1.360
Acciones directas no nucleares del Centro Común de Investigación (JRC)		1.962
EURATOM (2014-2018)		1.665

58

Precios constantes a 2011 en M€

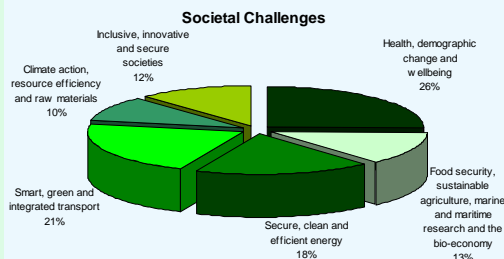
arrorollo trial



Prioridad «Retos sociales»

Propuesta CE

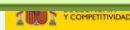
Esta parte responde directamente a las prioridades políticas y retos sociales expuestos en la estrategia Europa 2020 y se propone estimular la masa crítica de esfuerzos de investigación e innovación necesaria para alcanzar los objetivos políticos de la Unión.



III. Prioridad «Retos sociales»

31.748

- | | |
|---|-------|
| 1. Salud, cambio demográfico y bienestar | 8.033 |
| 2. Seguridad alimentaria, agricultura sostenible, investigación marina y marítima y bioeconomía | 4.152 |
| 3. Energía segura, limpia y eficiente | 5.782 |
| 4. Transporte inteligente, ecológico e integrado | 6.802 |
| 5. Acción por el clima, eficiencia de los recursos y materias primas | 3.160 |
| 6. Sociedades inclusivas, innovadoras y seguras | 3.819 |



Tecnológico Industrial
EUR million -Constant 2011 prices



Prioridad «Retos sociales»

Propuesta CE

1. Salud, cambio demográfico y bienestar: la salud a lo largo de la vida y el bienestar de todos, unos sistemas sanitarios y asistenciales de alta calidad y económicamente sostenibles y oportunidades para generar nuevos puestos de trabajo y crecimiento, efectuando así una importante contribución a Europa 2020.

2. Seguridad alimentaria, agricultura sostenible, investigación marina y marítima y bioeconomía: garantizar un abastecimiento suficiente de alimentos seguros y de gran calidad y otros bioproductos, mediante el desarrollo de sistemas de producción primaria productivos y que utilicen los recursos con eficiencia, el fomento de los correspondientes servicios ecosistémicos, junto con unas cadenas de abastecimiento competitivas y de baja emisión de carbono. De este modo se acelerará la transición a una bioeconomía europea sostenible.

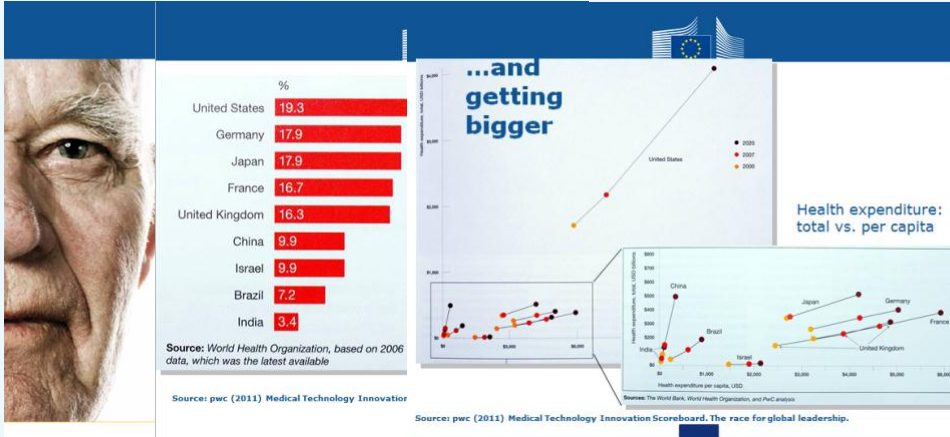
3. Energía segura, limpia y eficiente: hacer la transición hacia un sistema energético fiable, sostenible y competitivo, en un contexto de creciente escasez de recursos, aumento de las necesidades de energía y cambio climático.



THE CHALLENGE

Propuesta CE

- Health, demographic change and well-being -> major societal challenges (H2020)



61

(26/11/2012)



Centro para el Desarrollo Tecnológico Industrial



Salud, cambio demográfico y bienestar

Objetivos:

- la salud a lo largo de la vida y el bienestar de todos,
- unos sistemas sanitarios y asistenciales de alta calidad y económicamente sostenibles
- y oportunidades para generar nuevos puestos de trabajo y crecimiento.



Garantizar la salud a lo largo de la vida y el bienestar de todos



Eficacia de la prevención, tratamiento y gestión de la enf. y discapacidad

62

(26/11/2012)

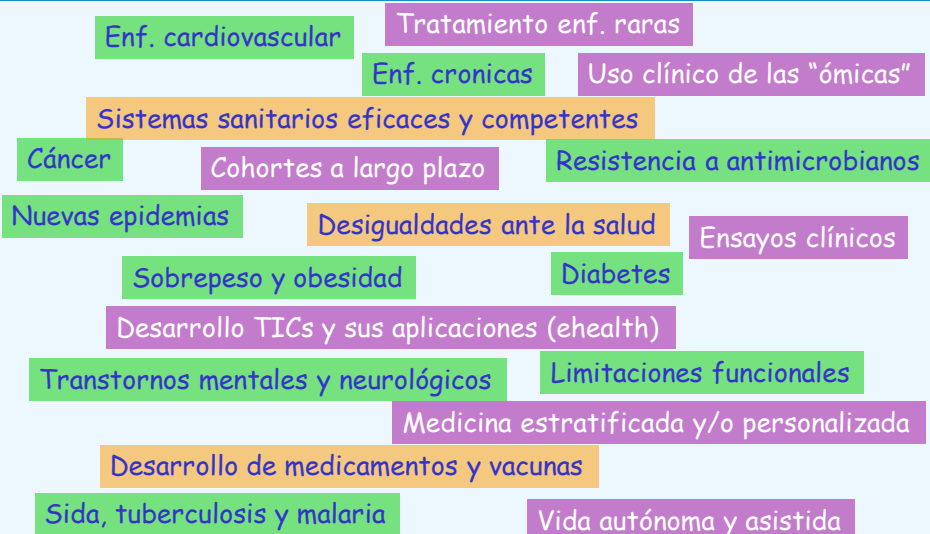


Centro para el Desarrollo Tecnológico Industrial



(COM CE) Retos identificados

Propuesta CE



63

Patologías Retos Planteamientos, herramientas y tecnologías Centro para el Desarrollo Tecnológico Industrial



Líneas generales de las actividades

Propuesta CE

1. Comprensión de los factores determinantes de la salud (incluidos los relacionados con el medio ambiente y el clima),
2. mejora de la promoción de la salud y la prevención de la enfermedad;
3. comprensión de la enfermedad y mejora del diagnóstico;
4. desarrollo de programas de detección eficaces y mejora de la evaluación de la propensión a las enfermedades;
5. mejora de la vigilancia y la preparación;
6. desarrollo de mejores vacunas preventivas;
7. uso de la medicina *in silico* para mejorar la predicción y la gestión de enfermedades;
8. tratamiento de las enfermedades;

64

(26/11/2012)



MINISTERIO DE ECONOMÍA Y COMPETITIVIDAD
Centro para el Desarrollo Tecnológico Industrial



Líneas generales de las actividades

Propuesta CE

9. transferencia de conocimientos a la práctica clínica y acciones de innovación modulares;
10. mejor uso de los datos sanitarios;
11. envejecimiento activo, vida autónoma y asistida;
12. capacitación de las personas para la autogestión de su salud;
13. promoción de la asistencia integrada;
14. mejora de herramientas y métodos científicos al servicio de la formulación de políticas y las necesidades normativas;
15. y optimización de la eficiencia y la eficacia de los sistemas de asistencia sanitaria y reducción de las desigualdades a través de la toma de decisiones basada en los datos y la divulgación de las mejores prácticas, y de tecnologías y planteamientos innovadores.



HEALTH, DEMOGRAPHIC CHANGE AND WELLBEING (I)

1.1. Understanding health, wellbeing and disease

1.1.1. Understanding the determinants of health, improving health promotion and disease prevention

1.1.2. Understanding disease

1.1.3. Improving surveillance and preparedness

1.2. Preventing disease

1.2.1. Developing effective prevention and screening programmes and improving the assessment of disease susceptibility

1.2.2. Improving diagnosis and prognosis

1.2.3. Developing better preventive and therapeutic vaccines

1.3. Treating and managing disease

1.3.1. Treating disease, including developing regenerative medicine

1.3.2. Transferring knowledge to clinical practice and scalable innovation actions

Cambio de estructura propuesto
EN DISCUSIÓN



HEALTH, DEMOGRAPHIC CHANGE AND WELLBEING (II)

1.4. Active ageing and self-management of health

1.4.1. Active ageing, independent and assisted living

1.4.2. Individual awareness and empowerment for self-management of health

1.5. Methods and data

1.5.1. Improving health information and better use of health data

1.5.2. Improving scientific tools and methods to support policy making and regulatory needs

1.5.3. Using in-silico medicine for improving disease management and prediction

Cambio de estructura propuesto
EN DISCUSIÓN

(26/11/2012)



Centro para el Desarrollo
Tecnológico Industrial



HEALTH, DEMOGRAPHIC CHANGE AND WELLBEING (III)

1.6. Health care provision and integrated care

1.6.1. Promoting integrated care

1.6.2. Optimising the efficiency and effectiveness of healthcare provision and reducing inequalities by evidence based decision making and dissemination of best practice, and innovative technologies and approaches

1.7. Specific implementation aspects

Cambio de estructura propuesto
EN DISCUSIÓN


(26/11/2012)



Centro para el Desarrollo
Tecnológico Industrial



Implementación (posible escenario)

 2 EDCTP (2) - The European and Developing Countries Clinical trials Partnership	 2 AAL (2) - Ambient Assisted Living	Pendiente definición y posterior aprobación	Art. 185 TFUE P2P	FINANCIACIÓN
 2 IMI (2) - Innovative Medicines Initiative	Art. 187 TFUE JTI / PPP			
 JPND - Neurodegenerative Disease Research (JPND) initiative	 More Years, Better Lives - The Potential and Challenges of Demographic Change	 JPI AMR - Microbial Challenge - An Emerging Threat to Human Health	 JPI - A Healthy Diet for a Healthy Life <i>Reto 2, parcial reto 1</i>	¿ESTRATEGIA?
 EIP AHA - European Innovation Partnership on Active and Healthy Ageing	EIP			
 EIT - European Institute of Innovation & Technology	KIC HL&AA - Knowledge Innovation Community for Healthy Living and Active Ageing	KIC	TBD	



Tentative scenario*

No oficial, sólo estimaciones

	Challenge 1: Health, Demographic Change & Wellbeing					
	Constant prices (M€)			Current prices (M€)		
	Conservative Scenario	Wild Scenario	Average Scenario	Conservative Scenario	Wild Scenario	Average Scenario
Proposed Budget (EC)	8.033,00	8.033,00	8.033,00	9.077,00	9.077,00	9.077,00
Contribution to EIT	254	254	254	292	292	292
Contribution to AAL2 (P2P)	175	175	175	175	175	175
Contribution to EDCTP2 (P2P)	500	1.000	750	500	1.000,00	750
Contribution to IMI2 (PPP)	1.500	3.000	2.250	1.500	3.000	2.250
Contribution to SME scheme (SBIR-like) 10%	803,3	803,3	803,3	907,7	907,7	907,7
Not committed	4.800,70	2.800,70	3.800,70	5.702,30	3.702,30	4.702,30
	60%	35%	47%	63%	41%	52%
To be defined contribution to JPIs, if any						



GLOSSARY

- **IMI:** Innovative Medicines Initiative www.imi.europa.eu
- **EC:** European Commission <http://ec.europa.eu>
- **PPP:** Public-Private Partnership & **P2P:** Public-Public Partnership http://ec.europa.eu/research/era/partnership/partnering_en.htm
- **EIT:** European Institute of Innovation & Technology <http://eit.europa.eu>
- **AAL:** Ambient Assisted Living www.aal-europe.eu
- **EDCTP:** The European and Developing Countries Clinical Trials Partnership www.edctp.org
- **SME:** Small and medium-sized enterprises http://ec.europa.eu/enterprise/policies/sme/index_en.htm
- **SBIR:** Small Business Innovation Research www.sbir.gov
- **JPI:** Joint Programming Initiative http://ec.europa.eu/research/era/areas/programming/joint_programming_en.htm
- **EFPIA:** The European Federation of Pharmaceutical Industries and Associations www.efpia.eu
- **COCIR:** European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry www.cocir.org



Fichas nuevas iniciativas

Centro para el Desarrollo Tecnológico Industrial / ...

Está usted en: Financiación empresarial / Internacionalización de la I+D+i / Programa Marco de la UE / Salud /

Qué es el CDTI

Financiación empresarial

- Financiación de proyectos de I+D+i
- 1 - Internacionalización de la I+D+i**
- Ayudas CDTI: INTERNACIONALIZA
- Ayudas CDTI: INVOLUCRA
- 2 - Programa Marco de la UE**
- 3 - Salud**
- Alimentación, Agricultura y Pesca, y Biotecnología
- Tecnologías de la Información y Comunicaciones
- Nanociencias, Nanotecnologías, Materiales y Nuevas Tecnologías de la Producción
- Financiación

Salud

Estrategia

- EIT-KIC: Propuesta CE y proceso de definición. 05 de octubre de 2012.
- Primera convocatoria de la Asociación Europea para la Innovación sobre un Envejecimiento Activo y Saludable (25.05.2012).
- Propuesta Horizonte 2020 e Investigación en Salud. Versión 22 de marzo de 2012.
- 4 - ESTRATEGIA EN SALUD:** Algunas iniciativas europeas nuevas o en implementación. Versión 01 de Diciembre de 2011.

Servicios

- Contacto / Buzón
- Listas de distribución
- Enlaces de interés
- Eventos
- Noticias
- Documentación relacionada
- Convocatorias
- Preguntas frecuentes
- Búsqueda de socios
- Listado de correos informativos
- 4 - Estrategia**
- Oficina Europea (MINECO)
- Inicio

<http://www.cdti.es/index.asp?MP=7&MS=51&MN=4&TR=C&IDR=1773&IDP=133&IDS=929>





The key messages of the Communication are:

- Partnering activities have demonstrated the potential to contribute to the objectives of Europe 2020, notably to the Innovation Union flagship. Therefore, they will continue to be an important element of future European research and innovation policy.
- There is a need for increased long-term commitment from all partners, including Member States and industry, to partnering.
- The partnering landscape will be simplified, including by rationalising the number of partnering instruments.



4. NEXT STEPS

The Commission's proposal for "Horizon 2020"¹⁰ will build on the steps set out in this Communication, providing a legislative basis for future EU P2Ps and PPPs in R&I. This should also provide a common set of rules for all initiatives supported under "Horizon 2020" in order to simplify participation, while leaving the necessary flexibility for individual initiatives to achieve their objectives, as well as ensure complementarity between the two Common Strategic Frameworks, for Research and Innovation and for Cohesion.

As we gain more experience with implementation of the partnering concepts and instruments developed under FP7, the Commission will launch a strategic exercise to determine where and how the partnering approach can be applied most successfully and the types of initiative to which the instruments are best suited.

As a first step, the Commission intends to establish benchmarks against which to assess the efficiency and effectiveness of the implementation of initiatives developed using the partnering concepts and instruments.

http://ec.europa.eu/research/era/pdf/partnering_communication.pdf



Future PPP



European Federation of Pharmaceutical Industries and Associations

Innovative Medicines Initiative - A Public Private Partnership success story

Magda Chlebus
Director Science Policy
Gdansk, 25 September 2012



European Federation of Pharmaceutical Industries and Associations

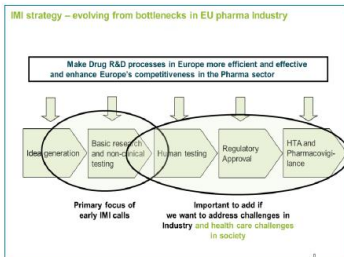
New generation PPP under Horizon 2020 – scientific contents

77



European Federation of Pharmaceutical Industries and Associations

Evolution that started in IMI



Horizon 2020: An opportunity we can't let go

Horizon 2020 is a unique opportunity and driver for creating the changes needed for both the industry and society.

Horizon 2020 provide a frame for developing a new forward looking frame for a Public Private Partnership in the Healthcare area, which should focus on open innovation and game changing projects.

Horizon 2020 should focus on the shared interests which society and industry have in solving the major healthcare challenges facing us.



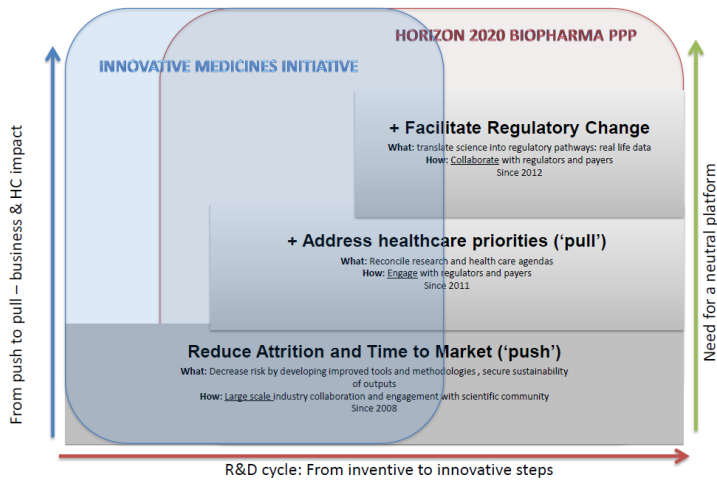
- From IMI to Horizon 2020
- From European to Global
- From bottlenecks in industry to a shared agenda between society and industry on healthcare challenges

78

irrollo
rial



EVOLUTION OF INDUSTRY/EU PPP CONCEPT FROM BOTTLENECKS IN INDUSTRY TO BOTTLENECKS IN SOCIETY



79



Desarrollo
tecnológico industrial



efpia

European Federation of Pharmaceutical
Industries and Associations

Contents – key principles

- **Societal bottlenecks:** move from scientific and technological challenges in the industry only to addressing industry bottlenecks and resolving healthcare and societal challenges.
- **Holistic view on disease burden** (not just primary care focus)
- **Starting point:** health priorities, e.g. priority medicines and diseases as outlined in the 2004 WHO report (under revision)

80

20

Desarrollo
Industrial



- What is different from current agenda?
 - Beyond technology platform – aligning health, research and regulatory agendas
 - Translating new sciences and technologies into health/societal benefits: drive necessary change in regulatory pathways and healthcare delivery
- “Healthy living – from conception to grave”
 - Prevention and therapy
 - High priority disease areas covered by 2004 WHO and main healthcare policies e.g. antimicrobial resistance, cancer, diabetes, autoimmune diseases, neuro-degeneration, psychiatry, vaccination ...
 - As well as cross cutting themes such as technology developments, population specific developments, delivery mechanisms, ...



- Examples of axes of activities within priority medicine area:
 - Understanding and classification of diseases
 - Target identification and clinical validation
 - Safety of compounds
 - Methodologies to evaluate treatment effects
 - Development and regulatory approval of novel therapeutic agents
 - Preventive and therapeutic vaccines (specific work stream)
- This is current snapshot – the agenda will continue to evolve
 - Continued consultations with key actors of the biomedical scientific community, healthcare professional and patients – tell us what your needs are!!
 - The agenda will have to adapt to scientific progress and developments in other R&D structures



Relevant events

Events 2012

13/11/2012 - **Health Research at a Crossroads**

Join IMI at the European Parliament in Brussels on Tuesday 13 November (17:00-20:00)...

11/10/2012 - **The Innovative Medicines Initiative**

Putting Policy into Practice IMI will hold a symposium on open innovation entitled...

04/10/2012 - **Connecting new science, research and healthcare needs**

Join IMI and the European Federation of Pharmaceutical Industries and...



Public consultation:

http://ec.europa.eu/research/consultations/life_science_h2020/consultation_en.htm

Title
Consultation on plans for a public-private partnership in life sciences research and innovation under Horizon 2020

Policy field(s)
Research

Target group(s)
All citizens and organisations are welcome to contribute to this consultation. Contributions are particularly sought from companies, organisations and researchers active in life sciences research and innovation.

Period of consultation
From 11.07.2012 to 04.10.2012

Contribution
If you are answering this consultation on behalf of a public authority, please [click here](#) to submit your contribution. Contributions will be published on the Internet. It is important to read the specific privacy statement.





Current situation

General

- Economic crisis
- Health sector strongly affected
- Pharma companies closing EU research&innovation units

IMI

- Tendency to bigger projects
- Some projects NO pre-competitive
- Increase in outside EU participation (as EFPIA contribution in kind)
- Big % of budget to be committed in last years -> Calls every month

85

(26/11/2012)



Centro para el Desarrollo Tecnológico Industrial



Points to reflect: now & for the future

• Open and competitive calls scheme

Coherent planning & enough time to prepare proposals

• European Union Industrial Competitiveness

- Others invited to contribute, but EU funding = EU industry contribution
- The potential of non-SME/non-EFPIA companies is underused

• Strategic Research Agenda

Focus on pre-competitive research -> still many gaps in the SRA for EU

• Future of IMI

Considering problems identified now & in line with EU needs.
States in formal committee to vote decisions

86

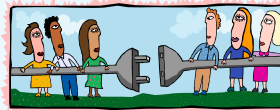
(26/11/2012)



Centro para el Desarrollo Tecnológico Industrial



IMI: Mirando al futuro



87

(26/11/2012)



Centro para el Desarrollo
Tecnológico Industrial



Last remarks

Opportunity rarely knocks on your door.
Knock rather on opportunity's door if you
ardently wish to enter.

B. C. Forbes

88

(26/11/2012)

Bertie Charles Forbes (May 14, 1880 - May 6, 1954) was a Scottish financial journalist and author who founded Forbes Magazine.



Centro para el Desarrollo
Tecnológico Industrial



CDTI - Contact details

CDTI	Contact Person	E-mail
Dpto. Progr. Marco de I+D. Dir. Programas Innovadores Globales	Marta Gómez Quintanilla Representante Salud e IMI	marta.gomez@cdti.es
Dpto. Biotecnología, Salud y Agroalimentación. Dirección Mercados Innovadores Globales	Carolina Carrasco NCP- HEALTH	carolina.carrasco@cdti.es
	Pilar Sanz	mariapilar.sanz@cdti.es
	M ^a Pilar de Miguel NCP-NMP	mariapilar.demiguel@cdti.es



www.cdti.es
915815500



Servicio de
Asesoramiento
Personalizado
www.cdti.es/pidi
902347434

89

(26/11/2012)



Centro para el Desarrollo
Tecnológico Industrial



LINKS



Mailing List

www.imi.europa.eu

www.cdti.es

Agenda

Info FP7 & IMI



90



Marta Gómez Quintanilla
Spanish Representative - HEALTH
Spanish Representative - IMI
Spanish MB Member - JPND
Ph: 34 91 581 55 62 / 00
[marta.gomez\[at\]cdti.es](mailto:marta.gomez[at]cdti.es) - www.cdti.es

