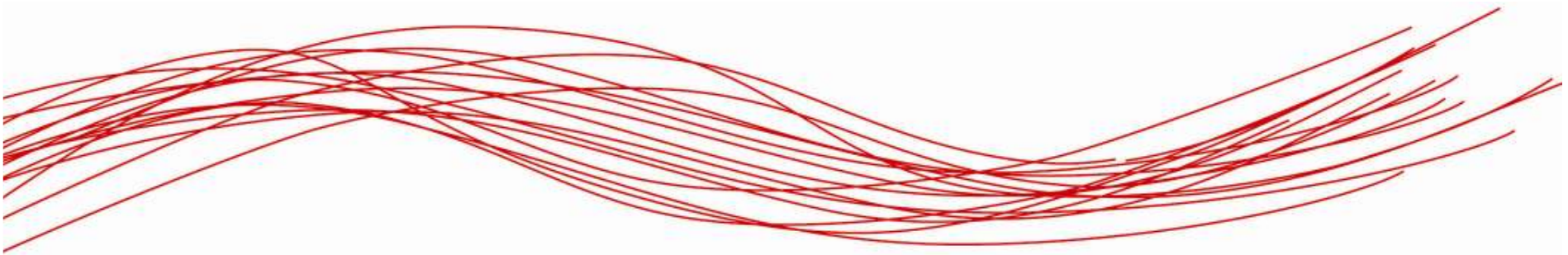


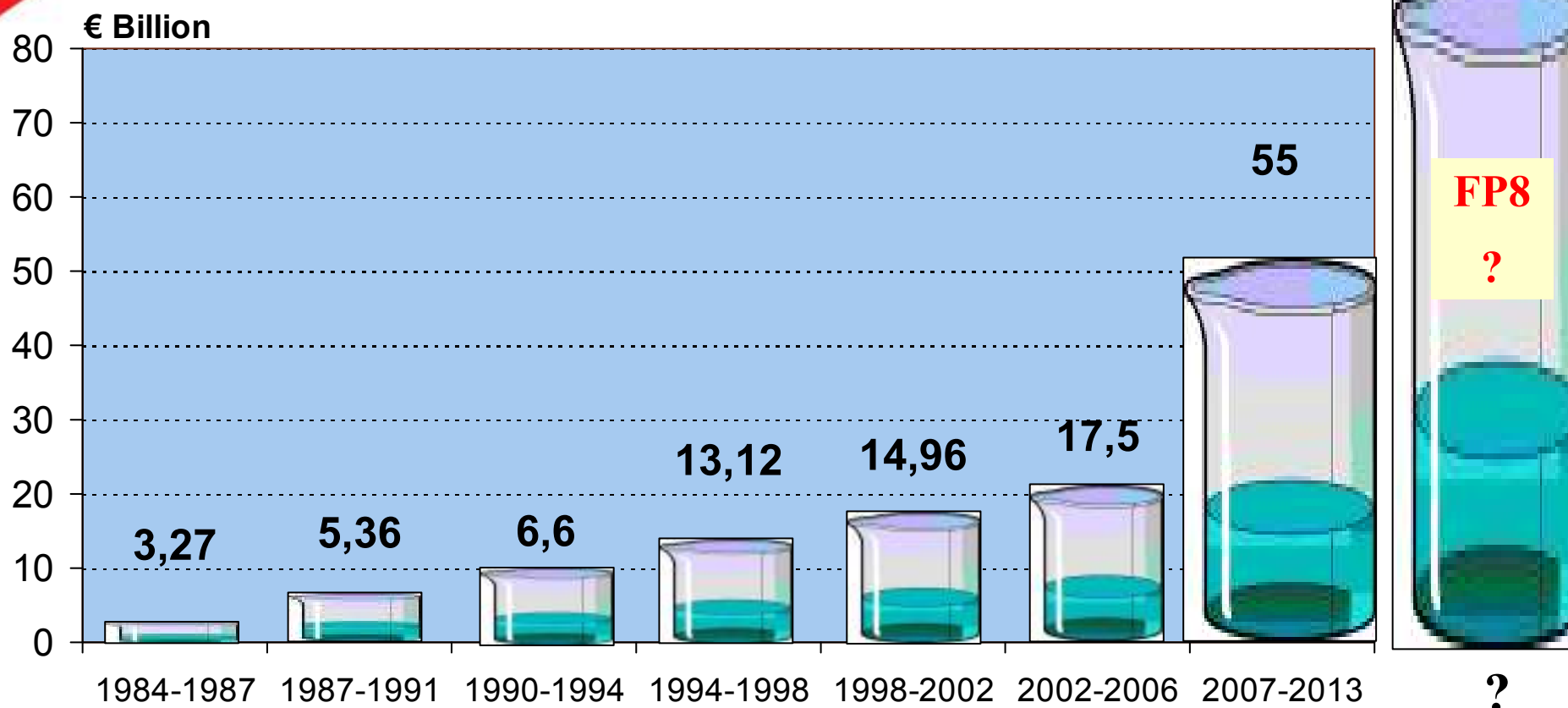
*XIV RIUNIONE ANNUALE  
NETWORK COCHRANE ITALIANO  
Perugia, 20-21 2009*

# **Priorità della Ricerca nel Programma Quadro Europeo (FP7)**



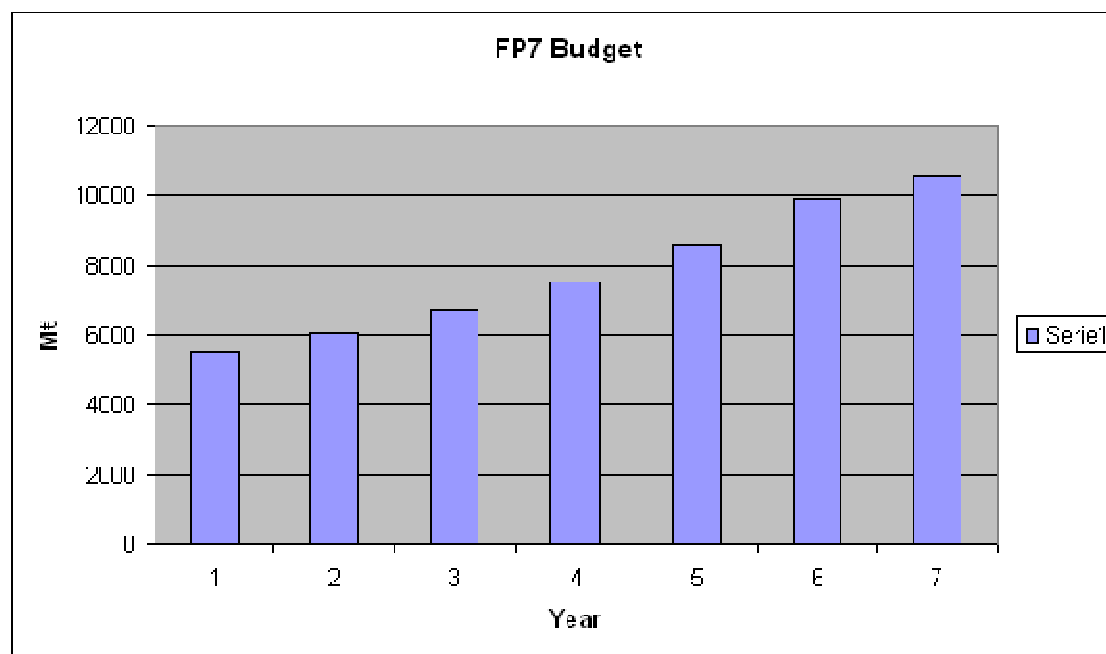
**Stefano Vella**  
*Istituto Superiore di Sanità*

# Budgets of the EU FP



Not legally binding: (based on draft documents) applicants must refer to final published work programme.





2007 – 2013 +60% (FP6)

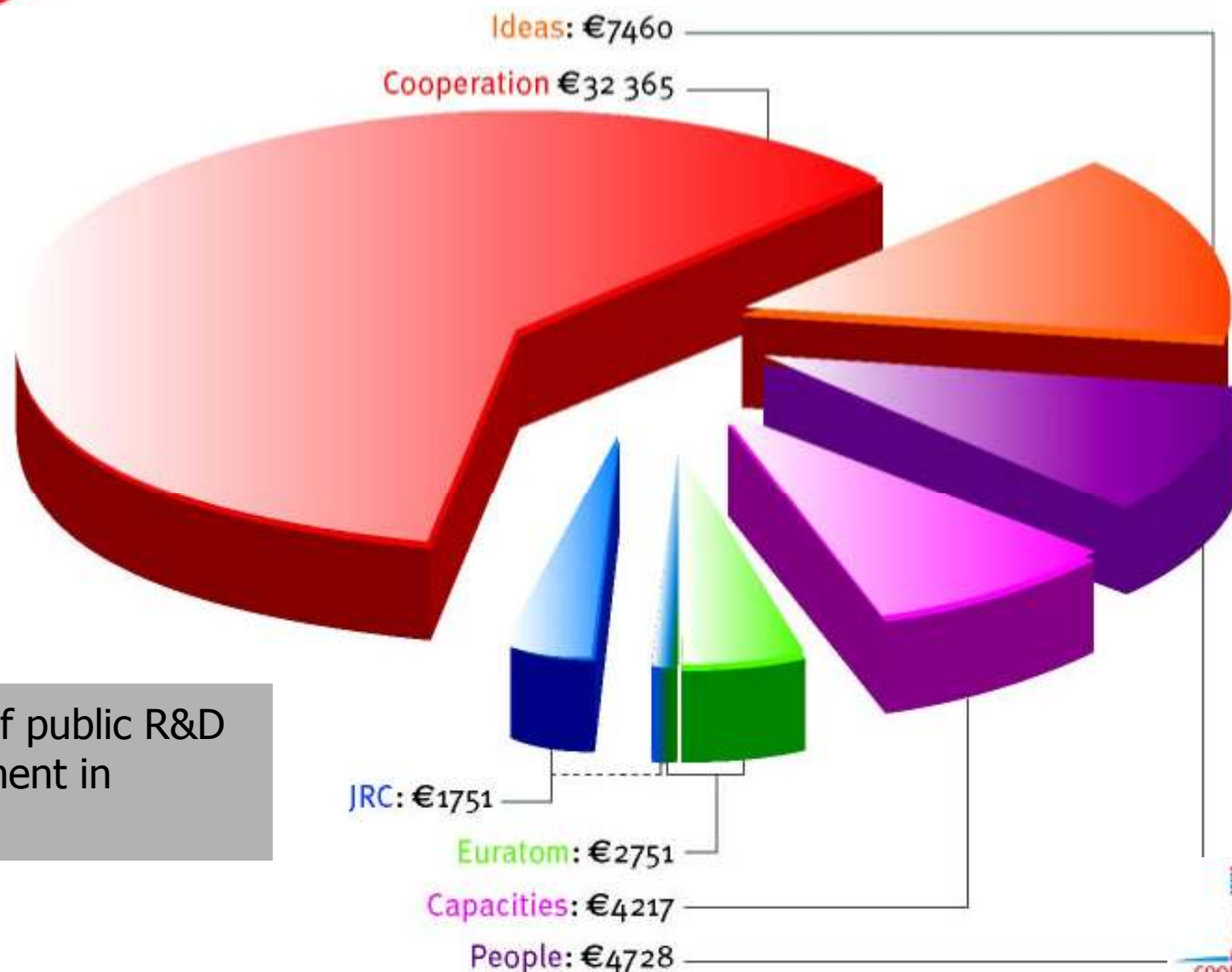
2007 – 2010 +35%

2011 – 2013 +90%

Not legally binding: (based on draft documents) applicants must refer to final published work programme.



# FP7 budget (2007-2013): €55 billion



= ~6% of public R&D investment in Europe

Not legally binding. (based on draft documents), applicants must refer to final published work programme



# The Cooperation programme

## *Thematic Priorities*

<b>1. Health</b>	6.1
2. Food, agriculture, fisheries and biotechnology	1.9
3. Information and communication technologies	9.1
4. Nanosciences, nanotechnologies	3.5
5. Energy	2.3
6. Environment (including climate change)	1.9
7. Transport (including aeronautics)	4.2
8. Socio-economic sciences and the humanities	0.6
9. Security & 10. Space	2.8
<b>Total for collaborative research</b>	<b>€32.4 billion</b>

Not legally binding: (based on draft documents) applicants must refer to final published work programme.



# Structure of the Health Theme

Not legally binding: (based on draft documents) applicants must refer to final published work programme.



# The Health Theme

## Three main activities (“pillars”)

### **Activity 1**

**Biotechnology,  
generic tools  
& technologies  
for health**

### **Activity 2**

**Translating  
research for  
human health**

### **Activity 3**

**Optimising  
the delivery  
of health care**



**The  
Innovative  
Medicines  
Initiative**

### **Activity 4:**

**Support actions & response to policy needs**

# Scope of research in the Health Theme

- Funding can support both basic and applied research, translational research and early clinical trials
- Normally phase I and II clinical trials
- In some exceptional cases, phase III can included

Not legally binding: (based on draft documents) applicants must refer to final published work programme.





# Policy dimensions: Industry (SME) participation & International Cooperation

Emphasis and special measures for:

- Small & Medium-sized Enterprises (SMEs)
  - Opportunities and support measures
- International Cooperation
  - Specific International Cooperation Actions (SICA)
  - Bilateral agreements for targeted co-funding

Not legally binding: (based on draft documents) applicants must refer to final published work programme.

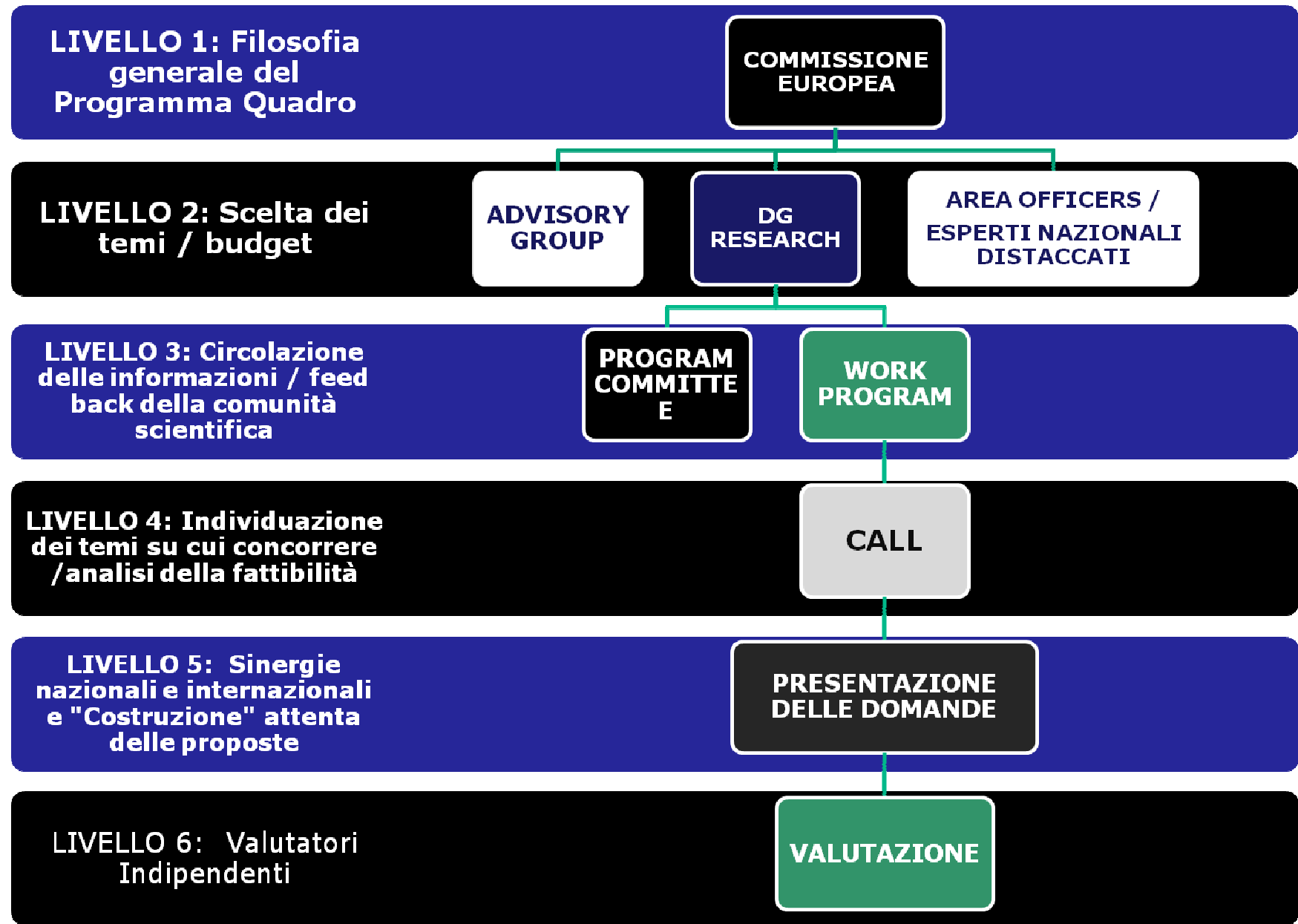


# THE PROCESS

- Overall Structure
- Topic definition
- Project Evaluation

Not legally binding: (based on draft documents) applicants must refer to final published work programme.





# Topic definition

- Each year, a work programme is prepared by the EC
- Not all topics / areas can be opened at any one time: some areas are closed in some calls
- Topics are drafted by the Commission service
- Workshops and conferences with scientists and other stakeholders
- Input from Member States & Associated Countries (Programme Committee)
- Advisory Groups

Not legally binding: (based on draft documents) applicants must refer to final published work programme.



# How topics are drafted...

- Topics drafted by DG Research in response to:
  - public health needs
  - new scientific/technological developments
  - existing (and to be promoted) research capacity in Europe
  - other policy needs (international collaboration, coherence with development aid, etc.)
- Input from Scientific Advisory Group, ECDC, SANCO (and other DGs), WHO, individual scientists, scientific societies...
- Not every disease in every call !
- Discussed and agreed with Committee of Member States (Programme Committee)

# Submission & evaluation

- Single-stage or two-stage
- Eligibility check (partners, limits, scope, deadline)
- Evaluation by panels of independent experts overseen by Independent Observers

- **3 criteria:**

- Science & Technology excellence
- Implementation & Management
- Potential Impact

## Thresholds:

3/5	
3/5	overall
3/5	10/15

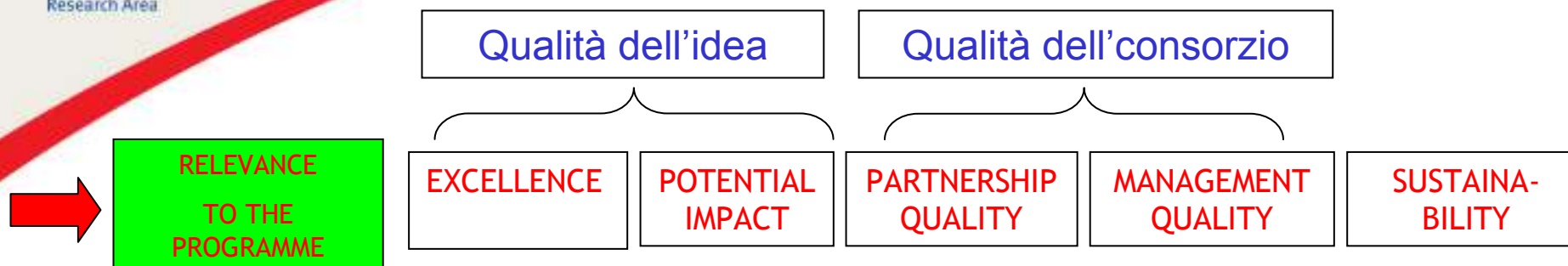
- Feedback: Evaluation Summary Reports (ESRs)

Not legally binding: (based on draft documents) applicants must refer to final published work programme.



# Key factors for success

# IL PROGETTO



- Le attività devono rispondere allo spirito della call
- Le attività devono essere misurabili sia dal punto di vista qualitativo che quantitativo
- Incorporare nel progetto lezioni tratte dal passato e/o risultati di precedenti progetti



## IL PROGETTO

Qualità dell'idea

Qualità dell'consorzio



RELEVANCE  
TO THE  
PROGRAMME

EXCELLENCE

POTENTIAL  
IMPACT

PARTNERSHIP  
QUALITY

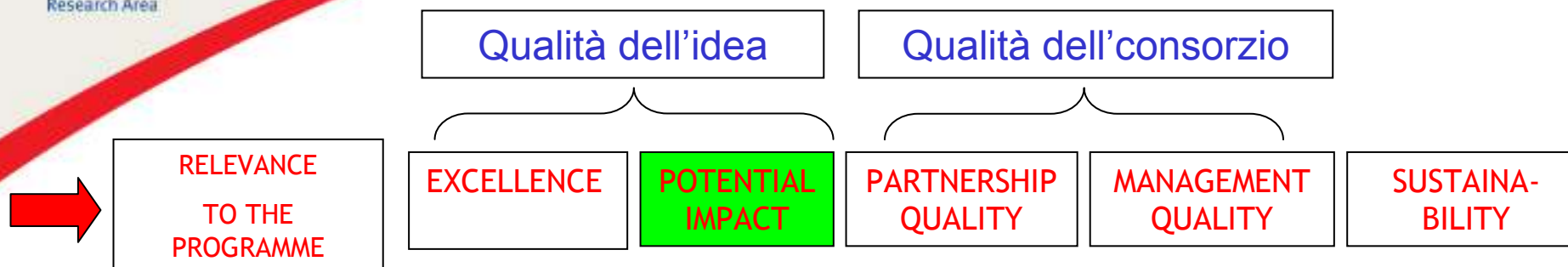
MANAGEMENT  
QUALITY

SUSTAINA-  
BILITY

- Considerare attentamente lo stato dell'arte
- Avere obiettivi chiari con analisi dei possibili fattori di rischio
- La metodologia descritta con chiarezza

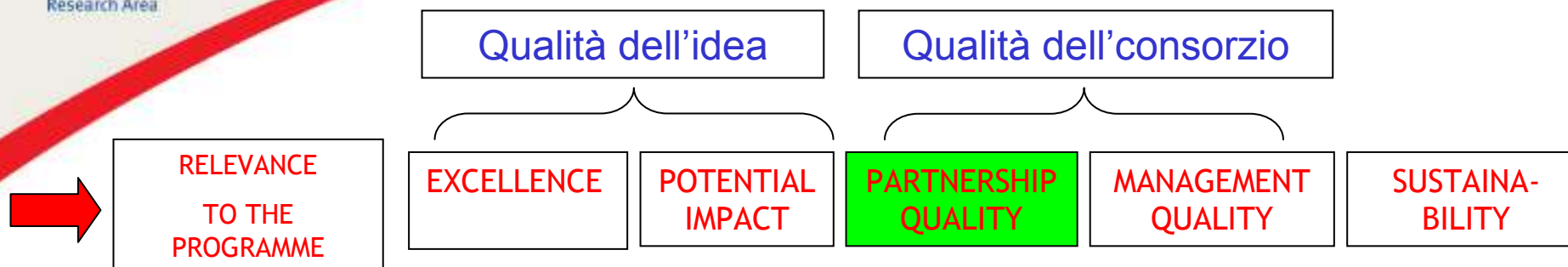
Not legally binding: (based on draft documents) applicants must refer to final published work programme.

# IL PROGETTO



- Deve avere una dimensione Europea
- Deve essere possibile identificare l'impatto in termini di benessere generale
- Elaborare una robusta strategia di divulgazione dei risultati (sito internet, report, libri, pubblicazioni scientifiche, workshop, etc)

# IL PROGETTO



- La competenza di ciascun partner deve essere adeguata
- Sinergia identificabile all'interno della partnership
- Spiegare i criteri con cui sono stati decisi i partner
- Un equilibrio geografico può contare, ma è essenziale che la competenza dei partner sia funzionale alle attività del progetto

not legally binding. (based on draft documents) applicants must refer to final published work programme.

# IL PROGETTO

Qualità dell'idea

Qualità dell'consorzio



RELEVANCE  
TO THE  
PROGRAMME

EXCELLENCE

POTENTIAL  
IMPACT

PARTNERSHIP  
QUALITY

MANAGEMENT  
QUALITY

SUSTAINA-  
BILITY

- La struttura del management deve essere semplice e contenuta in termini di costo (meglio non superiore al 7% del costo totale del progetto)
- Budget equilibrato tra risorse umane e materiali
- Il Coordinatore deve avere competenze scientifiche, amministrative, legali, finanziarie (e di pazienza) necessarie
- Le sue capacità manageriali e gestionali sono elemento importante nella valutazione del progetto
- Meglio se il coordinatore ha partecipato almeno da partner a precedenti progetti

## IL PROGETTO

Qualità dell'idea

Qualità dell'consorzio

RELEVANCE  
TO THE  
PROGRAMME

EXCELLENCE

POTENTIAL  
IMPACT

PARTNERSHIP  
QUALITY

MANAGEMENT  
QUALITY

SUSTAINA-  
BILITY

- Spiegare come la sostenibilità del progetto sarà garantita anche dopo la sua fine, per esempio...
  - Le attività sono utili e coerenti con quelle dell'ente di appartenenza, quindi saranno proseguite in futuro
  - C'è il supporto dei policy makers alle attività svolte
  - Il sito internet continuerà ad essere aggiornato
  - Sono state individuate altre fonti di finanziamento dopo quella della CE



EUROPEAN  
COMMISSION

European  
Research Area

## Outcome of first 3 calls

(2007-2008-2009):

431 projects, €1.8 billion awarded

# Overview of first calls in the Health theme

- 1st year (2007 budget): € 641 million
- 2nd year (2008 budget): € 577 million
- 3rd year (2009 budget): € 610 million
  
- 4th year (2010 budget): € 650 million

Not legally binding: (based on draft documents) applicants must refer to final published work programme.



# Outcome of first calls of FP7 Health

Call		Proposals evaluated	Projects funded	Success rate
2007		893	153	17%
2008		865	172	20%
2009	<i>1st</i>	513	95	18.5%
	<i>2st</i>	26	11	42%
<b>TOTAL</b>		<b>2,297</b>	<b>431</b>	<b>20%</b>

Not legally binding: (based on draft documents) applicants must refer to final published work programme.





# Selection rates and scores (first 3 years)

- Above all thresholds: 50% of proposals
- Scores of funded proposals:

Call	Projects funded	Score <11.0	Score <12.0	S&T <4.0
2007	153	0	10	0
2008	172	0	0	0
2009	106	0	2	0
<b>Total</b>	<b>431</b>	<b>0</b>	<b>12</b>	<b>0</b>

Not legally binding: (based on draft documents) applicants must refer to final published work programme.

# 2010 call for proposals (4<sup>th</sup> call)

WORK PROGRAMME 2010

*COOPERATION*

THEME 1

*HEALTH*

14 May 2009

*(European Commission C(2009)XXX of XX.XXX.2009)*

Not legally binding: (based on draft documents) applicants must refer to final published work programme.

COOPERATION

# 2010 calls for proposals

Publication 30 July 2009

- Two main calls:
  - **FP7-HEALTH-2010-single-stage** (40 topics) deadline: 19 Nov.'09
  - **FP7-HEALTH-2010-two-stage** (13 topics) deadline: 29 Oct. 2009
- plus special calls:
  - **Coordinated call for AFRICA** (with Food and Environment themes)  
6 topics, deadline: 14 Jan. 2010
  - **Coordinated call for Influenza** (coordinated with Food theme)  
one topic, deadline: 29 Oct. 2009
  - **FP7-ERANET-2010-RTD**  
3 topics, deadline: 12 Jan. 2010
  - **FP7-HEALTH-2010-Alternative-testing-strategies**  
1 topic, deadline: 3 Feb. 2010

Not legally binding: (based on draft documents) applicants must refer to final published work programme.



# Conditions for 2-stage submission/evaluation

- **First stage:**

- proposal size limited to 6 pages  
(5 pages max. on research and expected impact  
+1 page max. to describe consortium and financial  
resources)
- evaluation of 2 criteria only (S/T quality and Impact)
- Higher thresholds: 4/5 S/T; 3/5 Impact; 8/10 Overall

- **Second stage:**

- only proposals passing stage 1 will be invited to submit full  
proposals for stage 2
- evaluation on all 3 criteria
- Higher thresholds (overall 12/15)

Not legally binding: (based on draft documents) applicants must refer to final published work programme.



# Overview of 3<sup>rd</sup> calls results

# Response to 3<sup>rd</sup> call(s) overview

## Call FP7-HEALTH-2009- single-stage

64 topics

€476 million

531 proposals received

18 ineligible proposals

513 proposals evaluated

## two-stage

7 topics

€115 million

148 proposals received

3 ineligible

145 proposals evaluated (1<sup>st</sup> stage)

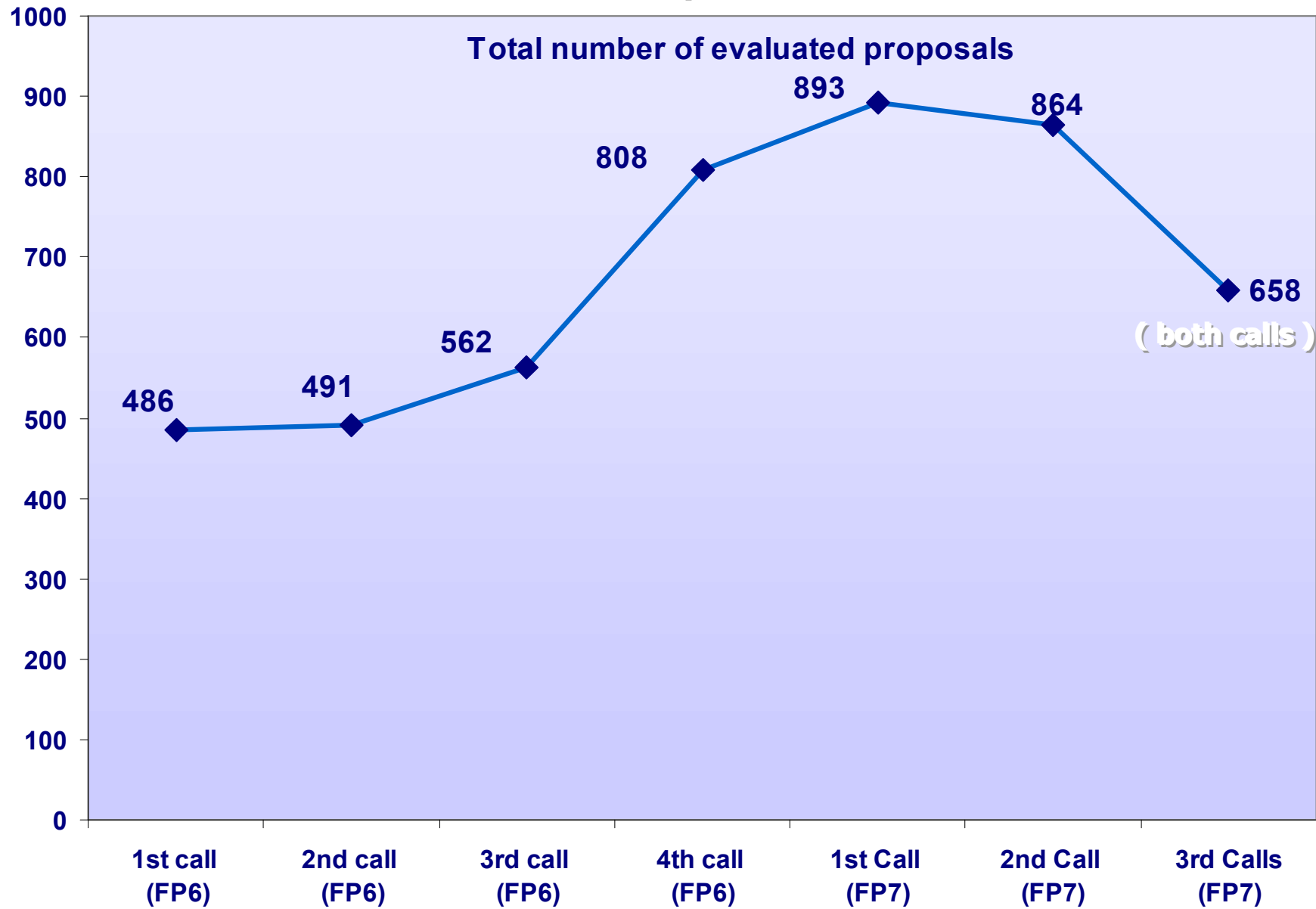
26 proposals evaluated (2<sup>nd</sup> stage)

+ ERA-NET call: one topic, €2m

Not legally binding: (based on draft documents) applicants must refer to final published work programme.

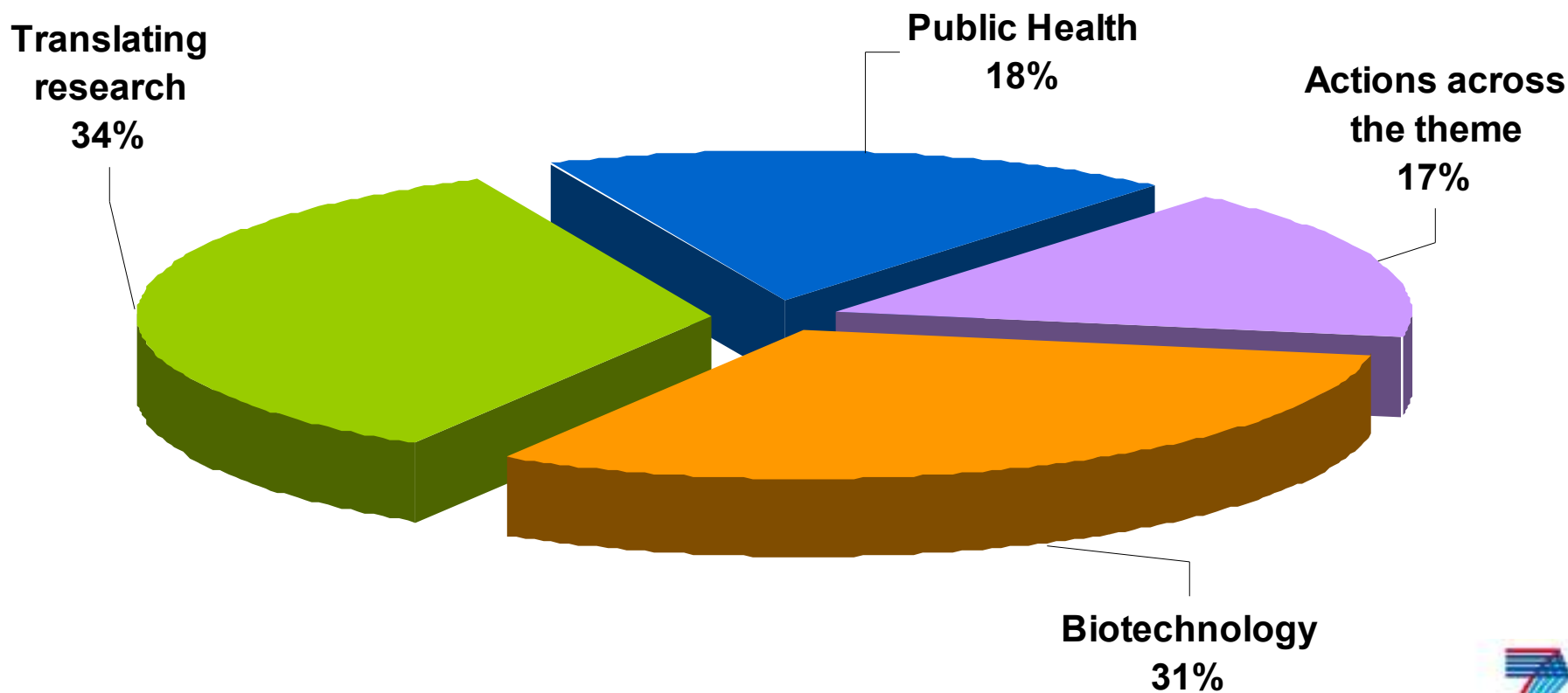


# Response to calls FP6 – FP7



# Proposals evaluated (per Activity)

## FP7-HEALTH-2009-single-stage Number of evaluated proposals per Activity

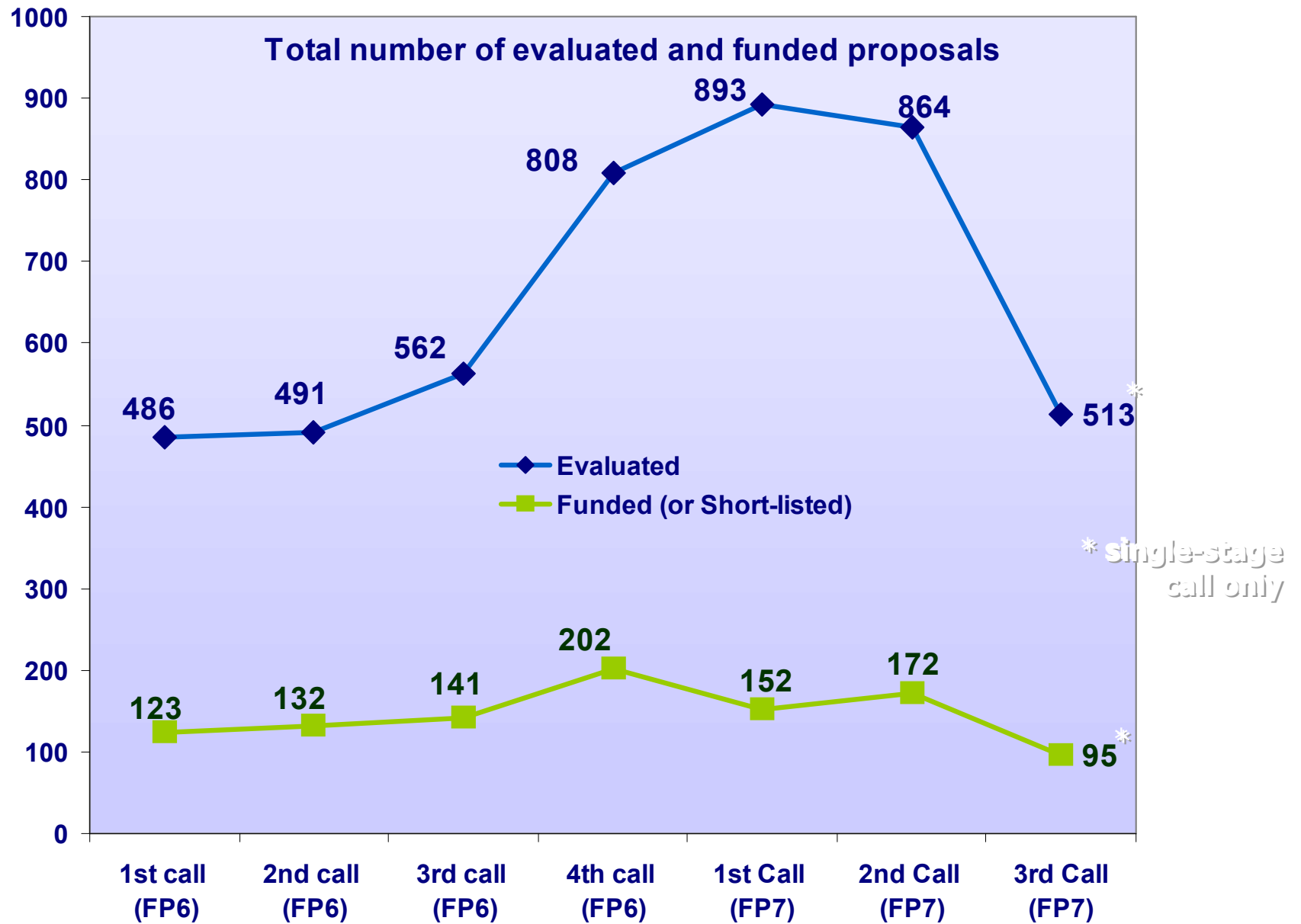


Not legally binding: (based on draft documents) applicants must refer to final published work programme.



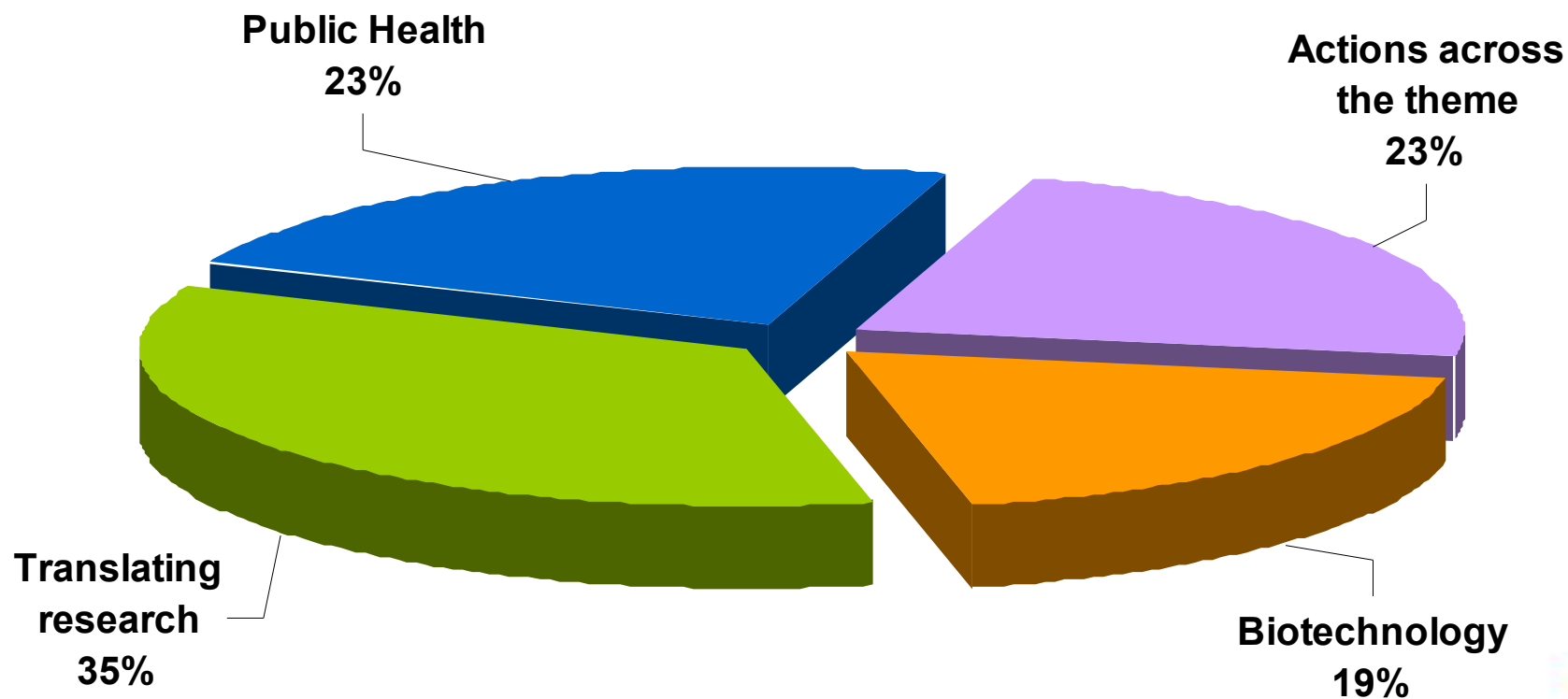


# Response to calls FP6 – FP7



# Proposals short-listed per Activity (= "pillar")

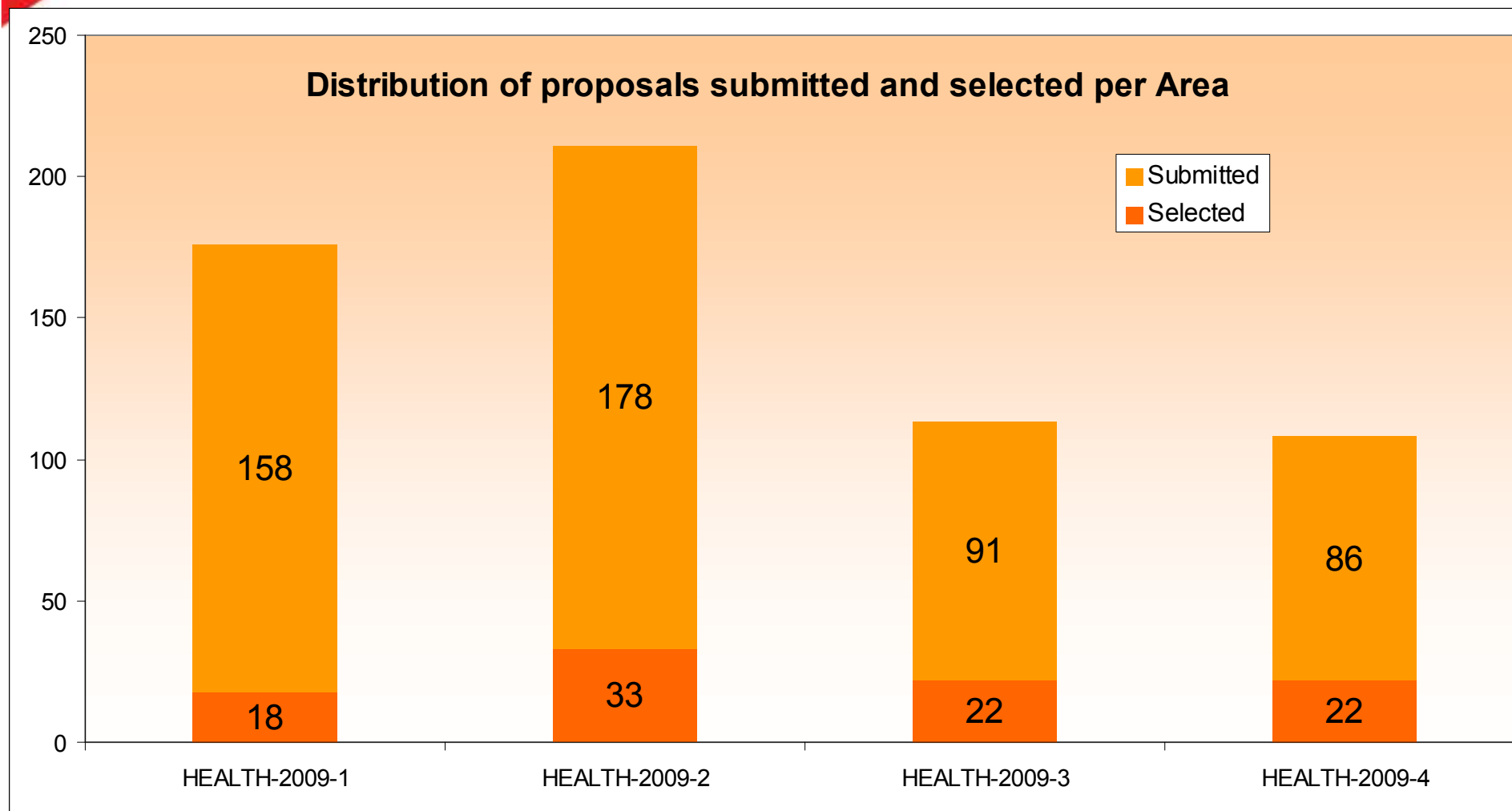
## FP7-HEALTH-2009-single-stage Number of short-listed proposals per Activity



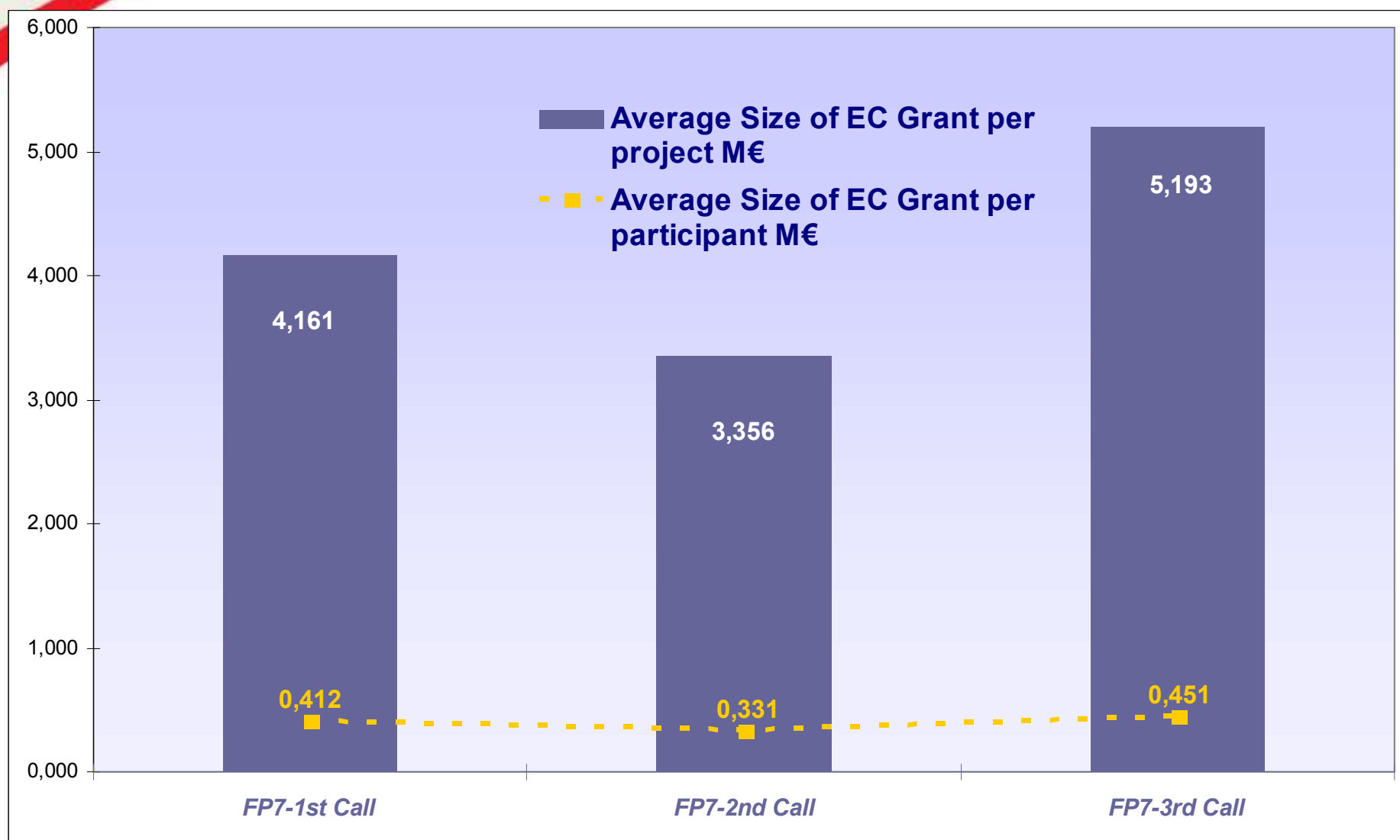
Not legally binding: (based on draft documents) applicants must refer to final published work programme.



# Proposals submitted & short-listed (per Activity)



# Average size of EC grant per project & per participant



## **RIENTRO FINANZIARIO PER PAESE E PER AREA (3° call)**

	DE	EL	ES	FR	IT	NL	UK
<b>Biotecnologia, strumenti generici e tecnologie mediche per la salute umana</b>	<b>22,4</b>	<b>0,7</b>	<b>2,9</b>	<b>10,2</b>	<b>10,9</b>	<b>6,3</b>	<b>15,2</b>
<b>Trasferire i risultati della ricerca alla salute umana</b>	<b>14,6</b>	<b>1,3</b>	<b>5,3</b>	<b>10,3</b>	<b>7,9</b>	<b>8,5</b>	<b>17,6</b>
<b>Ottimizzare le cure sanitarie dei cittadini Europei</b>	<b>9,7</b>	<b>2,2</b>	<b>4,0</b>	<b>2,6</b>	<b>4,5</b>	<b>11,2</b>	<b>20,6</b>
<b>Azioni di supporto e coordinate nel settore salute</b>	<b>16,7</b>	<b>1,3</b>	<b>5,2</b>	<b>13,1</b>	<b>7,6</b>	<b>9,6</b>	<b>16,8</b>
<b>Totale</b>	<b>16,1</b>	<b>1,3</b>	<b>4,8</b>	<b>10,7</b>	<b>8,0</b>	<b>8,7</b>	<b>17,2</b>

# **WP priorities for 2011**

**(and outlook for WP 2012 & 2013)**

# Overview of first calls

		1st call		2nd call				3rd call			4th call		
		Selected proposals	Final	Selected proposals	Final		Selected proposals	Final		Selected proposals	Budget (M€)		
I. BIOTECH	1.1. HIGH-THROUGHPUT	3 IP	35,6	9 FP(3m)	27	27	109	3 IP	11	11	74	0	
	1.2. DETECTION, DIAGNOSIS	2 IP + 8 FP(6m)	55,4	1IP + 3 FP(3m)	18	82		11P+4FP(6)+3FP(3)+2SA	40,5	131		80	80
	1.3. SAFETY...	2 IP + 2 FP(3m) + 1 CSA	29,5					1 CA	0,5				
	1.4. INNOVATIVE THERAPIES	4 FP(6m) + 1 FP(3m)	22,2	3 IP + 8 FP(3m)	64	7 IP *		90,2					
T R A N S L A T I O N A L R E S E A R C H	2.1. INTEGRATING	2.1.1. Large scale data gathering	7 IP	79,5		49,7	49,7	8 IP **	106	106	80	80	
		2.1.2. Systems biology	4 IP	45,3	15 FP(3m) + 5 CSA								
	2.2. BRAIN	2.2.1. Brain & brain diseases	1 IP + 11 FP(3m)	41	11P + 6 FP(6m) + 4 FP(3m)	48,0	48,0	3 IP + 2 FP(3m) + 1 CA	42,2	42,2	0,5	32,5	
		2.2.2. Development and ageing	3 IP + 2 CSA	31,7							32		
	2.3. INFECTIOUS DISEASES	2.3.1. Anti-microbial drug resis.			4 FP(6m) + 6 FP(3m)	40,0	122	1 IP + 2 FP(6m)	24,8	75,7	102	102	
		2.3.2. HIV/AIDS, TB, Malaria	2 IP + 15 FP(3m) + 1 CSA	62	2 IP + 9 FP(3m) + 6 CSA	47,7		1 NoE + 3 IP + 1 FP(3m) + 1 CA	50,9				
		2.3.3. Emerging epidemics	1FP(6)+7FP(3m)+3FP(1.5m)	27	1 IP	11,9		1 FP (3m)	0				
		2.3.4. Neglected diseases			8 FP(3m)	22,6		1IP+3FP(6m) (SICAs)	27				27
	2.4. OTHER MAJOR DISEASES	2.4.1. Cancer	22 FP(3m)+2CSA+ ERA-Net	70,4	3 IP + 1FP (3m)	38,7	105			104	187	187	
		2.4.2. Cardiovascular diseases	3 IP	33,2	8 FP(3m)	21,0		2 IP + 2 FP(3m)	29,7				
		2.4.3. Diabetes and obesity	2 FP(6m) + 3 FP(3m)	20,8	5 FP(6m)	19,5		1 IP + 2 FP(3m)	16,9				
		2.4.4. Rare diseases	10 FP(3m) + 1 CSA	30,6				2 FP(6m) + 7 FP(3m)	34,1				
2.4.5. Other chronic diseases		1 IP + 8 FP(3m) + 2 CSA	37,6	2 IP + 1 FP(3m)	25,4	1 IP + 1FP(6m)		23,5					
3. DELIVERY OF HEALTHCARE	3.1. CLINICAL PRACTICE						5 FP(3m) + 1 CA	18,4		18			
	3.2. HEALTH CARE SYSTEMS			38 FP(3m)+ 8 SA	88 + 24,9	113	113	2 FP(6m)+4 FP(3m)+2 CSA	23,3	64,1	14	64	
	3.3. HEALTH PROMOTION ...						1 IP + 3 FP(3m) + 2 CA	22,4					
4. OTHER ACTIONS	4.1. ACROSS THE THEME	14 CSA	10,7	1 CSA	2,2	31	31	4 CSA	3	2,4	2		
	4.2. EU POLICY NEEDS	1 FP(3m) + 3 SA	4	6 FP(6m) + 2 FP(3m)	28,8			5 FP(6m) + 3 FP(3m) + 1 CA	24,1	24,1	73	75	
	4.3. SICA							2 FP(3m) (4.3.3 only)	6	6			
<b>Total</b>		153: 28 IP + 15 FP(6m) + 83 FP(3) + 26 CSA + ERA-Net	<b>636</b>	172: 13 IP + 21 FP(6m) + 115FP(3m) + 22 CSA			<b>577</b>	106: 1NoE + 32 IP+ 19 FP(6m)+ 39 FP(3m)+ 15 CSA		<b>611</b>		614,5	

Final figures post negotiation (including reserve list FP & ERA-NET: €2m) **640,7**

5 reserve: 3 FP (3m) + 2 CSA

incl. SICAs  
incl. SICAs 44,5m

\* +7m from 3rd country contributions

\*\* +5m from 3rd country c

& 3 ERA-NETs 620,5

# Policy requests from DG and cabinet for next calls

- **Increased focus on limited number of strategic areas, building ERA**
  - avoid “shopping-list” approach
- **Joint programming and ERA-nets**
- **coverage of the specific programme:**
  - examine what has been done and what is left to do
- **Cross-thematic approaches:** i.e. coordinated calls
- **International cooperation**
- **Socio-economic dimension**
- **Dissemination actions**



# Strategy for Health theme in next calls (2011-2012-2013)

- **Increased focus on fewer areas**
  - to increase critical mass, impact and visibility
  - therefore, more areas closed in each call
- **Potential main priority fields:** brain, diabetes, lifestyle induced conditions, medical technologies, personalised medicines, health care systems, promotion & prevention ...
- **Overarching features: clinical trials, SMEs\*, immunology**
  - \*SME topics: broad, 2-stage, several projects/topic
- **Larger pilot projects may be introduced**
- **International cooperation**
- **No increase in budget in 2011 and 2012, but significant increase in 2013**

Not legally binding – preliminary ideas



# Budget for next calls (2011-2012-2013)

	2011	2012	2013
Total budget (EU+EFTA):	€684m	€657m	€818m
Evaluations, COST, CORDIS & HFSP0:	~€30-35m	~€30-35m	~€40m
Indicative call budget:	~€650m	~€620m	~€780m

Not included: Third Country contributions

Not legally binding – preliminary ideas



# International Cooperation

- All topics are open for international cooperation
  - partners from low and middle income countries can receive funding, and also from the USA
  - partners from other high income countries can exceptionally receive funding
- Specific International Cooperation Actions, SICAs, will continue to be opened for particular issues
- Programme level cooperation with particular countries
  - in large scale data gathering
  - in specific projects, which will be linked with other projects of the cooperating country

Not legally binding – preliminary ideas



# Programme level Cooperation

- For projects of specific interest to the cooperating country and to the EU.
- Funding of the EU/AC partners by the EC in a legally distinct grant, but support can also be given to international partners as in "normal" projects .
- Funding of the partners of the cooperating country provided by that country in another grant.
- Topics selected jointly with the Third country, assisted by experts from both sides.
- A close cooperation will be a requirement and detailed in the technical annex.

Not legally binding – preliminary ideas



# SME participation

- After first 3 years: ~12% SME participation
- Same expected in 2010 calls
- Need to reach 20% in remaining 3 calls for a 15% overall average  
(12% of €2440m + 20% of €2050m = 15.6% of total)
- Proposed approach for remaining calls :
  - % of budget for SME-friendly topics (with an estimated 40% SME participation)
  - % of budget for other topics (~10% SME participation)

# 5<sup>o</sup> call 2011

Not legally binding – preliminary ideas



# Overview of proposed focus of next calls

1 Oct. 2009

FP7 Health Theme - potential priorities for 5th call

		4th call 2010		5th call 2011		
1. BIOTECH		1.1. HIGH-THROUGHPUT			SME topics	
		1.2. DETECTION, DIAGNOSIS			closed	
		1.3. SAFETY & EFFICACY	Priority		closed (workshop only)	
		1.4. INNOVATIVE THERAPIES			SME topics	
T R A N S L A R C H I N G	2.1. INTEGRATING	2.1.1. Large scale data gather.			human epigenome	
		2.1.2. Systems biology			closed	
	2.2. BRAIN	2.2.1. Brain & brain diseases	closed			Priority (incl. addiction, trauma)
		2.2.2. Development & ageing				
	2.3. INFECTIOUS DISEASES	2.3.1. Anti-microbial drug resist.	closed			Priority (incl. SMEs, dev. countries)
		2.3.2. HIV/AIDS, TB, Malaria				closed
		2.3.3. Emerging epidemics				
		2.3.4. Neglected diseases				closed
	2.4. OTHER MAJOR DISEASES	2.4.1. Cancer	Priority			
		2.4.2. Cardiovascular diseases				
		2.4.3. Diabetes and obesity	closed			Priority
		2.4.4. Rare diseases				closed
		2.4.5. Other chronic diseases				closed
3. DELIVERY OF HEALTHCARE	3.1. CLINICAL PRACTICE	Priority			cross-cutting Priority	
	3.2. HEALTH CARE SYSTEMS	half closed				
	3.3. HEALTH PROMOTION	closed				
	INT. PUBLIC HEALTH RESEARCH	Priority				
4. OTHER ACTIONS	4.1. ACROSS THE THEME					
	4.2. EU POLICY NEEDS					
<b>Total budget</b>		budget	620	Estimated budget	650	
		balance 663				
		closed		potentially open	Priority	

# 2011 call - area 1.1

## High-throughput research

- **Focus on:**

- SME-intensive topics
- Innovative technologies for biospecimen research;
- New bioinformatics & biomathematical tools for systems biology & medicine
- Innovative tools and technologies for structural determination of challenging proteins relevant to drug discovery



# 2011 call - area 1.4

## Innovative therapeutic approaches and interventions

- **Focus on opportunities for SMEs**

- ➔ Regenerative medicine
- ➔ Medical technology (including devices) linked to regenerative medicine
- ➔ Synthetic antibodies (high-affinity proteins)

# 2011 call - area 2.1.1

## Large-scale data gathering

- **Focus on:**

- Support European participation in human epigenome project; involving very significant international cooperation
- Large-scale data gathering aimed at the development of personalised medicine

# 2011 call - Area 2.2.1 Brain

## Focus on:

- Comprehensively cover the brain area by focussing on areas not yet addressed in FP7 and complementing Joint Programming efforts in the field
- Proposed themes could include:
  - brain trauma
  - addiction
  - epilepsy
  - stress-related and obsessive-compulsive disorders
  - paediatric neurological and psychiatric disorders
- All areas proposed could be of interest to SMEs

# 2011 call - area 2.2.2 Human development & ageing

Cross cutting issue for the Health theme

- **Focus on:**

- Fundamental mechanisms, from early stages onwards and across life history; normal ("healthy") ageing in humans & fundamental mechanisms of age-related disorders and therapies for these
- Effects of quality of life in longevity and morbidity and vice versa
- Long term longitudinal studies (7+ years) of cohorts of patients to understand longevity could also be considered

# 2011 call - area 2.3.1 AMR

## Focus on:

- Mapping anti-microbial drug resistance in developing countries
  - Burden of drug resistance
  - Evolution and transfer of drug resistance
  - Multi-analyte diagnostics (see also IMI)
- Most proposed areas are of interest to SMEs and for international collaboration

# 2011 call – sub-area 2.3.3 Emerging Epidemics

## Focus on:

- Immunology, transmission and behavioural aspects
- Potential themes, supported by MS:
  - ➔ Transmission and immunology of influenza
  - ➔ Research on behavioural aspects relevant in preparation for and during pandemics
- Themes are of interest to SMEs

# 2011 call: sub-area 2.4.1 Cancer (1)

## Focus on:

- Prevention approaches and epidemiological studies, clinical trials and treatment strategies  
Complement IMI efforts in cancer (2009, 2<sup>nd</sup> call)
- Potential themes, supported by MS, include:
  - ➔ Prevention: strengthen patient's immune system, advance early detection (population-based screening); contribute to European Partnership against Cancer
  - ➔ Epidemiology: studies on (epi)genetic, environmental and life style risk factors
  - ➔ Clinical trials (eg: rare cancers, combination therapies)
  - ➔ Treatment strategies, clinical trials in general (SME relevant)

# 2011 call – sub-area 2.4.2 Cardiovascular diseases

## Focus on:

- Prevention approaches and clinical trials/studies as well as on epidemiological studies.
- Potential themes, supported by MS, include:
  - ➔ Prevention: development and/or standardisation of methodologies and biomarkers used in primary prevention, address subclinical CVD forms
  - ➔ Epidemiology: novel risk factors, life-style intervention studies
  - ➔ Clinical trials: hypertension
- Themes of relevance for SME participation: biomarkers, clinical trials at large, etc



# 2011 call - sub-area 2.4.3 Diabetes and Obesity

## Focus on:

- Prevention approaches and controlled intervention trials as well as on epidemiological studies.
- Potential themes, supported by MS, include:
  - ➔ Diabetes type 1 and particularly research on life style and/or therapeutic strategies, supported by many MS
  - ➔ (Epi-)genetic, environment and life-style risk factors
  - ➔ Biomarkers for obesity in children
  - ➔ Oral drug delivery systems for therapy and prevention
  - ➔ Epidemiological studies on paediatric obesity
- International Cooperation: global cooperation, including NIH on early life programming of obesity

# 2011 call – Activity 3

## Optimising the delivery of healthcare to European citizens

### Focus on:

- Social determinants of health
- Comparative Effectiveness Research (CER)
- Brokerage and dissemination
- Coordinated topics with Theme “Socio-Economic Sciences and the Humanities” and “KBBE”

# 2011 call – Activity 4

## Actions across theme (1)

### Focus on:

- Child health: paediatric medicines (off patent)
  - Fulfils requirement of Paediatric Medicines Regulation 1901/2006,
  - Responds to the need to test medicines *for* children *in* children,
  - Fulfils need to support clinical trials,
  - Fulfils need to support SMEs
  - Fulfils need to co-operate with Third Countries (US, elsewhere, ...)
- Supported by MS, learned paediatric societies, EMEA (Paediatric Committee), CHMP, ...

# 2011 call – Activity 4

## Actions across the theme (2)

### Focus on:

- Adverse Drug Reaction Research (ADRR) :
  - responds to the need for a more proactive conduct of pharmacovigilance as set out in the future Regulation and Directive
  - supported by
    - many MS due to public health interest
    - Pharmacovigilance Working Party of EMEA
    - learned pharmacoepidemiological societies
  - Requires careful development in function of heightened awareness

Not legally binding – preliminary ideas

