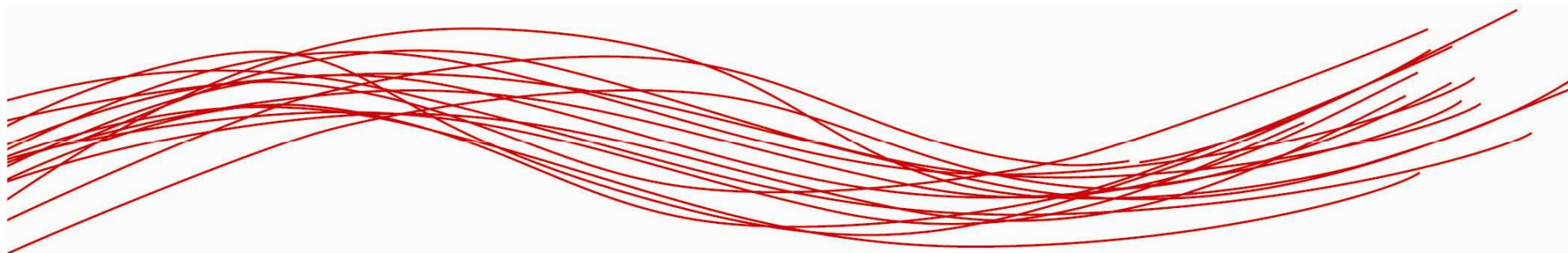


# European Health Research Implementing the Road Map for Ageing research



**Ruxandra Draghia-Akli, MD, PhD**  
**Director - Health  
Research and Innovation DG**  
**European Commission**

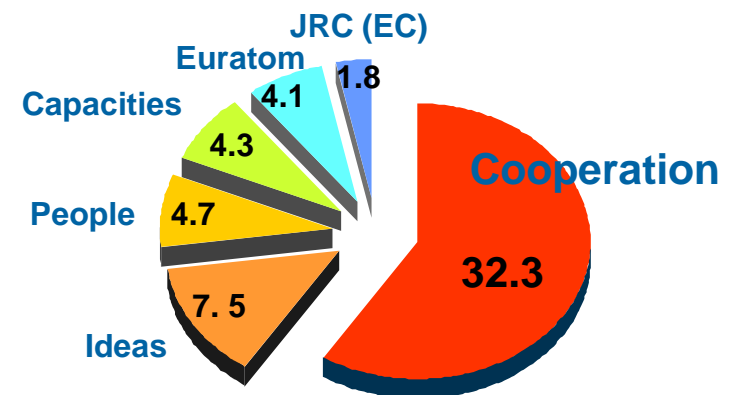
**STOA FUTURAGE Roadmap Launch Conference**  
**Brussels, 18/10/2011**



# FP7 and the Health Programme



- Personalised medicine
- Child Health
- Human development and ageing
- SMEs
- International Cooperation
- Clinical Trials



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

Total FP7 budget: € 54.6 billion  
 Health Priority in Cooperation: € 6.1 billion





# The Health Programme: main policy drivers

- Improving health of European citizens
- Increasing competitiveness of European health-related industries and businesses
- Addressing global health issues
- Supporting the aims of Europe 2020: the 'Innovation Union'
  - ▶ Collaborative research: **FP7 projects**
  - ▶ Coordinating national research programmes: **ERA-net**
  - ▶ Public-private partnerships: **Innovative Medicines Initiative**
  - ▶ Joint Programming: **Pilot Joint Programming Initiative on neurodegenerative diseases, in particular Alzheimer's**
  - ▶ **European Partnership for Action Against Cancer**
  - ▶ **European Partnership on Active and Healthy Ageing**



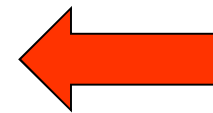
# Why European research on ageing?

- **In Europe, research on ageing is a relatively "young" and very multidisciplinary area**
- **Essential to achieve critical mass of data and resources and build proof-of-concept for new methods and approaches**
- **Reduce knowledge fragmentation and enhance collaboration and management of effective clinical research in Europe**
- **Need to exchange best practices, develop capacity building and provide research-based evidence for best care**
- **Need to focus on the whole life span and not only older people**



# How?

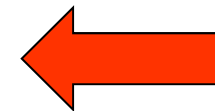
- Promote multi-disciplinarity
- Translate knowledge
- Reinforce basic-clinical links
- Reinforce investigator-industry links
- Build capacity
- Raise awareness of public
- Facilitate engagement
- Address social innovation



**Collaborative Research**

**EUR 177 million**

- via small and large scale collaborative research projects



**Policy Initiatives**

- Reinforce coordination of research activities between Member States

-via support, coordination, joint actions, ERA-NET, innovation partnership

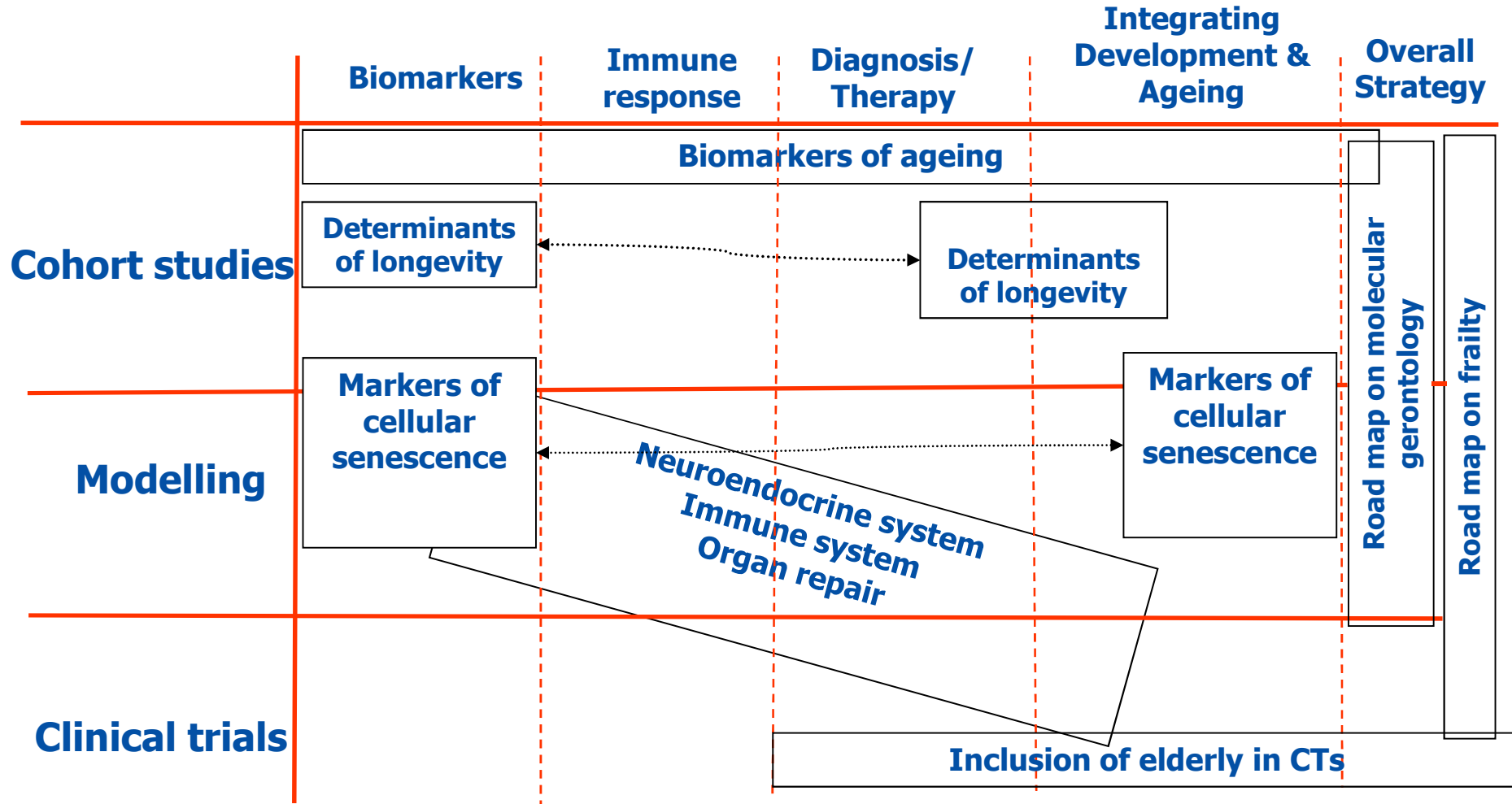


# What areas and questions have been addressed?





# Understanding human development and the ageing process



**HEALTH 2012: € 36 M – 2 topics: 1-Integrative systems biology and comparative genomics for studying human ageing and/or most common age-related diseases. 2-Investigator-driven clinical trials for optimisation of management of elderly patients with multiple diseases.**





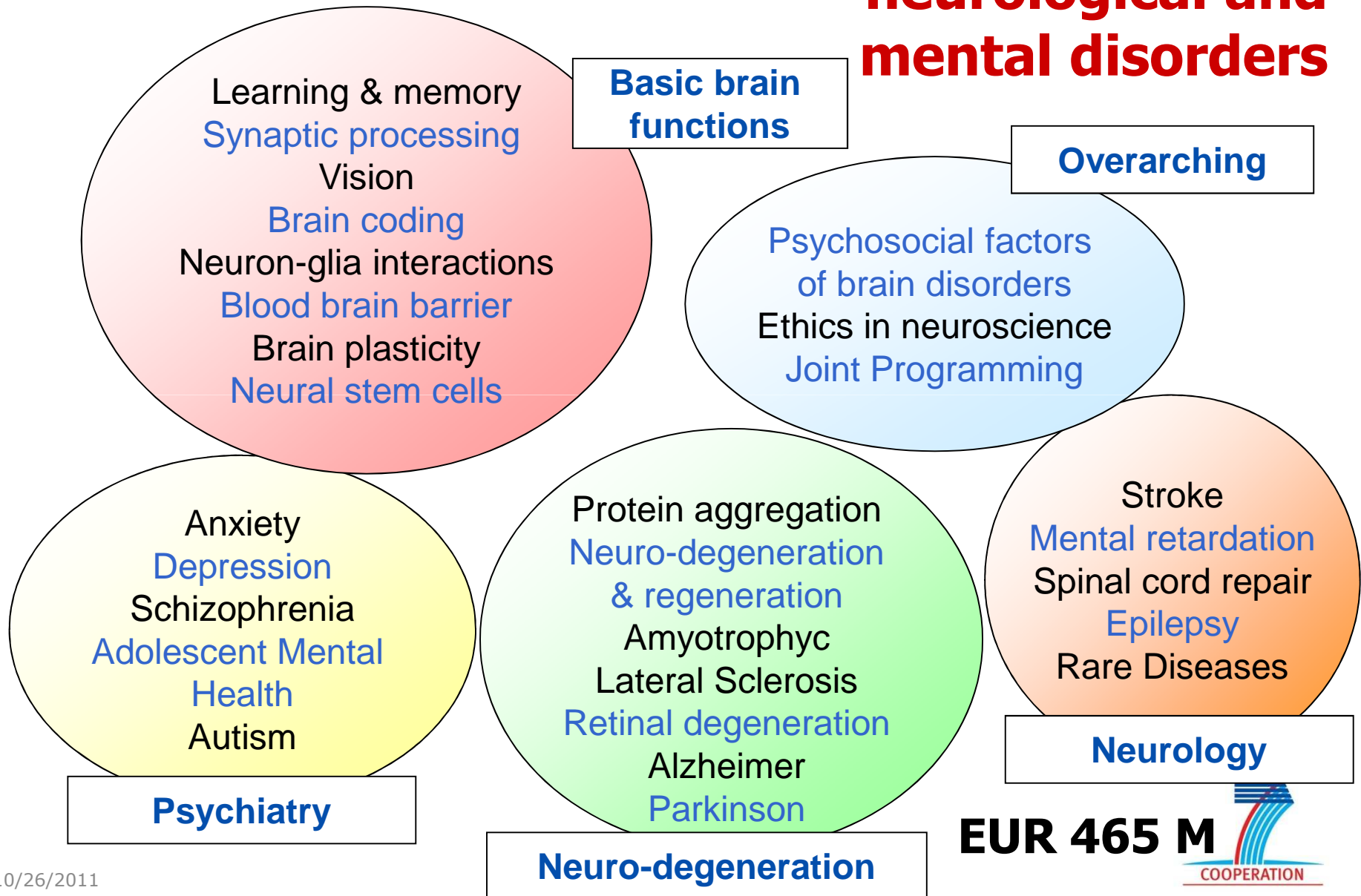
# Ensuring effectiveness and efficiency of care

- **RightTimePlaceCare** - organisation of dementia care
- **HEMECARE** - integrated approach to health care
- **CHANCES** - ageing cohorts
- **FOCUS** - cardiovascular prevention
- **LINNEAUS EURO & Monitoring Medicines** - patient safety research networks - primary care & safe use of medicines
- **Interlinks, SHELTER & ANCIEN** - health systems and long term care of the elderly
- **COURAGE & MentDis\_ICF65+** - health outcome measures and population ageing





# Addressing neurological and mental disorders



EUR 465 M



# Inclusion and participation of elderly in clinical trials

## The PREDICT Charter

- Older people have the right to access evidence-based treatments
- Promoting inclusion of older people in clinical trials and preventing discrimination
- Clinical trials should be made as practicable as possible for older people
- Safety of clinical trials in older people
- Outcome measures should be relevant for older people
- The values of older people participating in clinical trials should be respected



**European Charter for Older People in Clinical Trials**

- 1 OLDER PEOPLE HAVE THE RIGHT TO ACCESS EVIDENCE-BASED TREATMENTS**
  - 1.1 Older people have the right to be offered evidence-based treatments.
  - 1.1.1 Older people should expect to be offered drugs and other treatments that have been properly evaluated in clinical trials and demonstrated to be effective in people of their age.
- 2 PROMOTING THE INCLUSION OF OLDER PEOPLE IN CLINICAL TRIALS AND PREVENTING DISCRIMINATION**
  - 2.1 Older people should not be discriminated against in the recruitment for clinical trials
    - 2.1.1 Older people should be informed about and invited to participate in clinical trials of treatments that are intended for use in older people.
    - 2.1.2 National and International Regulators should ensure that older people are included in clinical trials without discrimination on grounds of age, gender, ethnicity or social class.
    - 2.1.3 Research Ethics Committees, Sponsors, Medical Journal Editors and Regulators should review all studies critically for unjustified exclusions based on age, other illnesses, disability and existing drug treatment. All such exclusions must be justified.
  - 2.2 The participation in clinical trials of people with multiple morbidities should be encouraged
    - 2.2.1 National and International Regulators should require that trials with drugs or other treatments intended for use in older people include those with multiple morbidities that are common in later life.
    - 2.2.2 National and International Regulators should require that trials with drugs or other treatments intended for use in later life include older people who are taking commonly prescribed medications.
- 3 CLINICAL TRIALS SHOULD BE MADE AS PRACTICABLE AS POSSIBLE FOR OLDER PEOPLE**
  - 3.1 Clinical trials should be designed so that older people can participate easily
    - 3.1.1 Older people should receive information about clinical trials that helps them make an informed decision about participation. Informed consent procedure should be adapted to the specific needs of older people, taking into account their level of literacy, any sensory deficits, and involving their family or caregiver if needed.
    - 3.1.2 Specific training is needed in order to perform clinical trials in older people. Researchers should be trained to conduct clinical trials in people with communication, sensory, mobility or cognitive problems.
    - 3.1.3 Researchers should be prepared to spend additional time with older people participating in a clinical trial in order to support their participation and adherence.
    - 3.1.4 Trial Sponsors should recognise that older people may need extra support to take part in trials.
  - 3.2 Trial sponsors should provide support to enhance the inclusion and adherence of older people, especially those with mobility and communication problems, and those who also have responsibilities caring for others.
  - 3.2.1 National and International regulators should encourage clinical trials that are designed to make the participation of older people easier.
- 4 THE SAFETY OF CLINICAL TRIALS IN OLDER PEOPLE**
  - 4.1 Clinical trials in older people should be as safe as possible.
    - 4.1.1 Researchers should assess the benefits and risks of older people's participation in clinical trials.
- 5 OUTCOME MEASURES SHOULD BE RELEVANT FOR OLDER PEOPLE**
  - 5.1 Clinical trials for common conditions in older people should employ outcome measures that are relevant for older people.
    - 5.1.1 Researchers, trial sponsors and regulators should ensure that clinical trials for common conditions in older people use outcome measures that are relevant for older people, including quality of life measurements.
    - 5.1.2 Clinical trial sponsors should involve older people and carers in the design of clinical trials and in the choice of outcome measures for clinical trials of diseases of later life.
- 6 THE VALUES OF OLDER PEOPLE PARTICIPATING IN CLINICAL TRIALS SHOULD BE RESPECTED.**
  - 6.1 The individual values of each older person participating in clinical trials should be respected.
    - 6.1.1 Researchers should respect the values of each older person as an individual.
    - 6.1.2 Older people should be able to withdraw from clinical trials without detriment to their treatments and their overall care.

<http://www.predicteu.org/>



# Addressing therapeutic interventions in the elderly

- **V-TIME** – multi-modal intervention combining Virtual Reality with treadmill training for enhancing mobility and reducing falls in the elderly
- **TRUST**: assessing the impact of thyroxine replacement in older adults with subclinical hypothyroidism
- **NILVAD**: testing the efficacy and safety of a marketed drug (Nilvadipine) for the new indication of Alzheimer's disease
- **MID-FRAIL-STUDY** – Effectiveness of multi-modal intervention in frail subjects with Type II Diabetes
- **DO-HEALTH** – beneficial effects of vitamin D, omega-3 fatty acids and home-based exercise in seniors aged 70 years or more

€ 29 million



# Data collection and life course studies CHANCES

## Consortium on Health and Ageing: Network of Cohorts in Europe and the United States

- To combine and integrate ongoing cohort studies to produce evidence on ageing-related health characteristics and determinants and their socioeconomic implications
- To focus on four groups of chronic diseases and conditions which are major contributors to the burden of disease in the elderly:
  - ▶ Cancer
  - ▶ Cardiovascular diseases and diabetes
  - ▶ Osteoporosis and fractures
  - ▶ Cognitive function and psychiatric disorders
- EUR 11.9 million



<http://www.chancesfp7.eu>



# Finding Biomarkers of Ageing MARK-AGE

- To conduct a population study (3,700 probands)
- To identify a set biomarkers of ageing
- To measure biological age
- EUR 11,99 million



## ► Website

<http://edukon.biologie.uni-konstanz.de/mark-age/>





# Coordinating national efforts on ageing research



**ERA-AGE  
2005 - 2009**



linking national and regional research funding programmes in the field of disease-related neuroscience. 15 national funding agencies from 12 countries

- Launched first Joint Call for Research Applications on "Active and Healthy Ageing across the Life Course"
- Multidisciplinary research groups representing 3 to 5 funding countries may submit pre-proposals. Deadline: 3.10.2011
- Areas:
  - Generate new knowledge on the biological, clinical, behavioural, social and environmental factors
  - Compare different models, methods, approaches and good practices in societal responses to increased longevity
- 13 national funding agencies from 13 countries





# Joint Programming Initiative on Neurodegenerative Diseases, in particular Alzheimer's Disease (JPND)

- Launched in July 2008 and adopted in Council Conclusions of 3.12.2009
- 23 participating countries (AL, BE, CH, CZ, DE, DK, EL, FR, IT, ES, FI, HU, IE, LU, NL, NO, PT, SE, SI, SK, PO, TR, UK).
- France (INSERM, Prof. P. AMOUYEL) is the Chair of the Management Board.
- Strategic Research Agenda to be adopted by end 2011, publication early 2012.
- 1st Pilot joint call on “Neurodegenerative Diseases - a call for European research projects for the optimisation of biomarkers and harmonisation of their use between clinical centres”, deadline 5.09.2011
- 20 countries; budget € 15 million





# Ageing: an overarching priority in Health 2012 call

**10 topics, estimated budget of EUR 261 million**

- **Technologies for personalised medicine applications**
- **Medical technology for transplantation and bio-artificial organs**
- **Stem cell based therapies in regenerative medicine**
- **“-omics” biomarkers for diseases affecting the elderly**
- **Systems biology for human ageing and/or most common age-related diseases**
- **Investigator-driven clinical trials for management of elderly patients with multiple diseases**
- **Technological approaches to combating sensory impairments**
- **Chronic inflammatory diseases of the joints and/or digestive system**
- **Improving the organisation of health service delivery**
- **New methodologies for health technology assessment**







# Towards Horizon 2020 – The Framework Programme for Research and Innovation

## Policy objectives

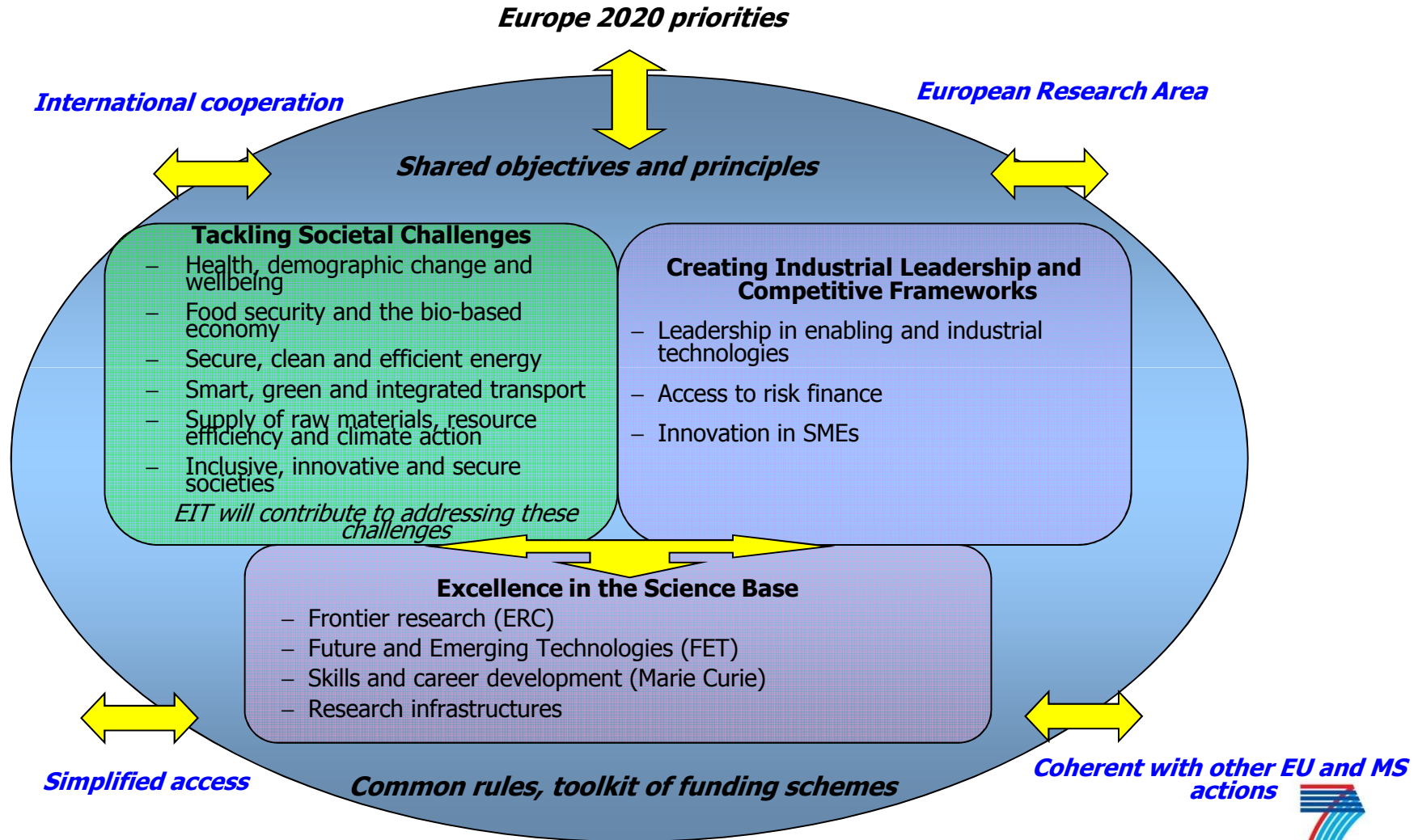
- **Europe needs** cutting edge research and innovation
- **Essential to ensure** competitiveness, growth and jobs
- **Vital to tackle pressing societal challenges** (climate change, energy security, demographic change,...)
- **3% of GDP** invested in R&D: headline target of Europe 2020
- **But: Europe's performance lags behind USA and JP, BRIC countries rapidly catching up**

→ Coordinated action **needed at EU level**

→ EU Budget can make the difference!



## Objectives and structure





# Health, Demographic Change and Wellbeing Challenge

- Aim to improve the lifelong health and wellbeing of all, acknowledging demographic change, maintaining an economically sustainable healthcare system and creating the potential for growth.
- Based on a programme which encompasses **health promotion, disease prevention; management, treatment and cure of disease; ensuring the sustainability of healthcare systems.**
- Provides support for cross cutting or underpinning technologies and actions: **cohort studies, clinical trials, -omics for fundamental understanding of health and disease, infrastructures, regulatory science.**
- Is implemented by the full range of available instruments, including Public-Private Partnerships (PPP).



## Next steps

- **Thematic** informal consultation workshops took place in July
- **Commission proposals for Horizon 2020: before the end of 2011**
- Legislative decisions **on Horizon 2020 by the Council and European Parliament (2012-13): during 2013**
- Horizon 2020 (**from 2014**)

Find out more at:

<http://www.ec.europa.eu/research/csfri/>



**THANK YOU FOR YOUR ATTENTION !**

<http://ec.europa.eu/research/health>