



# Adverse Drug Reaction Research in FP7 Health Theme

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# Adverse drug reactions present a major public health burden

**It is estimated that ADR cause**

- 5% of all hospital admissions
- 197000 deaths per year in the EU
- Total societal cost of €79 billion in the EU

# Adverse drug reaction research in FP7

## FP7 Health Theme

- Specific ADR topics based on EMA's priority areas
  - Scientific evidence for post-authorisation risk assessment
- Topic on patient stratification and pharmacogenomics approaches in WP 2011
  - New biomarkers to distinguish responders and non-responders and those at high risk for ADR

## Innovative Medicines Initiative (IMI)

- Tools and methodologies, education and training

# Funded Projects FP7 Health Theme



Acronym	Title	Coordinator / Website	Drugs studied
<b>ADDUCE</b>	Attention Deficit Hyperactivity Disorder Drugs Use Chronic Effects	School of Pharmacy, University of London  adhd-adduce.org	Methylphenidate
<b>ARITMO</b>	Arrhythmogenic potential of drugs	Erasmus Medical Center  www.aritmo- project.org	Antipsychotics, anti-infectives (antibacterials, antimycotics and antivirals) and H1-antihistamines
<b>EUROmediCAT</b>	EUROmediCAT: Safety of Medication use in Pregnancy in Relation to Risk of Congenital Malformations	UNIVERSITY OF ULSTER  euromedicat.eu	New antiepileptics, insulin analogs, SSRI antidepressants, and antiasthmatics

# Funded Projects

## FP7 Health Theme



Acronym	Title	Coordinator / Website	Drugs studied
<b>PHARMACHILD</b>	Long-term PHARMacovigilance for Adverse effects in Childhood arthritis focussing on Immune modulatory drugs	University Medical Center Utrecht <a href="http://www.printo.it/Pharmachild/">www.printo.it/Pharmachild/</a>	Immune modulatory drugs
<b>SOS</b>	Safety Of non-Steroidal anti-inflammatory drugs	Erasmus Medical Center <a href="http://www.sos-nsaids-project.org">www.sos-nsaids-project.org</a>	Traditional nonaspirin, nonsteroidal anti-inflammatory drugs (tNSAIDs) and cyclo-oxygenase II inhibitors (coxibs)
<b>STOP</b>	Suicidality: Treatment Occurring in Paediatrics	University College London, Institute of Child Health <a href="http://www.stop-study.com">www.stop-study.com</a>	Risperidone in conduct disorder; fluoxetine in depression, and montelukast in bronchial asthma



## New projects launched in 2011

Acronym	Title	Coordinator	Drugs studied
<b>CARING</b>	Cancer risk and insulin analogues	Utrecht University	Insulin analogues
<b>SAFEGUARD</b>	Safety evaluation of adverse reactions in diabetes	Erasmus Medical Center	Biguanides, sulfonamides, urea, alpha-glucosidase inhibitors, thiazolidinones, DDP-4, others
<b>ASTRO-LAB</b>	Assessment of safety of LABAS in asthma in routine care by combining health-care databases and direct patient follow-up	Université Lyon 1 Claude Bernard	Long-acting beta-agonists (LABAs)
<b>EPOCAN</b>	Gaining sage on the Epoetins' saga: assessing long term risks and advancing towards better Epoetin driven treatment modalities	Tel-Aviv University	Epoetins



## Projects funded in patient stratification and pharmacogenomics topic, WP 2011

Acronym	Title	Coordinator
ANGIOPREDICT	Predictive Genomic Biomarkers Methods for Combination Bevacizumab (Avastin) Therapy	ROYAL COLLEGE OF SURGEONS IN IRELAND
CRESTAR	Pharmacogenomic biomarkers as clinical decision making tools for clozapine treatment of schizophrenia	KING'S COLLEGE LONDON
EpiPGX	Epilepsy Pharmacogenomics: delivering biomarkers for clinical use	University College London <a href="http://www.epipgx.eu">www.epipgx.eu</a>



# **NEXT CALL FOR PROPOSALS EXPECTED TO BE OPENED IN JULY 2012**

**FP7 Health - 2013 orientation  
paper available on Cordis:**

**[http://cordis.europa.eu/fp7/health/home\\_en.html](http://cordis.europa.eu/fp7/health/home_en.html)**





# Indicative topic for ADR

## HEALTH.2013.4.2-2: Adverse drug reaction research.

- Long term safety of antipsychotic medication in patients with dementia
- Genetic causes of adverse drug reactions: angiotensin-converting enzyme inhibitors and angioedema, and statin-induced myopathy
- Long-term adverse skeletal effects of bisphosphonates

**Min. 15 % EU Contribution to SME(s)**

Based on working document, refer to final published call text



# Upcoming Call in the FP7 Health

- Two-stage submission and evaluation
- Expected to open in mid-July 2012
- Stage-1 short outline proposals
- Indicative closing date 2 October 2012 (stage-1)
- Successful applicants will be invited to submit full proposals

# Advice for applicants (1)

- Analyse the Work Programme carefully – topic, introduction and call fiche
- Follow the instructions in the Guide for Applicants
- Apply if you see a clear opportunity that fits your strategy
- Choose your partners carefully – they have to be appropriate for the tasks
- Appropriate study design, data processing and statistical analysis of results are important

## Advice for applicants (2)

- Address ethical issues, both in the proposed methodology and the possible implications of results
- Managing the project yourself is a major task – it needs to be properly planned & resourced
- Use support structures for preparing your proposal:
  - **National Contact Points (NCPs)**  
[http://cordis.europa.eu/fp7/ncp\\_en.html](http://cordis.europa.eu/fp7/ncp_en.html)
  - **Fit-for-Health**  
[www.fitforhealth.eu](http://www.fitforhealth.eu)



# Horizon 2020: The next Framework Programme for research and innovation

**Proposed budget: €80bn, a 46% increase compared to FP7**

Europe needs cutting edge research and innovation  
Essential to ensure competitiveness, growth and jobs  
Vital to tackle pressing societal challenges  
3% of GDP invested in R&D: headline target of Europe 2020





# Horizon 2020: Health, Demographic Change and Wellbeing Challenge – proposal ~ €8.5bn

*Understanding the determinants of health (including environmental and climate related factors), improving health promotion and disease prevention;*

*Developing effective screening programmes and improving the assessment of disease susceptibility*

*Improving surveillance and preparedness*

*Understanding disease*

*Developing better preventive vaccines*

*Improving diagnosis*

*Using in-silico medicine for improving disease management and prediction*

*Treating disease*

*Transferring knowledge to clinical practice and scalable innovation actions*

*Better use of health data*

***Improving scientific tools and methods to support policy making and regulatory needs***

*Active ageing, independent and assisted living*

*Individual empowerment for self-management of health*

*Promoting integrated care*

*Optimising the efficiency and effectiveness of healthcare systems and reducing inequalities through evidence based decision making and dissemination of best practice, and innovative technologies and approaches.*

# Next steps

- Ongoing:** Parliament and Council negotiations on the basis of the Commission proposals
- Ongoing:** Parliament and Council negotiations on EU budget 2014-2020 (including overall budget for Horizon 2020)
- Mid 2012:** Final calls under 7th Framework Programme for research to bridge gap towards Horizon 2020
- Mid 2013:** Adoption of legislative acts by Parliament and Council on Horizon 2020
- 1/1/2014:** **Horizon 2020 starts, launch of first calls**



## **EU research**

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

## ***EU Health Research***

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

## **Seventh Framework Programme**

*<http://ec.europa.eu/research/fp7>*

## ***IMI***

*<http://www.imi.europa.eu/>*

## ***Information on research programmes and projects***

*<http://cordis.europa.eu/>*

## ***Information requests***

*<http://ec.europa.eu/research/enquiries/>*