Thematic Actions

Coordinating Universities for the Proposal: UCM and UPM

Title of Action	**Developing a Clinical Validation and Pharmaco-vigilance Network**		
Participating partners	UCM, Associated Hospitals UPM	**Other participants**	CIEMAT, CSIC-CIB
Personnel involved (indicate institution)	UCM, UPM, Associated Hospitals		
Start date	1-1-2010	**End date**	31-12-2012
Cluster	i-Health (I-Medicine)	**Other clusters**	
Areas of action	Research / Teaching Improvement and EHEA Deployment / Knowledge Transfer		
Location	Moncloa Campus and others		
Infrastructures involved			
Keywords	Clinical trials; Biobanks; Clinical histories		

Objectives:

Included in the **i-Medicine** strand of action, the third action intends to make use of the remarkable strengths of the Spanish National Health System, bringing together clinical groups from three clinical hospitals in the RETICS networks and CIBER partnerships funded by the Carlos III Health Institute of the Spanish Ministry of Science and Technology. These key strengths include a large collection of samples from human patients regulated through biobanks as well as the data associated with those materials, and a database of clinical histories.

This action has three objectives: i) the implementation of a computerised management system of clinical histories, assisted by the **p-Health** strand of action aimed at facilitating clinical research and improving healthcare; ii) allowing the clinical validation of biomarkers identified in the second action and, iii) the facilitation of strategies for conducting clinical trials and pharmaco-vigilance studies.

Description of the action:

This action includes three closely interrelated services (Core group: Associated Hospitals, UPM).

- **Platform for the management of biobanks and clinical histories database**. This new platform seeks to implement a computerised management system of clinical histories, assisted by the **p-Health** strand of action , for a better knowledge and use by the Campus users. There are currently different databases of clinical histories and human sample biobanks (plasma, serum, urine, DNA, biopsies, ….) from patients diagnosed with prevalent diseases, usually regulated by the Carlos III Health Institute, through its RETICS networks or CIBER programmes. Most of the research groups participating in this platform are structured into these programmes. The utilisation of this platform will improve the healthcare received by patients and will foster clinical research.

- **Platform for the validation and identification of biomarkers**. This platform brings together clinical groups from the associated hospitals with the common goal of identifying and/or validating biomarkers, either new ones or those proposed by **i-Medicine** and **i-Maging** in the prevalent diseases studied. The validation of the utility of a biomarker as a diagnostic or prognostic tool will improve quality of healthcare provided. Furthermore, biomarkers are an important source of knowledge transfer from academia (the Moncloa Campus) to biotechnological companies for the development of diagnostic and prognostic kits.

- **Platform of clinical trials and pharmaco-vigilance studies**. One of the key strengths of the **i-Medicine** strand of action is the existence of three large clinical hospitals associated to the University, with their respective clinical research groups. This allows new clinical trials to be run with sufficiently large numbers of patients. The molecular and imaging biomarkers would facilitate the selection of patients suffering from a specific disease to be included in the clinical trials. This issue is of paramount important not only to reduce the size and duration of the clinical trials but also to carry out better patient control, thus improving quality of the healthcare provided.

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Key planned results:

- Acquisition of knowledge, providing a remarkable improvement of the scientific output of the Campus members.
- Delivery of knowledge to the industrial sector. Patents on new drugs and pharmaceutical technology.
- Fostering the development of better medicines (drugs and drug formulations), including advanced, innovative therapies.
- Attracting R&D biomedical investment from the pharmaceutical sector into the Campus.
- Stimulating the economical development and competitiveness of our environment.
- Training of competitive professionals for the biopharmaceutical sector. Improvement of the career prospects of our graduates.

Rationale for the action:

In Spain, few initiatives such as this one tackle the diagnosis and treatment of the most prevalent pathologies in a holistic fashion. Such an ambitious approach, although very feasible in a first-class environment such as the Moncloa Campus, is uncommon among public research institutions in Spain, and will contribute greatly to fostering excellence in this Campus.

International aspects:

This action addresses several European guidelines on the needs and priorities of the 7th Framework Programme of the European Commission, and the Innovative Medicines Initiative of the European Federation of Pharmaceutical Industries and Associations (EFPIA). Several of the participating groups possessing the know-how required for the action are partners of different EU-funded grants and have a solid track record of cooperation with leading international research groups.

Planned impact:

Several actors will benefit from this action, such as European citizens, Spanish and international researchers, biosanitary professionals and students.

Planned impacts are:

- Increasing the competitiveness of the Moncloa Campus, transferring knowledge to the industrial sector through patents, transfer contracts, publications and the diffusion of knowledge.
- Improving health and quality of life.
- New career prospects and job creation in R&D centres and companies.
- Boosting the innovative capacity of Spanish and European biopharmaceutical industries and businesses.
- Innovation in teaching and higher education, with opportunities for PhD Theses, Master's degrees, etc.