1ST CALL

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FULL PROJECT PROPOSALS (FPPS)

SELECTED FOR FUNDING

KEY INFORMATION AND ABSTRACTS

Call topic code:	**IMI_Call_2008_1_02**
Topic title:	**Non-genotoxic carcinogenesis**
Project acronym:	**MARCAR**
Project title:	**bioMARkers and molecular tumor classification for non-genotoxic CARcinogenesis**

The MARCAR consortium ("BioMARkers and molecular tumor classification for non-genotoxic CARcinogenesis") will apply a mechanism-based approach to establish reliable biomarkers for the early prediction of potential for non-genotoxic carcinogenesis, and to improve the molecular classification of tumors that can be caused by non-genotoxic carcinogenesis.

Goal:

- Improved drug safety, more efficient drug development, and progress in developing alternative research methods (such as the "3-R" concept: i.e. reduction, refinement and replacement of animal experimentation).

- Improved scientific basis for assessing carcinogenic potential of non-genotoxic drugs

- Early biomarkers for more reliably predicting which compounds have a potential for later cancer development

Bottlenecks addressed:

- Reliable tools for predicting which compounds have a potential for later cancer development

Call topic code:	**IMI_Call_2008_1_03**
Topic title:	**Development of expert (QSAR) system for in silico toxicity prediction**
Project acronym:	**eTOX**
Project title:	**Integrating bioinformatics and chemoinformatics approaches for the development of expert systems allowing the in silico prediction of toxicities**

The eTOX project will develop a computer-based database and novel software tools to better predict in silico the toxicological profiles of new compounds in early stages of drug development. Computer-based predictions of the potential toxicity profiles of new compounds will be based on their chemical structure.

Objectives:
- Create the largest toxicology database, combining public data and historical data from 14 pharmaceutical companies and device management tools for large databases
- the eTox database will comprise pharmacology, genomics, pathology, clinical pathology, genetic toxicology, safety pharmacology and pharmaco-kinetics data.
- Create systems and tools to harmonize toxicological standards and terms (ontology) as well as to support data entry and compatibility.
- Create a computer-based prediction system for potential toxicity profiles of new compounds based on the analysis of the above database
- Create a meta-tool for simultaneous analysis of data of various origins and formats

Potential Outcomes:
- New computer-based tools to make use of and to structure private and public historical data
- A new system to predict the potential toxicity profile of new compounds from their chemical structure
- eTox will be the largest, most comprehensive and most integrative toxicology database .

Bottlenecks addressed:
- No comprehensive computer toxicology database is currently available.
- Integrative tools to exploit such database do not exist yet

Call topic code:	**IMI_Call_2008_1_05**
Topic title:	**Qualification of Translational Safety Biomarkers**
Project acronym:	**SAFE-T**
Project title:	**Clinical biomarker qualification via SAFER and FASTER EVIDENCE-BASED TRANSLATION**

The SAFE-T (Safer And Faster Evidence-based Translation) project will qualify safety biomarkers for clinical use to help understand and "translate" preclinical data into clinic. The consortium will publish a validated scientific strategy as a general reference guide for qualification of translational safety biomarkers. The consortium will focus on three target organs with unmet diagnostic needs and will develop and qualify new translational and clinical safety biomarkers:

- The kidney, where current standards (BUN and serum creatinine) are insensitive and too late

- The liver, where current liver functional tests (ALT, AST) are not specific and cannot differentiate between transient changes and the development of a severe liver injury

- The vascular system, as there are no diagnostic standards available to detect drug-induced vascular injury in human.

Objectives:

- To evaluate utility of safety biomarkers (kidney, liver, and vascular biomarkers) for monitoring drug safety in humans.

- To develop assays and devices for clinical application of safety biomarkers.

- To qualify safety biomarkers for decision making in clinical drug development. Interactions with health authorities for advice and submission of biomarkers for regulatory acceptance will be a key aspect, as these biomarkers may be used in helping to understand and monitor the safety profile of new medicines.

Potential Outcome:

- Qualified safety biomarkers for decision making in translational and clinical contexts that are accepted by regulatory heath authorities, resulting in faster approval of safer and novel drugs.

Bottlenecks addressed:

Insufficiency of current safety biomarkers and diagnostic standards for monitoring drug safety in humans

Call topic code:	**IMI_Call_2008_1_06**
Topic title:	**Strengthening the monitoring of benefit/risk**
Project acronym:	**PROTECT**
Project title:	**Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium**

The goal of PROTECT is to strengthen the monitoring of the benefit-risk (B-R) of medicines in Europe. This will be achieved by developing a set of innovative tools and methods that will enhance the early detection and assessment of adverse drug reactions from different data sources, and enable the integration and presentation of data on benefits and risks. These methods will be tested in real-life situations in order to provide all stakeholders (patients, prescribers, public health authorities, regulators and pharmaceutical companies) with accurate and useful information supporting risk management and continuous B-R assessment.

A methodological framework for pharmacoepidemiological studies will be developed and tested to enable data mining, signal detection and evaluation in various types of datasets including data of spontaneous reports, registries and other electronic databases. Means of combining results from clinical trials, spontaneous reporting and observational data will be developed, comparing Bayesian modelling, multi-criteria decision analysis and other analytical methods. Methods for graphical expression of B-R will be tested with different stakeholders.

Collection of data directly from patients is essential in many situations. PROTECT will trial direct patient data collection in natural languages using web-based, telephone and text messaging systems. It will test the transferability of the data into a common language and explore linkages to data from electronic health records and registries.

Using methods developed in the Project, validation studies performed with additional data resources available in the EU will help create the foundation for multi-site investigations. Development will continue beyond the initial IMI funding, with training given and results disseminated using the EMEA-led European Network of Centres for Pharmacovigilance and Pharmacoepidemiology and relevant publications.

PROTECT consists of 29 public and private Partners coordinated by the European Medicines Agency (EMEA). It will be managed by a Coordinator and Deputy Coordinator with extensive experience in pharmacovigilance, aided by a strong governance structure including a Steering Committee, an experienced project management team and a distinguished international External Advisory Board.

Call topic code:	**IMI_Call_2008_1_07**
Topic title:	**Islet cell research**
Project acronym:	**IMIDIA**
Project title:	**Improving beta-cell function and identification of diagnostic biomarkers for treatment monitoring in diabetes**

A relative or complete decrease in insulin secretion by pancreatic beta-cells underlies the development of, respectively, type 2 and type 1 diabetes. These diseases impose huge burdens to welfare systems, both in Europe and in other developed and developing countries. There are so far limited therapeutic options to treat diabetes and none to cure or prevent the disease. This is due, in large part, to our limited knowledge of beta-cell biology in health and disease. Although a large body of knowledge has been gained on the function of beta-cells from animal models, knowledge on human beta-cell function, survival, and of the pathomechanisms that lead to their demise is still scarce.

The IMIDIA consortium, which consists of 14 leading European academic experts in the biology, physiology, and genetics of islet cells and in bioinformatics applied to systems biology, together with 8 major pharmaceutical industries and 1 SME, proposes an ambitious project to generate novel tools, biomarkers, and fundamental knowledge on beta-cell organization to accelerate the path to improved diabetes management.

The scientific program aims at delivering:

1- Novel tools for the study of human beta-cell development, function and survival; their modulation by potential therapeutic compounds; and for in vivo beta-cell imaging.

2- Biomarkers for the diagnosis and prognosis of beta-cell failure and for monitoring diabetes progression and treatment.

3- Knowledge on novel pathways and sites that control beta-cell proliferation, differentiation and apoptosis, and on the role of known nutrient regulated pathways and sites in controlling beta-cell mass and function.

The close interaction of academic teams, pharmaceutical companies and SMEs will provide a unique conjunction of expertise and will form a strong basis for a successful enterprise to ultimately improve industrial competitiveness and Public Health in Europe.

Call topic code:	**IMI_Call_2008_1_08**
Topic title:	**Surrogate Markers for Vascular Endpoints**
Project acronym:	**SUMMIT**
Project title:	**Surrogate markers for Micro- and Macro-vascular hard endpoints for Innovative diabetes Tools**

Diabetes mellitus is a lifelong, incapacitating disease affecting multiple organs. Worldwide prevalence figures estimate that there are 250 million diabetic patients today and this number will increase by 50% by 2025. The disease is associated with devastating chronic complications including coronary heart disease, stroke and peripheral vascular disease (macrovascular disease) as well as microvascular disorders leading to damage of kidneys (nephropathy) and eyes (rethinopathy). These complications impose an immense burden on the quality of life of the patients and account for more than 10% of health care costs in Europe. A key need in drug development is the ability to develop agency-acceptable surrogate markers for micro- and macrovascular complication that can be used in clinical trials. The central goal of the SUMMIT consortium is to identify and characterize factors that clearly modify an individual's susceptibility to develop complications and to use this information to make drug development studies more efficient and shorten clinical trials, overall.

The project is built upon 5 interrelated Work Packages, which refer to the topics outlined in the Call. Genetic markers discovery in well-characterized prospective cohorts (WP1), Biomarkers discovery (WP2) and Novel imaging techniques (WP3) including the same patients in the different studies to allow cross-fertilization between the WPs. Novel animal models (WP4) will explore existing and novel animal models for their propensity to develop diabetic complications. Data Mining and in silico modelling (WP5) will provide tools to help identify and prioritize novel biomarkers and novel mathematical models of chronic diabetic complications allowing simulated in silico trials.

The 5-year project is divided into three phases, 1) discovery of novel surrogate markers for diabetic vascular complications (first 18 months), 2) validation of these markers in appropriate cohorts (years 2-3) and 3) translation of these findings into clinically relevant setting by using these markers to predict and monitor progression of complications (years 4 and 5).

The SUMMIT consortium brings together investigators, expertise and clinical resources from 18 academic centers, one SME as well as 5 pharma partners to provide the necessary framework for achieving these goals.

Call topic code:	**IMI_Call_2008_1_09**
Topic title:	**Pain research**
Project acronym:	**EUROPAIN**
Project title:	**Understanding chronic pain and improving its treatment**

Chronic pain is common and incapacitating, but efficacious treatments are limited. We will establish an international team of leading researchers and clinicians (EuroPain), from both academia and industry, to undertake multidisciplinary translational research which will: 1) increase the understanding of chronic pain mechanisms; 2) facilitate the development of novel analgesics; with the ultimate aim to: 3) improve the treatment of chronic pain patients.

Our network will involve 3 well established academic European pain consortia (the London Pain Consortium, the German Pain Network, and the Danish Pain Research Centre), Neuroscience Technologies of Barcelona and the research resources and expertise of Europe's most active pharmaceutical companies working on pain.

We will undertake a series of six interlinked and mutually supportive programs of experimental research, underpinned and supported by a coordinated training and bioinformatics facility. These programs will form a series of workpackages each delivered through collaboration of network laboratories to bring together multiple techniques and considerable expertise to each area. In addition, there will be considerable synergies between the programs. Three of the research programs will study pain from the perspective of identifying translational novel pain mediators; elucidating different nervous system changes contributing to pain; pain biomarkers and increase confidence in what are relevant and predictive measurements of pain. Three programs will explore pain mechanisms from a patient perspective, aiming at establishing and validating mechanism-based pain models in volunteers; finding objective measures of spontaneous pain; detailed characterisation of clinical findings in chronic pain patients; and determining psychosocial and clinical risk factors for development of chronic pain. One program will integrate data and datamining via a common data warehouse.

Call topic code:	**IMI_Call_2008_1_10**
Topic title:	**New tools for the development of novel therapies in psychiatric disorders**
Project acronym:	**NEWMEDS**
Project title:	**Novel Methods leading to New Medications in Depression and Schizophrenia**

Despite remarkable advances in genetics, molecular and imaging technologies and nearly 15,000 articles on schizophrenia and depression every year, there have been few innovative new drugs. We think there are three major bottlenecks: i) a lack of pathophysiologically-accurate animal models; ii) a lack of tools and tests that can be used in humans to provide early indication of efficacy; and iii) the reliance of clinical trials on symptom-based DSM-categories which result in biologically heterogeneous groups of patients.

To specifically target these challenges the NEWMEDS consortium (12 EFPIA members, 7 academic institutions, 2 SMEs) will: a) develop animal models that focus on reliable cross-species endophenotypes (e.g., cognitive function, electrophysiology) and use cross-species methods (small-animal MRI, EEG and micro-PET) to bring animal models closer to clinical endpoints; b) validate the use of fMRI-based paradigms and PET approaches as early and surrogate markers for efficacy – thus providing tools that can be implemented in small Phase 1B studies to provide guidance for drug development; and c) identify pharmacogenetic and proteomic biomarkers that can be used to stratify patients within an umbrella DSM-diagnosis, thus allowing for targeted clinical trials, individualized treatment and back-translation of subgroup-specific biomarkers into preclinical drug discovery.

The project will be delivered through a series of integrated work-packages organized in three clusters – systemsbased animal models, translational imaging technologies and methods for patient stratification and biomarker development. Each work-package is being delivered through joint academia-industry partnership having achieved a greater than the required 1:1 in-kind match, indicative of the involvement and commitment of all EFPIA partners. By the end of the 5 year project we expect to provide ready to use new cross-validated animal models, new fMRI methods with dedicated analysis techniques, new PET radioligands, as well as new genetic and proteomic biomarkers for patient-segmentation or individual response prediction. These tools should provide our EFPIA partners with an added competitive advantage in developing new drugs for schizophrenia and depression.

Call topic code:	**IMI_Call_2008_1_11**
Topic title:	**Neurodegenerative disorders**
Project acronym:	**PHARMA-COG**
Project title:	**Prediction of cognitive properties of new drug candidates for neurodegenerative diseases in early clinical development.**

Recently the EU Council of Ministers for Health underlined the importance of generating novel therapeutic agents both for symptomatic and disease modifying treatment of Alzheimer's disease (AD). However, despite the increased in translational medicine activities attrition rates still remain high and progress in bringing these biomarkers and models to a state of readiness as effective decision making tools is slow as each academic and pharmaceutical company work in isolation.

Bringing together European experts in technologies fully translatable from animal to human, experts in translational medicine, drug discovery and mathematical modelling, PHARMA-COG proposes to accelerate this validation using a 'MATRIX' approach i.e. conducting parallel experiments in animals and human using a comprehensive and standardised battery of behavioural, neurophysiological, morphological/functional imaging, and biochemical endpoints to:

- develop models with greater predictive capacity for the clinics
- develop and validate translatable pharmacodynamic markers to support dose selection
- develop challenge models to support early hint of efficacy studies
- identify and validate of markers of disease progression and patient stratification.

The PHARMA-COG consortium consists of 30 public (Univeristies, Research Centres, Hospitals) and private partners (SMEs and EFPIA members), as well as a patients' Association Alzheimer Europe, coming from 10 different EU Members states. PHARMA-COG will also work closely with the EMEA, as an associated partner of this project, to share project progress and discuss the implications for drug development in Europe. The combined size and expertise of PHARMA-COG provides a truly unique opportunity to validate the tools required to fundamentally change the drug discovery process in AD and accelarte efficacious drug to patients across Europe.

By the end of this 5-year project PHARMA-COG will have a) validated the tools necessary to streamline AD drug discovery and accelerate effective medicine to patients, b) set the standard for European drug discovery providing optimised and validated protocols c) provided the infrastructure to sustain world class drug discovery in Europe and d) disseminate the obtained results from health professionals to patients.

Call topic code:	**IMI_Call_2008_1_12**
Topic title:	**Understand Severe Asthma**
Project acronym:	**U-BIOPRED**
Project title:	**Unbiased Biomarkers for the Prediction of Respiratory Disease Outcomes**

Rationale:
The inability of pre-clinical studies to predict clinical efficacy is a major bottleneck in drug development for severe asthma. This results from: lack of useful and validated biomarkers, underperforming pre-clinical models, inadequate and incomplete sub-phenotyping, and insufficient understanding of disease mechanisms.

Hypothesis:
The use of biomarker profiles comprised of various types of high-dimensional data, integrated with an innovative systems biology approach into distinct phenotype handprints, will enable significantly better prediction of therapeutic efficacy than single or even clustered biomarkers of one data type, and will identify novel targets.

Strategy:
U-BIOPRED will follow a staged-strategy leading to a step-change in understanding severe asthma and novel drug development:

1. Generating consensus and global standard operating procedures (SOPs) on diagnostic criteria, clinical phenotyping and disease outcome of severe asthma

2. Creating adult/paediatric cohorts and biobanks for cross-sectional and longitudinal studies in well characterized severe asthmatics and controls

3. Generating phenotype handprints of severe asthma by an innovative systems biology strategy (training set)

4. Validating the accuracy of phenotype handprints in identification of newly included patients (validation set)

5. Refining phenotype handprints with pre-clinical animal and human exacerbation models

6. Validating the handprints for their predictive efficacy in gold standard and experimental therapeutic intervention

7. Refining the diagnostic criteria and phenotypes of severe asthma by incorporating the newly established handprints

8. Establishing a platform for exchange, education and dissemination.

Innovative approach:
We will use a novel systems biology approach to integrate high dimensional data from invasive, non-invasive and patient-reported outcomes.

Consortium:
The consortium includes partners from academia (20), biopharma industry (EFPIA) (9), patients/care organisations (6), SMEs (4) and multinational industry (1). U-BIOPRED has a Management Board (day-to-day management), Strategic Advisory Board (external advice), Scientific Board (integrating the 10 Workpackages), Ethics Board, Safety Board, and a General Assembly (representing all partners).

Call topic code:	**IMI_Call_2008_1_13**
Topic title:	**COPD**
Project acronym:	**PROACTIVE**
Project title:	**Physical Activity as a crucial Patient Reported Outcome in COPD: 'PROactive'**

Chronic Obstructive Pulmonary Disease (COPD) is affecting an increasing number of European citizens. It is a treatable and preventable lung disease with extra-pulmonary effects contributing to morbidity and mortality. Physical inactivity and its associated symptoms are a hallmark of the disease contributing to the disease progression. Traditional physiologic outcomes for pharmacotherapy target the lungs, focus on laboratory or field exercise tests, count events (e.g. exacerbations) or address quality of life in a generic way. These outcomes do not fully cover the patients' experience of the consequences of the disease. Despite its importance, no patient reported outcome (PRO) exists, capturing physical activity (PA) in a way that it maximally reflects the experience of patients with COPD.

The aim of phase one of PROactive is to develop two PRO tools investigating all relevant dimensions of PA, using patient input, input from the literature and clinical experts, in line with guidelines for PRO development. A first PRO will assess PA on a daily basis. A second PRO will measure relevant dimensions of PA during clinical visits. PROactive will apply user friendly electronic interfaces (EPRO's) to record daily items and activity monitoring to cover the amount of daily PA.

The second phase will validate the PROs in clinical trials, focusing on patient groups covering the whole disease spectrum, securing prospective data in over 600 patients and culturally sensitive translations for at least 10 European languages.

The PROactive consortium will optimally use the complementarities of patient organizations, established academic institutes delivering front row COPD care and research, and a small to medium enterprise specialized in dissemination and PRO translations. Together with EFPIA members with a long lasting experience in conducting the largest multi-centre trials in COPD and established PROresearch units this will allow for a quality of studies not achievable by traditional research institutes or EFPIA partners alone.

PROactive is dedicated to disseminate its milestones to the relevant stakeholders, including patients, providers and regulatory authorities. With its innovative approach, the results of this project will further advance the field of COPD outcome research.

Call topic code:	**IMI_Call_2008_1_14**
Topic title:	**Establishment of a network to facilitate and coordinate European training and education relevant for stakeholders of medicines research and development**
Project acronym:	**EMTRAIN**
Project title:	**European Medicines Research Training Network**

EMTRAIN will establish a pan-European platform for education and training covering the whole lifecycle of medicines from basic research through clinical development to pharmaco-vigilance. The public consortium consists of the six pan-European biomedical research infrastructures from the ESFRI roadmap, that cover a broad spectrum of competencies from molecules to humans, with a pan-European dimension. The EFPIA consortium has considerable experience in Training and Education, management, pan-European geographical outreach, and an extensive external Network of contacts. The EMTRAIN participants, together with the coordinators of IMI topics 15-18, will participate in the Strategic Co-ordination Board to ensure coordination between the IMI T&E topics, whereas the Steering Committee will supervise the management of the project. Topics 15-18 representatives will be invited to participate in work packages activities. Based on extensive mapping of existing resources and on a gap and overlap analysis (WP3), the consortium will develop and implement a strategy (WP2) for harmonisation and accreditation (WP4) of Master level (WP5) and PhD programmes (WP6), as well as continuous education programmes (WP7). It will develop innovative concepts and methods in conjunction with the other IMI T&E topics (WP8) that will support the content for the IMI education programmes. National implementation will be facilitated through contacts with University authorities, Ministries of Higher Education, and through national liaison offices. After implementation in a core group of institutions, extension is planned both within countries represented in EMTRAIN and in additional countries (WP4), with the support of a dissemination and communication activity (WP9). The harmonisation and the modular nature of these programmes will allow trans-disciplinary curricula as well as trans-border mobility, and PhD programmes will be designed to foster industry/academia mobility and collaboration.

Call topic code:	**IMI_Call_2008_1_15**
Topic title:	**Safety Sciences for Medicines Training Programme**
Project acronym:	**SAFESCIMET**
Project title:	**European Modular Education and Training Programme in Safety Sciences for Medicines**

Background: In current drug safety education and training in Europe, an integrative and translational approach is lacking. This shortfall has been identified by EUFEPS. The IMI ('Strategic Research Agenda'), the FDA and the EMEA have also characterised this fact as a crucial gap in the education and training of scientists evaluating the safety of drug candidates and new medicines.

Scope and objectives: We present a new and unique pan-European education and training network, which solves this shortfall by developing and establishing a comprehensive modular Education and Training Programme in Safety Sciences for Medicines (SafeSciMET). This programme will fulfil the needs of pharmaceutical industry, regulatory authorities and academia. The network, consisting of top institutes for drug safety education and research, proposes a new type, high quality and sustainable programme for education and training in Safety Sciences for Medicines (S2M). The tailor-made training courses will encompass the safety, ethical, regulatory and societal aspects in all phases of drug development, with emphasis on integrative, translational and 3Rs aspects of drug safety assessment. Individual safety professionals who wish to address specific knowledge gaps will be able to follow single courses. The modular set up also provides an excellent opportunity for following dedicated subsets of courses, to be accredited for Continuing Professional Development (CPD). Scientists successfully completing the full programme, including an integrative MScthesis, will be awarded with an accredited Master of Advanced Safety Sciences of Medicines (MAS2M). All training courses and procedures will be aligned with the Bologna process.

Principle learning outcomes are novel competences in translational safety sciences, leading to safety scientists who are able to perform holistic and critical evaluations of the safety of drug candidates and new medicines by linking in vitro and animal data with patient data more effectively.

Project consortium: In this project a close collaboration is foreseen between 19 top-institutes for drug safety education and research and 16 industrial pharmaceutical companies, all members of EFPIA.

Call topic code:	**IMI_Call_2008_1_16**
Topic title:	**Pharmaceutical Medicine Training Programme**
Project acronym:	**PHARMATRAIN**
Project title:	**Pharmaceutical Medicine Training Programmes**

The proposed Pharmaceutical Medicine Training Programme, PharmaTrain, provides a comprehensive solution for complex training needs of integrated drug development (sciences) for all professionals involved, incl. physicians, pharmacists, pharmaceutical scientists, biologists, biometricians, health economists, safety and regulatory scientists from universities, regulatory agencies, large, small and middle-sized pharma-, bio-, med- and nano-tech-enterprises, and allied companies providing contract research-, financial-, supply- and information services, as well as research ethics committees.

The main objective of PharmaTrain is to create a new multi-modular Diploma / Master Level- three tier Programme for Advanced Studies in Pharmaceutical Medicine / Drug Development Sciences, based on the Bologna credit and title system with 60+ ECTS credits and a new teaching syllabus. This dynamic PharmaTrain programme with a prepare, learn, confirm and sustain phase will be started de novo in collaboration with 6 Universities, and harmonised with another 12 programmes, to form a pan-European, quality managed and self-sustaining network. Base Courses (30+ ECTS), will be harmonised at the same quality level with examinations, through a unified European system, assuring the knowledge requirements will be the basis of the Diploma / Master programme. Combined with the documentation of practical work, this will confer a new nationally accredited European Specialist in Pharmaceutical Medicine. The modular concept also provides an opportunity for accredited Continuing Professional Development as well as individualised training à la carte.

PharmaTrain network collaboration is planned between 60 leaders of 26 EFCPM University training programmes and 13 learned societies incl. 3 regulatory agencies and DIA Europe, matched with 20 representatives of 15 EFPIA member companies. PharmaTrain will encourage faculty exchanges between the industry, regulators and academia, and foster distance e-learning capability, and increased flexibility, transferability and mobility. This uniform high-level training in integrated drug development, harnesses a new strength of Europe, creating a competitive global advantage in developing new innovative medicines.

Call topic code:	**IMI_Call_2008_1_18**
Topic title:	**Pharmacovigilance Training Programme**
Project acronym:	**Eu2P**
Project title:	**European programme in Pharmacovigilance and Pharmacoepidemiology**

The Eu2P project aims to improve the understanding of medicines-related risk by developing an European training and education platform in Pharmacovigilance (PV) and Pharmacoepidemiology (PE) for academia, industry and regulatory bodies.

It will prepare degrees in PV and PE with subspecialities, using a modular approach integrating eteaching and e-learning, distance learning for on-the-job training, short courses with various proficiency levels and PhD-level courses. The target audiences are students in human sciences (medicine, pharmacy, etc.), specialists in the field, members of the media and other laypersons including patients or patient organisations, especially for communication training. Users will build custom training programmes that can lead to a full master's diploma, a PhD or training certificates, according to the options chosen. Emphasis will be put on hands-on training to maximise post-training employment opportunities. Courses will be delivered in English with a mix of face-to-face lectures and e-learning. In addition, short courses can be provided as needed to industrial and other partners. The gathering of seven Universities with EMEA, Afssaps and 15 EFPIA Pharmaceutical Companies makes up the Eu2P consortium, completed by other internationally recognized experts as needed. Of the nine work packages (WP) in this project, 3 will be devoted to coordination of work packages, to project management, and to building the technical e-learning and communication platform. Other WP will build courses on benefit assessment, regulatory aspects, risk quantification, public health and risk communication. The first 2 years will be devoted to setting up the programme, the next three to system testing and tuning, and obtaining academic accreditation. By the end of the 5th year the programme should be self-sustaining through excellence, and will be able to grow to other countries in Europe and beyond.