

The Innovative Medicines Initiative (IMI)



Education and Training First Call Topics IMI Information Day 30 April 2008

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IMI - SRA: The 4 Pillars



Safety

**Knowledge
Management**

**Education
& Training**

Efficacy

- Education on bachelor & master's level is excellent
- Ph.D. and post doc fragmented
 - varying levels of quality,
 - not satisfying need
- Difficult for industry to find scientists with the right skills
- Contemporary science requires trans-disciplinary action to stimulate research and innovation
- Implementation of training courses on new scientific knowledge
- Difficult to retain excellent researchers in Europe

- Needed
 - Critical mass and coordination of postgraduate training
 - Involvement of Industry - Academia – Regulators: PPP
 - Coordination of European efforts
 - Mobility, especially of young researchers
 - Specific courses addressing contemporary science



IMI E&T: Linking centres of excellence: Creating critical mass through networks



Education & Training: Organisation

1. LITHUANIA
2. LUXEMBOURG
3. LIECHTENSTEIN
4. CZECH REPUBLIC
5. BOSNIA & HERZEGOVINA
6. SERBIA & MONTENEGRO

Integrated medicines development

Medicines development

- Quality
- Non Clinical

- Clinical dev
- Investigators
- Monitors
- Regulatory

Education & Training: Areas to be addressed,



1. Integrated Medicines Development
2. Ethics Committee and patient organisation programmes
3. Safety Science programme
 - Including development of a (post graduate) curriculum for safety scientist
4. Pharmaceutical Medicine programmes
5. Scientists within pharmaceutical R&D
6. Regulatory Affairs based courses
7. Bio-statisticians
8. Bioinformaticians and biomedical informaticians

IMI Strategic
Research A
nda

Education & Training: Ph.d. programme



- 480 Ph.D. planned
 - Part of the Safety, Efficacy and KM projects
 - Specific Ph.D. from E&T pillar

Education & Training:

Ph.D. programme, general principles -from SRA



- Students with master degree and high marks/research activity
- Collaboration between a university and a company
 - Approx. 50/50 split of Ph.D. time
 - Supervisor from university and from company
 - Company pays 50% of Ph.D. salary + company overhead
 - Student employed in the company during the Ph.D. study
 - University awards the Ph.D. degree



IMI Education & Training Pillar, Topics for 1st call



1. European Medicines Research Training Network
2. Safety Sciences for Medicines Training Programme
3. Pharmaceutical Medicine Training Programme
4. Integrated Medicines Development Programme
5. Pharmacovigilance Training Programme

IMI Education & Training Pillar, Role of EFPIA participants



- Input on industry needs
- Lecturers
- In-house mentors
- Case studies
- Tutoring programmes in industry environment
- Share course material
- Hosting courses/modules
- Participants, paying course fee and expenses
- PhD fellows



European Medicines Research Training Network

- Establish a pan-European platform of excellence for education and training, covering the whole lifecycle of a medicine, from research to pharmacovigilance.
 - Coordinate training activities
 - Provide training courses for professionals
 - Guarantee quality
 - Stimulate mobility, innovation and PPP
 - A platform for IMI PhD students
- Scope
 - Establish network of research training centres to respond to existing and emerging biopharmaceutical training needs
 - Anchored in European universities characterised by high-quality industry contacts and recognised science
 - Strategy for extension to pan European coverage
- Duration: 7 years

Safety Sciences for Medicines Training Programme



- Predictive safety, bridging pre-clinical and clinical
 - Safety scientists are needed
 - Broader spectrum than the traditional toxicologist
 - Multidisciplinary approach
 - Linking animal and human safety data
 - Address late phase attrition due to safety issues
- Scope
 - A Master's level programme for scientists holding a degree in life sciences
- Duration: 5 years

Safety Sciences:

What is expected from a public consortium?



- Types of Academic Groups and SMEs contributions
 - Organise, set-up and deliver programme (innovative!)
 - Content
 - Modules
 - Timelines
 - Success criteria
 - Considerations on accreditation
 - Promotion of course
 - Half-way evaluation

Pharmaceutical Medicine Training Programme



- Satisfy the demand of highly qualified professionals in the field of **Pharmaceutical Medicine**
 - **Interdisciplinary** approach
 - **Harmonised** activity of existing and new courses in pharmaceutical medicine
 - **Integrated view of drug development** for scientists involved
 - 1: design the E&T product, 2: Implement
- Scope
 - A **Master's level programme** for scientists holding a degree in life sciences
- Duration: 5 years

Pharmaceutical Medicine: What is expected from a public consortium?



- Types of Academic Groups and SMEs contributions
 - Organise, set-up and deliver programme (innovative!)
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 - Promotion of course
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Integrated Medicines Development Course Programme for non-specialists



- Satisfy the need for **information on the medicines development process** for people not directly involved in the research
 - **Short track** (week) for e.g. journalists, patients, members of ethics committees, venture capitalists, and politicians with a special interest in health, research, environmental, or industrial matters
 - **Long track** (months) for e.g. SME personnel, project managers, general managers
- Scope
 - Providing an **integrated overview** of the process including regulatory requirements
 - Courses in English, **translatable to other EU languages**
- Duration: 5 years

Integrated Medicine:

What is expected from a public consortium?



- Types of Academic Groups and SMEs contributions
 - Organise, set-up and deliver programme (innovative!)
 - Content
 - Modules
 - Timelines
 - Success criteria
 - Specification of relevance for the various stakeholders
 - Promotion of course
 - Half-way evaluation
- Synergy with call for Pharmaceutical Medicine

Pharmacovigilance Training Programme



- Satisfy the need for **training in contemporary pharmacovigilance**
- Proactively ensure a **common basis** for pharmacovigilance
- 3 levels
 - **Short course on risk communication** for e.g. journalists, patients, HC providers, venture capitalists, etc.
 - **Master's level training programme** for professionals in industry and regulatory agencies
 - **Research (PhD) programme** to identify current gaps, and assess and develop methods for benefit-risk communication
- Scope
 - Common understanding and active use of pharmacovigilance in industry and regulatory agencies
- Duration: 5 years

Integrated Medicine:

What is expected from a public consortium?



- Types of Academic Groups and SMEs contributions
 - Organise, set-up and deliver programme (innovative!)
 - Content
 - Modules
 - Timelines
 - Success criteria
 - Specification of relevance for the various stakeholders
 - Promotion of course
 - Half-way evaluation
- Other global initiatives to be followed/contacted to avoid redundancies and build on synergies
 - EMEA activities