# Educación y formación dentro de la "Iniciativa Medicamentos Innovadores"

Jørgen Dirach

Los responsables del área de educación y formación (E+F) de la "Iniciativa Medicamentos Innovadores" (IMI), tras consultarlo con los principales estamentos implicados, han identificado ciertas deficiencias en E+F referentes al proceso de desarrollo de medicamentos. El análisis DAFO que se realizó aportó una serie de recomendaciones que se comentarán a continuación.

El ámbito de actividades de E+F se basa en establecer una Academia Europea de Investigación en Medicamentos (EMRA). La EMRA es una plataforma paneuropea para E+F que cubre el ciclo completo de vida de un medicamento. La EMRA apoya la E+F de actuales y futuros profesionales implicados en investigación y desarrollo (I+D) biomédico, incluyendo también a los responsables de registros. Además, la plataforma deberá establecer las bases para la información que sobre el proceso de desarrollo de medicamentos, incluidas las reglas que rigen el proceso, deberán dirigirse a los diferentes interesados no directamente involucrados en el proceso, como los miembros de los comités éticos de investigación, periodistas, inversores y pacientes. Para cerrar el círculo deberá involucrarse también a los pacientes, pues éstos pueden contribuir a determinar qué habilidades y conocimientos adquieren los profesionales y cómo lo hacen.

La EMRA deberá basarse en centros de excelencia ya existentes en las correspondientes disciplinas. No se pretende construir un sistema de E+F paralelo a las universidades y centros de educación superior ya existentes. Las actividades en el flujo de trabajo de E+F están estrechamente relacionadas con las actividades del Proceso de Bolonia para establecer el Espacio Europeo de Enseñanza Superior en 2010.

Las actividades propuestas han sido priorizadas, con la necesidad de establecer:

1) La EMRA, con inclusión de una unidad coordinadora central y un consejo asesor en E+F.
2) Programas para desarrollo integrado de medicamentos, comités éticos y organizaciones de pacientes.
3) Programas para estudios la seguridad, para científicos en el ámbito de la I+D farmacéutica y para profesionales de medicina farmacéutica.
4) Programas para asuntos reguladores.
5) Programas para profesionales bioestadísticos, bioinformáticos e informáticos biomédicos.

Se propone establecer, asimismo, los programas en centros de excelencia de toda Europa. Los cursos deberán celebrarse dos veces al año. En paralelo deberán realizarse otras actividades, a saber:

1) Establecimiento de criterios de excelencia e identificación de los mismos.
2) Opciones para una colaboración más estrecha entre los ámbitos académico e industrial en términos de E+F, incluido un sistema de incentivos para facilitar la movilidad.
3) Reevaluar el proceso de evaluación de los académicos.
4) Abrir el diálogo con los estados miembros de la UE sobre los planes de estudio, así como para establecer criterios europeos sobre éstos.
5) Desarrollar un sistema de acreditación de E+F.
6) Elaborar un mapa de las asociaciones público-privadas en E+F.

Es importante comprender que la I+D de medicamentos debe abordarse de forma transdisciplinaria para involucrar a muchas de las áreas científicas tradicionales en el ámbito de las ciencias de la vida, así como en áreas tecnológicas como biotecnología, nanotecnología, tecnología médica y tecnologías de la información (IT).

## Visión

Esta visión permite vislumbrar el futuro europeo en E+F relacionadas con el proceso de I+D de medicamentos. En 2013, la Plataforma Tecnológica Europea IMI habrá establecido la Academia Europea de Investigación en Medicamentos (EMRA). El programa de doctorado para las actividades de la IMI ya ha sido elaborado.

El desarrollo de la plataforma E+F corre en paralelo y se apoya en el Proceso de Bolonia, por el cual se establecerá en 2010 el Espacio Europeo de Educación Superior como resultado de las diez líneas de acción que establece dicho proceso.

## Misión

La misión define las acciones de la plataforma E+F en el futuro descrito en la visión. La plataforma E+F:

1) Contará con las universidades y centros de enseñanza superior ya existentes, identificando centros de excelencia en las diversas disciplinas de I+D de medicamentos y estimulando la colaboración entre dichos centros.
2) Proporcionará apoyo E+F para eliminar los cuellos de botella en el proceso de I+D de medicamentos.
3) Establecerá múltiples asociaciones público-privadas para E+F de licenciados, doctorados y posdoctorados.
4) Facilitará la movilidad entre los entornos académico, industrial y regulador.
5) Contribuirá a crear un liderazgo europeo en I+D biomédico que beneficie a los pacientes y a la sociedad.

## Plan de implementación y recursos

La plataforma paneuropea para E+F no puede establecerse de un día para otro. Por lo tanto, deben cartografiarse cuidadosamente las actividades existentes en E+F, como la identificación de los centros de excelencia europeos que pueden actuar como impulsores y modelos a seguir para otras instituciones y regiones europeas. El proceso de consulta con las partes implicadas ha originado numerosas propuestas. Partiendo del mapa elaborado, estas propuestas deberán consolidarse con planes de implementación detallados, entre ellos la evaluación de posibles concesiones de becas de doctorado específicas. Se establecerá un programa de E+F que se centre en los cuellos de botella científicos en I+D de medicamentos y en procesos de gestión, que cubrirá las ocho áreas siguientes:

1) Desarrollo de medicamentos integrado.
2) Programas para comités éticos y asociaciones de pacientes.
3) Programas para ciencias de la seguridad.
4) Otros científicos dentro de I+D farmacéutico.
5) Profesionales de medicina farmacéutica.
6) Programas basados en asuntos reguladores.
7) Programa para profesionales estadísticos.
8) Programa para profesionales bioinformáticos e informáticos biomédicos.

Las actividades se llevarán a cabo con la participación activa de los implicados, según el siguiente orden de prioridades a establecer:

1) Una unidad coordinadora central.
2) Un consejo asesor en E+F.
3) Un programa para el desarrollo integrado de medicamentos y para comités éticos y organizaciones de pacientes.
4) Programas para ciencias de la seguridad, así como para científicos en I+D farmacéutico.
5) Programas para profesionales en medicina farmacéutica, asuntos reguladores, bioestadísticos, bioinformáticos e informáticos biomédicos.

Se propone que los programas de la tercera y cuarta prioridad se establezcan en centros de ex-

celencia a identificar en toda Europa. Los cursos deberán celebrarse dos veces al año en cuatro centros para cada materia.

Durante el primer año será fundamental la elaboración del mapa que permita identificar los cursos que se realizarán, así como la planificación de los programas específicos expuestos a continuación, además de ciertas actividades paralelas. Se han identificado ocho áreas críticas básicas en las que hay una demanda específica de cursos para cubrir tanto las necesidades actuales como los cambios previstos en el proceso de I+D de medicamentos.

## Programa de doctorado

Para facilitar la interacción de la academia y la industria, y para asegurar que los investigadores se familiaricen con los aspectos comerciales de la I+D, se recomienda la creación de 60 becas de doctorado para cada una de las áreas preferenciales, es decir, un total de 480 becas. Este programa debe incluir la cooperación de una universidad, un(a) becario(a) de doctorado y una empresa en un proyecto de I+D definido, relacionado con actividades IMI, entre ellas doctorados que cubran el proceso de desarrollo de medicamentos. Dos supervisores guiarán al becario de doctorado industrial, uno procedente del ámbito universitario y el otro del ámbito empresarial. El becario de doctorado industrial será empleado por la empresa a tiempo completo y se le remunerará todo el periodo trabajado. El salario del becario podrá partirse como asociación público-privada, en que un 50% lo paga el programa de acción comunitario Marie Curie y el otro 50% la empresa en cuestión. Para facilitar la participación de las PyMES, parte de estas becas deberá ser financiada en su totalidad por la CE.

El plan es desplegar el programa de doctorado en tres convocatorias. La primera convocatoria se realizará en el segundo semestre de 2007, cubriendo un tercio del programa que se iniciará en 2008. La segunda y tercera convocatorias se realizarán en el segundo semestre de 2008 y 2009, respectivamente, con inicio en 2009 y 2010. Así, los alumnos de doctorado habrán completado sus estudios en 2013.

# Education and training within the "Innovative Medicines Initiative"

Jørgen Dirach

Based on consultation with stakeholders, the education and training (E&T) workstream within the Innovative Medicines Initiative (IMI) has identified a number of gaps within E&T in support of the medicines development process. A SWOT analysis was made, resulting in a number of recommendations which will be discussed below.

The scope of the activities within E&T is to establish the European Medicines Research Academy (EMRA). EMRA is a pan-European platform for E&T, covering the whole lifecycle of a medicine. EMRA supports the E&T of current and future professionals involved in biomedical research and development (R&D), including regulatory officers. Further, the platform should provide the basis for information on the medicines development process, including the rules governing the process, to stakeholders who are not directly involved in the process, such as members of research ethics committees, journalists, venture capitalists and patients. To complete the loop, patients should be involved as they can make a contribution to the determination of what and how the professionals acquire skills and knowledge.

The EMRA should be based on existing centres of excellence within the relevant disciplines. It is not intended to build a system for E&T parallel to existing universities and higher education institutions. The activities in the E&T work stream have close links to the activities in the Bologna Process to establish the European Higher Education Area by 2010.

The activities suggested have been prioritized. The top priorities to be established will be:

1. The EMRA, including a central coordinating unit and an advisory E&T council.
2. Programs for integrated medicines development and for ethics committees and patient organizations.
3. Programs for safety sciences, scientists within pharmaceutical R&D and Pharmaceutical Medicine professionals.
4. Regulatory affairs-based programs.
5. Programmes for bio-statisticians, bioinformaticians and biomedical informaticians.

It is proposed to establish the programs at centres of excellence across Europe. The courses are to be held twice a year. Other activities will be needed in parallel. These include:

1. Establishing criteria for centres of excellence and the identification of these.
2. Options for closer collaboration between academia and industry in terms of E&T, including an incentive system to facilitate mobility.
3. Re-evaluate the evaluation process for academics.
4. Open dialogue with EU member states on curricula, including establishing European criteria for curricula.
5. The development of an accreditation system for E&T.
6. Mapping existing public–private partnerships in E&T.
7. Identifying existing relevant European curricula.

It is important to realise that medicines R&D requires a transdisciplinary approach, involving many of the traditional scientific areas within life sciences and, in addition, technological areas such as bio-

technology, nanotechnology, medical technology and information technology (IT).

## Vision

This vision provides a view of the European future for E&T related to the medicines R&D process. By 2013, the European Technology Platform for Innovative Medicines will have established the European Medicines Research Academy (EMRA), a pan-European platform for E&T for professionals involved in biomedical R&D, including regulatory officers over the whole life-cycle of a medicine. The PhD programme supporting IMI activities has been completed.

The development of the E&T platform is in parallel with and supported by the Bologna Process, by which the European Higher Education Area will be established in 2010 as a result of the 10 action lines from the Bologna process.

## Mission

The mission defines what the E&T platform will be doing in the future described in the vision. The E&T platform will:

1. Build upon existing universities and higher education institutions in Europe by identifying centers of excellence within the various disciplines of medicines R&D, and stimulate collaboration between these centers.
2. Provide E&T support to remove bottlenecks in the medicines R&D process.
3. Establish multiple public–private partnerships within E&T for graduate, doctoral and postdoctoral E&T.
4. Facilitate mobility between academia, industry and regulators.
5. Help to create biomedical R&D leadership for Europe to benefit patients and society.

## Implementation Plan and Resources

The pan-European platform for E&T cannot be established overnight. Careful mapping of existing activities within E&T is needed, including the identification of European centers of excellence that can act as drivers and role models for other institutions and regions in Europe. Many proposals have been suggested during the consultation process with stakeholders. Based on the mapping, these proposals should be fleshed out with detailed implementation plans, including the evaluation of potential specific Ph.D. grants. An E&T program will be established to focus on scientific bottlenecks in the medicines R&D and management process, covering the following eight areas:

1. Integrated medicines development.
2. Ethics committee and patient organisation programs.
3. Safety science programs.
4. Other scientists within pharmaceutical R&D.
5. Pharmaceutical medicine professionals.
6. Regulatory affairs-based programmes.
7. Biostatisticians program.
8. Bioinformaticians and biomedical informaticians program.

The activities will be carried out with active participation of the relevant stakeholders, as shown below. It will be necessary to establish:

1. A central co-ordinating unit.
2. An advisory E&T council.
3. A programme for integrated medicines development and for ethics committees and patient organizations.
4. Programmes for safety sciences, and scientists within pharmaceutical R&D.
5. Programs for pharmaceutical medicine professionals, regulatory affairs, biostatisticians, bioinformaticians and biomedical informaticians.

It is proposed that the third and fourth priority programmes are to be established at centers of excellence to be identified across Europe. Courses are to be held twice a year at four centers for each topic.

Within the first year, mapping to identify courses that are to be carried out is a primary activity, as is planning the specific programs set out below, to-

gether with a number of parallel activities. Eight major critical areas have been identified where there is a specific need for courses to support both current need and foreseen changes to the medicines R&D process.

## Ph.D. Program

To facilitate interaction between academia and industry and to ensure that researchers gain an insight into the business-related aspects of R&D, it is recommended that 60 PhD grants should be established for each of the eight areas, i.e., 480 Ph.D. grants. This program should involve the cooperation of a university, a Ph.D. fellow and an enterprise in a defined R&D project, linked to IMI activities, including Ph.Ds. covering the medicines development process. Two supervisors will guide the industrial Ph.D. fellow, one from the university and one from the enterprise. The industrial Ph.D. fellow is employed by the company on a full-time basis, and is paid for the entire period. The salary for the Ph.D. student could be split as a public–private partnership, where 50% is paid by the EC/Marie Curie Action program and 50% by the enterprise in question. To facilitate participation from SMEs, a proportion of these Ph.Ds. should be fully financed by the EC.

The plan is to roll out the PhD program in three sequences. The first call will be in the second half of 2007, covering one-third of the program, for commencement in 2008. The second and third calls will be in the second halves of 2008 and 2009, for commencement in 2009 and 2010. The Ph.D. students will thus have completed their studies by 2013.

# Diapositivas / *Slides*

**Innovative Medicines Initiative:**

*Training and Education Programmes for Europe*

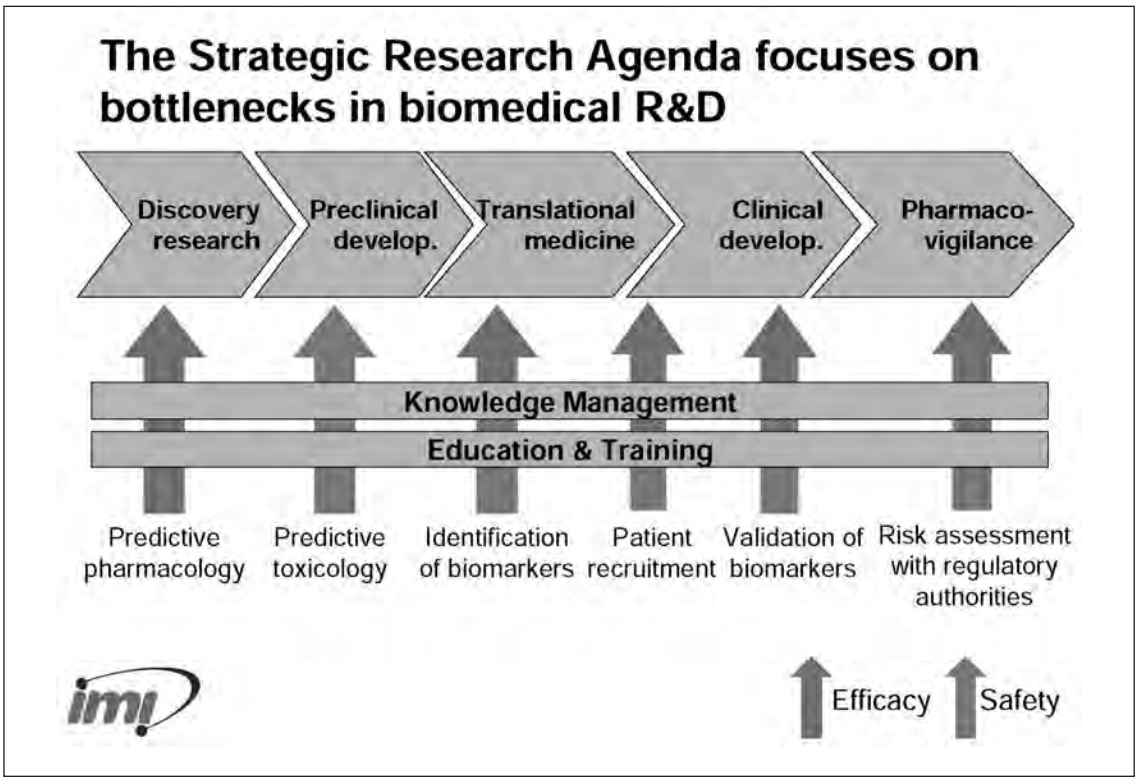
**Plataforma Tecnológica Española**
***Medicamentos Innovadores***

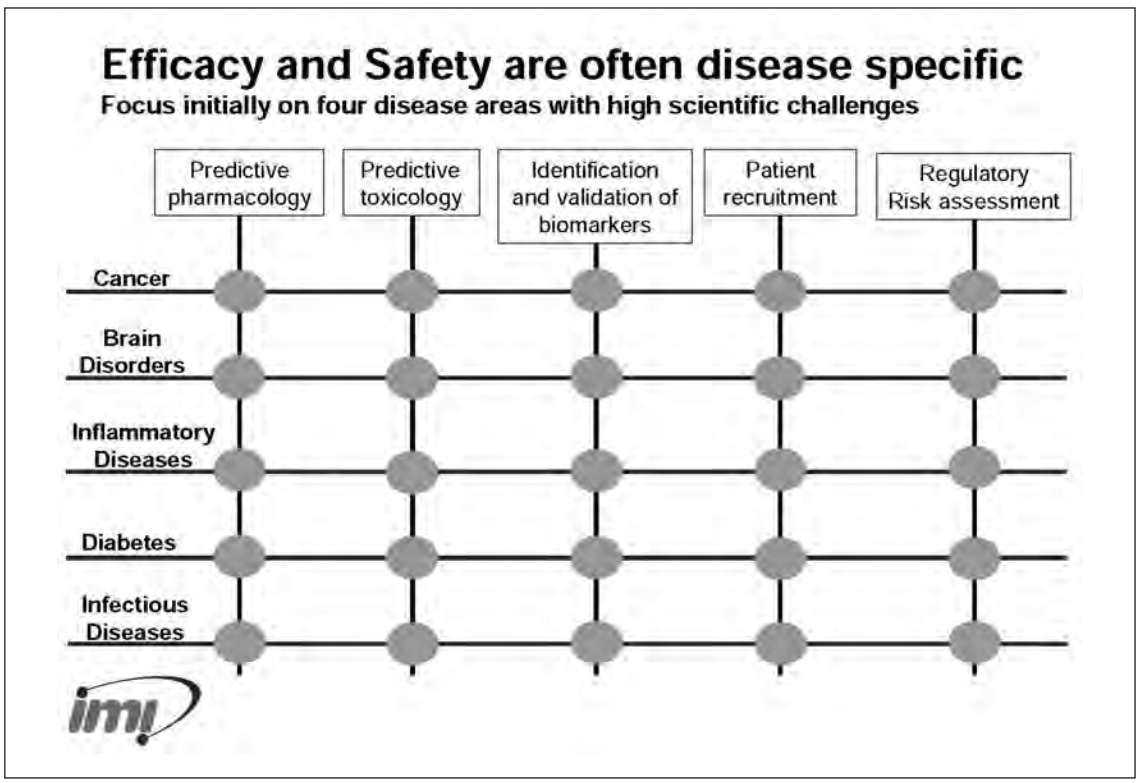
6 June 2006

Jørgen Dirach, MD. MBA. MFPM
Novo Nordisk, Corporate Research Affairs
Chairman, EFB Section on Medicines Development

The 4 pillars of IMI: A strong structure


Safety Knowledge Management Education & Training Efficacy

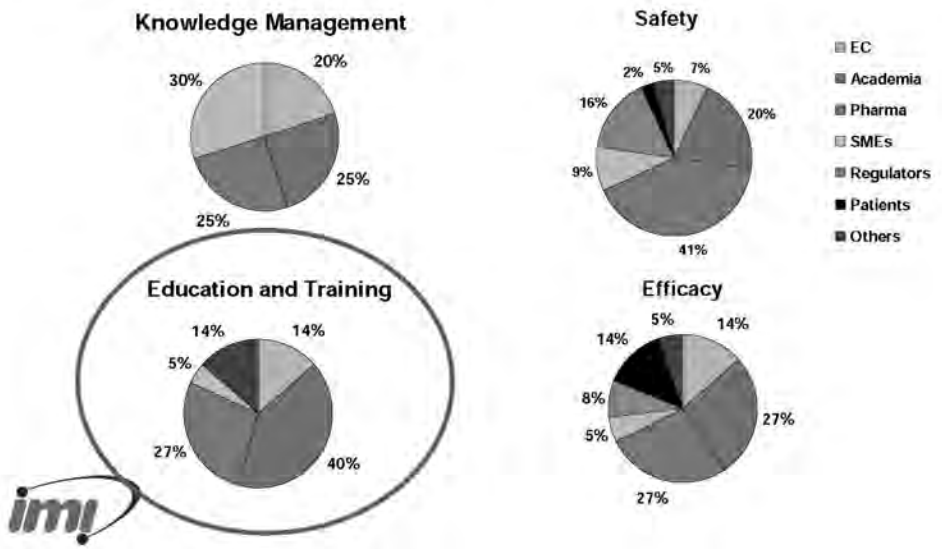

The Strategic Research Agenda focuses on bottlenecks in biomedical R&D
Discovery research
Preclinical develop.
Translational medicine
Clinical develop.
Pharmaco-vigilance
Knowledge Management
Education & Training
Predictive pharmacology
Predictive toxicology
Identification of biomarkers
Patient recruitment
Validation of biomarkers
Risk assessment with regulatory authorities
Efficacy
Safety


Efficacy and Safety are often disease specific
Focus initially on four disease areas with high scientific challenges
Predictive pharmacology
Predictive toxicology
Identification and validation of biomarkers
Patient recruitment
Regulatory Risk assessment
Cancer
Brain Disorders
Inflammatory Diseases
Diabetes
Infectious Diseases

## Education & Training: Input

- InnoMed IP Proposal Nov-2004
- E&T workshop, Brussels 24&25 Feb 2005
  - Dialogue with participants Mar & Apr
  - Report available
- E&T workshop, Barcelona 21&22 Apr 2005
  - Dialogue with participants
  - Report available
- E&T workshop, Brussels 20-May-2005
  - Report available
- SRA E&T 01
  - Consultation with stakeholders
- SRA Draft 1 July 2005
  - Public hearing autumn 2005
- SRA Draft 2

## Balanced Stakeholder Participation for the Four Thematic Workshops (Brussels Jan-May 2005) A total of 327 experts



## Education & Training: Issues

- Coordination
  - Funding
  - Bologna process
  - Industry involvement
  - Definition of E&T
  - Criteria for Centres of Excellence in Education to be established
- Flexibility
  - Start with training, -later to be included in curricula
- Quality
  - Little or no existing quality control of courses
    - academia
    - private vendors
- Mobility
  - Almost no movement from industry to academia
  - Mobility of teachers and students

## Education & Training: Definition

- Education encompasses teaching and learning specific skills, and also something less tangible but more profound: the imparting of knowledge, good judgement and wisdom
- Training is the teaching of vocational or practical proficiency and relates to specific useful skills

Source: Wikipedia, The Free Encyclopedia

## Education & Training: **Barriers**

- National barriers / priorities / cultural diversity
  - Think European!
- Established disciplines (Silo thinking)
  - Transdisciplinary approach needed
- Pan-European grades, coordination needed
- Language
- Mobility
- IP
- Lack of political will

## Education & Training: **Gaps to be addressed**

- Translational science
- Specific needs
  - Safety scientists, Pharmacology, pre-clinical and clinical, Bioinformatics, Knowledge Management, Systems Biology and Systems Pharmacology and physiology, Medical statistics/Biostatisticians, Medical imaging
- Continuous professional development
- Traditional thinking within professions on career opportunities
- Clinical Trials Directive: Need for training
- Programmes for Ethics Committee Members, Journalists, patient organisations, patients
- Programmes for SME and VC

## Education & Training: **General conclusions**

- There is a profound need for qualified personnel within the natural, technical pharmaceutical and medical sciences (specialists)
- Need for knowledge across disciplines (overview)
- Ongoing training to keep updated with technology developments (specialists)
- Training for people in other sci. areas (bridging)
- Need for business skills and understanding of the business environment for SMEs (overview)
- Need for better pharma insight for Venture Capitalists (overview)

## Education & Training: Vision

By 2013 European Medicines Research Academy (EMRA) is well established and results are emerging

A pan-European platform for education and training for professionals involved in biomedical R&D including regulatory officers over the whole lifecycle of a medicine.

- No parallel E&T system
- A physical institution should *not* be build
- Link to Bologna process

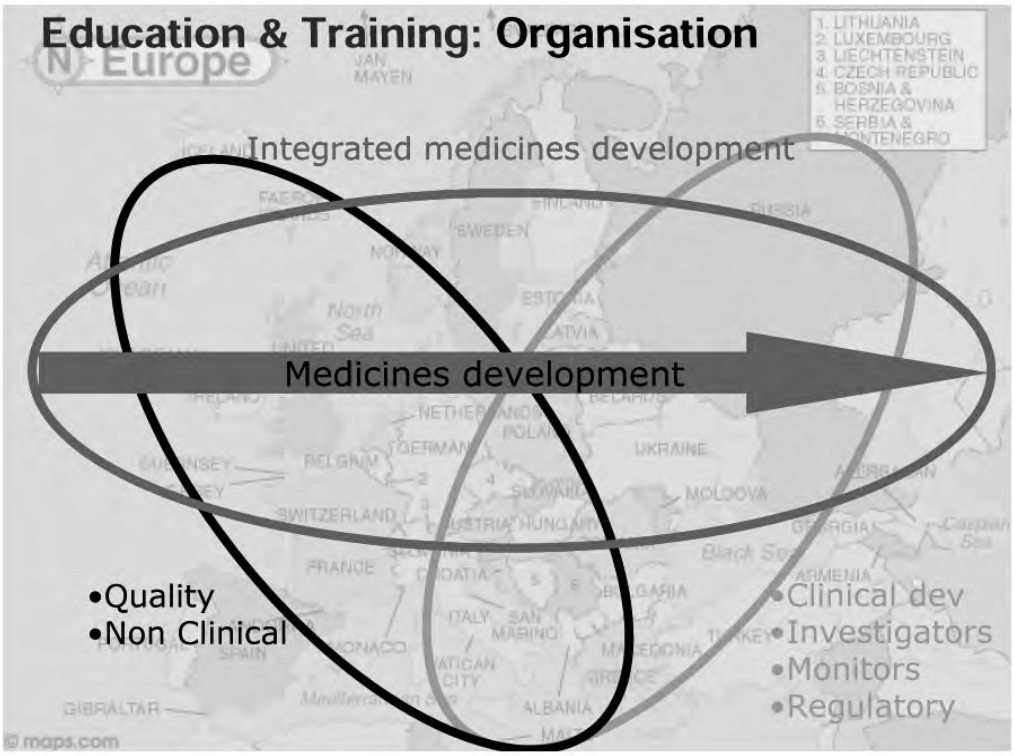
## Bologna process

- Pan-European comparable degrees based on a 2-cycle system,
- An established ECTS system of credits,
- Increased mobility of students and university staff,
- Established quality assurance standards for education,
- Implemented lifelong learning strategies,
- Active involvement of stakeholders of higher education,
- Attractiveness of European higher education to students from Europe and other parts of the world,
- A clear link between the European Higher Education Area and the European Research Area linking undergraduate, graduate, doctoral and postdoctoral education and training.

**To be achieved by 2010**

## Education & Training: Mission

- EMRA is based upon existing centres of excellence within the disciplines
  - Stimulate collaboration between these
- E&T Support to remove bottlenecks
- Create public-private E&T partnerships within graduate, doctoral and postdoctoral
- Facilitate mobility between academia, industry and regulators
- Help to create biomedical R&D leadership for Europe to benefit patients and society

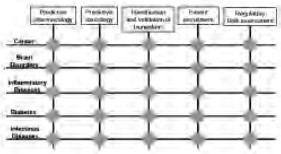



## Education & Training: Areas to be addressed, -mapping and implementation plan, programmes for

1. Integrated Medicines Development
2. Ethics Committee and patient organisation programmes
3. Safety Science programme
   - Including development of a 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

## Education & Training: **Actions**

- Establish the EMRA including a central coordinating unit and an advisory E&T council
- For each of the 8 programmes, per year:
  - 2 courses
  - 1 month duration
  - 26 participants
  - 4 regions of Europe
  - Accreditation of courses included
- 60 PhD grants for each of the 8 areas (480), PPP
  - Linking to the grid:



## Education & Training: **PhD programme**

- Students with master degree and high marks/research activity
- Collaboration between a university and a company
  - Appr 50/50 split of PhD time
  - Supervisor from university and from company
  - Company pays 50% of PhD salary + company overhead
  - Student employed in the company during the PhD study
  - University awards the PhD degree
- Programme pay
  - Lump sum to university for bench fee, supervision, courses,
  - Grant available for travelling

## Education & Training: **Key success factors**

- Stakeholder support including:
  - European biomedical industry, academia, learned societies, patient groups, regulatory bodies, the European Commission, and ministries of education
- Establishment of an optimal organisational structure
- Minimum bureaucracy
- Results from the Bologna process

## Education & Training: **Performance Measures Quantitative/ qualitative**

- Number of attendees at courses, qualifications achieved
- Number of trainees employed in Pharma Industry and related fields
- Boost of relevant scientific disciplines in Europe including attraction of scientists
- Curricula accepted by the Scientific Community
- Acceptance of qualifications
- Raised level towards innovation
- Increased investment in EU biomedical
- Better informed public and patient groups
- Increased understanding of the R&D conditions for Pharma Industry
- Biomedical R&D leadership for Europe

## EDUCATION & TRAINING

**Goal:** Europe should support the interdisciplinary education essential to the biomedical sector.

**Main recommendations:**

- ❑ Create a European Medicines Research Academy for education and training for professionals involved in biomedical R&D including regulatory officers over the whole lifecycle of a medicine,
- ❑ Map existing activities within E&T including identification of European centres of excellence and develop programmes and implementation plans for the critical areas relevant to the biomedical R&D process,
- ❑ Evaluate options to foster mobility between academia and industry.
- ❑ Ph.D. programme to stimulate academia-industry interaction and support identified need for scientists