SafeSciMET

European Modular Education and Training Programme in Safety Sciences for Medicines
What patients need
What Europe needs

• ☀ Rapid exploitation of insights in disease mechanisms for introduction of innovative treatment modalities
  ☹ Fast pace of new scientific advancements contrasts with slow drug development process.

• ☀ Impact of new technologies on the development of new medicines
  ☹ Drug discovery but not development benefits from new technologies.

• ☀ Economical and efficient drug development process
  ☹ Expanding knowledge in many areas relevant for new drug therapies creates new interfaces between different disciplines leading to higher complexity of interdisciplinary work.
What patients need
What Europe needs

• 😊 **Drug development scientists bridging between disciplines**
  😞 We have many specialists in different fields - but only few who can join the puzzle stones together to a coherent picture.

• 😊 **Opening of bottlenecks in drug development**
  😞 Translating knowledge on a new drug candidate gained in preclinical *in silico, in vitro* or in animal models to humans is a difficult, yet critical step.

• 😊 **Educational programmes focusing on key areas in drug development**
  😞 In current drug safety education and training, an integrative and translational approach is mostly lacking.
Key steps in drug development: Interspecies scaling

- Safety margin
- Effects
- Metabolism
- PK/PD relationship
- Target organs for toxicity
- Mech. of action
- Accumulation
- Clearances
- Distribution
- Absorption

PRECLINICAL → TRANSLATION → CLINICAL
Translation of pre-clinical findings into human-relevant information

Translational Safety Questions

• How relevant are safety flags observed in animals for man?
• What is the expected safety margin in humans as projected from pre-clinical information?
• What is the efficacious dose/plasma level?
• What is the expected human exposure to a drug candidate?
• What is the drug-drug interaction potential?
• Where are uncertainties in the prediction?
Interspecies scaling –
Not just a simple question of size!
Interspecies and individual differences at molecular level

Human enzyme vs. mouse enzyme

John’s enzyme vs. Mary’s enzyme
(gender, age, developmental maturation, disease)

(tissue-specific) Abundance
Substrate-specificity
Enzyme kinetics (Kd/Vmax)
What SafeSciMET will do about the gap

- Develop and deliver a pan-European education and training program on drug safety emphasizing integrative and translational aspects lacking largely in today’s educational programs.

- E&T programme
  - fulfilling the needs of pharmaceutical industry, regulatory authorities, academia
  - targeting graduates from life sciences, medical, veterinary sciences

- Implement modular approaches applying virtual / e-learning strategies, industry case studies and rigorous examination.

- Enable formation of a new generation of safety scientists embracing new technologies to enhance innovative approaches to drug development.
pan-European Modular Education and Training Program in Safety Sciences for Medicines (SafeSciMET)

- 20 Core courses (3 ECTS)
- Suppl. courses
- MSc-thesis

SafeSciMET building blocks

Single course

Individualized CPD

17 Core courses + 3 Suppl. courses + MSc-thesis

MSc of Adv. Safety Sciences (70 ECTS)

60 ECTS (i.e. 1 acad. year), can be completed part-time (i.e. 1-4 years)
SafeSciMET courses characteristics

• Each course covers an important safety topic
• Consists of
  – 1 week on-site teaching and
  – 1 week of self-training and distance learning using industry-supplied case studies – e-accessibility of coach
• Uses a variety of teaching modalities: frontal, e-learning, break-out groups, Ask-the-Expert sessions, Power Luncheons, participant presentations
• Concludes with a written examination
• Benefits from diverse backgrounds of teachers
• Can be combined for individualized CPD in a flexible time-frame
SafeSciMET course fee structure ¹)

Individual Course
Industry: € 2’500; Governmental: €1’500; Academia: € 750

Entire Program for Masters degree: € 25’000

Discount schemes:
- multiple participants from same institution in same course
- multiple courses by one participant
- Students from Eastern European Countries

¹) approval from Steering Committee pending
SafeSciMET’s innovative approach (1):
Diversity of consortium participants

Unique collaboration between universities and companies across Europe

Public partners (N=18):
- VU University Amsterdam
- University of Konstanz
- University of Surrey
- EUFEPS
- University of Copenhagen
- University of Leiden
- Top Instituut Pharma Leiden
- University of Basel
- University Henri Poincare Nancy
- Hospices Civils de Lyon
- Martin-Luther-University Halle
- Karolinska Institutet Stockholm
- University of Vienna
- Université de Paris-Sud
- MRC Centre for Drug Safety Science
- Universidade de Lisboa
- Charité University Medicine Berlin
- Uppsala Universitet

EFPIA partners: (N=15)
- Almirall
- AstraZeneca Ltd
- Bayer-Schering Pharma AG
- Boehringer-Ingelheim Pharma
- Eli-Lilly Ltd
- GlaxoSmithKline Ltd
- F. Hoffmann-La Roche Ltd
- Lundbeck A/S
- Merck KGaA
- Novartis Pharma AG
- Novo Nordisk A/S
- Orion Pharma
- Pfizer
- Sanofi-Aventis
- UCB Parma S.A.
SafeSciMET’s innovative approach (2)

- Broad coverage of safety-related aspects in development and use of medicines
- Strong focus on translational aspects – from bench to bedside / from animal to human
- Emphasis of industry / drug development aspects
- Real-life case studies offered by industry experts
- Diversity of background of teachers
- Diversity in teaching modalities
- Modular structure for Continuous Professional Development
- Flexible time frame for completion of program
- Possibility to conclude with Masters Degree
SafeSciMET will lead to safety scientists:

- with novel **competencies in translational safety sciences**
- performing a **holistic and critical evaluation of the safety of** drug candidates and new medicines by linking *in vitro* as well as animal and patient safety data more effectively
- facilitating the implementation of the **3Rs** concept on reducing the overall use of experimental animals.
- **in regulatory agencies** who are better equipped to judge the safety of innovative and existing medicines.
- **in academia** with unique industrial know-how
E&T has long-term goals:

*Improve education of young and established scientists so that scientific and technological advances become accessible more rapidly for drug development*

⇒ better treatment for patients
⇒ access to innovative medicines
⇒ more efficient drug development
⇒ cost containment in health sector
Added value of the consortium

- Needs of industry brought together with teaching experience of academia
- Pan-European effort focusing all available knowledge for best possible outcome
- Contribution of real-life case studies by industry experts
- Makes knowledge management a supra-national, cross-discipline effort
- Increased understanding in academia of issues in translating theory into practical applications
- Start of a new educational landscape in Europe, inclusion of new EU member states
Results / achievements so far

Year 2010 is preparation phase to ramp-up SafeSciMET teaching program.

Present Focus:
- Definition of courses content, harmonization, scheduling
- Students’ Office (functionalities, procedures)
- Communication plan
- Set up internal communication platform
- Accreditation procedures (CPD; Master)
- Sustainability plan
SafeSciMET: Time and money

Financing:
- Total project costs: 5.52 Mio Eur
- IMI funding: 2.22 Mio Eur
- EFPIA contribution, mainly in kind: 2.52 Mio Eur
- EFPIA in-cash (guaranteed course fees): 1.04 Mio Eur
- Additional income from course fees

Timing:
- Duration of entire Project 5 years: 2010-2014
- Ramp-up phase: January – December 2010
- Starting date: First course delivered November 2010
- Duration of course cycle: 2 years (2011/2; 2013/4)
Further information

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Thank you!

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