SafeSciMET

European Modular Education and Training Programme in Safety Sciences for Medicines

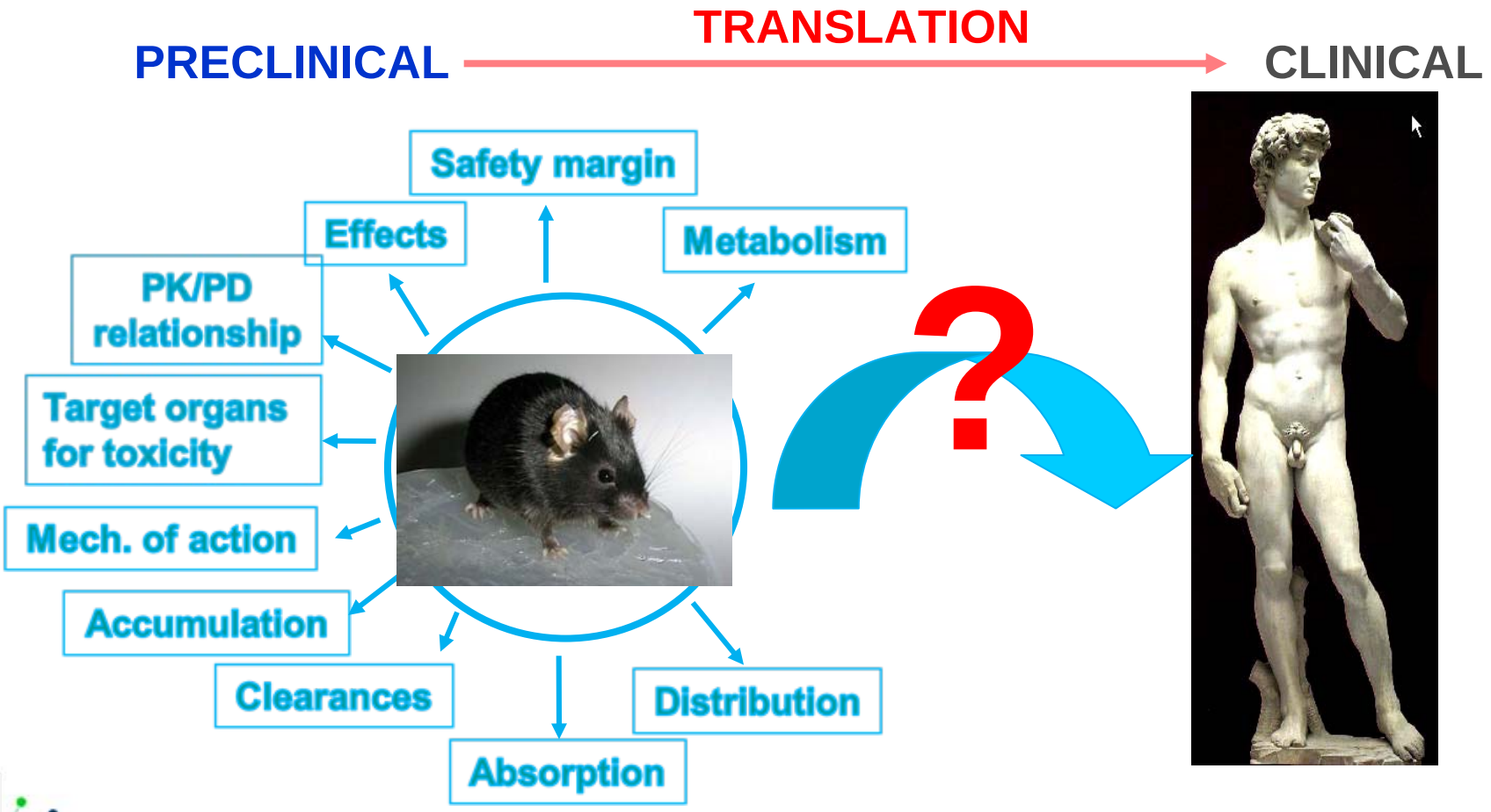
What patients need
What Europe needs

- ☺ ***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

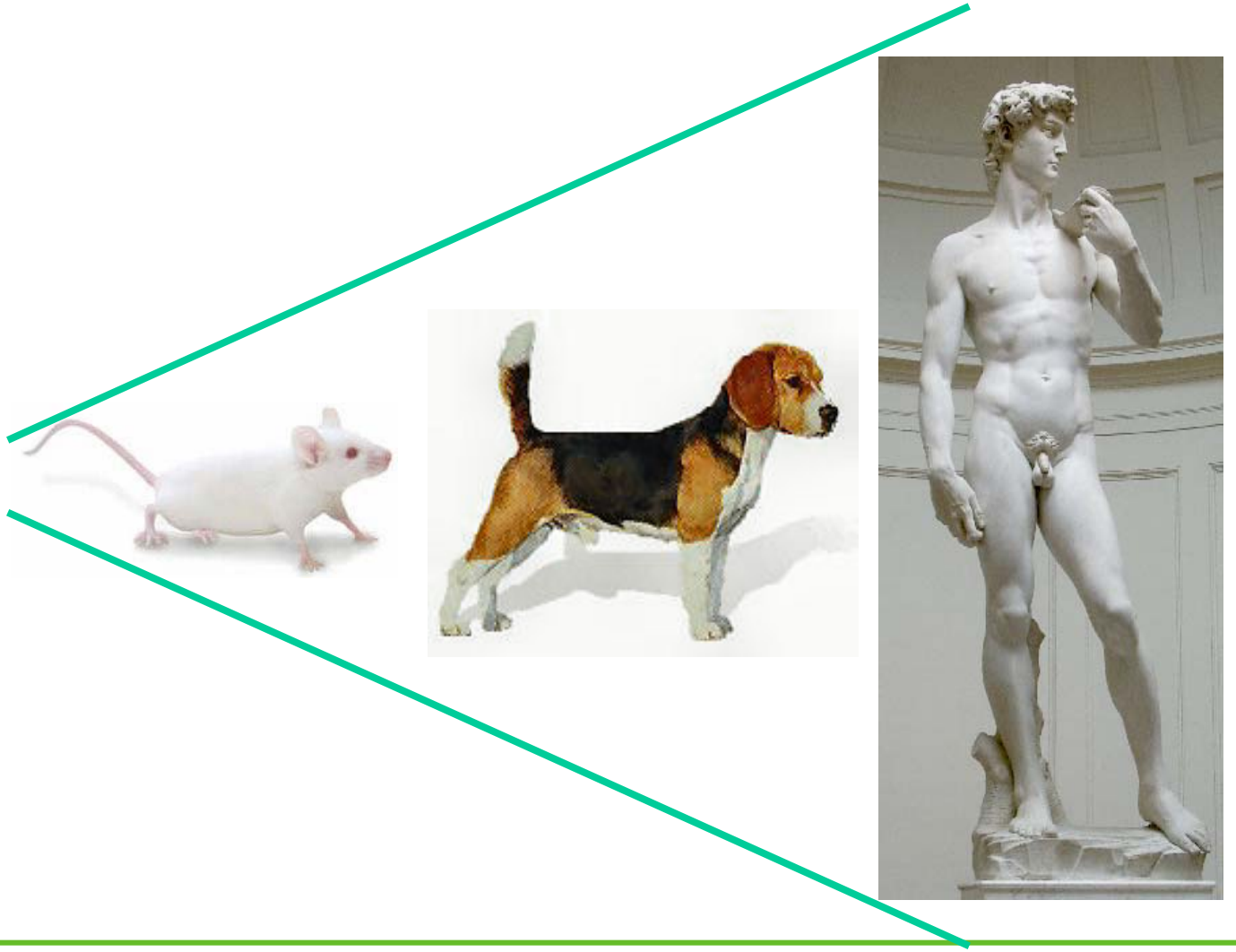


Translation of pre-clinical findings into human-relevant information

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)

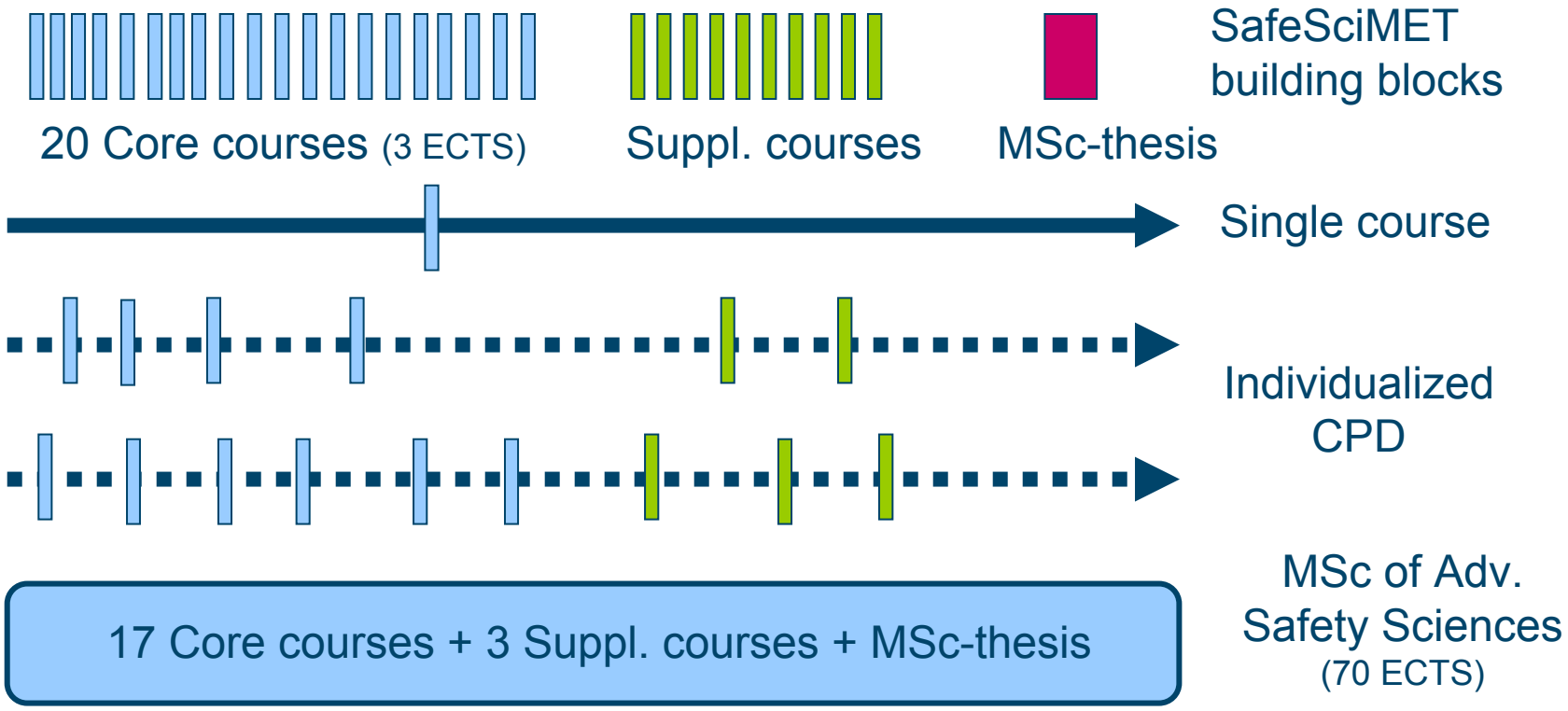
(tissue-specific) Abundance
Substrate-specificity
Enzyme kinetics (Kd/Vmax)

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.

SafeSciMET: Modular Program

pan-European Modular Education and Training Program in Safety Sciences for Medicines *(SafeSciMET)*



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

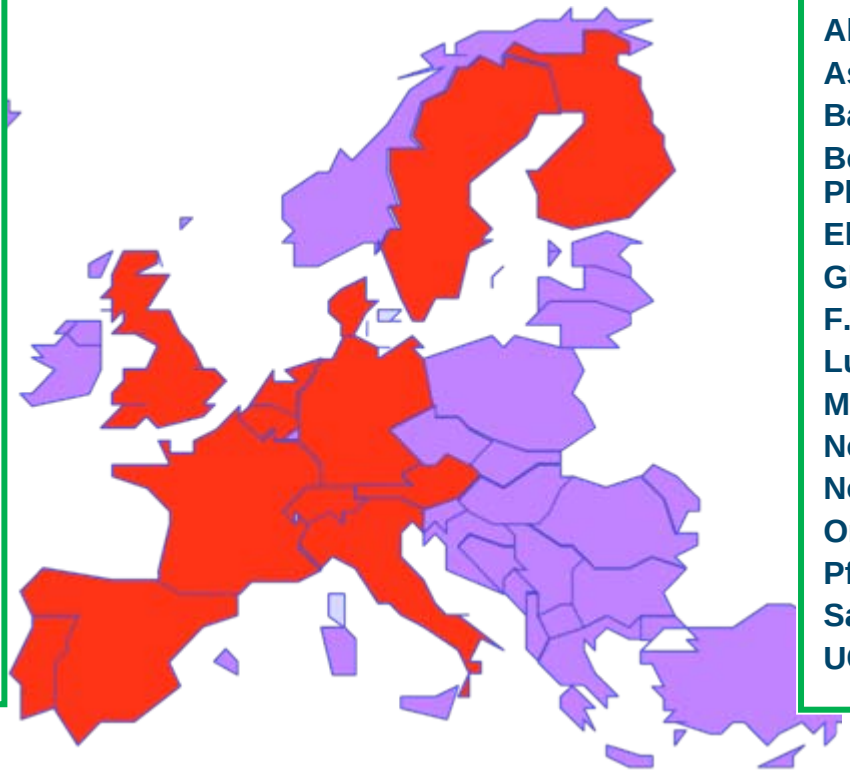
[1)] *approval from Steering Committee pending*

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 KGgaA
- 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: Expected outcome

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

Expected benefit to patients

- 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

- Coordinator: F. Hoffmann-La Roche Ltd
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Thank you!

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