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1) SafeSciMET Workshop 1 in Vienna

Key issues

Current and emerging education and training needs and long-term sustainability of SafeSciMET are important issues. As this is written, about half the number of Courses in the first cycle has been successfully completed. Planning for the second course cycle (2012-2014) is underway. Where required, Courses will be updated to follow new developments and needs in safety sciences. These needs may vary between big and smaller pharma, the regulatory field, academia and any other relevant institutions. The SafeSciMET Project Plan included a workshop addressing this issue of needs in safety sciences in medicine development and a second workshop focusing on sustainability of the Course programme.

A Workshop on Needs

The first workshop was held on May 6, 2011, in Vienna, Austria. To add value, it was scheduled back-to-back to a Hot-topics Conference in Safety Sciences with EUFEPS, on May 5 and the SafeSciMET Steering Committee meeting on May 7. Representatives of the SafeSciMET consortium, but also delegates representing other stakeholders, the scientific community and their organisations (e.g. learned societies), academia and the regulatory worlds were invited to join the workshop. Many did.

First out was C. Freichel (Basel CH, SafeSciMET Coordinator and Workshop Co-chair) welcoming delegates and addressing aims, objectives and progress of SafeSciMET and together with H.H. Linden (Stockholm SE), WP6 Leader and Workshop Co-chair, contributing to a shared understanding of how far we are into the project and what ambitions and expected outcomes there are for the short and long term.

Better insight

Next on the agenda was an update on industrial and related needs and gaps in meeting internal, external and ethical requirements. K. Meyer (Berlin DE) discussed drug safety assessment in transition from the past to promising new developments to identify education and training needs. A. Hartmann (Basel CH) and E-M. Muchitsch (Vienna AT) reported on outcomes of the safety sciences hot topics conference, on the day before. Parallel breakout sessions followed on “hurdles, bottlenecks, challenges, breakthroughs, and priority needs and gaps...” in drug discovery (targeting and design), drug development (delivery to site of action in the body), and drug usage (adverse reactions and clinical safety in practice), but also in collaborative non/pre-competitive research and outsourcing, including IP issues, integrative and translational approaches and achievements, and the reactive and proactive balance in drug regulation.

European status

After a break for lunch, toxicology and drug safety sciences related education and training in Europe were discussed, including objectives, plans and progress of the other (three) IMI JU Education and Training projects – EMTRAIN, Eu2P and PharmaTrain – for a better overview of the European situation and the driving forces for change. H. Foth (Halle DE) reported on status, issues and needs as to basic toxicology and safety education and training in Europe, including for registered toxicologists in light of less and less resources. Developments of the EMTRAIN On-Course catalogue, gap analysis initiative, e-learning surveys and continuing professional development (CPD) plans were presented by C. Janko (Vienna AT). Slides on the Eu2P by A. Fourrier (Bordeaux FR) on needs assessment and plans in pharmacovigilance and pharmacoepidemiology were shown by H.H. Linden. S. Kerpel-Fronius (Budapest HU) presented PharmaTrain observations as to gaps and needs in developing, providing and harmonising course curricula in pharmaceutical medicines/integrated drug development. Additional input from the day-before safety sciences hot topics conference was delivered by D. Dietrich (Konstanz DE).

Even more to do

Plans also included a presentation on “personal medicines as of today and of tomorrow” and related safety issues. However, this did not work out for this workshop. Since this is a field of fast growing interest and many expectations, it should be re-visited e.g. in another SafeSciMET meeting.

The informative workshop day ended with a general discussion, also trying to make conclusions and sum it all up. The contributions to the workshop programme, and due outcomes of this first SafeSciMET Workshop will be further expanded on in the Outcomes Report, which is in progress.

2) Second Steering Committee meeting in Vienna

The second SafeSciMET Steering Committee (SC) meeting was hosted by Prof. Ivo Schmerold at the Veterinary University of Vienna in May. At this meeting, the first annual report and the deliverables achieved in 2010 were discussed. Furthermore, we exchanged ideas on how to optimize communication and the recruitment of as many students as possible for future SafeSciMET Courses. SC members can find the minutes of the meeting, as well as all presentations in the Curriculum Discussion section on Blackboard.

3) Farewell to Theo Guentert

At the dinner between the Workshop1 and Steering Committee meeting days in the Rathauskeller in Vienna, SafeSciMET bid farewell to its first Coordinator: Theo Guentert.



The Rathaus in Vienna at night



Theo receiving the SafeSciMET coordinator certificate from Nico Vermeulen

Theo was instrumental in the initial discussions about the new education and training programme that was to become SafeSciMET and guided the project through its preparation phase and its setup year. We are very grateful for his contribution and are sorry to lose his excellent input in the project.

4) SafeSciMET Courses in full swing

Since the first Course 1.1 in November 2010, SafeSciMET has delivered seven more Courses:

2.1: Pharmaceutics and Safety	Uppsala	February
2.3: Pharmaco / Toxicokinetics and -dynamics	Uppsala	March
4.1: Biochemical and Molecular Toxicology	Amsterdam	June
4.2: Cellular / Predictive Toxicology	Leiden	June
2.2: Regulatory Requirements and Guidelines	Lisbon	September
4.3: Organ / Systems Toxicology	Konstanz	October
4.4: Reproductive Toxicology	Berlin	October

All courses generated excellent feedback from both the students and the teachers. Some student interviews can be found at www.safescimet.eu/news/. The Executive Committee (ExCo) is planning an evaluation of the first seven Courses to extract valuable lessons for the future.

There is still room in the upcoming Courses in 2011 and 2012; the Course schedule is listed below.

5) SafeSciMET communications plan

In order to optimize dissemination activities and reach as wide an audience of potential students as possible, we have set up a communications taskforce consisting of Louise Cornes, Hans Linden, Lennart Dencker, Myron Zaluha, Christoph Wilhelm, Nico Vermeulen and Kevin Augustijn. So far the “Comms TF” has taken the following actions:

- Represent SafeSciMET at meetings
- Create promotional material (posters, brochures)
 - Underway: business cards, lanyards, memory sticks
- Collect relevant e-mail addresses for a SafeSciMET distribution list
 - CROs, national societies, personal contacts, previous related courses
- Coordinate with the Cross-Project Communications group (containing all four IMI Education and training projects)
 - Joint IMI education and training promotional video

In addition, we will follow up on an excellent suggestion from Ole Bjerrum (our Course 1.1 leader) to write a commentary in Drug Discovery Today on the first SafeSciMET Courses. Of course, we welcome good ideas and would encourage everyone to contact us if you have suggestions on how to improve our communications and recruitment of students.

6) The first SafeSciMET Annual Report accepted by IMI

The first SafeSciMET Annual Report, which describes the project progress for 2010 and financial statements from all the academic project partners, was accepted by IMI. The funds covering the associated expenses were distributed to the relevant partners on October 19.

7) LifeTrain – off to a flying start

The first LifeTrain workshop was run by the Innovative Medicines Initiative (IMI) Education and Training projects on 4-5 October 2011

In order to make Europe more competitive, a broad group of European Professional/Scientific bodies came together to develop a common framework for Continuous Professional Development (CPD). This enhanced guidance will support scientists working in all aspects of medicines' discovery, development, processing and usage to maintain their professional competence in a rapidly changing environment.



"There was tremendous enthusiasm from all participants to combine forces for the good of R&D in Europe. The workshop outputs exceeded our expectations and we are now working together on the next steps" said Mike Hardman who chaired the LifeTrain workshop steering committee.

In parallel with the development of this new and unique common framework, work is underway with a range of employers and with academia/course providers to ensure that there is close alignment

between: the individuals' and employers' needs; the guidance from the scientific bodies; and the provision of flexible, high quality courses like SafeSciMET.

For more information see www.emtrain.eu

8) Agenda and course schedule

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| <ul style="list-style-type: none"> • Course 4.5: Mutagenesis and carcinogenesis • Steering Committee meeting III • Course 4.6: Safety Pharmacology • Course 5.1: Non-clinical safety assessment • Course 5.2: Biomolecular analysis • Course 5.3: Predictive cell culture systems • Course 5.4: Toxicogenomics & Systems Toxicology | <p><u>Face to Face dates</u></p> <p>Nov 28-Dec 2, Vienna</p> <p>January 2012, TBD</p> <p>Jan 9-13, Liverpool</p> <p>Jan 23-27, Vienna</p> <p>Jan 30-Feb 3, Amsterdam</p> <p>Feb 13-17, Halle</p> <p>March 26-30, Leiden</p> |
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