

SafeSciMET Workshop on New and Emerging Education and Training Needs

Vienna Veterinary Medical University Lecture Hall
Veterinärplatz 1, AT-1210, Vienna, Austria

Friday, May 6, 2011

Co-chairs	Hans H. Linden, EUFEPS, Stockholm SE Andreas Hartmann, Novartis, Basel CH	
Notes of Outcomes	Chairs and rapporteurs	
0900 – 0910	Welcome Introduction of meeting delegates	Christian Freichel
	Aim, objectives and progress of the SafeSciMET project, including its Workshop1 and 2, respectively <u>Expected Outcome:</u> Shared understanding of how far into the project, what ambitions and expected outcomes, short and long range	
0910 – 0930	Reports and agenda <ul style="list-style-type: none"> • SafeSciMET overall objectives and achievements to date, current and planned activities • Aim and objectives of the SafeSciMET Work Package 6 on long-term sustainability of SafeSciMET, including two workshops, one on needs and one on business models • The agenda of the (today's) Workshop 	Christian Freichel Hans H. Linden
	Scientific developments, trends and paradigm shifts in medicines toxicology and drug safety research <u>Expected Outcome:</u> Update insight in industrial and related needs and gaps in meeting internal, external and ethical requirements, all to identify education and training needs	

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0930 – 0955	From past mistakes in drug safety studies to promising new developments	Eckard von Keutz
0955 – 1025	Key outcomes and take-home messages of the Hot Topics Conference (May 5)	Andreas Hartmann Eva-M. Muchitsch
1025 – 1050	Coffee Break	
	<p>Breakout discussion sessions on toxicology and drug safety research related issues (number of parallel sessions depending of number of workshop delegates)</p> <p><u>Expected Outcome:</u> List of hurdles, bottlenecks, challenges, breakthroughs, and priority needs and gaps...</p>	

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1050 – 1140	<p>Break out discussion items (two per group if three groups)</p> <ul style="list-style-type: none"> • Discovery phase: New paradigms to be considered, promoted and implemented (in drug targeting and design) • Development phase: Toxicology and safety issues and ways through in drug delivery to site of action (in the body) • Usage phase: Needs and priorities as to adverse drug reactions and clinical safety (in practice) • Collaboration: Non/pre-competitive research and outsourcing, including IP issues not yet/to be addressed • All through: Integrative and translational approaches and achievements needed • Regulatory side: The reactive and proactive balance 	<p>Discussion Leaders and Rapporteurs</p> <p>Pool: <i>Lennart Dencker & Joergen Dirach</i></p> <p><i>Ole J Bjerrum & Jacqueline Piner</i></p> <p><i>Philippe Detillieux & Chris Vos</i></p>
1140 – 1200	Reports from breakout discussion sessions	Rapporteurs
1200 –1300	Lunch	
	Toxicology and drug safety sciences related Education and Training in Europe and the EU-EFPIA (IMI) initiatives	

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	<p><u>Expected Outcome:</u> Better overview of the European situation and what the driving forces are for change</p>	
1300 – 1325	Basic toxicology and safety education and training in Europe, including for registered toxicologists, in light of less and less resources: Status, issues and needs	Heidi Foth
1325 – 1425	<p>Needs and gaps being met and filled in current IMI Education and Training projects</p> <ul style="list-style-type: none"> • EMTRAIN course catalogue development and gap analysis outcomes, e-learning surveys and continuing professional development initiatives (CPD) • Eu2P needs assessment and plans for in pharmacovigilance and pharmacoepidemiology • PharmaTrain gaps and needs observations in developing, providing and harmonising course curricula in “integrated drug development” • SafeSciMET – needs met as reflected in course module curricula and teaching material 	Representatives of each IMI Project

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1425 – 1500	<p>Discussion – conclusions and recommendations</p> <ul style="list-style-type: none"> • How about the (current and future) balance between undergraduate and postgraduate education and training? • What are the (education and training differences) in (EU) New Member Countries compared to other? • Would (one or several) surveys be needed to better understand where we are, including as to gaps and needs? 	<p>Moderator: Andreas Hartmann</p> <p>Notes: Kevin Augustijn</p>
1500 – 1520	Coffee Break	
	<p>Drug safety research, risk assessment and new regulations</p> <p><u>Expected Outcome:</u> Consensus towards coordination and concerted actions in education and training, research and regulation?</p>	
1520 – 1545	Personal medicines as of today and of tomorrow	David Thurston

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1545 – 1605	Key outcomes and take-home messages from the Hot Topics Conference (May 5)	Dan Dietrich Shirley Price
1605 – 1650	Discussion – conclusions and recommendations <ul style="list-style-type: none"> • Will environmental considerations hamper drug safety research and development – and if so how to cope with it? • Are more translational emphasis and more of personalised medicines the way forward? • Would better and coordinated research and related education and training help – and if so by whom and when? • And what about the gaps and needs in education and training? 	Moderator: Christian R Noe Notes: Hans H. Linden
1645 – 1700	Workshop wrap-up and closing	Christian Freichel Nico Vermeulen
Evening	Steering Committee Dinner in Downtown Vienna Restaurant – and Farewell Theodor Guentert	