EUFEPS

NEWS Letter

European Federation for Pharmaceutical Sciences March Vol 14 No2 2005

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LEADING ARTICLE

Importance of Research Linked with the EMEA

There is a vital service that the EMEA can perform by researching, or making available for research, the large body of generic data it holds. Such research would increase the informativeness, efficiency, and predictability of future clinical trials to the benefit of the citizens of Europe, and improve the competitiveness and economic effectiveness of the European pharmaceutical and biotechnology industries, in the development of innovative medicines for unmet medical needs.

Malcolm Rowland
Professor Emeritus

One of the perceived, and de facto, primary functions of the EMEA is to ensure that the citizens of the European Union are provided with high quality, effective medicines that are as safe as reasonably possible. It achieves this through a thorough evaluation process of each submitted application for the registration of a new medicinal product, followed by a continuous monitoring of the safety profile of registered medicines. Dealing with this evaluation process is time-consuming, occupying much of limited resources of the EMEA. There is, however, another important activity, and it may be argued responsibility, that the EMEA should embrace. Namely, to research and analyse the large body of data submitted by the pharmaceutical and biotechnology industries to provide basic information and understanding that would improve the design, efficiency and cost-effectiveness of future clinical trials. A few examples of the type of research that could profitably be undertaken follow.

Control Group or Baseline Data. To prove the effectiveness of a medicinal product for a given indication, as well as assessing its safety profile, comparative studies are undertaken in appropriate patients either against a placebo, a reference treatment, or occasionally both. Each company submits such data when filing for registration of **its drug**. The number of patients needed in the placebo-control or reference-treatment group is determined from some prior information. This historic information may be gained in house, if the company has engaged previously in the therapeutic area, or from some external source. Yet, in most cases, the company in-house baseline data are limited, and are also not made generally available to others. In contrast, the EMEA (and other national agencies) often receives clinical trial information submitted by several or more companies for the same therapeutic indication, such that the placebo-control and reference-treatment data pertains to a common patient group, which **if collectively analysed** would provide important baseline information not only about the placebo group but also the reference group, who are often receiving some agreed standard drug treatment, thereby providing updated information on its efficacy and safety profile. Furthermore, the more that is known about these groups the more accurate (and often the smaller) the corresponding patient size needed in subsequent studies, without significant loss of statistical power, and hence the lower the cost of the overall clinical trial. As each new trial is undertaken, the resultant information can be added to the existing pooled database, thereby providing more confident population data.

Predicting Interpatient Variability in Pharmacokinetics

Apart from a few exceptions, such as enzyme induction, transporter up or down regulation, and possibly cardiac output-induced changes in clearance, the pharmacokinetics of drugs reflect rather than alter the state of an individual. Hence, all other factors being constant, all substrates for a given enzyme should equally reflect the underlying functional variation of that enzyme within the population. This being the case, **collective analysis of pharmacokinetic data on say all substrates of CYP2C9 or 3A4** should provide information not only on the inherent functional variability of these enzymes within the patient population, but also allow one to determine quantitatively the contribution of such factors as age, gender, disease, and inhibitors of these enzymes to the variability. Each company has specific data on its drug, such as knowledge of the enzymes responsible for its elimination, but only on a limited number of subjects, whereas the collective data held within the EMEA would provide a far more comprehensive and informative dataset to address the above questions on variability. Armed with this generic information, one should be able to predict *a priori* the likely variability of the pharmacokinetics of a new drug within the patient population, under a variety of situations, thereby facilitating future design of clinical studies and subsequent product labeling, and also improve the cost-efficiency of such studies.

What are the impediments to the EMEA engaging in this research?

Arguably, there are three impediments. One is the resistance of the pharmaceutical and biotechnology companies to allow their data to be collectively analysed. Second are potential legal restrictions imposed on the EMEA (and other national agencies) in pooling and analysing collective data. And, finally, is the issue of adequate resources to undertake this research. Each is considered in turn.

Company resistance. It may be argued that companies concerned with confidentiality would not agree to allow the pooling of their data with that of other companies. However, the proposed research would only deal with placebo or reference treatment data, and there are many ways of ensuring the anonymity of such data. Furthermore, informal discussions with some company persons would suggest that there would be support for this type of research if the results of the research were made publicly available, as it would aid in the efficient design and cost-effectiveness of their future clinical studies.

Legal Restrictions. There may be legal restrictions to what the EMEA (and national agencies) can do with data received from companies, which currently limits what research can be done on the submitted data. If so, this problem would need to be addressed and should be resolvable, particularly if the proposal has the support of the industry.

Research Resources. Money, additional to what the EMEA receives in its recurrent budget, would be needed to engage in the type of proposed research. As the beneficiaries within Europe of the results of this research would be numerous, including companies developing innovative medicines, the scientific and clinical community, regulatory agencies, and interested patient groups, it is argued that the resources should be made available from the EU Framework programme scheme, with a starting point, as part of the Seventh Framework proposed Pharmaceutical Technology Platform for Innovative Medicines. Furthermore, while the research could be undertaken solely within the EMEA (or in collaboration with the national agencies) it is argued that it would best be undertaken as a collaborative activity between the EMEA, academia, industry, and appropriate professional scientific organisations.

Malcolm Rowland
Professor Emeritus
University of Manchester

BBBB Conference on Pharmaceutical Sciences

September 26-28 • 2005 • Siófok HU

Do not forget to involve in this first event of the BBBB Conference Series (Balaton; Baltic; Bled; Bosporus). It will offer a good opportunity for the development and deepening of scientific cooperation between the members of and the organising societies themselves, promoting scientific exchanges, not the least, for talented young pharmacists and common research projects – all towards new, safe and more effective medicines. Abstracts for oral presentations and posters are welcome. Siófok is situated on the shore of Lake Balaton, approximately 105 km away from Budapest Ferihegy Airport on the motorway M7.

For more information, rate and registration information, consult the Website of the Hungarian Pharmaceutical Society (www.mgyt.hu) or the EUFEPS Online (www.eufeps.org).

EMBO Call for Action; Scientists petition for increased EC funding for research

Dear Colleague,

The collapse of the discussions on the EU budget has been highlighted in the media. What receives less attention is the fact that preparatory discussions on a new budget were pointing towards a very major reduction on the doubling of funds for Framework Programme 7 which had been requested by the Commission. Included in this funding were increases for the Marie Curie programme, expansion of the standard Framework activities and, significantly, the funding of the European Research Council (ERC).

All of this is now at risk and the voices of scientists need to be heard. As one effort to ensure that the politicians get a message from the scientific community, we, supported by ELSF, (European Life Sciences Forum, http://www.elsf.org) and ISE (Initiative for Science in Europe, http://www.initiative-science-europe.org) have opened an online petition on the EMBO website.

If you are in agreement with the petition, sign it at http://www.embo.org/petition/petition.php

Please ensure that all of the scientists in your institute are aware of it and encourage them also to sign. This is a case where numbers and a rapid reaction are very important!

Please note also that ELSO, (European Life Scientists Organization) have prepared a letter to be sent to Ministers of Research to underline the importance of the ERC; http://ultr23.vub.ac.be/petition/

This is your opportunity to influence the future of research in Europe, so I suggest that you act on these initiatives now.

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Pharmaceutical Sciences: Towards a more competitive Europe

EUFEPS coordinated a workshop on "How to Establish a European Technology Platform for Innovative Medicines" in conjunction with the 3rd World Conference on "Drug Absorption, Transport and Delivery Medicines" at Barceló Hotel Sants, Barcelona, Spain, April 21-22, 2005.

The consortium

The workshop was supported by the EU under the Sixth Framework Programme Life Science, Genomics and Biotechnology for Health. A consortium consisting of: EUFEPS, the European Clinical Research Infrastructure Network (ECRIN), the European Federation for Medicinal Chemistry (EFMC), the European Federation of Pharmaceutical Industries and Associations (EFPIA), EUROTOX and the University of Cyprus planned the workshop.

The workshop was originally planned in the autumn 2003. However, it became part of the European Commission and EFPIA's work on a Strategic Research Agenda for Innovative Medicines for the Citizens of Europe, providing input for the Seventh Framework Programme. [Editor; see also the EMBO call for action in this Newsletter]

The first day

It started with a series of lectures on the background for the workshop. They concerned:

- European Technology platform for Innovative Medicines (Octavi Quintana Trias)
- European Strategic Research Agenda (Jonathan Knowles)
- Reports of recent workshops on Safety (Friedlich Pfannkuch), Efficacy (Ian Ragan), Knowledge Management (Nicolas Grandjean), and Education & Training (Jorgen Dirach))

The introduction was followed by four parallel workshop discussions on topics suggested for the Strategic Research Agenda:

1) Knowledge Management to resolve current and future needs
2) Approaches and means to optimise development of efficacious drugs and effective treatment strategies
3) Understanding and predicting drug safety and ways to secure safe drug therapy
4) Appropriate education and training to fill existing gaps and to meet emerging needs throughout drug research, development and evaluation.

The second day

Through SWOT analyses, a series of stakeholders gave their views on their involvement and possible contributions to the Platform;
Academia (Daan JA Crommelin)
Clinical sector (Josep Torrent-Farnell)
Biotech SME (Axel Mesheder)
Regulatory (Rolf Bass)
Learned Societies (Christian R Noe)
Patients (Yann Le Cam).

After this, four parallel workshop discussions took place around key questions;

1) How to start and sustain a European stakeholders' collaboration for new safe medicines? How to attract relevant stakeholders, good talent and potential collaborating partners through an attractive working environment in Europe?
2) How to exploit existing assets and resources in Europe better and build on European strengths, e.g. academia, clinical sector, regulatory world, government, learned societies, IT development etc., to gain competitive advantage and to create value, including for biotech SMEs?
3) How should postgraduate training be organised to increase the European competitiveness in drug discovery, development and evaluation?
4) How should European university research and education support the European Strategic Research Agenda, particularly, in fostering better collaboration between basic and clinical research?

Finally, the outcome of these parallel workshop discussions was discussed in plenum.

Like the first EUFEPS-organised New Safe Medicines Faster workshop (April 2000, Brussels), this workshop brought in all the stakeholders of the drug development process. Of the 134 delegates from 21 countries, who accepted the invitation, one third represented industry (19 from big pharma and 31 from SMEs), one third academia and the remaining third represented other institutions, such as the European Commission (8), Regulatory agencies (5) patients' organisations (4) and additional organisations (18). The female to male ratio was 1 to 5.

Outcomes

The concept of a Technology Platform for the pharmaceutical sector was discussed from the basics upwards, and many constructive ideas were brought forward.

There was general agreement throughout the workshop that implementing the European Technology Platform for innovative Medicines is an important component of re-establishing Europe as the primary location for biopharmaceutical research and development. The stakeholders acknowledged the value of industry leadership, the importance of the four topics of the Strategic Research Agenda, and the pre-competitive approach. The public-private collaboration as support for the platform was also positively received. Education & Training is a critical component of the Strategic Research Agenda, and the

need for a pan-European organisation of academic institutions engaging in drug development became obvious.

Stakeholder input

For Academia, improvements are needed in the critical mass of research groups, scientist and student mobility, new technologies, cross-disciplinary issues and positive public perception.

The Clinical Sector's contribution to European competitiveness builds on the quality of clinical research infrastructures, capacity of investigation, databases and biobanks. In addition, the industry needs Europe-wide networks to make clinical research more efficient.

For SMEs, weaknesses include inefficient technology transfer from basic research, too few management experts and broadly educated drug developers, as well as lack of existing accessible biology facilities, GMP units and toxicology databases.

For Regulatory, more research, conducted at the agencies, was recommended, e.g. by compilation of relevant generic data from old application files. Openness to modern methodologies and reorientation of the regulatory assessment demands were also seen as important.

Learned Societies, which already organise scientists from academia, industry, the regulatory agencies and clinical fields, have a long tradition, based on a discipline-oriented European structure. However, they will need to create a European organisation, which covers the complete drug development process. They could contribute by participating in a number of the coordination functions needed for the forthcoming Platform.

Active involvement of Patients and Patients' Associations will promote drug development in line with patients' needs, foster their enrolment in studies, and encourage the implementation of new treatment strategies.

First reporting available

A summary outcomes report from the workshop is already posted on the EUFEPS website; www.eufeps.org (New Safe Medicines Faster). A full report will be issued in the summer, at the same time as the Strategic Research Agenda is published, together with the outcomes of the series of the four workshops regarding Efficacy, Safety, Knowledge Management and Training & Education.

Innovative Medicines replace New Safe Medicines Faster

The heavy involvement of EFPIA and EU in drug science R&D means that you may not hear so much about the well-known "New Safe Medicine Faster" in the future, but instead about "Innovative Medicines Project for the Citizens of Europe". It is interesting to note that the new initiative covers many of the same issues as EUFEPS presented in 1999;

- Optimising the drug development process by removing bottlenecks
- Giving Europe the best drug development system in the world by early introduction of state-of-the-art technologies
- Rethinking all regulatory procedures from a science-based view to minimize bureaucracy and maximize validity

Further visions

The wording is different but the content is along the same lines. The current platform leadership now rests with EFPIA and EU, and EUFEPS is in the loop as a stakeholder. EUFEPS is also a consortium member of the EU-supported integrated research project InnoMed that will bring the initiative further forward. As an ambassador and promoter of the platform initiative, Hans H. Lindén plans to visit to several of the European stakeholders this autumn.

In addition, EUFEPS is creating further visions on how pharmaceutical sciences can be advanced in Europe. A number of working parties have also been established to transform such visions into workable strategies, to be presented and discussed at the forthcoming EUFEPS Council in September this year, in Hungary.

Ole J. Bjerrum
EUFEPS President

Input from Member Society Presidents to EUFEPS Strategy

To intensify the dialogue between the EUFEPS Member Societies and the Executive Committee, the society presidents met the EUFEPS Executive Committee twice during the spring.

Background

Almost 15 years have passed since the inauguration of EUFEPS in 1991. In this period, EUFEPS has grown steadily in numbers and prestige across Europe. However in the same period, the environment, in which EUFEPS is operating, has been changing rapidly. Not least, the European drug industry is in crisis, hard pressed by competition from USA and Southeast Asia. Luckily, the European Commission and national governments are aware of these threats to the whole pharmaceutical sector and their implications for national economies. These changes provide many possibilities for a learned society like EUFEPS and its membership, provided we remain united, determined and capable.

At the EUFEPS Council meeting of October 2004, several important issues were raised about European collaboration and the future roles of EUFEPS and its Member Societies on the European scene. To avoid addressing these issues in isolation before the next Council, the Executive Committee wanted to plan face-to-face with the presidents for EUFEPS future. This would give a strengthened mandate for the strategy to be presented at Council.

First President's Conference

The first President's Conference was held on April 16th, in Barcelona, Spain, (during the weekend prior to the 3rd EUFEPS Conference on Drug Absorption, Transport and Delivery). The key objective was to re-examine the future path for EUFEPS, as a viable, sustainable federation, beneficial for its entire constituency.

It was a very pleasant day in Barcelona. It provided a lot of information, including a good exchange of opinions and some weighty discussions. The day ended with a series of recommendations that EUFEPS should:

- Establish closer collaboration with its Member Societies for normal scientific events with regional/international audiences, focussing on important disciplines and crucial processes, as well as sharing the revenue of such events
- Increase further the current organisational sphere, striving towards a "European Drug Science Forum/Platform", embracing all relevant associations, societies, federations and networks. Commit to establishing good relations and collaborations throughout such a sphere
- Enter the "Political Arena" – engage with stakeholders in drug research and research policy – to pursue important issues and support new approaches, especially in Brussels. Help to take significant national initiatives to the regional (European) and global levels
- Continue involvement in some ground-breaking or path-clearing scientific events, such as workshops and summits for drug discoverers, developers and decision-makers

Second President's Conference

As the attendance at the first President's meeting was limited, a second conference was set up on June 12th in Nice, France, in conjunction with the PharmSciFair. Fortunately, further presidents were able to come, so the basis of the recommendations was broader. The recommendations mentioned above were well received and, through continued open discussion, it was concluded that six Working Parties should be established, which will report at the EUFEPS 2005 Council taking place in Siófok, Hungary, on 26th September 2005 (in conjunction with the 1st BBBB Conference on Pharmaceutical Sciences). Issues to be addressed by the Working Parties include how to:

- further consolidate the pharmaceutical sciences
- create a wider forum of learned societies
- arrange a recurring PharmSciFair
- arrive at better research training
- continue to set up influential conferences and workshops
- explore and utilise all available resources.

Final Words

I am confident that through these meetings, we have established a modus operandi for EUFEPS, which is optimal for interaction and dialogue. See you in Siófok.

Ole J. Bjerrum
EUFEPS President

Risk-Benefit Balance in Drug Development

September 29 • 2005 • Basel CH

This is the theme of a one-day workshop organised by ECPM in collaboration with EUFEPS, in the Frontiers in Drug Development series. Recently, safety issues with authorised and marketed medicines have violently shaken the pharmaceutical industry with enormous impact and pressure on the quality of drug development and regulation. The workshop will evaluate current and new models for benefit-risk assessment in the trade of multiple benefits and risks. It is open to all involved in the drug development process and aims at increasing the awareness and broadening the methodological understanding of the risk-benefit balance in drug development, regulation and marketing.

For more information, rate and registration information, consult the ECPM Website (www.ecpm.ch) or the EUFEPS Online (www.eufeps.org).

Biochemical and Bioimaging Endpoints in Cardiocerebrovascular Diagnosis, Prevention, Therapy and Drug Development

October 27-29 • 2005 • Lugano CH

This is the 1st Int'l Course on Integrated Biomarkers, and it is cosponsored by EUFEPS. It is there to verify and endorse the knowledge of and the experience in the combined use of the predictive value of integrated biochemical and bioimaging markers in the clinical decision-making and in drug development in the cardiocerebrovascular diseases. Interactive discussions will be facilitated. Researchers, physicians, regulatory affairs officers, and scientists from imaging, diagnostic and pharmaceutical industries, who are interested in the use of integrated biomarkers to support decision-making and to improve patient assessment, should attend.

For more information, rate and registration information, consult the Giovanni Lorenzini Medical Foundation Website (www.lorenzinifoundation.org) or the EUFEPS Online (www.eufeps.org).

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SE–111 81 Stockholm
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CALENDAR

Advanced Course in Pharmacokinetic/ Pharmacodynamic Data Analysis
August 8-12, 2005, Copenhagen, Denmark
Contact: Pia Sjelle, The Danish University of Pharmaceutical Sciences, Universitetsparken 2 DK-2100 Copenhagen, Denmark
Email pia@dfuni.dk, www.dfuni.dk/phd/courses
The same contact details for other courses on diverse topics in Pharmaceutical Sciences run by this institution

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FIP Industrial Pharmacy Section (IPS) Workshops
September 2-4, 2005, Cairo, Egypt
Contact: FIP Congresses & Conferences P.O. Box 84200, NL-2508 AE The Hague The Netherlands, Fax +31 700 3021998
Email congress@fip.org www.fip./org/cairo2005

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FIP 2005
September 3-8, 2005, Cairo, Egypt
Contact: FIP Congresses & Conferences P.O. Box 84200, NL-2508 AE The Hague The Netherlands, Fax +31 700 3021998
Email congress@fip.org www.fip./org/cairo2005

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Training Course Reserach Models in Integrative Pharmacology
September 5-9, 2005, Pécs, Hungary
Contact: Erika Pintér, University of Pécs Faculty of Medicine
Hungary. Fax +36 72 536218
Email erika.pinter@aok.pte.hu

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1st BBB Conference on Pharmaceutical Sciences
September 26-28, 2005, Siófok, Hungary
Contact: Hungarian Society for Pharmaceutical Sciences, Gyulai Pál u. 16, HU-1085 Budapest
Hungary, Fax +361 4831465
Email titkarsag@mgyt.hu www.mgyt.hu

British Pharmaceutical Conference 2005 - "A common vision for health: linking science with practice"
September 26-28, 2005, Manchester International Convention Centre, Manchester, UK
Details from Health Link Tel. +44 121 2483399
www.bpc2005.org

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Advanced Course in Rational Drug Policy and Management – The challenge of diseases of poverty
September 26 - October 7, 2005, Ifakara, Tanzania
Contact: Swiss Tropical Institute, P O Box Socinstrasse 57, CH-4002 Basel, Switzerland
Fax +41 61 2848106
Email courses-sti@unibas.che www.sti.ch

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2nd Conference on Optimising Drug Delivery and Formulation: Evaluation of Drug Delivery Systems – Issues and Perspectives
November 20-23, 2005, Versailles, France
Contact: EUFEPS Secretariat
P.O. Box 1136, SE-111 81 Stockholm, Sweden
Email secretariat@eufeps.org www.eufeps.org

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Cellular and Molecular Pharmacology and Toxicology
November 21-25, 2005, Copenhagen, Denmark
Contact: Pia Sjelle, The Danish University of Pharmaceutical Sciences, Universitetsparken 2 DK-2100 Copenhagen, Denmark
Email pia@dfuni.dk, www.dfuni.dk/phd/courses

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Joint PKUK 2005 & Rosenön Meeting
November 22-23, 2005, Brighton, UK
Contact: www.pkuk.org.uk

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8th International Symposium on Advances in Extraction Techniques, ExTech /R/ 2006
February 6-8, 2006, York, UK
Contact: Robert Smits, Roelsstraat 20, BE-8670 Oostduinkerke, Belgium, Fax +32 58 514575
Email htc@ordibo.be

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9th International Symposium on Hyphenated Techniques in Chromatography and Hyphenated Chromatographic Analyzers, HTC-9
February 8-10, 2006, York, UK
Contact: Robert Smits, Roelsstraat 20, BE-8670 Oostduinkerke, Belgium, Fax +32 58 514575
Email htc@ordibo.be

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10th International Conference on Perspectives in Percutaneous Penetration and Dermochannels Symposium on Minimally Invasive Disruption of the Stratum Corneum Barrier
April 18-22, 2006, La Grande Motte, France
Contact: PPP Conference, Redwood Building King Edward VII Ave., Cardiff, CF10 3XF, UK
Tel/Fax +44 2920 875247
Email kaw@pppconference.org

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8th International Symposium on Pharmaceutical Sciences
June 13-16, 2006, Ankara, Turkey
Contact: Symposium Secretariat, Prof. Dr. Sibel A. Ozkan, Ankara University Faculty of Pharmacy Tandogan 06100 Ankara, Turkey
Phone +90 312 223 82 43 Fax +90 312 213 10 81
Email ankpharm@pharmacy.ankara.edu.tr
www.pharmacy.ankara.edu.tr

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EUFEPS Conference

When Poor Solubility Becomes an Issue: From Early Stage to Proof of Principles

April 26-27 • 2006 • Verona • Italy

Invitation
This Conference is a new initiative by the EUFEPS Committee on Industrial relations (CIR). Obviously, it will address an important issue in the development of new medicines. It is intended for all those struggling with such problems, as well as for students and young scientists entering the field.

Scope and Aim
The pressing challenge pharmaceutical scientists (product-development scientists) have to face is the poor solubility of drug candidates. In a scenario where an increasing number of drug molecules are generated (high-throughput discovery screening methods, combinatorial synthesis, etc.), the impact of biopharmaceutical properties, including solubility, on drug development tend to be underestimated. Nonetheless, water insolubility can hamper or completely halt new drug development.

This Conference will explore the physico-chemical and biopharmaceutical properties important in order to have a "drugable" candidate together with formulation stra-tegies to overcome insolubility related hurdles during "hit-to-lead" research. In this EUFEPS conference highly experienced leaders from industry and academia in areas of preformulation, product development (pre-clinical and clinical) and in silico modelling will walk participants through the key tools available in order to recognise if a solubility problem would be an issue in the developability of a drug substance. Discussion sessions will facilitate open dialog among participants from drug discovery and development.

Conference Objectives and Attributes
- Bring together scientists from industry and academia and PhD students from diverse disciplines of pharmaceutical sciences, physical pharmacy, biopharmaceutics, pharmacokinetics and modelling and clinical pharmacology
- Understand the relevance of preformulation in processes of drug discovery and drug development
- Review current techniques and strategies for drug candidate selection and formulation
- Explore the linkage of in vitro and preclinical in vivo data to formulation performance in humans
- Contribute to the development of tools for the prediction and measurement of drug-like properties and application in discovery
- View Posters offering unique experience and insight
- Meet in a learning environment conducive to thoughtful consideration and interaction