New Approaches in Pharmacy Education – German view

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7th Symposium on New Developments in Clinical Pharmacy and Clinical Pharmacology
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Current global status and views

Time for Quantitative Clinical Pharmacology: A Proposal for a Pharmacometrics Curriculum

PROPOSAL

A central theme of our proposal relates to the need to consider time in an essential component of almost all descriptions of drug actions in clinical trials. We explore how much time is needed to learn pharmacometrics, and at what times it could fit into the undergraduate, postgraduate, and postdoctoral training sequence. Finally, we propose that the time is upon us for renewed efforts in pharmacometrics training.

Pharmacometrics at FDA: Evolution and Impact on Decisions

- Training: Currently, there are limited academic programs in the US and Europe training pharmacometrics. Many of the people performing this work have prior quantitative skills (e.g., pharmacokinetics, statistics, engineering) and are trained on the job. Changes in 5 years, there will be

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Pharmacometrics curriculum

Undergraduate level

Graduate level

Postgraduate level

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Motivation
- Pharmacometrics & computational disease modelling (PM & CDM)
  - highly interdisciplinary field: underlying biological/pharmacological/pharmaceutical and disease mechanisms and the formal mathematical methods
  - gaining increasing attraction
- In Germany, qualifying in PM & CDM: difficult to master for a PhD student (interdisciplinary character, lack of a curriculum)
- At the same time: high demand for thoroughly trained young scientists
  ➔ boost field in academia as well as in pharmaceutical companies

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A long way to go ...
2004/05: First ideas
Sep 2006: Concrete initiative paper
Jan-Dec 2007: Negotiations about Contract between 8 partners
  - How to deal with Results/IP and publications
  - Location of PhD students
  - Role and involvement of Industry Partners
Mar 2008: Start of Graduate Research Training Program

Launch of a Graduate Research Training Program in Germany

“Pharmacometrics & Computational Disease Modelling” (PharMetrX)
Charlotte Kloft, Wilhelm Huisinga (Chairs)
Martin-Luther-Universität Halle-Wittenberg, Dept Clinical Pharmacy, Halle, Germany
Hamilton Institute/NUIM, Ireland & MATHEON/Freie Universität Berlin, Germany

7th Symposium
New Developments in Clinical Pharmacy and Clinical Pharmacology
Pharmacometrics & Computational Disease Modelling

Aims
- Train junior scientists in Pharmacometrics & computational disease modelling (PM & CDM)
- Convey method and software expertise
- Implement PM & CDM in the academic environment
- Promote PM & CDM within and outside academia and bridging the gap between academia and industry
Pharmacometrics & Computational Disease Modelling

Realisation
3 year PhD program:
1. Research Projects of PhD student
   - Generic/methodological topics
   - Motivated by theoretical or industrial considerations
2. Research Training: Module Curriculum
3. Mentoring by an Industry Partner

Structured research training curriculum
1. Academic modules
   - 30 h en bloc (1 week)
   - subdivided into
     i) theoretical concepts & methods (2/3) and
     ii) practical hands-on exercises (1/3)
2. Industry modules
   - variable duration
   - at site/s of companies

Research training modules

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<thead>
<tr>
<th>Semester</th>
<th>Research Training Modules</th>
<th>Research</th>
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<tbody>
<tr>
<td>1st</td>
<td>A-module 1: PK/PD modelling</td>
<td>Continuous work in research project for PhD thesis</td>
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<td>A-module 2: PBPK modelling</td>
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<td>A-module 3: Population analysis</td>
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<td>A-module 4: Systems Biology</td>
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<td>A-module 5: Stats &amp; data analysis</td>
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<td>2nd</td>
<td>A-module 6: Biometrics &amp; Trial designs/simulation</td>
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<td>A-module 7: Pharmacology</td>
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<td>6th</td>
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* At the University or Industry Partner

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Structured research training curriculum

1. Academic modules
   - Introduce to the field: framework, theoretical concepts and methodology
   - Method and software expertise
   - Illustrative examples of relevance to drug development and use

2. Industry modules
   - Insight into the mission and tasks of pharmaceutical companies
   - Learn about fields of application of modelling approaches
   - Learn about the value chain of drug discovery and development

Attractiveness to graduate students

The new program offers graduate students a

- unique opportunity to experience research in drug development and optimising drug therapy
- close link and strong interaction within academia and industry
- a competitive research fellowship
- Online-application process

Key Characteristics of the PharMetrX Program

- Thematic orientation in a promising, expanding area
- Trans-disciplinary approach
- Close partnership and strong link with Pharma Industry

Outlook & Perspectives

- Continuous monitoring and evaluation process
- Integration and expansion of international Faculty Network
- Integration of new partners, exchange with and linkage to other programs (internationally)
6th Symposium
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