

- SECOND ANNUAL -

Advancing Biologics from the lab to the clinic

Designing and implementing complex phase I & II clinical trials to demonstrate proof of concept.
Conference Dates: 25th-26th, January, 2011
Venue: Radisson BLU Hotel Amsterdam, Netherlands

Event Overview

The development of biologics faces many of the same challenges as their traditional, small molecule counterparts: escalating development costs, identifying novel targets with unproven therapeutic potential, and regulatory agencies demanding more compelling demonstrations of the value of new products.

These difficulties are increasing as clinical development for biologics is considered to be more challenging, expensive, and risky than small molecule development. Besides the standard considerations of safety and efficacy, a clinical development program should also consider immunogenicity, optimal dosage levels, and the evaluation of available biomarkers and imaging technologies to measure the effects on a given target. These critical issues have many biopharma companies re-evaluating their development strategies in order to factor in the unique properties of biologics and design their studies accordingly.

This two day event will develop upon the previous, highly successful event to further provide focused and in depth industry, regulatory and scientific perspectives in terms of what the factors are that hinder the progression of biologics in clinical development. Industry experts will talk about their experiences and give insight into the vital components that make up a successful early-stage strategy for biologic studies. The attendees of this event will obtain an advanced understanding of how to strategically incorporate the requirements that are specific to biologics into the operational planning for an early-phase clinical trial that provides the best opportunity to save time, reduce risk, cut costs, and demonstrate product value early in development.

Why Attend?

- ◆ Discover what is a "best practice" approach to injecting more biologic drugs into your clinical portfolio.
- ◆ Meet experts directly involved in biologic trial design and implementation.
- ◆ Learn about the specific regulatory guidance and level of proof required to satisfy the governing bodies.
- ◆ Understand the perspectives of all stakeholders involved, i.e. regulators, sponsors, CROs, SMOs, central labs and experienced biologic investigators.
- ◆ Come to benchmark, share experiences and help to develop a best-practice approach to biologic clinical development.
- ◆ Build stronger relationships based upon a better understanding of the challenges faced by various stakeholders, who are all vital to the planning and implementation of a successful study.

Who Will Benefit?

Experienced executives from Pharma, Biotech and Academia involved in Biologic development

VPs, Professors, Senior Directors and Managers involved in biologics, discovery, pre-clinical development, exploratory development, early phase clinical development, clinical operations, clinical science, clinical pharmacology, immunogenicity, biomarkers, translational medicine, regulatory affairs, therapy area heads, and R&D.

Your Prestigious Speaker Panel:

LARGE PHARMA

Miro Venturi Ph.D.
Senior Biomarker &
Experimental Medicine
Leader Oncology
**Roche Pharma Research
and Early Development,
Germany**

**Joachim Scholpp, MD
PhD, DESA**
Director Clinical
Pharmacology
Nycomed, Germany

Lolke de Haan, PhD
Associate Director,
Toxicology
MedImmune, UK

SMALLER BIOTECHS

Prof. Dr. Andreas J. Kungl
CSO
**ProtAffin Biotechnologie,
Austria**

Erik Van Den Berg
VP Corporate Development
AM Pharma, Netherlands

Mary Reilly MSC
VP Pharmaceutical and
Clinical Development
**Opona Therapeutics,
Ireland**

Josi Holz
Chief Medical Officer
Ablynx, Belgium

Sol Langermann
Vice President R&D
Amplimmune, USA

Lisl Shoda
Associate Director, In Silico
Research and Development
Entelos, Inc, USA

REGULATORS, INSTITUTES & ACADEMIA

Dr. Hartmut Krafft
Head, Section Clinical Trials
**Paul Ehrlich Institute,
Germany**

Serhiy Souchelnytskyi, Ph.D.,
Group Leader
Associate, Professor
Karolinska Institutet,
Department of
Oncology-Pathology,
**Karolinska Biomics
Center, Sweden**

Anne S. De Groot, M.D.
Adjunct Associate
Professor of Medicine
Brown University
Founder, CEO & CSO
EpiVax, Inc, USA

EXPERT SOLUTION PROVIDERS & CONSULTANTS

**Ewoud-Jan van
Hoogdalem**
Founder &
Managing
Director
**Clinical Reach Drug
Development b.v,
Netherlands**

Serge Guzy; Ph.D.,
President/CEO
POP PHARM, USA

Edwin Janssen, PhD
Head Biomarkers and
Biopharmaceuticals,
Scientific Advisor
**Eurofins Global Central
Laboratory**

Gold Sponsor:





08.30 Registration & Coffee
09.00 Chairperson's opening remarks: **Ewoud-Jan van Hoogdalem**,
 Founder & Managing Director, **Clinical Reach Drug Development b.v**,
 Netherlands

CURRENT PERSPECTIVE ON GLOBAL BIOLOGICS MARKET

09.10 Opening Roundtable Discussion

This opening session will draw upon the panel and the audience to debate on where hurdles and barriers exist, in order to facilitate later discussion.

- ✦ What are the main areas for concern?
 - ✦ Understanding our product?
 - ✦ The challenges of manufacturing and upscaling?
 - ✦ The evolving regulatory expectations?
 - ✦ Profitability in a changing and competitive landscape?
 - ✦ Immunogenicity by surprise?
- ✦ How are biologics development approaches shifting?
 - ✦ The increase of post-marketing commitments – is it real?
 - ✦ Similar, non-inferior, interchangeable, substitutable, switchable and other goalposts.
- ✦ Biosimilars – opportunity, threat, or dead in the water?
 - ✦ What are the real successes so far?
 - ✦ Will Biobetters outsmart Biosimilars?
- ✦ Future expectations & areas for improvement.

Led by **Ewoud-Jan van Hoogdalem**, Founder & Managing Director,
Clinical Reach Drug Development b.v, Netherlands

UTILISING PRE-CLINICAL DATA TO ENHANCE CLINICAL DECISION MAKING

09.50 Preclinical translational pharmacokinetic and pharmacodynamic endpoints in support of clinical development of monoclonal antibodies

- ✦ Challenges for preclinical safety/toxicology testing.
- ✦ Translational PK/PD - predictive safety and efficacy.
- ✦ 2 case studies.

Lolke de Haan, PhD, Associate Director Toxicology, **MedImmune, UK**

10.30 How to use pre-clinical data as a guide in advancing biologics development; what we can learn from novel therapeutic proteins with applications in oncology, infectious diseases and inflammation

- ✦ How to utilize pre-clinical data effectively to determine dosing levels, regimens, PK/PD activity.
- ✦ Incorporating the right design approach: translational methods & their place in overall development of therapeutics.
- ✦ Differences between oncology biologics vs. non-oncology biologics.

Sol Langermann, Vice President, R&D, **Amplimmune**

11.10 Networking & Coffee Session

11.30 Panel Discussion: How can safety and efficacy data be best interpreted to make early go/ no-go decisions for Biologics?

Lolke de Haan, PhD, Associate Director Toxicology, **MedImmune, UK**
Sol Langermann, Vice President, R&D, **Amplimmune**

REGULATORY CHALLENGES & SOLUTIONS

12.00 Strategies to speed up regulatory consideration & approval of biologics

- ✦ Introduction to the Paul-Ehrlich-Institut as an example of a European national regulatory agency.
- ✦ The European Regulatory System (EMA, EC, HMA), and legislation for Biologics.
- ✦ Speeding up Biologic approval in Europe: VHP as an instrument for rapid harmonisation.
- ✦ How can faster outcomes be achieved with both parties timely input.

Dr. Hartmut Krafft, Head Section Clinical Trials, **Paul Ehrlich Institute, Germany**

12.40 Luncheon Break

13.40 Showcase presentation from Pharmnet

PHARMNET

IMMUNOGENICITY ISSUES

13.50 Regulating Immune Response in Biologics - A Paradigm-Shifting Solution?

- ✦ What drives 'adverse' response in biologics and transplantation development.
- ✦ How "Regulatory T cells" can be engaged to suppress immunogenicity.
- ✦ Why the Tregitope concept represents a paradigm shift for the development of therapeutic biologics.

Anne S. De Groot, M.D., Adjunct Associate Professor of Medicine, **Brown University**
 Founder, CEO & CSO, **EpiVax, Inc, USA**

TRANSITIONING INTO THE CLINIC

14.30 Transitioning pre-clinical material into the clinic - a different biotech approach

- ✦ Portfolio approach identifying priority candidates from preclinical programmes.
- ✦ Stage gate approach & evaluation of costs up to proof of concept.
- ✦ Utilising pre-clinical data effectively & biomarker discovery as prerequisite for development.
- ✦ Use of modelling and simulations to support decision making, study design and applications.
- ✦ Alternative to "safe" biotech model - taking clinically non-validated targets to p.II.

Josi Holz, Chief Medical Officer, **Ablynx, Belgium**

15.10 Networking & Coffee Session

15.30 A roadmap through early phase development

- ✦ Overview and experiences in:
 - ✦ Humanisation.
 - ✦ Manufacturing and scale up.
 - ✦ Toxicology.
 - ✦ Orphan drug status and proceeding to First in Human.
- ✦ Pre-clin to clinical cross-over.
 - ✦ Overview of pre-clinical efficacy strategy and data.
 - ✦ Plans on how this information will guide Ph/Ia study design.
- ✦ Managing subcontracting and contract organisations.
 - ✦ Adjusting plans to incorporate unexpected developments.
 - ✦ Challenges small versus large organizations.

Mary Reilly MSC, VP Pharmaceutical and Clinical Development
Opsona Therapeutics, Ireland

16.10 Developing a biologic through exploratory clinical phases: A large pharma approach

- ✦ Improving development efficiency.
- ✦ Specific requirements of biologics.
- ✦ Case study.

Joachim Scholpp, MD, PhD, DESA, Director Clinical Pharmacology
Nycomed, Germany

16:50 Chairperson's closing remarks

17:00 End of day one

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Designing and implementing complex phase I & II clinical trials to demonstrate proof of concept.

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09.00 Chairperson's opening remarks: **Ewoud-Jan van Hoogdalem**,
Founder & Managing Director, **Clinical Reach Drug Development b.v**,
Netherlands

OVERCOMING DEVELOPMENT BARRIERS - CASE STUDY EXAMPLES

09.10 Switching from bovine-sourced to a recombinant human Alkaline Phosphatase

- ◆ Working with customer/ endpoint in mind.
- ◆ Efficient action plans that don't diminish value of product.
- ◆ Decision making process - based on prior experience & contact with big pharma (collaborations/ consultations without agreements in place).
- ◆ Project managing outsourced components.

Erik Van Den Berg, VP Corporate Development
AM Pharma, Netherlands

09.50 Exploring novel targets outside antibodies in COPD

- ◆ Present platform development of engineered decoy chemokines which target glycan structures on cell surfaces.
- ◆ Possibilities of such therapies.
- ◆ Obstacles and challenges of preclinical development in COPD.
- ◆ Project dependent difficulties - how they were solved/ how ongoing problems are being managed.
- ◆ Outlook of clinical phase Ia/b plan.

Prof. Dr. Andreas J. Kungl, CSO
ProtAffin Biotechnologie, Austria.

OUTSOURCED ACTIVITY CONSIDERATIONS

10.30 Drug Development support for Biopharmaceuticals; a Central laboratory perspective.

- ◆ Regulated bioanalysis of Biopharmaceuticals and Biosimilars.
- ◆ Applications of Immunogenicity and Biomarker analysis in clinical studies.
- ◆ Significance of Fit-for-purpose biomarker assay validation.
- ◆ Benefits of integrating Biomarker and Biopharmaceutical analysis in a central laboratory setting.
- ◆ Translating "lessons learned".

Edwin Janssen, PhD, Head Biomarkers and Biopharmaceuticals, Scientific Advisor
Eurofins Global Central Laboratory

11.10 Networking & Coffee Session

11.30 Panel Discussion: How to evaluate information from early clinical trials and develop an adaptive, flexible response?

Sol Langermann, Vice President, R&D, **Amplimmune, USA**
Mary Reilly MSC, VP Pharmaceutical and Clinical Development
Opsona Therapeutics, Ireland
Joachim Scholpp, Director Clinical Pharmacology, **Nycomed Pharma, Germany**

BIOMARKERS & ADVANCED SOLUTIONS TO AID EARLY PHASE BIOLOGICS DEVELOPMENT

12.10 Solution to the old matchmaking problem? Application of proteomics to matching patients with drugs - before and during clinical trials.

- ◆ Drugs act on or via proteins. To ensure that a patient would respond to a drug, it has to be confirmed that there is a drug target, that the drug does act on that target, and that there is no detrimental off-target effects.
- ◆ Protein-based proteomics allows characterization of drug targets in unbiased way. In a combination with functional studies, proteomics provides indications about drug specificity, efficiency, toxicity and side effects.
- ◆ Challenges and solutions in development of a monitoring assay to select responders. How to incorporate it in a trial protocol.
- ◆ From a bench to trials - an example of TGFbeta kinase inhibitors.

Serhiy Souchelnytskyi, Ph.D., Group Leader Associate Professor Karolinska Institutet, Department of Oncology-Pathology,
Karolinska Biomics Center, Sweden

12.50 Luncheon Break

13.50 How efficacy predictions using modeling & simulation can inform and streamline clinical development

- ◆ Predicting efficacy in rheumatoid arthritis virtual patients biomarkers for patient selection.
- ◆ Competitive analysis against standards of care or biologic competitors.
- ◆ Extensive exploration of alternate trial designs (dose, frequency, route of administration).

Lisl Shoda, Associate Director, In Silico Research and Development
Entelos, Inc, USA

14.40 Networking & Coffee Session

15.00 Building a robust personalized medicine strategy by using translational and biomarker approaches

- ◆ Appropriate and clinically relevant translational approaches to develop a sound biomarker strategy.
- ◆ Generating robust scientific biomarker hypotheses for testing during clinical development.
- ◆ Challenges in the clinical implementation of biomarker read-outs according to trial type and design.
- ◆ Opportunities and limitations in the use and modeling of pre-clinical data.
- ◆ Case studies in Oncology.
- ◆ Developing companion diagnostic test alongside drug development.
- ◆ Managing in-house collaborations effectively.

Miro Venturi, PhD., Senior Biomarker & Experimental Medicine Leader,
Oncology, Roche Pharma Research and Early Development, Germany

15.40 Optimizing the entire drug development process using pharmacometric tools: From preclinical to marketing

- ◆ Characterize the PK correlation with PD biomarker using as input Phase 1 observed data and Population PK/PD modeling as the tool to estimate the Patient PK/PD Population characteristics.
- ◆ Propose the optimal trial conditions for the upcoming Phase 2 trial using simulation procedures.
- ◆ Estimate using the characterized PK/PD model the probability of technical success (PTS) for Phase 2 using the target Product Profile criteria.
- ◆ Modify the current decision analysis based estimation of the product value (Expected Net Present value, ENPV) using the model based estimation of the Phase 2 PTS.
- ◆ Transfer the information gathered by the modeling exercise to business development as input in the establishment of optimal partner conditions (deal valuation) for the product considered.

Serge Guzy, Ph.D, President/CEO
POP_PHARM, USA

16.20 Summing up session: Shortening the road to success: where in the biologic development process can we improve with highest impact?

This concluding discussion will involve the audience and panel to judge where cost and time reductions can be realised, while maximising value and quality, and what are the possible next steps to improve biologic development.

Led by **Ewoud-Jan van Hoogdalem**, Founder & Managing Director,
Clinical Reach Drug Development b.v, Netherlands

17:00 Chairperson's closing remarks

17:10 End of day two

Upcoming Event: NextLevel Pharma



- FOURTH ANNUAL -

Best Practice in Clinical Site Selection & Performance Management

Achieving global patient recruitment objectives by overcoming time, cost & quality challenges at the clinical front-end.

Location: Prague, Czech Republic - Dates: March 22nd-23rd, 2011

Speaker Biographies

Ewoud-Jan van Hoogdalem, Founder & Managing Director Clinical Reach Drug Development b.v

Ewoud-Jan van Hoogdalem is a licensed pharmacist and clinical pharmacologist and he holds a Ph.D. in Pharmacology from Leiden University. He is founder and managing director of Clinical Reach Drug Development b.v., an independent advisory firm assisting clients in developing biologics and new chemical entities towards a well defined target product profile. His has held positions in bioanalysis and pharmacokinetics at Brocades Pharma and Yamanouchi Europe (now Astellas) as well as being a European project leader for drug development projects in urology, CNS and GI at the same company. From 2000 to 2006 he designed and executed clinical proof-of-concept programs in different therapeutic areas, including metabolic disorders, in Johnson & Johnson. From 2006 to mid 2009 he oversaw the clinical development portfolio of OctoPlus as Chief Medical Officer. He is member of various professional organisations, including DIA, and is first author or co-author of approximately 30 publications in peer-reviewed journals or book chapters. He is co-organiser of various events on clinical pharmacology and pharmacotherapy, including EACPT 2007.



Lolke de Haan, PhD, Associate Director Toxicology MedImmune, UK

Lolke de Haan is currently Associate Director, Toxicology at MedImmune in the UK. After academic training in biochemistry and immunology, a PhD in Medical Sciences from the University of Groningen, and postdoctoral training at the University of Bristol (UK), he joined AstraZeneca as a discovery toxicologist, focusing mainly on early toxicology support to drug development projects. After Cambridge Antibody Technology (CAT) was acquired by AstraZeneca, he joined CAT which was then incorporated into MedImmune, initially as a toxicology project leader. Since 2008, he has led the Cambridge toxicology team, which is responsible for the preclinical development of a large portfolio of antibody and non-antibody-based biologics.



Dr. Hartmut Krafft, Head Section Clinical Trials Paul Ehrlich Institute, Germany

Dr Krafft studied Biology, Chemistry, and Physics at the Ruprecht-Karls University in Heidelberg, Germany/ He took his Masters degree and PhD thesis at the German Cancer Research Centre in Heidelberg, in the department of Cell Biology and Immunology. His current position in the Paul-Ehrlich-Institut is Head of the clinical trials section. He is also the Coordinator of the CTFGs Voluntary Harmonisation Procedure and a member of the EU-Commission Ad hoc Group on directive 2001/20/EC



Anne (Annie) S. De Groot, M.D., CEO & CSO, EpiVax, Inc, USA

Annie is also currently a Director at the Institute for Immunology and Informatics in the University of Rhode Island and an Associate Professor, Pediatric Infectious Disease, at Brown Alpert Medical School. She was studied her BA at Smith College and then at Pritzker School of Medicine in the University of Chicago for her MD. Following additional training in immunoinformatics, vaccinology and infectious disease she joined Brown University Medical School, and opened the TB/HIV Research Laboratory in 1992. She then licensed the EpiMatrix vaccine design technology from her laboratory at Brown and established EpiVax with Bill Martin, 1998. She is also the founder and scientific director of the GAIA Vaccine Foundation (NGO doing HIV prevention in Bamako, Mali) and co-founder and volunteer Medical Director, Clinica Esperanza, a free care clinic for Rhode Island's uninsured citizens located in Providence, RI. She is the recipient of many awards and honors and has been awarded over \$26M in NIH and foundation research funding and has published more than 120 papers, chapters, and reviews.



Mary Reilly MSC, VP Pharmaceutical and Clinical Development Opsona Therapeutics Dublin, Ireland

Mary Reilly joined the Opsona management team in March 2005 to lead the pharmaceutical development of Opsona's pre-clinical candidates. Her role is to direct the development of lead compounds from discovery through pharmaceutical development including chemistry, manufacturing and controls (CMC) and their progression into the clinic. She is currently leading Opsona's key development asset OPN-305 into the clinic early next year having led the preclinical, CMC, nonclinical and overall development of the project for the last number of years. Before joining Opsona, Mary worked for 15 years with Elan Pharmaceuticals where she was Associate Director and Project Leader for development projects. She has extensive experience in drug development from late-stage discovery to registration and approval of products at all stages of the development cycle within Europe and the USA. She also has experience in Parenteral sterile drug development, manufacture and registration. Mary has QP qualifications in line with EU clinical directive 2001/20/EC



Joachim Scholpp, MD, PhD Director Clinical Pharmacology/Exploratory Clinical Science Nycomed Pharma, Germany

Joachim joined Nycomed in 2009 as Head of Clinical Pharmacology / Exploratory Clinical Science. Together with his group he is responsible for the exploratory clinical strategy and the transition of preclinical candidates through first-in-man to clinical proof-of-concept. Further responsibilities include the coordination of processes at preclinical and full clinical development interfaces, to provide medical expertise to preclinical research teams, and to support late stage development projects and licensing evaluations. Before his current position Joachim held positions at Boehringer Ingelheim and GlaxoSmithKline in early and late clinical development in the areas of pain, anaesthesia, and neuroscience. Joachim is board certified in Anaesthesia and Intensive Care and a Diplomee of the European Society of Anaesthesiology with an education in advanced pain management. He is a member of several professional organisations including the International Association for the Study of Pain (IASP), the Neuropathic Pain Special Interest Group (NP-SIG), and the European Society of Anaesthesiology (ESA).

Erik Van den Berg, VP Corporate Development AM Pharma, Netherlands

Erik van den Berg works as senior executive in strategic and commercial roles in the pharmaceutical and biotechnology industry. He has been involved in financial transactions and fund raising totaling over €100M for high-tech start-up companies and has had marketing & sales responsibility for a business-to-business service provider growing sales to over €30M annually. Erik realized more than 20 licensing collaborations. Currently, Erik is chief business officer at AM-Pharma involved in external collaborations and product development. Previously, he was at Organon as executive director global biotech business development and director of marketing and sales Diosynth Biotechnology. Erik has a MSc in Chemistry from the University of Utrecht and a MBA from Manchester University.



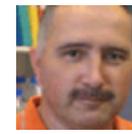
Prof. Dr Andreas Kugl, CSO AM Pharma, Netherlands

Andreas is Co-Founder and Chief Scientific Officer of ProtAffin Biotechnologie. He studied biochemistry at the University of Vienna and spend his post-doctoral time at the Max-Planck-Institute of Biochemistry in Martinsried with Robert Huber. Andreas worked at Sandoz/Novartis before being appointed as Associate Professor for Biophysical Chemistry in Graz, a title which he is still holding. In this position, Andreas coordinated a European Research Consortium under FP5 in which glycosaminoglycans and their pathophysiological role was investigated by four academic and three industrial partners. In 2003 he filed the first patent on glycan antagonistic decoy proteins which was the basis for founding ProtAffin in 2005. Since then ProtAffin has established a very strong IP position in the glycan targeting field. Andreas developed the CellJammer technology platform which provided the company's lead compound PA401, an IL-8 based anti-inflammatory protein therapeutic currently in pre-clinical development for chronic respiratory indications. In addition, Andreas is managing the company's pipeline products based on MCP-1 and SDF-1, which are in lead optimisation, as well as further validating the platform with a view on oncology targets.



Serhiy Souchelnyskiy, Associate Professor Karolinska Institutet

Dr. Souchelnyskiy is an Associate Professor and a group leader at Karolinska Institutet, Department of Oncology-Pathology, Karolinska Biomics Center, Stockholm, Sweden. He graduated from the Lviv State University, Lviv, Ukraine, 1985, in biochemistry. Dr. Souchelnyskiy received his PhD at the Institute of Biochemistry, National Academy of Sciences of Ukraine, Lviv. He did a post-doc at the INSERM U244, in Grenoble, France, and had a group leader position at the Ludwig Institute for Cancer Research in Uppsala, Sweden. Dr. Souchelnyskiy has contributed to unveiling of molecular mechanisms initiated by growth factors, e.g. transforming growth factor-beta family. Dr. Souchelnyskiy works have also contributed to key achievements in proteome profiling of human breast tumorigenesis. Proteome markers delivered by Dr. Souchelnyskiy works are used for early detection of breast cancer, for diagnostics and for prediction of cancer aggressiveness. Scientific interests of Dr. Souchelnyskiy are in studies of carcinogenic transformation. Proteomics and systems biology are the main tools used to understand proteome changes during human breast carcinogenesis. Molecular mechanisms governing tumor growth and response to anti-cancer treatments are explored for establishment of personalized medicine. Development of specific inhibitors to manipulate transforming growth factor-beta signalling and proteomics-based search for markers of human breast cancer are another translation-oriented projects in group of Dr. Souchelnyskiy.



Miro Venturi, Senior Biomarker & Experimental Medicine Leader Roche Pharma Development

Miro studied his Master of Science Thesis in the Biochemistry department at the University of Bologna and took his Ph.D at the Max-Planck Institute for Biophysics, Frankfurt, Germany. He followed this with a post-doctoral specialization in Vaccine Research and Molecular Medicine, at the NIH in the U.S.A. and residence training at Johns Hopkins University, Baltimore. Currently he is a Senior Biomarker & Experimental Medicine Leader at Hoffmann-la Roche Pharma Development, based in Penzberg, Germany. Among other duties, responsible for devising and implementing a Companion/ Pharmacodiagnosics team serving projects needs across the Oncology portfolio. Prior to this he worked at Novartis, Pharmacia (now Pfizer) and was also Adjunct Professor of Preclinical and Early Clinical Development of Biopharmaceuticals at the University of Vita-Salute San Raffaele, Milano, Italy.

Serge Guzy, Principal Scientist, Global Modeling and Simulation Xoma, USA

With 20 years of experience with modeling and simulation, Serge Guzy is currently President, CEO of POP-PHARM, a consulting and software Development Company. He established new methods for statistical population approaches in drug development, based on Monte Carlo simulation algorithms. The resulting MC-PEM methodology and Population software development made him now internationally recognized. These new tools have already been well utilized in drug development, from the early stage of antibody discovery and lead selection programs as a useful tool to guide antibody design goals and inform teams for better decision making, as well as in clinical development as a tool for guiding optimally new trial designs. Beyond supporting Preclinical R&D and Clinical development for PK/PD modeling and analysis, Serge has branched out to the use of Decision tree analysis combined with Monte Carlo simulation and Real Option Analysis to evaluate stochastically company portfolio.



Lisl Shoda, Associate Director, In Silico Research and Development, Entelos, Inc, USA

Lisl Shoda is an Associate Director of Research & Development at Entelos, Inc. with responsibility for Immunology and Inflammation programs. In 10 years at Entelos, she has primarily focused on the study of autoimmune diseases, particularly type 1 diabetes and rheumatoid arthritis, leading the development of mathematical models and their application to drug discovery and development. Lisl Shoda is an Associate Director of Research & Development at Entelos, Inc. with responsibility for Immunology and Inflammation programs. In 10 years at Entelos, she has primarily focused on the study of autoimmune diseases, particularly type 1 diabetes and rheumatoid arthritis, leading the development of mathematical models and their application to drug discovery and development.

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