# Predictive Modelling in Drug Development
# Satellite Meeting

## 23 June 2009

Predictive modelling and simulation can optimise the drug development programme by improving the inferences taken before making subsequent decisions on the rationale for drug development, labelling and even more often to guide the termination of less successful programs as early as possible.

GlaxoSmithKline and Pfizer are committed to creating additional opportunities to share views about a major challenge in pharmaceutical R&D, i.e. the ability to generate information with predictive value. We hope you will join us in the scientific discussion on the future of intelligent drug development.

Venue: St Petersburg State I.P. Pavlov Medical University

Address: Lev Tolstoy str. 6/8,
Metro station "*Petrogradskaya*"
197022 Saint Petersburg, Russia
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## *Final Programme*

Chair: Lutz O Harnisch

**I - Modelling & Simulation to guide decision making: from Lead Optimisation to Candidate Selection**

13.00 - 13.20 **Influencing early portfolio decision making using preclinical M&S: how early is early and when is it too late?**
Piet Van Der Graaf / Peter Milligan
Pharmacokinetics, Dynamics & Metabolism, Pfizer, UK
Global Pharmacometrics, Pfizer, UK

13.20 - 13.40 **Receptor pharmacology or animal models for dose selection in humans?**
Bart Laurijssens
Clinical Pharmacology Modelling & Simulation, GlaxoSmithKline, UK

**II - Modelling & Simulation to guide decision making: from First time in Man to Phase II**

13.40 - 14.00 **Enhanced Quantitative Decision Making - Reducing the likelihood of incorrect decisions**
Mike Smith
Global Pharmacometrics, Pfizer, UK

14.00 - 14.20 **Bayesian posterior predictive probability: what do interim analyses mean for decision making?**
Oscar Della Pasqua / Gijs Santen
Clinical Pharmacology, Modelling & Simulation, GlaxoSmithKline, UK

14.20 -15.00 **To adapt or to confirm: what is the question?**
Vladimir Dragalin
Global Bisotatistics and Programming, Wyeth, USA

15.00 -15.20 Coffee break

Chair: Oscar Della Pasqua

**III - Modelling & Simulation to guide decision making: from Full Development to Product Line Extension**

15.20 -15.40 **Defining clinical relevance: model-based update of the label**
Monica Simeoni
Clinical Pharmacology, Modelling & Simulation,
GlaxoSmithKline, UK

15.40 -16.00 **Influencing the design of dose titration schemes to minimise AEs and subsequent dropout**
Raymond Miller
Global Pharmacometrics, Pfizer, USA

16.00 - 16.20 Tea break

**IV - Keynote Lecture**

16.20 - 17.30 **Consequences of exposure-response modelling for dose finding**
Jose Pinheiro
Clinical Development & Medical Affairs, Novartis, USA

17.30 - 18.00 Reception

## REGISTRATION:

There are no fees for the Satellite Symposium, but formal registration is required.

Due to limited venue capacity, attendance will be restricted to a maximum of 150 participants.

Please confirm your interest in attending the symposium by email to Mrs Pam Paul (pam.p.paul@gsk.com). Include arrival date to St Petersburg, if known.

**Registration will be confirmed by email before 01 May 09.**