NextLevel pharma

Webinar: Thursday 3rd September, 2009
Date: **Thursday 3rd September: 4pm (CET), 3pm (GMT), 10am (EST)**
Knowledge Solutions for Life Sciences

Pediatric pharmacology

Understanding ADMET to improve drug design for children

AN INTERACTIVE WEBINAR POWERED BY NEXTLEVEL PHARMA

Event overview

This will be a half day webinar for clinical pharmacologists, scientists and pediatricians to discuss overcoming the scientific challenges in designing PK/PD studies to aid developing new pediatric medicines.

It is widely known that recent regulatory changes on both sides of the Atlantic have meant a higher priority is placed on developing medicines for children that have undergone rigorous examination. Many previous discussions have taken place on the difficult topic of clinical trials in pediatric populations. However this webinar will not be just another discussion about issues surrounding submitting PIPs, the changes in regulatory requirements or the operational challenges in locating pediatric subjects and informed consent.

NextLevel Pharma's focused and interactive webinar will look to concentrate on the position that pharmacokinetic and pharmacodynamic modelling and simulations have to answer the questions of how children metabolize drugs differently, how to assess optimal drug dosage levels and optimise the design of pediatric studies.

Experienced industry pharmacologists and pediatricians will join us to discuss recent developments and assess how to better understand drug interaction, determine the optimal dosage and report on efficacy in children.

Why participate?

- Understand the need for pk/pk studies: the when, how and why in the eyes of the regulators.
- Learn what roles pk/pd studies have in the development of pediatric drugs and how they can be used more effectively to determine dosages, measure efficacy and demonstrate value to the pediatric world.
- Hear case study presentations from industry leaders on how to adapt methods used from adult to children and gain fresh perspectives from experienced pharmaceutical companies who have successfully integrated pk/pd into pediatric studies for optimal design.
- Discover which approaches are best to predict dosage, utilize existing (adult) data, and understand the interactions between drug and child.

Who will benefit:

Pharmaceutical & Biotechnology Organisations:

Vice- Presidents, Directors, Managers;

Pediatrics, Pre-Clinical and Clinical Pharmacologists, Pharmacokinetics, Pharmacodynamics, Modelling and simulation specialists, Early Drug Development, Clinical development and strategy, Clinical scientists, Medical directors

Academics;

Pediatricians, pharmacologists and scientists involved in the development of new pediatric medicines

Prestigious Speaker Panel

Chairperson:
Roger D. Toothaker, PhD,
Vice President, Pharmacokinetics, Pharmacodynamics, Modeling & Simulation
ICON Development Solutions

Andrew E Mulberg, MD, FAAP, CPI
Portfolio Leader, Internal Medicine, Established Products CNS/IM Late Development
Johnson & Johnson Pharmaceutical Research and Development, USA

Jeffrey S. Barrett, Ph.D., FCP,
Research Associate Professor, Pediatrics Director, Pediatric Pharmacology Research Unit
Laboratory for Applied PK/PD Clinical Pharmacology & Therapeutics Abramson Research Center, The Children's Hospital of Philadelphia

Pravin R Jadhav
Pharmacometrics Team Leader
FDA, USA

Armel Stockis
Senior Director, Global exploratory development
UCB, Belgium

Pieter Guelen, Chairman
Pharmacokinetic Consultancy Services
Netherlands

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Interactive Webinar Programme

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Vice President, Pharmacokinetics, Pharmacodynamics Modeling & Simulation
ICON Development Solutions

CET

15.45 Online login

16.00 Chairperson's opening remarks

16.15 **Obstacles and approaches to successful pediatric development**

- Overview of the issues across pediatric age groups.
- Position/Value of PK/PD studies, models and simulations to pediatric drug development.
- What the scientific differences between the pediatric and the adult subject mean to study design.

Andrew E Mulberg, MD, FAAP, CPI
Portfolio Leader, Internal Medicine, Established Products CNS/IM Late Development,
Johnson & Johnson Pharmaceutical Research and Development, USA

16.55 **Defining the therapeutic window in children via biomarkers and PK/PD modelling when Pediatric**

- Bridging of adult to pediatric experience in NME with similar adult/pediatric indications.
- Need to explore, define, and ultimately defend the pediatric therapeutic window.
- Availability of suitable biomarkers to discriminate doses and regimens.
- Characterizing the time course of doses and exposures that map the concentration-effect or dose-response surface.
- Examples of such approaches.

Jeffrey S. Barrett, Ph.D., FCP
Research Associate Professor, Pediatrics Director, Pediatric Pharmacology Research Unit,
Laboratory for Applied PK/PD Clinical Pharmacology & Therapeutics Abramson Research Center, The Children's Hospital of Philadelphia

17.35 **Correct pediatric dosing through modelling & simulation**

Dr Jadhav will cover the current approach used by scientists at the Office of Clinical Pharmacology in guiding pediatric drug development. Case studies will be presented to demonstrate various methods used and issues encountered in guiding pediatric protocol development. These case studies will demonstrate evaluations of the following aspects of study design:

- Appropriate dose range
- Sample size to design informative PK and efficacy studies
- Use of prior knowledge (adult data or relevant pediatric data)

Pravin R Jadhav, Pharmacometrics Team Leader
FDA, USA

18.05 **Pediatric modelling and simulation for trial design: Case study in anti-epilepsy drugs**

- Physiologically-based pediatric pk predictions (including hepatic and renal maturation factors).
- Pop-pk extrapolations from adult data.

  Pediatric pop-pk for dosing recommendations extrapolating clinical response from adults using pop pk/pd.
- Oral to intravenous prediction.
- Optimal trial design.

Armel Stockis, Senior Director Global exploratory development
UCB, Belgium

18.45 **Panel Discussion "Considerations in pediatric study design to enable high operational performance"**

- Audience members will be able to submit questions prior or during the event for discussion.
- Best approaches to pediatric planning / strategy (considerations on company size, drug indication).
- How to utilize existing (adult) data to improve study design.
- Designing pediatric protocol to meet scientific & operational requirements.
- How to incorporate patient and investigator compliance into the protocol.

Pieter Guelen, Chairman
Pharmacokinetic Consultancy Services, Netherlands

19.30 End of webinar

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4. Participate and interact

The sessions will then begin all the while you can ask questions via typing them in. Only during the designated question time (at the end of each session) can you verbally ask questions. During the interactive panel discussions you'll need to type your name in the question area, before the moderator will call on you to ask your question. There will be online mini-surveys occasionally during the webinar.

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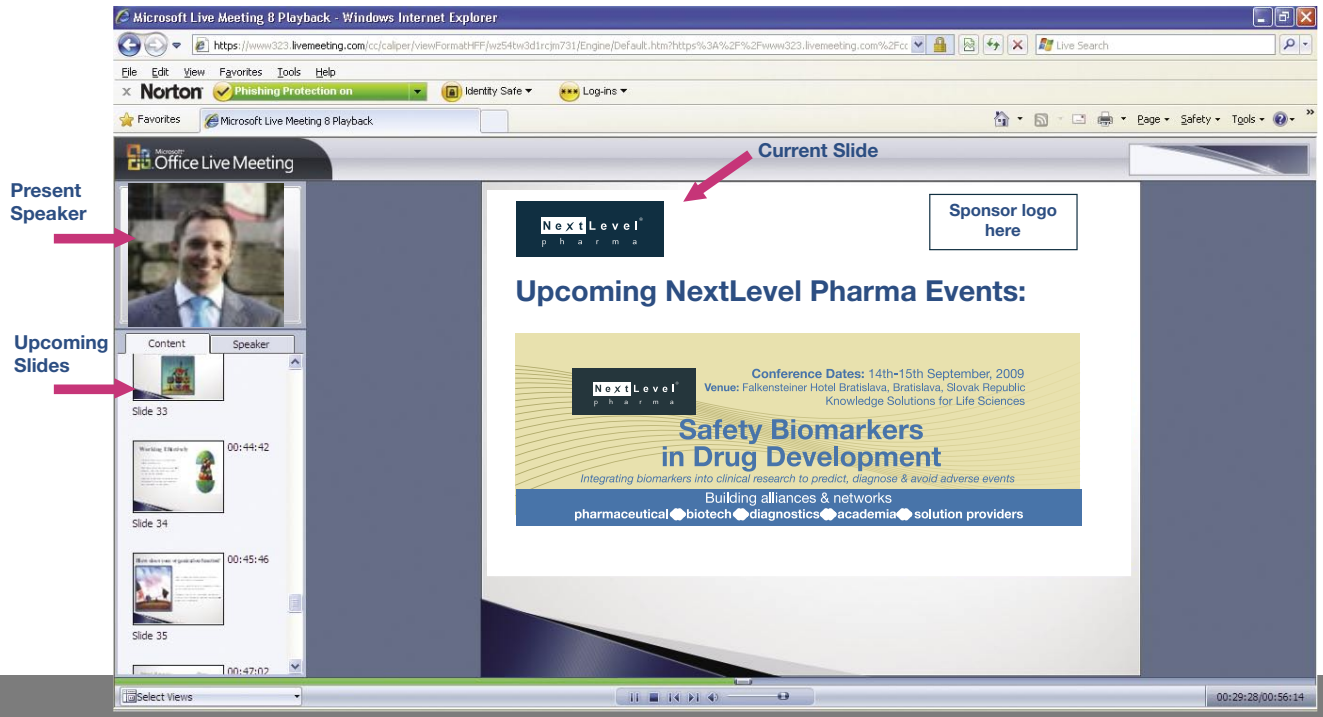

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Pediatric pharmacology

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Attention: Andrea Valent
andrea.valent@nextlevelpharma.com

Please write in BLOCK CAPITALS

Participant Information

PARTICIPANT 1

Name: _____
Job Title: _____
Email: _____

PARTICIPANT 2

Name: _____
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PARTICIPANT 3

Name: _____
Job Title: _____
Email: _____
Organisation: _____
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Pediatric pharmacology webinar

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