

FDASIA Regulation Discussed at Paediatric Clinical Trials

Global Head for Pediatric and Maternal Health Policy from Novartis, presents a key note address at the 8th annual event on Paediatric Clinical Trials.

LONDON, LONDON, UNITED KINGDOM, January 13, 2014 /EINPresswire.com/ -- SMI are pleased

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The SMI paediatric conference is a brilliant opportunity to keep up to date with the diverse and complex requirements of paediatric drug development”

Jane Lamprill, Paediatric Research Consultancy

to announce that Dr Christina Bucci-Rechtweg, Global Head for Pediatric and Maternal Health Policy from Novartis, will be presenting a key note address at the 8th annual event on [Paediatric Clinical Trials](#), taking place on 31st March and 1st April in London, UK.

FDASIA requires drug manufacturers subject to the Pediatric Research Equity Act to submit their paediatric study plans earlier in the development process and gives FDA new authority to issue non-compliance letters to companies that fail to complete some requirements.

Dr Bucci-Rechtweg, will be discussing FDASIA regulation and providing unique insights on global harmonisation.

The presentation entitled: How does FDSIA change the regulatory landscape for paediatric drug development in the US, will spotlight on:

- The Paediatric Study Plan (PSP) as a tool to encourage paediatric research earlier during product development
- A new approach toward considerations for an overarching paediatric program development plan
- Non-compliance in the post-FDASIA environment
- An opportunity for global harmonisation

Paediatric Clinical Trials 2014 will feature further case study driven updates on:

- Global paediatric legislations including an impact assessment of the EU legislation.
- PIP submission; requirements and strategic considerations

- Facilitating clinical research and ethical considerations
- Formulation dosing and extrapolation

[Click here](#) to download the conference agenda and speaker line-up for 2014.

This informative conference will bring together key opinion leaders provide attendees with an in depth look into current advances in paediatric clinical trials and drug development. For those wishing to register there is an £100 early bird discount that expires on 31st January. Click here to book online.

Further speakers will include:

- Bruno Reigner, Senior Clinical Pharmacologist, Roche Pharmaceuticals
- David McIntosh, Global Scientific Affairs Senior Expert, Novartis Vaccines
- Philippe Auby, Director, International Clinical Research, Paediatric Neuro-Psychiatry, Lundbeck
- Klaus Rose, CEO, Klausrose Consulting
- Elin Haf Davies, Director & Founder, Empowering Children | Enabling Research
- Daniel Bar-Shalom, Associate Professor, University of Copenhagen
- Daniel De Wolf, Director - Department of Paediatric Cardiology, Ghent University Hospital
- Karl-Heinz Huemer, Scientific Office, Austrian Agency for Health and Food Safety
- Otto Skoran, CEO, Svabhegy Paediatric Hospital
- Mark Sorrentino, Executive Medical Director, PPD Consulting

Paediatric Clinical Trials

31st March - 1st April 2014

The Kensington Close Hotel, London UK

www.paediatric-trials.co.uk

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The poster for the 8th annual Paediatric Clinical Trials conference, presented by SMi. It features a laboratory setting with a beaker containing colorful test tubes (red, green, yellow) and a petri dish with a pipette. The text on the poster includes: 'SMi present the 8th annual conference on...', 'Paediatric Clinical Trials', 'London UK', '31ST MARCH - 1ST APRIL 2014', and the website 'www.paediatric-trials.co.uk'. Below the poster, the text 'Paediatric Clinical Trials | 31st March and 1st April 2014' is displayed.

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