



**Workshop on Extrapolation and Evidence Synthesis in the  
Development and Therapeutic Use of Medicines in Children**  
*11<sup>th</sup> June 2013 – Strathclyde University, Glasgow, UK*

**PRELIMINARY PROGRAMME:**

***09:15 – Welcome and objectives of the workshop***

***SESSION 1 – EVIDENCE GENERATION***

*09:30 – Nonlinear mixed effects modelling and simulation for the analysis and optimisation of study protocols*

*10:00 – Incorporation of historical data as priors in hierarchical models for the evaluation of response*

*10:30 – Panel Discussion and Q&A.*

*11:00 – Coffee break*

***SESSION 2 – EVIDENCE SYNTHESIS***

*11:20 – Use of meta-analysis in evidence synthesis: an example based on dose selection for antibiotics*

*11:50 – Defining the level of evidence in the evaluation of adverse events and risk*

*12:20 – Panel Discussion and Q&A*

*13:00 – Lunch*

***SESSION 3 – FOCUS ISSUES - RARE DISEASES AND NEONATOLOGY***

*14:00 – Requirements for the evaluation of orphan drugs*

*14:30 – Clinical trials and evidence generation in neonates*

*15:00 – Panel Discussion and Q&A*

*15:30 – Tea break*

***SESSION 4 – REGULATORY and PATIENT PERSPECTIVES***

*15:50 – Evidence synthesis, bridging and extrapolation in Paediatric Investigational Plans vs. Pediatric Study Plans*

*16:20 – Patients and parents' insight on novel methodologies and regulatory requirements*

*16:45 – Panel Discussion and Q&A*

*17:15 – Final remarks and closure*