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