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The European paediatric regulation: Strategies for effective negotiation and agreement of a pragmatic paediatric investigation plan (PIP)

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The Paediatric Regulation (Regulation (EC) No 1901/2006) came into force almost eight years ago; however its implementation still presents numerous challenges to medicinal product development for the EU market. The regulation indicates that the timing of the Paediatric Investigation Plan (PIP) or waiver submission to the Paediatric Committee (PDCO) should be no later than the completion of human PK studies in adults, yet the agreement of a PIP in early stages of development when available evidence and scientific findings are limited often dictates the requirement for frequent PIP modification, as knowledge and experience with the medicinal product in the adult population increases. Furthermore, companies may be required to propose plans for studies in paediatric indications not directly related to their target adult indication for EU marketing authorisation, owing to the Agency's policy on determination of the paediatric condition. Given that compliance with an agreed PIP is a critical element for validation of an EU application for marketing authorisation, the agreement of a pragmatic PIP to ensure that companies are not committed to an overly burdensome paediatric programme is critical. This presentation will discuss the challenges of the paediatric regulation in Europe, compare the requirements of paediatric development in Europe relative to those from the US FDA, and present strategic advice for negotiation and agreement of a PIP with the PDCO.

Biography

Natalie Thomas received her PhD from Monash University, working on the pre-clinical development of a novel monoclonal antibody for the treatment of breast cancer. She subsequently worked as a Research Scientist in the pharmaceutical industry in Australia prior to joining a specialist European regulatory affairs and product development consultancy in 2010. She specializes in development of biopharmaceuticals and cell based therapies, and has worked on over 50 products in various therapeutic indications. She is a regularly invited speaker on EU regulatory affairs, and has conducted training sessions for regulators in emerging markets.

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