**Abstract**

Purpose: To summarise contemporary approaches to evaluating medicines in children, emphasizing topics that are often misunderstood by one or more stakeholder groups.

Methods: A narrative review that integrates the literature with experience in multiple settings.

Findings: Children and young people need specific approaches to research about drugs because of growth and development. Specific approaches include practicalities such as the volume, frequency and technique of blood samples, and recruitment, including consent by proxy decision-makers and assent by children/young people. The design of drug development programmes includes working with children/young people from an early stage and minimising the burden of research through careful design while optimizing the contribution of extant, high quality information (including extrapolation).

Regulators, academics, the pharmaceutical industry and other communities are well-placed to support pediatric drug development. Regulatory challenges include legislation that drives the extension to children of medicines used in adults (rather than a focus on the needs of children) and diversity between jurisdictions. Academics can improve the impact of their work by ensuring that data can be used in drug development programmes after they have answered a well-defined study question. Pharmaceutical companies, and public research funders can promote good return on the investment made in research (including the investment made by children/young people) by supporting data management to allow data reuse.

Implications: a greater understanding of pediatric issues is relevant to diverse research communities that work to advance pharmacotherapy.