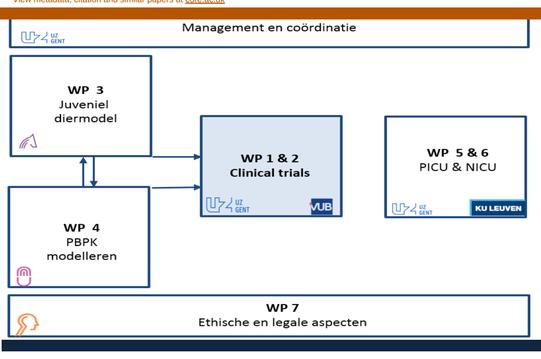

The SAFE-PEDRUG project:

an opportunity for academia to close the gap

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1. BACKGROUND

The Paediatric Regulation (1) was launched ten years ago. As was also identified in the ten year report (2), this regulation has had a positive impact on paediatric research in Europe. However, some specific patient populations (such as neonates, critically ill children, children with comorbidities) do not receive enough attention in paediatric drug development. Furthermore, the top-down approach (from adults to children) results in considerable delays in making medicines available to children. For most of the drugs long term follow-up is missing.

2. METHODS

The SAFE-PEDRUG project was initiated in Belgium in 2014 and is a collaboration of experts in paediatrics, pharmaceutical sciences, veterinary medicine, and ethics of three Belgian universities: Ghent University, KULeuven, and Vrije Universiteit Brussel. An advisory board and stakeholder group consisting of national and international stakeholders support this consortium in the valorisation of results.

3. RESULTS

The SAFE-PEDRUG project explored the value of the porcine juvenile animal model and modelling and simulation (population pharmacokinetics and physiologically based pharmacokinetic modelling) in providing prior paediatric PK/PD knowledge, before the actual adult trials have been completed. For the evaluation of this approach, three case compounds were selected: desmopressin, lisinopril, and fluoroquinolones. The results of the models are plotted against human paediatric data, including data in neonates and critically ill children.

4. CONCLUSION

A close collaboration of experts and stakeholders can help to tailor paediatric clinical trials to the needs of children. Pharmaceutical industry and regulatory authorities are key players in the paediatric drug development process. However, academia can also play an important role in rendering the paediatric drug development process more efficient by development and correct use of innovative tools (figure 1). Besides, academia should defend the rights of the most important stakeholders: patients and their parents. During the SAFE-PEDRUG project additional opportunities for academia have been identified: initiation of networking; centralisation in registries and networks to improve transparency and efficiency; and education of paediatric clinical pharmacologists.

Figure 1:

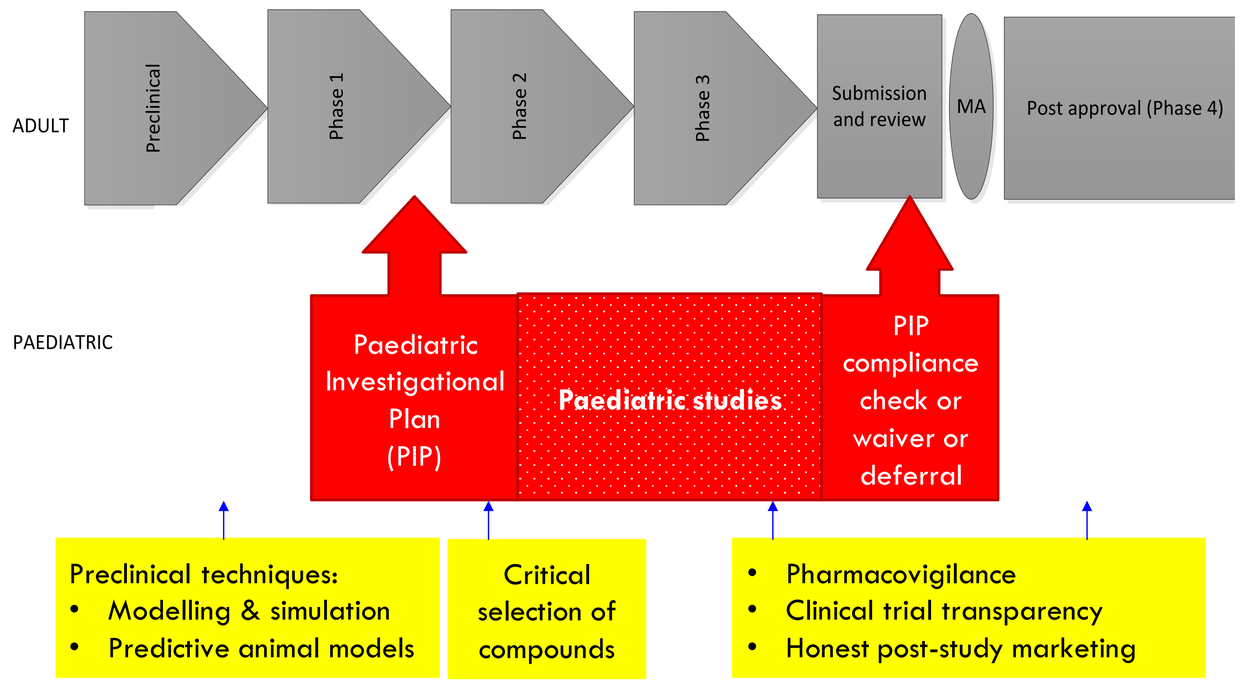

Figure 1: Timelines for paediatric drug research. Opportunities for paediatric drug research (indicated in yellow).
MA: marketing authorisation

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