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An innovative checklist for paediatric biosamples management

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Abstract

Conducting clinical research in paediatrics poses many distinctive challenges that need to be considered when planning, managing and delivering clinical trials and that require specific competences and infrastructure. Biological samples, like blood and blood fraction, tissue, urine and saliva/buccal cells, are commonly used in biomedical and clinical research. Analyses from biological samples provide key outputs in clinical trials, as for pharmacokinetic, safety and efficacy evaluations of investigational medicinal products. Consequently, it is essential that sample collection, management, storage and analysis are performed according to high standards. This is even more important in paediatrics considering that blood sampling may be difficult, the number of samples is usually limited, especially in newborns, and all the efforts should be made to minimise sample volumes. Ethical and regulatory requirements (consent, assent and data protection, particularly with respect to long-term storage), training and facilities required for samples collection and storage are relevant to grant a proper management and use of biological samples. Considering the crucial role of biological samples and the challenges they pose for researchers planning and conducting paediatric clinical trials, in the context of the PedCRIN project a tool to support the management of biological samples and associated data in the context of paediatric clinical trials has been developed. This checklist will favour the adherence to the recommended standards and will allow releasing an easy-to-use tool to help the investigators, sponsors and other research actors involved in paediatric clinical trials in the management of bio-samples.

Biography:

He is working in Consortium for Biological and Pharmacological Evaluations, Italy. Also, responsible for conducting a survey targeting paediatric and neonatal users, as well as patient communities to identify the needs of paediatricians in terms of infrastructures and tools for clinical trials in CVBF Project.

Speaker Publications:

1. "Ethical Issues and Barriers for Multi-National Paediatric Clinical Trials: The Challenging Experience of the DEEP Project"; Blood / 2019 / 134(Supplement_1):4820-4820
2. "Survey by TEDDY European Network of Excellence for Paediatric Clinical Research demonstrates potential for Europe-wide trials"; Acta Pediatrica / 2019 / 10.1111/apa.15020
3. "Challenges and New Frontiers in the Paediatric Drug Discovery and Development"; Drug Discovery and Development - New Advances / 2019 / 10.5772/intechopen.85635

10th International Conference on Clinical Research and Clinical Trials; Amsterdam, Netherlands- March 18-19, 2020.

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