Interview to Dr. Donato Bonifazi, PedCRIN consortium member (CVBF, Italy)

As part of our series of interviews with the PedCRIN Consortium members, we had a pleasure to speak with Donato Bonifazi to ask him about the role of Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF) in the PedCRIN project.

CVBF co-leads PedCRIN WP3 (Tools for paediatric trials) along with INSERM. The main task of this workpackage is to develop or adapt existing tools to be used for the management and set-up of the multinational neonatal and paediatric clinical trials, to disseminate tools to PedCRIN partners and to train and support partners on the use of the tools. In PedCRIN project, CVBF is responsible for (i) 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, (ii) performing gap analysis to detect missing tools and services to support paediatric and neonatal trials, (iii) upgrading, maintaining and ensuring the sustainability of tools for neonatal and paediatric trials (ethical and regulatory database, pharmacovigilance, etc.), (iv) disseminating tools to paediatric community and (v) developing a procedure to enable access to individual patient clinical trial data. CVBF is also involved in other WPs i.e. Sustainability, Support to multinational trials and Communication.

When speaking about contributions of PedCRIN to the current European framework of paediatric research, Donato said that the survey performed among the paediatric community depicted that the researchers involved in non-commercial/academic paediatric trials have a strong need for structured support in the set up and conduct of paediatric clinical studies. “The survey also helped PedCRIN to identify other areas where support is strongly requested. Gaps in paediatric research could be positively covered if the paediatric researchers get access to the multinational clinical trial management support and tools developed in PedCRIN”.

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Donato stated that PedCRIN WP3 tools were not able to be tested in the PedCRIN funded trials because the trials were already running in the coordinated countries. This reduces the possibility to provide a real contribution to the current European framework of paediatric research. He suggested that the tools developed in PedCRIN should be tested in current and future European initiatives for paediatric and neonatal clinical research. This will also be a great way not only for the update and/or implementation of the available tools but also for strengthening the collaboration among the PedCRIN project partners.

Donato highlighted that among the tools that are being developed or updated within WP3, particularly the **procedure for the management and setup of the neonatal and the paediatric clinical trials** like CTUs certification criteria, pharmacovigilance, the ethical and regulatory database (ECRIN, CAMPUS) etc., will provide dividends over time.

In his opinion, the main limitation of PedCRIN is the **lack of a sustainability plan** and the scarce clarity about the concurrent role of PedCRIN and other parallel European initiatives for paediatric clinical research. “These limitations are reducing the relevance of the role that PedCRIN was aimed to cover”, he indicated.

According to Donato, ECRIN the existing clinical research infrastructure will benefit the most from this project and will enhance its capacity for the management of the multinational neonatal and the paediatric clinical trials. When speaking about the areas that need more support in paediatric research, he referred to the data obtained from the surveys i.e. **support in the preparation of protocols for paediatric interventional clinical trials, the inclusion of innovative study designs into the paediatric developmental plans, the identification of relevant funding opportunities and support in the preparation of applications**.”