TEDDY - European Network of Excellence for Paediatric Clinical Research

Scientific Meeting and General Assembly - Rome, 19th December 2016

The paediatric theme in the forthcoming clinical research scenario

Paediatric population has been long-time neglected from the clinical research scenario. As a direct consequence of this, in the pharmaceuticals field despite the great contribution done by the biomedical science, innovative medicines are available to children only after years respect to adults and the off-label use of the existing medicines is still a widespread phenomenon in all the countries and in almost all therapeutic areas.

The Paediatric Regulation has highlighted the specific features of paediatric patients in terms of drug disposition, drug activity and response to therapy. For this reason, ad hoc paediatric drug development plans have to be prepared and performed. However, many scientific, methodological, economical and ethical factors still complicate the performance of clinical trials in children.

New funding strategies, focused on long-term self-sustainable Paediatric Networks and Research Infrastructures, represent a key to address the forthcoming challenges of paediatric clinical research.

In the occasion of its General Assembly, TEDDY Network, in collaboration with GRiP (the Global Research in Paediatrics Network) organises a scientific session in which the most recent advancements in paediatric research will be discussed and shared with the academy and other stakeholders interested in the field. In addition, the most recent paediatric initiatives at European and National level (including PedCRIN, INCiPiT, RECLIP) will be presented together with concrete and realistic plans for the next future to address the most relevant priorities in the paediatric research agenda.

9,30 Participants' registration

9,40-13,30 Clinical research in adult and children: commonalities and specificities (Chair: A. Ceci)

- 9,40 Research Infrastructures in biomedicine: a system pipeline to support biomedical research (M. Lavitrano, BBMRI-ERIC Management Committee Co-Chair)
- 10.00- The new clinical trials regulation to improve the clinical research in Europe: the ECRIN contribution *(J. Demotes, ECRIN General Director)*
- 10.20 Paediatric clinical trials: challenges and opportunities - The contribution of PedCRIN *(M. Turner, EnprEMA Chair)*
- 10,40 Scientific expertise and specialty level needed to design scientifically-sounded paediatric trials and research
    - *C. Giaquinto, GRiP-PENTA,*
    - *N. Ruperto, PRINTO*
    - *P. Telfer, DEEP*
    - *E. Jacqz-Aigrain (Paediatric Pharmacology)*
    - *Oscar della Pasqua (Dose selection and innovative study design)*
    - *F. Bonifazi (HTA and disease Registries)*
- 12,10 Q&A and discussion

- 12,30 National networks and initiatives contributing to the European Paediatric Clinical Trial Research Infrastructure (EPCTRI):
    - Kalle Hoppu (FinPEDMED, Finland)
    - Paolo Rossi (INCiPiT, Italy)
    - tbc (RECLIP, Spain)
    - Anila Godo (Albania)
    - Marek Migdal (Poland)

13,30 Lunch

14,30- 15,50 TEDDY Network activities and plan of action (M. Turner)

- TEDDY Network in the paediatric research agenda (*A. Ceci*, *TEDDY Scientific Coordinator*)
- The TEDDY Working Group on Off Label Use in Paediatrics: current status and next actions *(S. de Wildt, TEDDY GOLUP Working Group coordinator)*
- The TEDDY survey to identify paediatric trials competences and capacities at site level *(L. Ruggieri, TEDDY Network Scientific Secretariat)*
- TEDDY Inventory of procedures for obtaining Paediatric Clinical Trials approvals *(C. Manfredi, TEDDY Network Management)*

15,50 General Assembly - Paediatric clinical trials sustainability in the framework of the paediatric regulation. TEDDY commitments and plans

Chair: D. Bonifazi

Participants: All

17,30 Goodbye cocktail

This initiative is organised in the framework of the project GRiP (Global Research in Paediatrics – Network of Excellence)

THE GRiP Project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no. 261060