

A novel simulation-based approach to train study teams for clinical trials in neonates, infants and children with heart failure

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Introduction: Based on the need of an orally administered age-appropriate enalapril formulation for use in children, the EU's Seventh Framework Programme (FP7)-funded research project LENA (Labeling Enalapril from Neonates up to Adolescents; grant agreement n°602295) was initiated. Within the project, paediatric clinical trials assessing pharmacokinetic (PK), pharmacodynamics (PD) and safety data have to be performed in neonates, infants and children. In addition to challenges involved in every paediatric drug development, the strict framework of FP7 adds further time pressure and budget limitations. To meet these particular challenges, a novel approach for the training of study teams was chosen that goes beyond current standards. A simulation training was used to improve the study teams' skills in PK/PD investigations and patient recruitment. This intense, focused training allows study teams to practice critical situations under realistic circumstances. Thus it is expected to reduce preventable sampling and recruitment failure. This hypothesis is subject to a systematic evaluation study.

Methods: Small-volume sampling of time-critical and sensitive parameters as well as communication to potential participants, parents and colleagues were identified as most critical hurdles in the trials. Thus, simulation scenarios for the training of these skills have been implemented using simulation manikins and original medical devices. All study teams attended a two-days-training. Video-based debriefing of the scenarios enriched the learning experience. Participants' performance and preparedness for the study as well as the usefulness of the training were assessed using surveys based on five-point Likert scales.

Results: 23 participants from five different European countries were trained at the Salzburg simulation centre. The performance in sampling of time-critical humoral parameters was optimised to meet the predefined time limits, and to enable maximum reliable data extraction by reducing invalid samples. Communication scenarios allowed improving of critical communication skills. Video-based debriefing facilitated self-reflection and joint discussion. Participants' abilities to communicate core elements of the studies and to successfully perform PK/PD sampling increased significantly ($p=0.0003$).

Conclusions: Simulation training significantly improved the participants' performance. This tailored training was assessed as a helpful teaching tool in trial preparation. Further follow-up surveys will assess the actual impact of this training on the study success.