European CRO Federation

"The interface between Industry – CRO and Clinical Trials Networks: Defining the Roles"

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Agenda

- Key Points
- Network Support
- CRO Support
- Collaboration
- Conclusion

Key Points

- CRO and Network Coordinator as key contact points
- Network facilitates study
  - Project set up
  - Investigator selection facilitation
  - Fast recruitment
- CRO manage the study
  - CRO to keep dialogue with the Network Coordinator
  - Open and transparent communication with the Network during whole project

Network Support
Drug and Study Development

- PIP Preparation
  - Scientific consultation, input for proposed studies
  - Standard of care definition (especially in Neonatology)
  - The sooner the Network is involved the better the PIP
- Formulation
  - Scientific support in respect to adequate formulation
- Protocol Elaboration
  - Scientific support to optimize study design and feasibility
  - Advice on innovative methodological approaches

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Network Support
Study Start

- Local Informed Consent Form
  - Assistance in local ICF design
  - Optimal risk/benefit wording
  - Input regarding the terms request from certain ECs
- Patient Information Leaflets
  - Review including consulting Parent Representatives and Young Person's Advisory Group

Network Support - Feasibility

- Assistance with Site Identification
- Investigator Selection
  - Type of study
  - Identification KOL sites (scientific board)
  - Identification performer sites (site recommendation)
  - Resources availability (Advice on workload of sites)
  - Advice on the technical/logistical solution available at the sites

Network Support - Study Conduct

- Collaboration during study conduct
  - Database for assistance with patient identification
  - Optimization of patient inclusion and compliance
  - Recruitment in a child friendly environment
  - Site motivation
  - Problem resolution

Network Support - Study Conduct

- Site support for Patient recruitment
  - Support site staff and advice on recruitment strategies
  - If recruitment rates are below expectations, Network staff works with sites to identify and resolve constraints
- New site identification
  - During recruitment phase, Network staff to identify additional study sites, if required

Network Support - Study Conduct

- Support with Research Nurses
  - Local site nurses to assist with study procedures
  - Network-based nurses to assist with study procedures
- Data collection
  - Form completion and data submissions

Network Support - Study End

- Scientific input for data analysis
  - Network involved as advisory board
  - Network involved in the final report
- Share outcome of the study
  - Study report and beyond

CRO Support
Project Initiation to Project End

- PIP Preparation, Submission, follow-up
- Regulatory submissions
- Study medication management
- Randomisation: IVRS, IWRS….
- Study Set-Up
- Site selection validation
- SOPs

CRO Support
Project Initiation to Project End

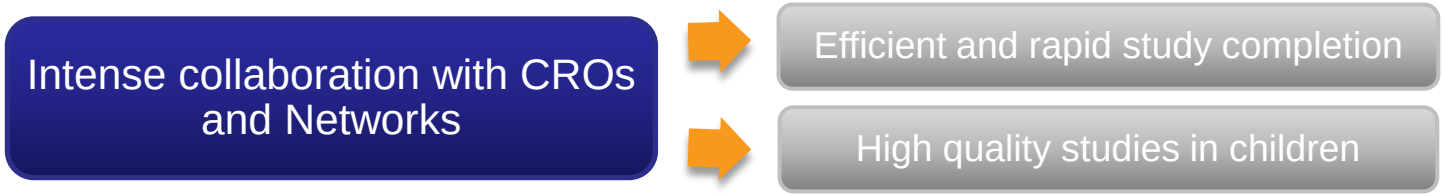
- Project and Study Management
  - Ensure study well performed, timelines met, etc..
- Assure high Quality Data
  - Monitoring with CRAs experienced in paediatrics
- Data Management & Data Analysis with validated tools
- Study Report
- GCP& Regulatory compliance

Network, CRO & Industry Collaboration

- Good collaboration will result in
  - Optimizing the PIPs and Study Protocols
  - Fast patient recruitment, thus fast trial execution
  - Performance of high standard clinical trials
  - High quality data
- Network & CRO: Different roles, complement each other
  - Network: Creation of data
  - CRO: Study management, monitoring and data analysis
- Communication is crucial. All parties to be involved during the whole project
- CRO contribute to awareness of Network capacities

Conclusion

- Network support from PIP preparation through Study Development, Feasibility, Site Identification, and Recruitment
- CRO preparation PIP, study initiation, management, data analysis, final Study Report
- CRO for assurance of regulatory compliance
- Benefit for Industry



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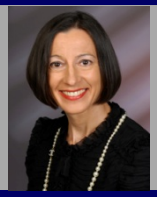
THANK YOU FOR YOUR ATTENTION!



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