efpia
European Federation of Pharmaceutical Industries and Associations

Summary of the Break-out sessions

Day 1

Regulatory processes and system
As the EU regulatory landscape and policy initiatives continue to evolve, this session will provide a platform for exchange between drug developers, regulators (EMA, CTFG, EU-IN) and other stakeholders to discuss the current regulatory process and system for CCT trial advice and authorisation. The session will use case studies and research on CTT proposals accepted by regulators to highlight learnings and opportunities for regulatory convergence. A panel discussion at the end of the session will provide perspective on policy opportunities from all experts.

Patient Involvement
Patient involvement in clinical trials is attracting more and more interest, and experience is growing. This interactive breakout session will be not only the opportunity to share the experience so far but also to identify recommendations to optimise patient's involvement in the design and conduct of complex trials. A few flash presentations will open up the discussion by representatives of key stakeholders. We cannot expect to solve all the issues through this session, but the goal is to identify recommendations and next steps including synergies with the Education & Training breakout session.>

Design of Master Protocols
Master protocols designs are supporting innovation strategies for evidence generation. This session will use 2 case studies, one in oncology and one in non-oncology, to illustrate some of the key challenges and sources of complexity when designing master protocols. The discussion will focus on key and critical points for different stakeholders. Their views will be shared and solutions proposed to enable recommendations and increased alignment across stakeholders regarding an optimal design of master protocols.

Day 2

Operation and Implementation
Complex innovative trial designs require much more upfront planning, anticipation, strong communication and flexible problem-solving approaches across multiple stakeholders. This session will discuss each of the steps: planning, implementation, execution and oversight of complex clinical to identify the most important challenges in the implementation of complex innovative clinical trials. Aspects such as collaboration vs. competition, use of common templates and governance will be discussed to elaborate best practices and recommendations.

Education and Training
Having patients, regulators and HTA bodies, ethic committees, investigators and sponsors sufficiently

familiarized with complex innovative clinical trials is essential for a healthy clinical research environment. This breakout session will provide a status update on available education and training material and identify training gaps regarding complex clinical trials. The session will help to assess the most pressing educational needs for the various stakeholders and start brainstorming on best suited organisations to provide such training and develop the necessary material/guidance.

Trials incorporating historical controls or with adaptive features

This session highlights two case studies of complex innovative clinical trials that incorporate historical control data or have adaptive features. The first case study illustrates the borrowing of information from external data sources in a randomized pediatric trial in multiple sclerosis. The second case study uses a complex Bayesian adaptive design to explore dose ranging and generate safety and efficacy evidence. The discussion focuses on key questions allowing different stakeholder views to be shared, with the objective to foster the use of such clinical trials designs.