Parallel session PS 8: "New medicines, medical technologies, clinical trials & stakeholders support"

22 November 14:20 – 15:50

Session leaders: ▪ Victoria Hedley - Rare Diseases Joint Action/ Newcastle University ▪ Luca Sangiorgi - Coordinator ERN BOND	**Chair:** Victoria Hedley – Rare Diseases Joint Action/ Rare Disease Policy Manager, Newcastle University
Speakers: ▪ Luca Sangiorgi (ERN BOND) ▪ Flora Giorgio (DG SANTE) ▪ Helen Lee (DG SANTE - Expert Group STAMP) ▪ Jean-Noël Bouillon (MedTech Europe) **Additional Expert Panellists include:** ▪ Isabella Brambilla (ePAG advocate) ▪ Thomas Allvin (EFPIA representative); ▪ Eileen Treacy (BoMS Representative for Ireland)	**EC support official:** Patrizia Tosetti. Unit B3 DG SANTE

Aim of the parallel session:

To address some of the challenges and barriers facing ERNs when conducting clinical research to develop new medicines/medical devices, and explore how to optimise collaboration with relevant stakeholders to achieve streamlined, more effective research and better outcomes for patients

Main issues to be addressed:

- The added value which ERNs offer, in terms of advancing clinical trials for rare diseases and highly specialised domains
- The scope of ERN-led research relating to new medicine development, drug repurposing, and development of medical devices.
- Opportunities and options for engaging with Regulatory Bodies, Companies, and Complementary initiatives, and possible ways to facilitate this collaboration
- How to realise the identified opportunities, as part of a comprehensive Research Strategy for ERNs

Format of the session:

The session will begin with the Chair setting the scene. Luca Sangiorgi will present the state of play of this area of research for the ERNs, including the possible research priorities of the Networks.
The session will continue as three interrelated sub-sessions, with one short connecting presentation:

- **Sub-session 1: How can ERNs lead/participate to clinical trials of new medicines?** (This topic will explore ERN activities in leading clinical trials and participating to trials - both Industry-led and academic-led.)
    - Opening presentation: Luca Sangiorgi, ERN BOND 'Key Actions for ERNs and Clinical Research'
    - Panel Debate

- Presentation from Flora Giorgio, DG SANTE: **'The status quo of Health Technology Assessment (HTA) at EU level'**

- **Sub-session 2: Repurposing a medicine**
    - Opening presentation: Helen Lee, DG SANTE 'Repurposing medicines - the European status quo'
    - Panel Debate

- **Sub-session 3: Developing new medical devices**
    - Opening presentation: Jean-Noël Bouillon, MedTech Europe: 'Medical Technology in rare diseases and specialised domains – the status quo'
    - Panel Debate

Each of these sub-sessions will consider the following ***key Questions***:

- *How could ERNs approach/add value to each activity?*
- *What are the challenges and what solutions exist (with reference to case study examples, where relevant)?*
- *Which stakeholders need to be engaged for each activity and how might this be achieved?*

Each sub-session will be followed by Q&A and discussion with the audience

A short report highlighting the key issues and main highlights of the parallel session will be produced and disseminated after the Conference.