REGULATORY READINESS – WHAT IS IT AND WHY SHOULD WE CARE?

Room:	**Breezaal**
Time:	**Monday 15:00 to 16:30**
Chair(s):	**Pieter Stolk & Saco Visser**
Organizing FIGON-partner(s):	**RSNN en ZonMw**

For innovative technologies, methods, or data sources to be able to play a role in the development and authorization of medical technologies, decision-makers have to be assured that these innovations do what they say within acceptable bounds of uncertainty. This means that innovations have to go through a process that will give confidence that they are fit for purpose. An example is the qualification procedure used by EMA and other regulators. In this session we want to review what it takes for new innovations to be accepted by regulators, HTA bodies and payers for making decisions, what lessons can be drawn for innovators, and what policy makers can do to make the translation from idea to implementation as smooth as possible.

This session will focus on the “readiness” of registry data for the purpose of medicine development and authorisation as well as the accompanying experiences, problems, and solutions from the perspective of the regulator, academics, and industry.

Invited lectures:

15.00 - 15.05	**Introduction and relevance Regulatory Readiness** *Pieter Stolk*, RSNN
15:05 - 15:25	**Regulatory Readiness Levels as a tool to drive regulatory innovation** *Sjaak Bot*, RSNN/Janssen
15:25 - 15:45	**The impact and use of quality registries - Can real-world data complement post-approval clinical trials?** *Rawa Ismail*, DICA/UU & *Michel Wouters*, DICA/NKI
15:45 - 16:05	**An academia-led registry for metachromatic leukodystrophy – the MLD initiative** *Daphne Schoenmakers,* AmsterdamUMC
16.05 - 16.25	**Perspective of the regulator on readiness of registry data** *Marjon Pasmooij*, RSNN, MEB
16.25 - 16.30	**Discussion** *Pieter Stolk*, RSNN

Indicated speaker time includes 5 minutes for discussion