RSNN workshop, 17 April 2019

"The future of clinical trials and evidence generation, and their use in regulatory decision making"

On Wednesday 17 April 2019, the Regulatory Science Network Netherlands (RSNN) will organize the fourth RSNN workshop (14:00-21:00 at Villa Jongerius, Utrecht). This year's topic will be "The future of clinical trials and evidence generation, and their use in regulatory decision making". Register now!

For decades, clinical trials have been a cornerstone for ascertaining the benefit-risk ratio of medicines. Recent years have seen growing awareness that the gap has grown too wide between the current trial system and the scientific demands of innovative developments. Average trial size, complexity, and cost have also increased. Furthermore, stakeholders such as HTA agencies and payers have additional evidence requirements.

Initiatives to rethink the current trial system focus on methodological innovations in trial design (e.g. basket trials); innovative use of (new) data sources (e.g. use of wearables); and better use of study results (e.g. indirect comparisons). However, such innovations and new ways of thinking find their way only slowly beyond the academic and experimental stage into clinical development and the regulatory arena. Intense regulation and the operational complexity of current trials have resulted in a status quo where players such as industry, regulators, CROs, and others, each have limited incentives – or room – to change.

There is a clear need to rethink and refurbish the current clinical ecosystem. The next RSNN workshop will explore how regulatory science can contribute to, and have an informed impact on, areas such as the development of innovative study designs, and their potential use in regulatory decision-making. **Joop van Gerven** (CCMO), **Rolf Groenwold** (LUMC), **Nick Sykes** (Pfizer) and **Ton de Boer** (CBG-MEB) will reflect on this topic from different perspectives.

Participants will contribute to the discussion during break-out sessions, where the focus will be on the potential added value of trial innovations, and the barriers and opportunities for implementation. The results of the workshop will provide critical input for future RSNN publications and events.

The day will end with a dinner, including a speech by **Sabine Straus** (CBG-MEB), chair of the Pharmacovigilance Risk Assessment Committee (PRAC) of the EMA.

Program
The full program can be found here.

Registration
Free of charge. Registration can be found here.