PSI Webinar
Patient Reported Outcomes (PROs) - Clinically Meaningful Interpretation

Tuesday 8th May 2018

2.00-3.30pm (UK time)

Clinical Trials are increasingly featuring a wide variety of Patient Reported Outcomes (PROs). PROs are important endpoints to both regulatory and health technology bodies in their assessments and approvals. There are standard ways in which PRO instruments are developed and validated, as well as important concepts for designing and interpretation of PRO data in clinical trials such as assessing the Minimally Clinically Important Differences (MCIDs/MIDs) and the use of a Responder definition.

The intent of this webinar is to describe an overview of how PROs tools are developed and used in clinical trial settings and how results can be clinically and meaningfully interpreted. In addition, a regulatory viewpoint will be shared on the key considerations for PROs. The talks will also include examples and case-studies showing the derivation of a validated thresholds for treatment responder and interpretation of PROs in the context of regulatory approval.

We are pleased to announce that three speakers will be presenting:

- Kim Cocks (Adelphi Values)
- Andrew Thompson (EMA)
- Christoph Gerlinger (Bayer)

For more information & registration see www.psiweb.org/events

[Organised by members of the PSI Scientific Committee: Martin Jenkins, Jennifer Gilbride, Rachael Lawrance and Tony Cornelius]