

**IP9: ISPOR issue panel**

**10 Nov 2015, 1345-1445hrs. Room: Gold (L2)**

**IS A SINGLE EVIDENCE BASE POSSIBLE ACROSS EUROPE? HOW SHOULD EVIDENCE GENERATION EFFORTS BE FOCUSED TO MEET PAYER REQUIREMENTS FOR MARKET ACCESS?**

Moderator:

**Ad Rietveld, MD, MBA, Director, RJW & Partners, Royston, UK**

Panelists:

- **Wil Toenders, PharmD**, Consultant, ToendersdeGroot, Utrecht, The Netherlands
- **Oriol Solà-Morales, MD**, Founding Partner, HITT, BARCELONA, Spain
- **Timm Volmer, MPH, MBA**, Managing Partner, SmartStep Consulting GmbH, Hamburg, Germany

**ISSUE:**

As healthcare budgets across Europe are becoming increasingly strained, payers are becoming ever more focused on the clinical value of products in relation to the price requested. The key issue is that although European evidence requirements for regulatory approval are relatively clear, the data requirements and methodology applied by payer organisations across Europe can be diverse. A key challenge is how to focus efforts to create an evidence package for new pharmaceutical products to optimise market access across Europe and satisfy payer bodies in an era of increasing scrutiny about the clinical and economic contribution. Using concrete product examples, we will present research on the divergence of payer decisions between countries and the supporting evidence packages.

**OVERVIEW:**

The different evidence required by payer bodies for successful reimbursement across Europe can cause significant challenges from a clinical development perspective. However, despite the differences between markets, there are common issues and perspectives payers take towards evidence packages for new products. Timm Volmer will utilise his experience of the German healthcare market and the evidence requirements for the AMNOG process. Wil Toenders will provide a perspective from the Netherlands and the data packages which are necessary to secure reimbursement via the ZIN. Oriol Sola-Morales will outline how bodies such as Catsalut review clinical evidence and what is needed to provide favourable reimbursement in Spain. All participants will utilise examples from their markets to enrich the discussion and provide an outlook for the future.

For further details please visit:

<http://www.ispor.org/Event/ProgramList/2015Milan?type=IssuePanel#IssuePanel1>