

THE PREMIER CONFERENCE DEVELOPED BY TOP EXPERTS FROM THE BIOPHARMACEUTICAL INDUSTRY AND GLOBAL REGULATORY AGENCIES



NEW: The 2019 conference will be a full three days, ensuring maximum learning opportunities



Opening Keynote by Katherine High, MD, President and Head of R&D, Spark Therapeutics



Regulatory policy and guidance updates from around the world



Knowledge for optimizing current practices and preparing for the impact of new therapies and technologies



Luncheon Round Table discussions with key thought leaders



Full- and half-day preconference short courses on January 27



KEY SESSIONS

- Generating Real World Evidence Fit for Regulatory Decisions: Learning from Safety
- Pharmacovigilance and Risk Management Challenges in Advanced Therapeutics
- Immuno-oncology – The Benefits and the Safety Challenges
- Patient Perspectives and Engagement in Benefit-Risk Assessment of Opioid Therapy



HOT TOPICS

- New perspectives on Drug-Induced Liver Injury (DILI)
- Using Reference Safety Information (RSI) in clinical trials
- Meeting expectations of the new pharmacovigilance regulations in China
- Benefit-risk assessment and managing uncertainty for orphan drugs
- The WHO 3S Project: Smart Safety Surveillance

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