



ISPOR Summit 2019

ISPOR'S Real-World Evidence Transparency Initiative

October 11 | 8:00 am – 4:00 pm

Baltimore Marriott Inner Harbor at Camden Yards

Baltimore, MD, USA



Building Trust in Real-World Evidence: The Role of Study Registration

Real-world evidence on treatment outcomes can be an important aspect of the evidence basis for decision making if it is seen as credible. For real-world studies that are meant to test hypotheses about comparative-effectiveness or safety, a key aspect of credibility is that they are conducted transparently with analyses that follow a prespecified analytic protocol. Preregistration of such study protocols on a public website would help build trust that their results can be used for decision-making purposes.

The 2019 Summit will be a forum for discussion of the work of the Real-World Transparency Partnership, led by ISPOR, International Society for Pharmacoepidemiology (ISPE), Duke-Margolis, and National Pharmaceutical Council (NPC), and involving a number of other organizations and stakeholders. It will focus on the key elements needed for the creation of a common registration site for these real-world studies that will be oriented for regular use by researchers and seen as a credible registry by decision-makers. The work already completed in this effort will be presented and the future steps envisioned will be discussed with Summit attendees. A white paper summarizing the initiative and recommendations will be publicly available for review and comment prior to the Summit.

Sessions:

Transparency in RWE — Time for a Unified Approach

This session will provide an overview of the history and goals of the RWE Transparency Initiative and why it is timely, as well as its work to date. This will include a summary of the white paper and its responses. It will cover fundamental aspects of this issue including credibility vs. transparency, characteristics of studies recommended for registration (ie, Hypothesis-Evaluating Treatment Effect [HETE] studies), the importance of reporting, and replicability and the totality of evidence.

Registration site(s) — Opportunities to Optimize

During this session, we will hear from representatives of three potential sites - clinicaltrials.gov, ENCePP, and Open Source Forum, regarding their current capabilities for registering retrospective observational studies and their plans in this area going forward. The potential to align on a common protocol template and what that might entail also will be discussed.

Nuts and Bolts of Fit-for-Purpose

This session will include discussion of a number of key characteristics of a registration site needed to achieve its desired purposes. These include: a "lockbox" capability, allowing time-stamped pre-registration without making details immediately available to the public, allowing for a period of confidentiality; protocol elements needed for pre-registration to sufficiently specify the hypothesis, its supporting rationale, and how it will be tested, in enough detail to allow transparency of intended vs. actual analysis performed; the level of detail of post-analysis reporting needed to enable replication of the analysis; and potentially other considerations.

Behavior Modification — Boosting and Nudging

In this session, aspects of registration related to the "behavioral" elements of pre-registration will be examined. What level of detail and attestation about "pre-looks" at the data are appropriate? What is the right balance between information required and overall feasibility — is some pilot testing called for? What external conditions on pre-registration would be the best incentives for encouraging its use?

Transparency in RWE — Moving Forward

This panel will reflect on the day's discussion and review the next steps needed to move towards making pre-registration common practice for RWD hypothesis-testing studies in light of both the opportunities and the challenges. There will be time for audience interaction.

Join us at this Summit to learn more about this initiative and help shape its work to come.

Register at www.ispor.org/Summit2019

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Healthcare Digitalization Unpacked - Learn, Innovate, and Find Your “Hygge” at ISPOR Europe 2019

Program Committee Co-Chairs:

Dorte Gyrd-Hansen, PhD, MSc, University of Southern Denmark, Odense, Denmark;
Carole Longson, PhD, Association of the British Pharmaceutical Industry (ABPI),
 London, England, UK; **Hans Severens, PhD**, Erasmus University Rotterdam,
 Rotterdam, The Netherlands



Gyrd-Hansen



Longson



Severens

Dear Colleagues and Friends,

We are very pleased to invite you to join us in Copenhagen for ISPOR Europe 2019, the leading European conference for health economics and outcomes research (HEOR). Given the acceleration of the digitalization of the healthcare landscape worldwide, this year's theme, *Digital Transformation of Healthcare: Changing Roles and Sharing Responsibilities*, is especially relevant. Rapid advances in information technology and data science—along with increasing emphasis on using real-world data and evidence to inform regulatory and healthcare coverage—raise questions regarding the ability of the healthcare ecosystem to adapt, critically assess, embrace, and even thrive given the opportunities that these advances hold. These issues and others will be addressed during the scientific program, which is highlighted by three plenary sessions.

The plenary sessions will focus attention on the incentives of the new players in the digital transformation and how roles are changing, the impact that the digital healthcare system can have on providers and patients, and emerging opportunities and challenges to creating real-time learning healthcare systems.

The first plenary, on Monday, 4 November, “Healthcare Digitalization: Instant, On Demand, and Always Connected,” will address the rapid change affecting healthcare systems in real time, especially as to how care is organized and delivered. The panel will explore the objectives, incentives, and aspirations of the new players in digital transformation and how the roles of traditional stakeholders are changing.

The second plenary, on Tuesday, 5 November, “Shaping the Digital Healthcare System,” will explore how the key “actors” in healthcare systems are adapting to the technological developments to deliver more productive, more effective, and more personal care for patients who are enabled by various digital technologies to actively influence their medical journey.

The third and final plenary session on Wednesday, 6 November, is titled, “Big Healthcare Data: Endless Opportunities for Research and Learning.” Big data present a tremendous opportunity for the measurement and reporting of quality in healthcare and new methods are needed to harness the potential for these data to have real impact. Speakers will provide examples of using these tools not only for research, but also for driving learning at the healthcare-system level.

These plenaries are only one aspect of our scientific program. ISPOR Europe in Copenhagen offers opportunities for learning through a diverse short-course program on Saturday and Sunday, followed by innovative spotlight sessions, topical breakout sessions, and over 2500 research poster presentations. A new featured session, ISPOR Ideas Lab, will be launched in Copenhagen and is designed to fuel original views and fresh perspectives and to trigger and strengthen innovative thinking and the spirit of discovery in the HEOR community.

We are sure that both an outstanding scientific program and your curiosity to experience the authenticity of one of the most livable cities in the world will convince you to join ISPOR Europe this year. Copenhagen¹, labeled the “City for Life,” will offer plenty of “hygge” when you go for a walk or a bicycle ride after a day at the conference.

Copenhagen is large enough to offer a selection of 15 Michelin starred restaurants, but small enough to bicycle from one end to the other in 20 minutes. The city offers a vibrant urban pulse with plenty of Nordic cuisine and Nordic fashion amongst cobbled streets, castles, and bell towers. Take a stroll down one of Europe's longest pedestrian shopping streets (Strøget), and have beer and smorgasbord at the 17th-century waterfront, Nyhavn, or visit the hipster districts of Nørrebro and Vesterbro, where you will find interesting quirky shops and restaurants in streets such as Jægersborggade and Ravnsborggade, and plenty of nightlife in The Meatpacking District.

We look forward to joining you in Copenhagen as we gather to further ISPOR's mission of promoting HEOR excellence to improve decision making for health globally.

See you in the “City for Life!”
 — Dorte, Carole, Hans

REFERENCE

1. Hohn H. Fresh off the press: Mapping the world's prices 2019. Deutsche Bank website. https://www.db.com/newsroom_news/2019/fresh-off-the-press-mapping-the-world-s-prices-2019-en-11494.htm. Published May 20, 2019. Accessed September 2, 2019.

2. <https://www.visitdenmark.com/denmark/highlights/hygge/what-hygge>



ISPOR Europe 2019

Digital Transformation of Healthcare: Changing Roles and Sharing Responsibilities

**2-6 November | Bella Center Copenhagen
Copenhagen, Denmark**

Join more than 5000 global healthcare leaders at ISPOR Europe 2019 — an energizing meeting ground for sound science, robust methodology, relevant policy discussions, and multistakeholder perspectives.

ISPOR Europe 2019 in Copenhagen offers opportunities to debate value in healthcare beyond cost-containment and short-term interventions — strategic perspectives, scientific validity and diverse global experiences. During the five days of the conference you will:

- Learn about digitization, digitalization, and digital transformation in healthcare and explore their impact on HEOR.
- Present and debate your research results and ideas in an open and neutral environment.
- Advance your career while staying current on emerging trends and attending short courses.
- Engage with recognized global experts and network with colleagues, collaborators, and clients.

Conference Highlights Include:

37 pre-conference short courses

Offered in conjunction with ISPOR Europe 2019 these are a series of half- and full-day training courses, designed to enhance your knowledge and technique in seven key topic areas ("Tracks") related to health economics and outcomes research (HEOR).

9 NEW short course sessions include



- US Payers — Understanding the Healthcare System™
- Fitting the Structure to the Task — Choosing the Right Dynamic Simulation Model to Inform Decisions about Healthcare Delivery
- Health State Utility (HSU) Recommendations for Identification and Use of HSU Data in Cost-Effectiveness Modeling
- Why All the Hype? Nordic Data Explained
- Digital Real-World Evidence Generation Approaches in Rare Diseases and Oncology
- Market Access & Value Assessment of Medical Devices
- Probabilistic Graphical Models with Openmarkov, an Open-Source Tool
- Creating Natural, Flexible Models with DICE Simulation
- Mapping to Estimate Utility Values from Non-Preference Based Outcome Measures — Part 2



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Plenary sessions

Healthcare Digitalization: Instant, On Demand, and Always Connected (Monday, 4 November)

An expert panel will explore the objectives, incentives and aspirations of new players in digital transformation of healthcare, how the roles of traditional stakeholders in healthcare are changing, and what needs to be done to strengthen the effectiveness of the change efforts in delivering desired results.

Shaping the Digital Healthcare System (Tuesday, 5 November)

In this session we will explore how the key “actors” in healthcare systems are adapting to the technological developments in healthcare (ie, genomics, artificial intelligence, digital and real-time medicine, robotics) to deliver more productive, more effective and more personal care for patients.

Big Healthcare Data: Endless Opportunities for Research and Learning (Wednesday, 6 November)

The final plenary will offer discussion of the need for innovative forms of information processing (ie, big data, social media, data analytics) to ensure enhanced insight and decision-making for the measurement and reporting of quality in healthcare.

Spotlight Sessions

Sessions will highlight timely topics in HEOR and promote areas of innovation of interest to the ISPOR community.

- Transparency in RWE — Time for a Unified Approach
- Genomics in the Future of Health — The Road to Better Outcomes?
- The Evolving Demands for Medical Device Evidence Development: What the Future Holds

ISPOR Ideas Lab

New Insights to Improve Decision-Making for Health Globally

The ISPOR Ideas Lab is designed to fuel original views and fresh perspectives. Topics include new thinking on “social determinants” and alternative perspective on the “O” and the “E” in HEOR, sustainability index to futureproof healthcare, and next generation HTA for complex and personalized combinations of health technologies. The session is designed to fuel original views and fresh perspectives and to trigger and strengthen innovative thinking and the spirit of discovery in the HEOR community.

- Ecosystems of Health Value: A Value Design Framework
- Futureproofing Healthcare: Improving the Sustainability of Healthcare Systems Through Data
- HTx — Next Generation Health Technology Assessment

Special Sessions

Two highlighted Issue Panels will bring together leaders in the field to discuss timely issues facing healthcare today.

- IP9: Transparency in RWE — Can We Navigate the Key Challenges?
- IP11: Cross-Border Collaboration on Availability of Pharmaceuticals in Europe — What, Why and What If?

2800+ Conference Presentations

Focusing on topics such as real-world evidence, digital health, health technology assessment, value assessment, medical devices, and patient preferences, featured in issue panels, workshops, forums, oral podium presentations and poster presentations and symposia.

Be an Exhibitor or Sponsor

Join the 100+ exhibitors and sponsors in the Poster and Exhibit Hall at Copenhagen. Your organization will get invaluable networking, business development, and brand recognition opportunities at ISPOR Europe 2019. Participate in the HEOR Theater and share your message with 30-minutes of valuable uninterrupted time. Benefits are provided at www.ispor.org/Europe2019sponsorship

Register at www.ispor.org/Europe2019Reg

JOIN THE CONVERSATION ON TWITTER [#ISPOREUROPE](https://twitter.com/ISPOREUROPE)



Mark Your Calendars for 2020!

ISPOR 2020

May 16-20

**Disney Coronado Springs Convention Center
Orlando, FL, USA**

Join us for a 20-20 view of the state of HEOR today at ISPOR 2020.

We are planning a robust five-day program with two pre-conference days featuring the ISPOR Short Course program and 1800+ presentations in the forms of plenary sessions, advanced spotlight sessions, workshops, issue panels, forums, oral podium presentations, abstract poster presentations and symposia. You can continue your education by visiting the ISPOR Exhibit Hall meeting and speaking with industry experts and taking part in the Exhibitor HEOR Theater.

There will be plenty of networking opportunities with some of the leading names in HEOR today at the Women in HEOR events, Students and New Professionals events, welcome and networking receptions in the Poster and Exhibit Hall, the 2nd Annual Awards Banquet, and more.

Come early or stay late — bring your family and take advantage of the beautiful setting and surroundings of Disney's Coronado Springs Resort and all that Orlando has to offer.

Abstract Submission Opens: October 1, 2019

Abstract Submission Deadline: January 15, 2020

Registration opens October 2019



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Partner. Participate. Progress.

Gain access to influential leaders and decision-makers in HEOR by sponsoring or exhibiting at ISPOR's conferences. ISPOR provides a platform for connecting with thousands of leaders and experts representing all facets of healthcare, including researchers and academicians, regulators and assessors, decision-makers, clinicians, industry, and patient representatives.

Exhibit Opportunities

The Society's conferences draw an audience of researchers and decision-makers from biopharmaceutical medical device, and diagnostics industries; payers, health ministries, government organizations, academia, and other healthcare organizations. Exhibit at a booth, table, and reserve your half-hour slot at our newest exhibitor offering, the HEOR Theater!

Sponsorship Opportunities

Increase your visibility and prominence in the field of HEOR by becoming a conference sponsor. Benefits can include conference and exhibit hall registrations and highlighted listings in the exhibitor directory. Sponsor a symposium, a charging lounge, internet or WiFi access, a coffee break, notebooks, lanyards and more!



Contact us for more information or to discuss specific conference sponsorship and exhibit opportunities at exhibit@ispor.org

Upcoming 2020 Events

ISPOR 2020

May 16-20
Orlando, FL

Abstract Submission Opens: October 1, 2019

Abstract Submission Deadline: January 15, 2020

ISPOR Asia Pacific 2020

12-15 September
Seoul, South Korea

Abstract Submission Opens: 2 December 2019

Abstract Submission Deadline: 11 March 2020

ISPOR Dubai 2020

29-30 September
Dubai, United Arab Emirates

ISPOR Europe 2020

14-18 November
Milan, Italy

Abstract Submission Opens: 2 March 2020

Abstract Submission Deadline: 10 June 2020