increasing specialization within our field and to develop consensus on how ISPE can work with other societies to promote common goals and values.

Objectives: The aims of this study were to provide a broad overview of the some of the largest general epidemiologic societies and to learn about the specific challenges facing these organizations and about new initiatives to expand and retain members. We will engage the audience in a discussion about the relations between epidemiologic societies and ISPE, how we can learn from each other's experiences and work together to achieve common goals.

Description: This symposium, sponsored by the ISPE Membership Committee, will start with the moderator providing an overview of the goals for the session and an introduction of the invited speakers. Each of the four society leadership presenters will then have 10 minutes to describe their organization and address specific challenges faced by their society. Following the individual presentations, the invited speakers will be joined on stage by five additional panelists representing different epidemiology societies and academic, industry and government perspectives for an open 35-minute discussion with the audience about the presentations. The final 10 minutes will be used to summarize the discussion and develop consensus action items to present to the various society leadership committees.

Speakers: Timothy L. Lash (SER), Til Stürmer (ISPE), John Acquavella (ACE), and Henrik Støvring (IEA-EEF)

Panelists: Malcolm Maclure (ISPE, Government), Francine Laden (ISEE, Academic), Vincent Lo Re (ISPE, Membership Committee, Academic), Martha Werler (SPER, Academic (tentative)), and Susan Sacks (SER, ISPE, Industry)

78. Data Driven Regulatory Science

Marie L. De Bruin,[1] Haggar H. Ampadu,[2] Jarno Hoekman,[1] Xavier Kurz,[3] Hubert G. M. Leufkens,[1] Shohko Sekine,[4,5] and Gerald Dal Pan.[4] *[1]WHO Collaborating Centre for Pharmaceutical Policy and Regulation, Utrecht University, Utrecht, The Netherlands; [2]The WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, Accra, Ghana; [3]European Medicines Agency, London, UK; [4]Center for Drug Evaluation and Research, FDA, Silver Spring, MD, USA; [5]Pharmaceuticals and Medical Devices Agency (PMDA), Tokyo, Japan.*

Background: Drug regulatory science closely relates to pharmacoepidemiology, particularly where epidemiologic methods are used to derive empirical evidence on the outcomes and implications of drug regulation.

Objectives: In this symposium, we will present the results from recent regulatory science studies on the functioning of post-marketing surveillance systems.

Description: After a short introduction of the scientific field and methods applied to evaluate pharmacovigilance systems, results from four recently performed studies will be presented. The studies cover different aspects from the pharmacovigilance system in different continents:

(1) Predictors of successful pharmacovigilance systems in Africa: determinants of ADR reporting in African countries (Hilda Ampadu)
(2) FDAAA mandated 18 months, 10 000 patient reviews: experiences with the first cohort of newly approved products in the USA since 2007 (Shohko Sekine)
(3) Characteristics and follow-up of post-marketing obligations of medicinal products with a conditional marketing authorization in Europe, 2006–2014 (Jarno Hoekman)
(4) The role of registries in European post-marketing surveillance, a retrospective analysis of centrally approved products, 2005–2013 (Xavier Kurz)

A multidisciplinary panel will provide their views and results of the studies. Implications for policy and further research will be discussed with panelists and the broader audience. Three different angles of focus will be chosen.

The academic perspective: What are the implications for data collection and methodologies?

The regulatory perspective: What are the implications for design and enforcement of post-marketing obligations?

The pharmacovigilance perspective: What are the implications for how to organize to post-marketing surveillance in practice?

79. Human–Algorithm Interaction to Define Variables from Free-Text Notes in Electronic Health Records—Introduction and Examples

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