23 September 2019
Duke-NUS Medical School

Duke-NUS CoRE/Duke-Margolis Joint Symposium

Regional Approaches to the Development and Use of Real-World Data and Evidence

130
Participants
government, regulatory authority, industry, healthcare institutions and academia

5
Faculty Members
internationally recognised experts

Introduction

The Duke-NUS Centre of Regulatory Excellence (CoRE) and the Duke-University's Robert J. Margolis, MD, Center for Health Policy jointly hosted a symposium convening thought leaders and health stakeholders to discuss current approaches to the development and use of real-world data and evidence (RWD/RWE) in health.

Over 130 stakeholders from government, regulatory authority, industry, healthcare institutions and academia attended the seminar.

Regional Approaches to the Development and Use of Real-World Data and Evidence

Keynote speaker Professor Mark McClellan, Director of the Duke-Margolis Center for Health Policy, provided an overview of the current landscape and the ongoing efforts undertaken in the US to improve the development and use of RWD and RWE. Potential remains for RWD and RWE to address the inefficiency of "traditional" randomised controlled trials (RCTs) and fill evidence gaps in the post-market phase of an approved drug's lifecycle.

Keynote Speaker

Prof Mark McClellan
Professor of Business Medicine and Policy

Director
Duke-Margolis Center for Health Policy
Duke University

Former Commissioner
U.S. Food and Drug Administration

Former Administrator
Centers for Medicare and Medicaid Services

In US, strong support for RWE development has been shown in the form of a congressional mandate passed in 2016 directed the US Food and Drug Administration (FDA) to enhance the use of RWE for regulatory purposes such as label expansions and changes. The US FDA has since issued a preliminary RWE framework in December 2018, with further collaborations with external institutions to continue refining the framework through research addressing data, methods, and infrastructure considerations and challenges. Beyond the US FDA, multiple players are involved in similar research efforts, including the Duke-Margolis RWE Collaborative which brings together public and private stakeholders to advance RWE development and use for regulatory decision-making.

Prof McClellan highlighted that although efforts were in progress, the actual uptake of RWE applications has been limited. Several areas remained to be addressed, including data quality issues, research design considerations for observational studies and real-world trials, the need for a guidance for use of RWE, and the need for global platforms to promote RWE, and identifying appropriate use cases for piloting RWE studies.

Prior to the panel discussion, Mr Bart Barefoot (GlaxoSmithKline) gave a brief overview of the RWE landscape in Europe, highlighting similar concerns about data quality and the reliability of RWE for regulatory decision-making as well as additional challenges posed by the heterogenous nature of RWD sources across Europe. He underlined the importance of multi-stakeholder collaboration (e.g. GetReal Initiative) in bringing together diverse players to advance the development and acceptance of quality and reliable RWE.

Mr Bart Barefoot
Director
Value Evidence & Outcomes and Real-World Evidence Policy, Advocacy, and External Collaboration
GlaxoSmithKline

Ms Sally Soh
Regulatory Consultant
Vigilance and Compliance Branch
Health Products Regulation Group
Health Sciences Authority
Singapore

Sharing the Singapore experience in harnessing the potential of RWD in the post-market setting to improve health, Ms Sally Soh (Health Sciences Authority Singapore) described the research aimed at leveraging electronic medical record capabilities to enable active drug safety surveillance.

A/Prof Kelvin Bryan Tan
Director
Policy, Research and Evaluation Division
Ministry of Health
Adjunct Associate Professor
Centre of Regulatory Excellence
Duke-NUS Medical School

A/Prof James Yip
Group Chief *Medical Information Officer*
National University Health System
Chief Data Advisor
Ministry of Health
Singapore

Joining Prof McClellan at the panel session were Mr Bart Barefoot, Ms Sally Soh, and Associate Professor James Yip (National University Health System, Singapore). Associate Professor Kelvin Bryan Tan (CoRE Adjunct Faculty) moderated the discussion.

The expert panel and the audience engaged in lively discussion, touching on the credibility of observational studies and concerns about data quality and data privacy. The discussion highlighted the foremost need to promote the collection of clear and good quality RWD in order to support the use of RWE in healthcare and regulatory decision-making. Given the right incentives in addition to efforts to educate and raise awareness, data quality could be encouraged and improved.