Get Real Annual Conference: Panel discussion: Increasing Use of RWE in Asia

Prof Churn-Shioh Gau (National Taiwan University), Ms Hu Suk Kwan (NPRA) & Gracy Crane (Roche Pharmaceuticals)

Thanks to Finny Liu & Soo Li-Ping (Roche Pharmaceuticals)

Publication highlighted

CURRENT MEDICAL RESEARCH AND OPINION
2022, VOL. 38, NO. 9, 1543–1551
https://doi.org/10.1080/03007995.2022.2096354
Article RT-0305.R1/2096354

Taylor & Francis
Taylor & Francis Group

REVIEW ARTICLE

OPEN ACCESS Check for updates

The challenges and opportunities in using real-world data to drive advances in healthcare in East Asia: expert panel recommendations

Gracy Crane[a], John C. W. Lim[b], Churn-Shiouh Gau[c], Jipan Xie[d] and Laura Chu[e]

[a]F. Hoffmann-La Roche Ltd, Welwyn Garden City, UK; [b]Centre of Regulatory Excellence, Duke-National University of Singapore Medical School, Singapore and Consortium for Clinical Research & Innovation, Singapore; [c]School of Pharmacy, National Taiwan University, Taipei, Taiwan; [d]XL Source, Inc., Los Angeles, CA, USA; [e]Genentech, Inc., San Francisco, CA, USA

ABSTRACT

Objective: To provide recommendations for overcoming the challenges associated with the generation and use of real-world evidence (RWE) in regulatory approvals, health technology assessments (HTAs), and reimbursement decision-making in East Asia.

Methods: A panel of experts convened at the International Society for Pharmacoeconomics and Outcomes Research Asia Pacific 2020 congress to discuss the challenges limiting the use of RWE in healthcare decision-making and to provide insights into the perspectives of regulators, HTA agencies, the pharmaceutical industry, and physicians in China, Japan, and Taiwan. A nonsystematic literature review was conducted to expand on the themes addressed.

Results: The use of RWE in regulatory approvals, HTAs, and reimbursement decision-making remains limited by legal/regulatory, technical, and attitudinal challenges in East Asia.

Conclusions: We recommend approaches and initiatives that aim to drive improvements in the utilization of RWE in healthcare decision-making in East Asia and other regions. We encourage large-scale collaborations that leverage the full range of skills offered by different stakeholders. Government agencies, hospitals, research organizations, patient groups, and the pharmaceutical industry must collaborate to ensure appropriate access to robust and reliable real-world data and seek alignment on how to address prioritized evidence needs. Increasingly, we believe that this work will be conducted by multidisciplinary teams with expertise in healthcare research and delivery, data science, and information technology. We hope this work will encourage further discussion among all stakeholders seeking to shape the RWE landscape in East Asia and other regions and drive next-generation healthcare.

ARTICLE HISTORY
Received 25 April 2022
Revised 27 June 2022
Accepted 28 June 2022

KEYWORDS
Real-world data; real-world evidence; East Asia; policy recommendations; decision-making support

Introduction

Real-world data (RWD) relating to patient health status and/or the delivery of healthcare can be broadly defined as data that are collected outside of conventional clinical trials[1]. These data are derived from a variety of sources, including electronic medical records (EMRs), insurance claims and billing systems, treatment and disease registries, and information directly contributed by physicians and patients[1]. High-quality real-world evidence (RWE) relies on appropriate analysis of RWD collected in ways that maximize completeness, accuracy, standardization, and timeliness, and reduce bias. Such RWE has long been used in postmarketing research and regulatory monitoring, including in long-term safety assessments, and to inform clinical decision-making[2]. There is a need for flexible regulatory mechanisms to support decision-making[3], and RWE is increasingly used to inform regulatory decisions[4], health technology assessments (HTAs), and reimbursement decisions[5].

Appropriate use of RWE can supplement evidence from clinical trials, aid development of treatments and clinical decision-making, lead to efficiency gains in healthcare delivery, and may improve access to treatments for under-served populations[6]. In some settings, where clinical trials may not be feasible, appropriate, or by themselves sufficient (e.g. oncology[7], rare diseases[8], or healthcare crises[9]), RWD may be crucial in addressing clinical evidence gaps. For instance, during the COVID-19 pandemic, an unprecedented effort led to many rapid real-world observational studies to assess potential treatments and to the emergence of RWD platforms and databases. Examples of such projects include RWD-driven initiatives by the US Food and Drug Administration (FDA) and the International Coalition of Medicines Regulatory Authorities (ICMRA)[10], and the COVID-19 Research Database[11], a platform to enable nonprofit COVID-19 research projects to obtain de-identified data from multiple healthcare institutions. Moreover, the Observational Health Data Sciences and Informatics (OHDSI) program set the foundation for characterization, estimation, and prediction studies early on in the pandemic[12]. These examples highlight the benefits RWE can provide in critical situations. In addition, COVID-19 vaccines and diagnostic tests are currently being

CONTACT Gracy Crane gracy.crane@roche.com F. Hoffmann-La Roche Ltd, Welwyn Garden City, UK

Following a panel discussion at ISPOR Asia, this publication was released

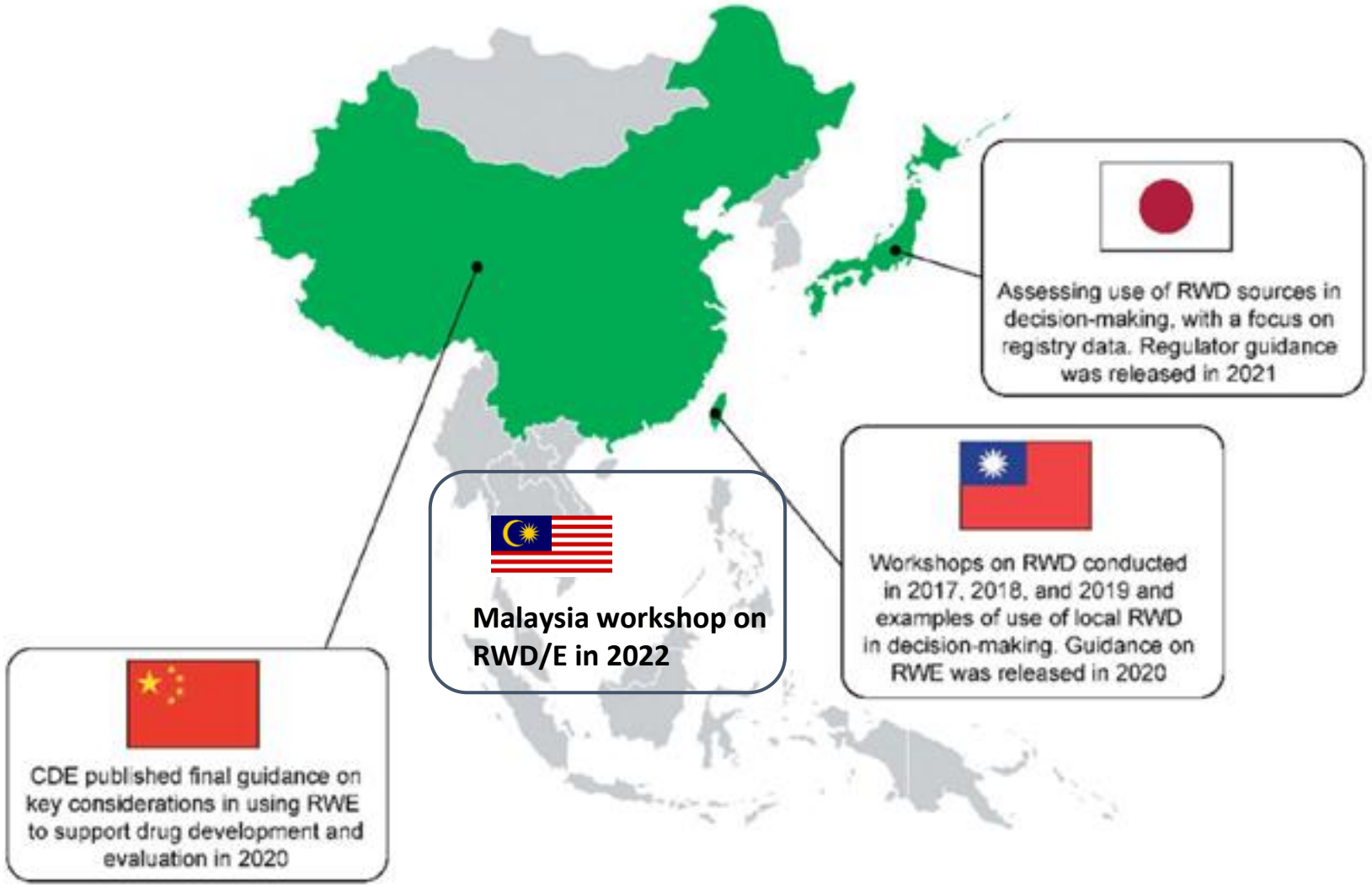


Figure 2. Examples of the development or adoption of regulatory frameworks for RWE in East Asia.
Abbreviations. CDE, Center for Drug Evaluation (China); RWD, real-world data; RWE, real-world evidence.

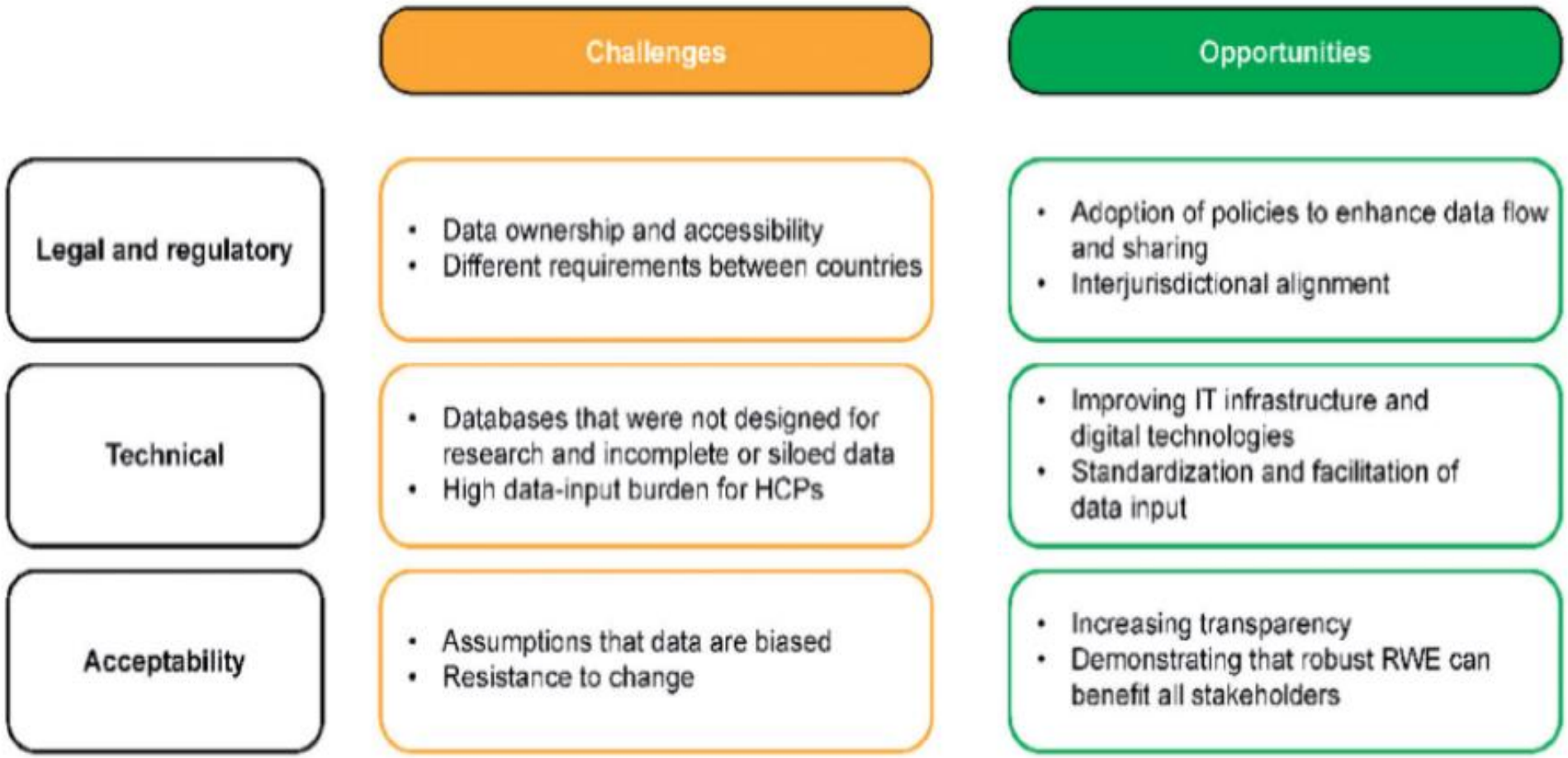


Figure 1. RWD challenges and opportunities in East Asia.
Abbreviations. HCP, healthcare professional; IT, information technology; RWD, real-world data; RWE, real-world evidence.

Standards & Frameworks for Evaluating RWD (Non-exhaustive)

Jurisdiction	Frameworks & Standards	Links
US	FDA Framework for RWE Programme	Link
	Eight guidances for different sources of RWD and External Controls	Link
	Duke Margolis Centre for Health Policy – determining RWD fitness for use and role of reliability	Link
EU	CHMP guideline on Registry-based studies	Link
	Data quality framework for EU medicines regulation	
	Data standardization strategy	
NMPA	Guidance for Real-World Data Used to Generate Real-World Evidences (Interim)	Link
PMDA	Several guidances released on use of registry data and post marketing safety	Link
Australia	Real world evidence and patient reported outcomes	Link

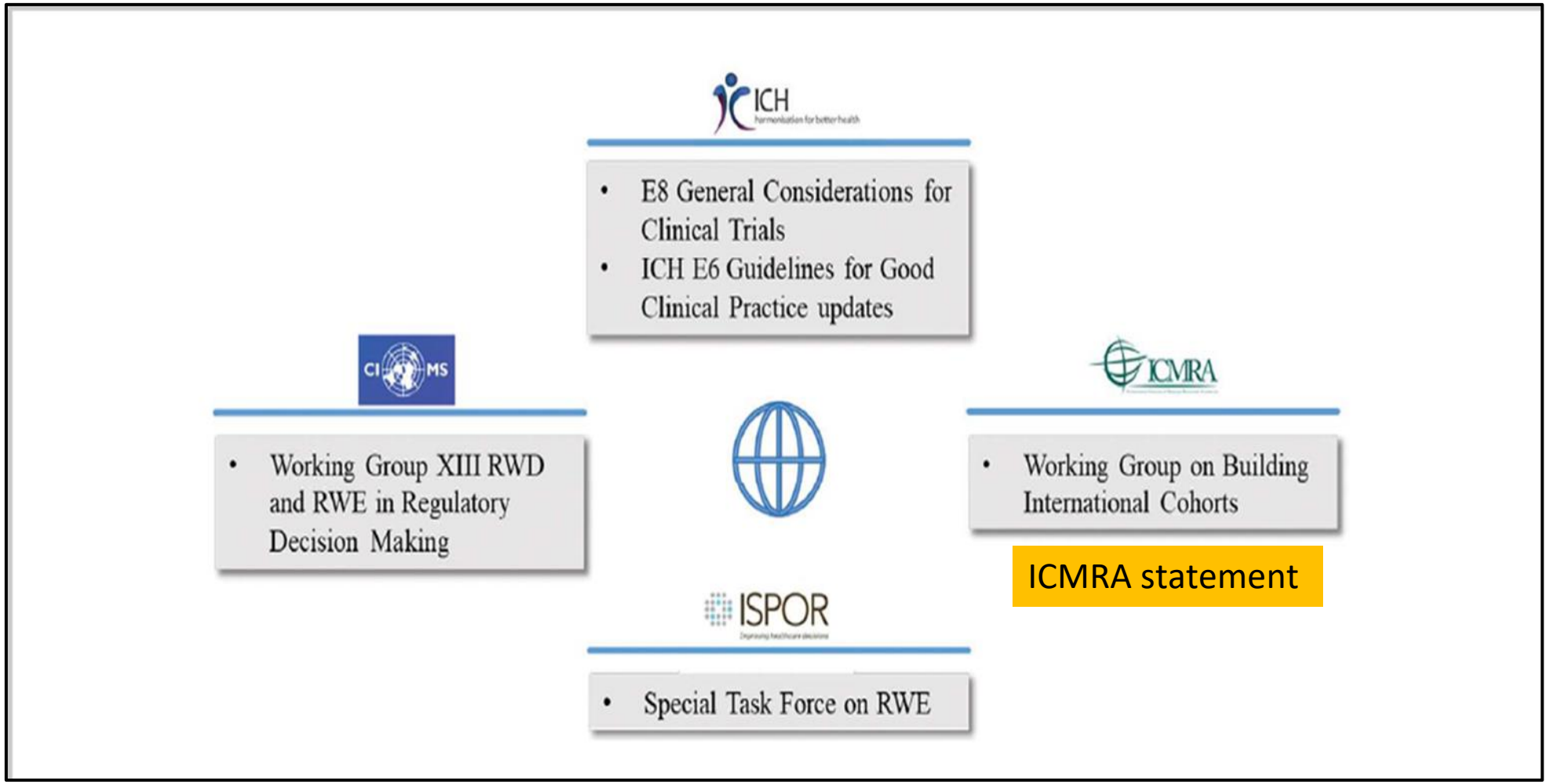
Deep Dive

- Today we want to take the opportunity to deep dive into 2 countries: Taiwan and Malaysia
- We will look at the overview or landscape of RWD initiatives in each country
- We will also think about some key challenges in these countries

Handover to Prof Gau For Deep Dive on Taiwan

Handover to Ms Suk Kwan for Deep Dive on Malaysia

Overarching initiatives on harmonization around the world



APAC Digital Health & Data Consortium*

APAC Digital Health & Data Consortium: add link to publication

Recommendations & Closing remarks