Efficiently Leveraging Your RWD Investment Across the Product Life Cycle

Stijn Rogiers, Pr. Industry Consultant, SAS Global Health and Life Sciences Practice
Real World Evidence

A Hot topic today...
Maximize product value beyond efficacy and safety

Comparative effectiveness
Cost-utility
Budget Impact
Long-term Outcomes

Direct/Indirect Cost
Cost:Outcomes
Cost Consequences
Resource Utilization
QALY

Efficacy
Safety
Morbidity
Mortality

Society

Equal access to healthcare
Return to work
Caregiver burden
Productivity

Morbidity, Mortality
Symptoms, Functionality
Preferences, Quality of Life

Effectiveness
Tolerability
Safety
Compliance
Adherence
Convenience

Payer

Patient

Economic

Provider

Clinical

Case Study: Maximize Product Value with Real World Evidence
Maria Kubin, VP Bayer – Eye for Pharma

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Real-world data (RWD) and real-world evidence (RWE) are playing an increasing role in health care decisions

US FDA
1. Publication and Guidance documents incl. submission
2. Framework for FDA's RWE Program (Dec 2018)

HMA-EMA Joint Big Data Task Force
1. Publications incl. Big Data Steering Group workplan for 2020-21
2. Summary Report (Feb 2019)

National Academies of Science (US)
1. Real-World Evidence Generation and Evaluation of Therapeutics (Workshop 2017)
2. Examining the Impact of Real-World Evidence on Medical Product Development I. Incentives (Feb 2018)

The Academy of Medical Sciences (UK)
1. Real-World Evidence Generation Scoping Roundtable (Jan 2018)
2. Next steps for using real world evidence (May 2018)
Big Data – Challenges and Opportunities
Moving forward with recommendations from the HMA-EMA Joint Big Data taskforce

Dr Alison Cave
Principal Scientific Administrator
Pharmacovigilance and Epidemiology Department
CDISC European Exchange May 2019

RWE stream @ CDISC EU Interchanges
2019 & 2020
Expanding the Use of Real-World Evidence in Regulatory and Value-Based Payment Decision-Making for Drugs and Biologics (Aug 2019)

How to ensure that novel analytic methods are fit for decision-making (Oct 2019)

News 02/10/2019

The past decade has seen the increased generation and availability of new data sources such as real-world evidence, as well as patient-level data from completed randomised clinical trials. While these data provide an opportunity to learn more about a medicine’s benefits and risks, and can complement the main body of evidence coming from randomised clinical trials, they will not necessarily translate into credible evidence for regulators and other decision-makers in the absence of adequate statistical methods to extract, analyse, and interpret them.

In an article published in Clinical Pharmacology & Therapeutics, regulators and academics explain how proper methodological validation can ensure the credibility of these data sources and allow authorities to rely on them to draw reliable scientific conclusions. The article is co-signed by a number of EMA staff members, academics.

Using RWE may provide advantages in cost, cohort sizes and ethical considerations.

This PHUSE paper attempts to collate all related information such as sources of RWD (Real-World Data), privacy laws and use cases in one document which can act as a reference point for individuals or companies who wish to design, conduct, and submit studies using RWE (Real-World Evidence).

It includes FDA’s current direction and guidance as of the date of this publication.
Real World Evidence

Examples
J&J performed a **pragmatic** real-world trial, a randomized trial that used measures that are collected in clinical practice.

“...INVEGA SUSTENNA® (paliperidone palmitate), a once-monthly schizophrenia treatment, is the first and only antipsychotic to have the U.S. Food and Drug Administration (FDA) approve the inclusion of real-world data in its product labeling”


What's scary, and appealing, about real-world evidence (StatNews 2019)

**Reference:** “Real World Evidence in Clinical development, life cycle management and/or repurposing” (Julijana Dukanovic, Andrew Leary – Dr. Regenold GmbH, SAS HLS Exec Forum Basel, 25 June 2019)
Example (Apr, 2019)

Pfizer Uses EHR Data to Support Expanded Indication for Breast Cancer Drug

“...The approval is based on RWD from electronic health records and post-marketing reports of Ibrance™ in male patients sourced from three databases: IQVIA Insurance database, Flatiron Health Breast Cancer database and the Pfizer global safety database”

The new label reads: “Based on limited data from postmarketing reports and electronic health records, the safety profile for men treated with IBRANCE is consistent with the safety profile in women treated with IBRANCE.”


Synthetic Control Arms

RW02 - Addressing industry disruptions in Clinical Trials with Real World Data in lieu of COVID19

Sherrine Eid, Stijn Rogiers, Robert Collins

Link In Post - PHUSE EU Connect 2020
Real World Evidence

CDISC
Call for Abstracts (incl. RWE stream)

CDISC EU Interchange 2021
Stijn Bogiers
EJC Member and Principal Industry Consultant, Global Health and Life Sciences Practice, SAS

Earlier this year we made a drastic decision and changed the EU CDISC Interchange 2020 from an in-person (Berlin) conference to a virtual event in a matter of weeks/days. It was a real challenge, but we did it! What a great CDISC EJC/CDISC team effort, considering the short deadline we faced. You can only do this when you are well-prepared and act as ONE team.

Approximately six months later, the EJC team met virtually for two half days (10-11 Sep) to start planning the EU Interchange 2021. As COVID-19 will continue to impact our lives for a while, the logical decision was made by CDISC and the CDISC EJC team to start preparing for another virtual event (most probably last week of April 2021).

CDISC EJC "Godfather" Joerg Dillert kept an eye on the Virtual EJC meeting and noticed that the preparation with new lead Nick De Donder and co-lead Sujit Khune ran very smoothly.

Meeting topics included feedback from this year CDISC 2020 Europe Virtual Interchange, new ideas and trends for the upcoming event, the new virtual platform and its capabilities, COVID-19, CDISC-360, keynote presentations), CDISC (virtual) trainings, the collaboration with CDISC (country) teams and many more.

- The call for abstracts will open 9 Oct 2020. Check out the CDISC website and follow CDISC and EJC team members on social media to get all latest updates on this upcoming event.
- Final submission deadline is set for 8 Jan 2021.  We encourage you to share your expertise by submitting an abstract. Don't forget... Sharing Is Caring!

Are you interested in joining the CDISC EJC team?
We are always looking for enthusiastic industry talents from Pharma, CRO, Academia, Technology, or Regulatory to strengthen our diverse team.
Stay tuned for an official CDISC announcement soon.
Don't hesitate to contact us in the meantime.

Linked In Post
cdisc eu interchange 2021 (EJC article)
Real World Evidence

How does SAS support our customers?
Overcome challenges

DATA STANDARDIZATION

BIAS
FIT FOR PURPOSE
DATA
TRANSPARENCY
GOVERNANCE
REPRODUCIBILITY
SAS® Health

SAS® Health Solutions

SAS® Life Science Analytics Framework
**SAS® Cohort Builder**
SAS® Episode Builder
**SAS® Data Mapper**
SAS® Visual Investigator

SAS® Health
Analytic Insight Modules - AIMS

Payer
Provider
Public Health
Life Sciences
(App Store)

SAS® Analytics
Manage the complete Analytical Life Cycle for Continuous Innovation

SAS® Health – Managing your Data Sources
# SAS® Health – Data Sources insights

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**Distribution Metrics**

**Distribution By Gender**

**Distribution By Ethnicity**

**Distribution By Race**

**Distribution By Age Group**
SAS® Health – Collaboration across departments and user Profiles
SAS® Health – Building Cohorts in minutes/hours instead of days/weeks
SAS® Health – Analysis on Cohorts of interest
SAS® Health – Analysis on Cohorts of interest
SAS® Health – Meet Regulatory Requirements
Submit Code and Logs
SAS® Health – OPEN platform
Any Questions?

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Thank you!