SVMPHARMA
Real World Evidence

Generating the Outcomes that Matter

REAL WORLD EVIDENCE (RWE)

FROM CONCEPT TO ACTION: A TIMELINE

Real World Evidence (RWE) is clinical data collected outside of conventional randomised controlled trials (RCTs). Today you will encounter the term RWE wherever you look in the pharmaceutical industry. However, we only have to go back a few years to see when this was not the case.

RWE is an example of a rapidly growing phenomenon and here we explore its rising influence, highlighting the key milestones on its journey into prominence.

The origins of the definition of Real World Evidence can be traced back to 2007, when the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) assembled a task force with the purpose of defining and creating a framework for real-world data within the pharmaceutical industry. Read More

Although real-world data would not come to the forefront for many more years, this report lay the foundations which have remained unchanged. As you will see, over the last few years RWE has caught the imagination and become increasingly influential.

David Haslam, the chairman of the **National Institute for Health and Care Excellence (NICE)** gives a presentation titled 'From promise to reality: how is real world evidence shaping the future of healthcare'

Feb 2014

"Evidence used in guidance is based on RCTs that exclude confounding risks and conditions"
This presentation gave the initial hints as to NICE's vision for RWE and since this moment there has been a rapidly growing role for RWE within NICE. Read More

The €16.3 million (£12m) **Innovative Medicines Initiative (IMI) GETREAL** project is officially launched with the aim of incorporating RWE in drug development and decision making.

Mar 2014

"GETREAL is in a unique position to improve the efficiency of R&D and the decision-making process"
This substantial investment in GETREAL was indicative of the importance and value placed on RWE by multiple stakeholders. Read More

The **European Medicines Agency (EMA)** launches the Adaptive Pathways pilot project, which is the initial step of a an overhaul of the existing drug development, licensing, and market authorisation process.

Mar 2014

"…moving away from exclusively using RCTs to instead using the entire toolbox of evidence generation"
This shows clear action and forward momentum with this RWE-focused multi-stakeholder initiative. Read More

Alexia Tonnel (**NICE Director of Evidence Resources**) speaks about RWE at the Financial Times (FT) Digital Health Conference

Jul 2015

"Real world data will have a role in future appraisals"
This makes it clear that NICE will evaluate RWE data submitted as part of their decision making process. Read More

The NHS proposes a requirement for RWE data as part of combined **Cancer Drugs Fund (CDF)** and NICE appraisal process for cancer drugs.

Jul 2015

"…the drug would be given conditional approval by NICE…whilst further evidence from real world use was collected…"
These proposals outline a new policy that could make RWE data collection essential in many instances. Read More

NICE makes a conditional recommendation for rare disease drug Vimizim but dependent on RWE data collection.

Sep 2015

"…generate evidence…through research and collection of 'real-world' data directly relevant to patients in the UK"
This is the first time NICE has explicitly called for RWE within their recommendations and shows their plans for RWE widening to non-cancer drugs. Read More

2016 looks set to be a big year for Real World Evidence

Have you made your plans?

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