International Journal Of

Recent Scientific Research

ISSN: 0976-3031
Volume: 7(6) June -2016

INFLUENCE OF REAL WORLD DATA IN THE PHARMACEUTICAL INDUSTRY

Manu Somanath., Sakshi Mittal., Rituraj Mohanty., Arun Gowda., Anand Patil and Behsad Zomorodi

THE OFFICIAL PUBLICATION OF
INTERNATIONAL JOURNAL OF RECENT SCIENTIFIC RESEARCH (IJRSR)
http://www.recentscientific.com/ recentscientific@gmail.com

ISSN: 0976-3031

Available Online at http://www.recentscientific.com

International Journal of Recent Scientific Research
Vol. 7, Issue, 6, pp. 12013-12014, June, 2016

International Journal of Recent Scientific Research

Research Article

INFLUENCE OF REAL WORLD DATA IN THE PHARMACEUTICAL INDUSTRY

Manu Somanath[1]., Sakshi Mittal[2]., Rituraj Mohanty[3]., Arun Gowda[4]., Anand Patil[5] and Behsad Zomorodi[6]

Focus Scientific Research Centre (FSRC), part of phamax Analytic Resources Private Limited, #19 KMJ Ascend, 1stCross, 17th C Main, 5thBlock, Koramangala, Bangalore, Karnataka, India – 560095

ARTICLE INFO

Article History:

Received 05th March, 2016
Received in revised form 08th April, 2016
Accepted 10th May, 2016
Published online 28st June, 2016

Key Words:

Real world evidence, Real world data, Registries, Healthcare, Payers, Pharma

ABSTRACT

Real-world evidence (RWE) research is essential for biopharmaceutical product development and commercialization. The pharmaceutical industry essentially depends on the information on a product's real-world effectiveness and safety data. This information impacts the ensuing reimbursement and utilization of new products. Regulators, public and private payers, and prescribers, are all keen to know the impact of a new product in a real-world setting. The viewpoint for RWE generation is promising, with the potential to improve health outcomes and cost-effectiveness of new health technologies. The demand for RWE is increasing and is unlikely to subside as health care decision-makers become gradually aware of what it offers

INTRODUCTION

Real-world data (RWD) is relevant to biopharmaceutical sponsors, providers, payers and regulators for insights that can increase quality, push down costs and improve patient safety. RWE data depicts the performance of a product in a widespread and more representative population in the longer run, unlike clinical trial data [1]. RWE data also makes comparisons and evaluates outcomes that are not part of a clinical trial. The pharmaceutical industry is already engaging patients alongside prescribers and payers because healthcare is now focused more on patient outcomes [2].

Approach

Healthcare decision-makers are becoming increasingly aware of the massive potential of RWE research, hence the growing demands. Payers today demand the validation of a product's real-world clinical value and cost-effectiveness to determine an optimal formulary, due to the concerns about a product's safety and cost implications when it becomes widely prescribed [1].

New pricing strategies are determined now based as per real-world evidence studies and they are more specifically generated as perthe therapeutic value for patients and the health outcome benefits for health systems and risk-bearers. RWE also provides the support and confidence needed to undertake value-based contracting, deploy patient services, run the emerging new patient care management businesses that best manage care processes and optimize resource utilization [3].

Data about real-world patient experience helps the adaptation of new therapies and technologies into everyday clinical practice. It also improves the quality and delivery of medical care, reduces overall costs and improves outcomes. Essentially, these fill the knowledge gap between clinical trials and actual clinical practice [1].

The US Food and Drug Administration recently tightened its demand on drug developers to conduct more certain, effective, and timely post marketing studies. Although most of these studies fall under mandatory post marketing commitments (PMCs), some voluntary studies are starting to gain popularity as ways to conduct outcomes research. Pharmaceutical companies are now particularly adding patient registries to their post marketing toolkits [4].

RWE is of two types

- **Primary data** – It is collected specifically for research purposes. Primary data are generally obtained from study-specific case report forms, electronic, medical and health records, and/or clinical outcomes assessments. These data are collected in interventional phase IV studies and in non-interventional prospective observational studies, patient registries and health surveys.

Corresponding author: **Manu Somanath*
Focus Scientific Research Centre (FSRC), part of phamax Analytic Resources Private Limited, #19 KMJ Ascend, 1stCross, 17th C Main, 5thBlock, Koramangala, Bangalore, Karnataka, India – 560095

- **Secondary data** – It is collected for other purposes. Secondary data are often obtained from clinical chart reviews, registries and/or insurance claims databases, and are used in retrospective database studies or as an input to prospective study design or hybrid studies [1, 6].

RWD is becoming extensive and has reached areas that were unexplored before. National and large global private payers are investing more into their data infrastructures for more focused research into the total cost of care and the therapeutic context of the drug regimen. Pharmaceutical companies are now obliged to build the capability to respond.

Payers and regulators are rapidly accepting systematic reviews of RWD on in-market pharma products in large developed markets to confirm product safety and comparative effectiveness versus incumbent products. The more developed healthcare systems are using RWD to determine product cost-effectiveness, pricing and its overall value.

RWD will influence pharmaceutical companies in four primary areas:

- **Characterize diseases and patient populations:** Understand epidemiology trends, treatment patterns, patient adherence and disease management opportunities
- **Develop products and therapies:** Assess use of current competitive in-market products, design inclusion/exclusion criteria for clinical trials, perform predictive models on virtual trials, identify patients for recruitment, and identify unintended uses/indications (i.e., phase IV leads).
- **Assess products and therapies in use:** Observe drug safety, compare product effectiveness, assess health economics, and design pay-for-performance criteria.
- **Target products and services:** Identify underserved patient populations, high-cost areas for risk-based product pricing, subpopulations with superior product response, and track message effectiveness through prescribing behaviour [5].

CONCLUSION

A lot of thought will go into the ways that real world data can be collected in the future. There are modern methods using existing healthcare databases and registries. But, companies are seeking newer, innovative methods as well, including predictive modelling techniques. Real world evidence is here to stay and characterizes an unparalleled opportunity to adopt Big Data in all aspects of healthcare and change the ways in which it functions.

Acknowledgment

The authors would like to acknowledge the efforts of Nidish Narayanan, Senior Editor at phamax and AntoVijaykanth, Clinical Research Associate at focus scientific research center (FSRC) for supporting us to develop this article.

References

1. Real-World Evidence Studies [Internet]. Appliedclinicaltrialsonline.com. 2016 [cited 24 May 2016]. Available from: http://www.appliedclinicaltrialsonline.com/print/301835?page=full
2. Get Real! The Rise of Observational Data In Healthcare - PMLiVE [Internet]. Pmlive.com. 2016 [cited 24 May 2016]. Available from: http://www.pmlive.com/pharma_news/get_real!_the_rise_of_observational_data_in_healthcare_705710
3. The Reality Behind Real-World Data and Real-World Evidence | Thought leadership and innovation for the Pharmaceutical Industry - EyeforPharma [Internet]. Social.eyeforpharma.com. 2016 [cited 24 May 2016]. Available from: http://social.eyeforpharma.com/column/reality-behind-real-world-data-and-real-world-evidence
4. Patient Registries: Observations of the Real World – Pharma VOICE [Internet]. Pharma VOICE. 2016 [cited 24 May 2016]. Available from: http://www.pharmavoice.com/article/71/
5. Cattell J, Groves P, Hughes B, Savas S. How can pharmacos take advantage of the real world data opportunity in healthcare? [Internet]. 1st ed. 2016 [cited 24 May 2016]. Available from: https://www.google.co.in/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwiU6K23tvLMAhWLKo8KHRQ6CRYQFggcMAA&url=https%3A%2F%2Fwww.mckinsey.com%2F~%2Fmedia%2Fmckinsey%2Fdotcom%2Fclient_service%2FPharma%2520and%2520Medical%2520Products%2FPMP%2520NEW%2FPDFs%2FPharma%2520%2520RWD%2520opportunity%2520October%25202011.ashx&usg=AFQjCNGMe7OylApQyrbhEyfUYynVsXJMA&sig2=7FAbMVf18uSaZ4Eyo1LfZQ&bvm=bv.122676328,d.c2I
6. Using Real-World Data for Outcomes Research and Comparative Effectiveness Studies [Internet]. Drug Discovery & Development. 2014 [cited 2 June 2016]. Available from: http://www.dddmag.com/article/2014/11/using-real-world-data-outcomes-research-and-comparative-effectiveness-studies

****

How to cite this article:

Manu Somanath *et al*.2016, Influence of Real World Data In The Pharmaceutical Industry. *Int J Recent Sci Res.* 7(6), pp. 12013-12014.

TSSN 0976-3031