ROLE OF REAL-WORLD EVIDENCE IN HEALTHCARE DECISION MAKING

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Hospital and Health Management

by

Dr. Astha Sharma

Under the Supervision and Guidance of

Dr. Sunita Nigam

2021

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled **Role of Real-World Evidence in Healthcare Decision Making** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Name of Student:
Dr. Astha Sharma

Date:
July 02, 2021

HEALTHARK

Date: 14th June, 2021

Whom So Ever It May Concern

This is to certify that **Ms. Astha Sharma** worked with Healthark Insights Wellness Solutions LLP as an Intern Consultant from 25th March 2020 to 25th June 2020. During her internship she conducted market assessment involving secondary research and basic excel modelling across Latin American, Russian and Saudi Arabian markets. She supported her seniors in preparing client deliverables in form of PowerPoint presentation and excel formats.

She has always shown responsible attitude towards the tasks assigned to her and completed them within time with utmost sincerity. She has been a good team player and was supportive to her other colleagues in the organization.

We wish her a bright future and success in her future endeavours.

Purav Gandhi

Sincerely,
Dr. Purav Gandhi
Founder & CEO
Healthark Insights

CERTIFICATE

This is to certify that dissertation titled **Role of Real-World Evidence in Healthcare Decision Making** is a record of the research work undertaken by **Dr. Astha Sharma** in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management) from The IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific and analytical.

Dr. Sunita Nigam

Faculty Guide
IIHMR University, Jaipur

Date

Dr. Dhirendra Kumar

School Dean
IIHMR University, Jaipur

Date

ABSTRACT

TITLE: Role of Real-World Evidence in Healthcare Decision Making.

STUDY OBJECTIVES:

- To define Real-World Evidence and Real-World Data.
- To identify the strengths and weaknesses of Real-World Evidence and conduct a SWOT analysis.
- To determine the role of Real-World Evidence in Healthcare decision making.
- To understand the role of Real-World Evidence in context of COVID 19.

METHODOLODY:

Study design: Descriptive study

Duration of study: March 22 – June 18

Study area: India and US

Data Collection Procedure: Secondary data collected based on available literature on internet.

IMPLICATIONS:

My research will help in:

Understanding RWE and RWD and then identifying major challenges in conducting RWE studies. Conducting a SWOT analysis to identify future scope of RWE studies and then conducting a secondary research to identify use of RWE in healthcare decision making. Finally, understanding the association of RWE with COVID 19 which will help in conducting future research and understanding the value of RWE so that it can be used in an efficient manner and act as a miracle for improving health conditions of patients, drug discovery, enhancing treatment protocols and much more.

ACKNOWLEDGEMENT

I am very grateful to have so many supportive people around me whom I would like to thank and wants to mention here.

I am extremely thankful to my IIHMR Guide Dr. Sunita Nigam. During these hard times, when I was in severe condition due to COVID 19, and was on rest for more than a month, her constant guidance and motivation kept me going.

I also owe special thanks to CEO, Healthark Insights, Dr. Purav Gandhi for constantly supporting and guiding me, and most of all, introducing me to the Healthark family.

I also express sincere gratitude to my Manager, Ms. Ritu Baliya. She always explained me everything with utmost patience, and never gave up on me. I always looked up to her, whenever I faced any problem.

How can I miss my world: my parents!! During these tough times, when I was suffering from severe symptoms of COVID 19, I saw them suffer even more. My parents Dr. Vinod Sharma and Mrs. Swarnlata Sharma are my pillars, my strength. I owe them everything.

I thank God for keeping me surrounded by such wonderful people.

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LIST OF FIGURES

LIST OF ABBREVIATIONS

- **CBER -** Center for Biologics Evaluation and Research
- **CDRH -** Center for Devices and Radiological Health
- **CIHS -** Center for Integrated Health Solutions
- **CMS -** Center for Medicare & Medicaid Services
- **CRO –** Clinical Research Organization
- **EDA –** Eating Disorders Association
- **EDC -** Electronic Data Capture
- **EHRs -** Electronic Health Records
- **FDA –** Food & Drug Administration
- **HHS -** Health and Human Services
- **IDE -** Investigational Device Exemption
- **IND -** Investigational New Drug Application
- **IRB –** Institutional Review Board
- **LTCH -** Long-Term Care Hospitals
- **OPC-** Objective Performance Criteria
- **PBHCI -** Primary Care Funding and Behavioural Health Care Integration
- **PG -** Performance Goals
- **RCT -** Randomized Controlled Trials
- **RWD –** Real World Data
- **RWE –** Real World Evidence
- **SAMHSA -** Substance Abuse and Mental Health Services Administration
- **SMI -** Severe Mental Illness
- **TAVR -** Transcatheter Aortic Valve Replacement

Title: Role of Real-World Evidence in Healthcare Decision Making

OVERVIEW

Research Question

What is the role of Real-World Evidence in Healthcare Decision Making?

Objectives

- To define Real-World evidence and Real-World data.
- To identify the strengths and weaknesses of Real-World evidence and conduct a SWOT analysis.
- To determine the role of Real-World Evidence in Healthcare decision making.
- To understand the role of Real-World Evidence in context of COVID 19.

Methodology

Study type: Descriptive study

Study area: India and US

Duration of study: March 22 – June 18

Data Collection Procedure: Secondary data collected based on available literature on internet (last 5 years data)

CHAPTER ONE: INTRODUCTION

1.1 Real-World Data

It is the data consisting of patient health status or the delivery of health care routine collected from multiple sources and health records.

Sources:

- Medical records and EHRs
- Claims bills
- Product and disease registries
- Data generated by patients
- Data gathered from other sources that can inform on health status, such as mobile devices
- Prescription records
- Surveys (patients/providers)

1.2 Real-World Evidence

Real-World evidence is the clinical evidence regarding the usage and potential benefits, or risks of a medical product derived from analysis of RWD.

RWE can be generated by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies.

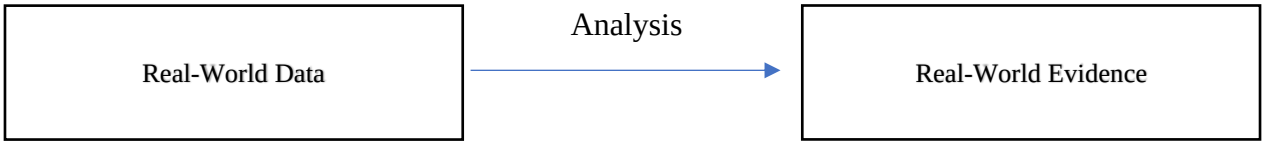


Fig 1.1: Relation between Real-World Data and Real-World Evidence

1.3 Uses of RWD

- RWD helps us to know about drug/device effectiveness, for example:

a) outcomes not previously collected in (RCTs) could be determined (health outcomes reported by patients, standards of living, and health-related symptoms, etc.)

b) comparing multiple alternative interventions (e.g., existing and novel) or clinical strategies to provide the optimal treatment option.

c) Clinical, financial, and net benefits to patients after implementing insurance or billing policies or other health care programs.

d) use of resources for the economic evaluation of medical services.

- Estimate a profile of evolving risks and benefits of new interventions. This includes long-term (and rare) clinical benefit and harm dynamic critical safety signal detection and monitoring.
- See how a drug or device works in a variety of research populations that reflect the different makeup and typical care cohorts and the range and distribution of patients found in clinical practice. For example:

a) how the product is applied in a clinical setting;

b) to determine adherence in the treatment of the patient;

c) defining standards and guidelines of care

- When there is neither time nor opportunity to conduct RCT.
- Facilitation of further research and development and business development, including: generating hypotheses to specify new drug targets or potentially beneficial patient populations, and
- To facilitate drug relocation to inform corporate and portfolio development strategies, including mergers and acquisitions.

RWD is neither a panacea nor an alternative to RCT and may sooner or later continue as the 'gold standard' to prove safety and effectiveness. The growing use of RWD is expected to accelerate the improvement and confidence in the methodologies and regulatory sciences associated with the use of RWD in this regard.

CHAPTER 2: LITERATURE REVIEW

Study title	*Authors*	*Key Learnings*
The Expanding Role of Real-World Evidence Trials in Healthcare Decision Making	David C. Klonoff	• RWE will help in post-approval RCTs. • RWE is useful in generating hypothesis, comparative effectiveness, identify rare diseases better than RCTs. • Restriction in data sharing may occur due to various ethical and legal issues.
Real-World Evidence: Bridging Gaps in Evidence to Guide Payer Decisions	Melissa H. Roberts, Gary T. Ferguson	• RWE helps in providing evidence to support healthcare decision making in following areas: Comparative effectiveness, Safety reporting, Patient related outcomes, Healthcare resource utilization and cost. • RWE can generate additional information by analyzing RWD in following areas: Personalized medicine, Prescription patterns, Medication adherence and persistence.
Making Real-World Evidence More Useful for Decision Making	Sheldon Greenfield	• Following the given recommendations will help in making RWE useful in decision making: a. Publication of the study b. Complete transparency of the data, including full sharing of patient information. c. Confirmation of the findings from another data source d. Addressing the methodological criticism of a study after the publication publicly
The Role of Real-World Evidence in Supporting a Product's Value Story	Article by Covance: a Global CRO	• Sources of RWD: Pre- and post-hospitalized data, administrative claims, medical records, laboratory test records. • RWE in effective strategy formulation: identifying stakeholders, product development, best sources of RWD, events causing re-evaluation of strategy.

Role of Real-World Evidence for coverage decisions: opportunities and challenges	Grace Hampson, Adrian Towse, William B Dreitlein, Chris Hemshall, & Steven D Pearson	• RWE is used in the following areas: drug expansion, regulatory compliance decision making, post-approval surveillance of safety signals, making initial HTA assessments and payer insurance decisions, and solutions procurement. • Challenges in utilising RWE: Bias and confounding, insufficient data, data collection, access to data, a lack of widely accepted implementation of quality management, a lack of investigating officer expertise, and outdated evidential hierarchies are all issues that must be addressed. • Opportunities: Raise the effectiveness and authenticity of RWE research; Establish appropriate organisational preparations that specify how much information is shared; and Establish appropriate organisational preparations that specify how much information is shared; Additional RWE generation and utilisation opportunities:- Evidence-based medicine in real time; Patient evaluation in real time; Improved access to novel therapies
Combatting COVID 19 with Real World Evidence	Jennifer B. Christian, Matthew W. Reynolds	• RWE act as an essential element in deciding Coronavirus behavior in different populations. This will help clinicians to adapt to the treatment plans and reduce the treatment complications. • RWE help in understanding long term symptomology in patients. • Assessing safety and effectiveness of Covid vaccine.
A Real-World Evidence Framework for Optimizing Dosing in All Patients with COVID 19	Richard W. Peck, Daniel Weiner, Jack Cook, J. Robert Powell	• Global heads of pharmaceutical companies and organizations interested in becoming trusted third parties, key regulatory and academic opinion leaders should meet and discuss the model for sharing data on deidentified patients. • They should also discuss about the key RWD on it's collection and implementation. • They should agree upon: how analysis and publishing of RWD should be done. • A mechanism should be developed for rapid, initial and temporary approval of new COVID 19 treatment.

CHAPTER 3: EVOLUTION OF REAL-WORLD EVIDENCE IN US

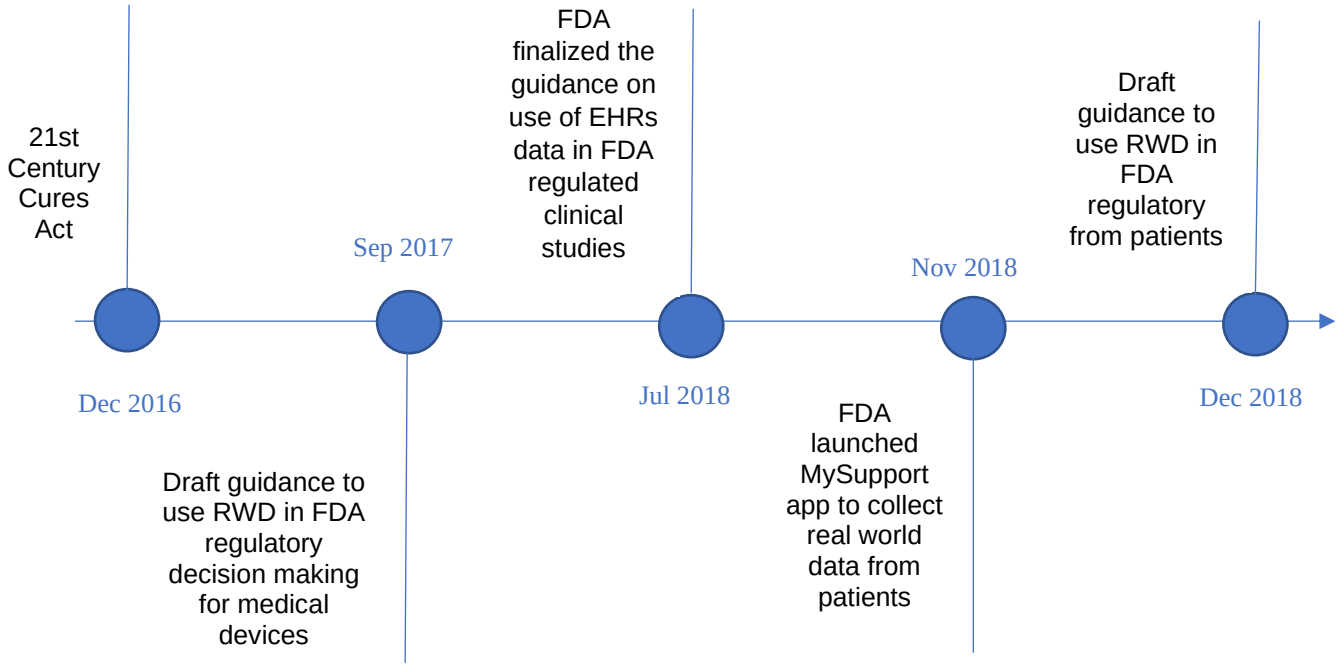


Fig3.1: FDAs Real-World Evidence Guidance and Framework for Drug Regulation

3.1 21st Century Cures Act (Dec 2016)

US Congress passed and President Obama signed the 21st Century Cures Act in December 2016, a comprehensive bill that includes key elements in the treatment of mental health and addiction. The bill will approve $1billion over the next two years and re-approve several federal mental health grant programs to address the opioid crisis. It also includes medical informatics provisions for interoperability, data sharing / exchange and electronic medical records.

Here are some selected highlights of provisions in the bill:

Mental Health

The bill does not allocate new federal funds to the nation's public mental health system, but it does make significant policy changes:
The Substance Abuse and Mental Health Services Administration (SAMHSA) has been reorganized with a focus on servicing people with severe mental illness. This includes the US Department of Health and Human Services (HHS) Assistant Secretary of State for Mental Health and Material Use, increasing the importance of behavioral health and treatment.

- Approves a serious mental illness coordinating committee between new departments, including other enforcement agencies such as the Veterans Administration and the US Department of Justice.
- It promotes the integration of behavioural health across health systems:
  a. The Medicaid change allows you to pay on the same day, in the same facility, for the same patient, for mental health and primary care (sometimes called "same-day billing").
  b. Shift the focus of the Primary Care Funding and Behavioural Health Care Integration (PBHCI) program to a state-wide implementation.
  c. It is permanently installed within the Center for Integrated Health Solutions (CIHS) under federal law and is now managed by the National Commission for Behavioural Health. Netsmart is an Associate of the National Council and provides the National Council's Care Transition Network for People with Severe Mental Illness (SMI) with treatment coordination and management techniques.
- Stay up-to-date on a range of key federal mental health initiatives, including a dedicated homeless effort and the National Suicide Prevention Lifeline Program.

Substance Use Treatment Funds

The most important behavioral health development in 21st century treatment is the dramatic increase in funding for drug treatment:

- Approves $ 1 billion ($ 500 million annually in fiscal years 2018 and 2019) to allocate addiction services to substance abuse agencies for two years a week.
- Specifies that these additional funds will be used to extend opioid-specific therapies, including drug therapies (Eg: Methadone, Vivitrol, Suboxone and Buprenorphine).

Home Health

An electronic visit confirmation system is required for Medicaid home and personal care services. It primarily directs Medicaid and home care services to use the electronic home visit confirmation system for personal care services (although this policy requires providers statewide to apply using a single system does not exist). Percentages were down slightly in states that did not require the personal care service system on January 1, 2019 and did not require home care services on January 1, 2023.

Long-Term Care

This allows for the deregulation of long-term care hospitals (LTCHs) by allowing LTCHs to qualify for a "temporary construction" exception to the termination of existing bed extension laws. This is offset by a reduction in external payments for LTCH, which requires a higher threshold for LTCH issues to qualify for external payments.

Health Information Technology

21st Century Cures modifies the Meaningful Use Program in three important ways:

- Interoperability: EHR to develop and support voluntary and mutually agreed model frameworks for the secure exchange of medical information to facilitate connections between networks by promoting interoperability with EMRs by:

❖ Hiring digital healthcare providers to facilitate exchange.

❖ Ask HHS to review standards developed in the private sector.

❖ HHS must issue regulations that enforce these regulations. Until these details are identified, their impact on existing patient recruitment combinations is unknown.

- Information Blocking: Prevents legitimate sharing of patient data between different EHR systems by establishing the authority to investigate blocking requests and impose sanctions for detected behaviour.
- Confidentiality of Electronic Addiction Treatment Medical Records: Within one year of completing the updated rules for the confidentiality of health records related to alcohol and substance abuse, the HHS Secretary will summon stakeholders to treat the patient, which affects their health. and determine the impact of regulation on information.

Provisions for RWE

- This Act had a provision requiring FDA to develop a guidelines for analysing real-world evidence in the context of drug regulation in order to support approvals of new indications for current medications, as well as to support or complete post-approval research requirements.
- The instructions to use RWE within the realm of drugs was significantly attention-grabbing because authority had issued a draft policy on the utilization of RWE within the context of medical devices, however had usually remained silent on applying RWE to pharmaceutical and biologic regulative concerns.
- It defined RWE as - information on a drug's use, as well as its possible advantages and hazards, collected from sources other than randomised clinical studies.
- The provisions require that FDA develops guidelines for the RWE programme in collaboration with key drug industry partners, and to implement that framework within two years of the Cures Act's passage date, with the goal of issuing advice to support additional indications.
- For medication using real world evidence, instead of additional long and costly clinical trials presently demanded by the FDA.
- The section specifically says that the Cures Act's new RWE requirements do not limit FDA's use of RWE for various purposes.

3.2 FDA RWE Guidance for Medical Devices 2017

- In June 2017, the FDA authorised a replacement indication for a medical device without requiring any further clinical trials. This clearance signalled the start of a new era in drug and medical device regulation, as well as the widespread use of Real-World Evidence. Instead of relying on sporadic clinical trials, the FDA approved the medicine based on records of real patient use.
- On August 31, 2017, the FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) issued a guidance document outlining the circumstances under which they may accept RWE in support of regulatory decisions involving medical devices. The directive was issued to clarify how RWE is commonly known to support regulatory decisions.

3.3 FDA guidance for EHR data in clinical investigations for industry (Aug 2018)

A guidance was issued to help sponsors, clinical investigations, CROs, institutional review boards (IRBs) and different interested parties on use of EHR knowledge in government agency regulated clinical investigations. The guidance was specifically restricted to the employment of EHR knowledge in:

- Prospective clinical investigations of human medication and biological product, medical devices, and combination product, as well as clinical investigations conducted in clinical observe settings.
- Foreign clinical studies not conducted beneath associate degree investigational new drug application (IND) or investigational device exemption (IDE) is a document filed to the FDA in support of a request for marketing authorisation of a medical product.

The goal of the guidance is to modernize and contour clinical investigations through the employment of EHR knowledge and therefore the inclusion of planet knowledge in clinical investigations. additionally, the steerage conjointly encourage sponsors and health care organizations to figure with EHR and Electronic knowledge Capture (EDC) system vendors to any advance the ability and integration of EHR and EDC systems.

3.4 FDA launched new digital tool to help capture Real World Data from patients and help inform regulatory decision making (Nov 2018)

My Studies app, a brand-new mobile technology that enables patients' mobile devices to collect real-world evidence. RWD can be obtained from a variety of sources, including electronic health records, claims and billing operations, product and illness registries, patient-generated data, data collected in home-use settings, and data gathered from alternative sources, such as mobile devices.

3.5 FDA Framework of RWE for Drugs and Biological Products (Dec 2018)

- On December 7, 2018, the FDA published the “framework for the FDA's real-world evidence programme” for drugs and biologics. Commissioner Gottlieb acknowledged the opportunities and challenges of using RWD and RWE in healthcare decision-making in a statement announcing the Framework, noting that providing this information is a “top strategic priority for the FDA.”
- The FDA's RWE plan seeks to be diverse, featuring development activities, stakeholder involvement, and organizational operations to bring top leadership input into RWE evaluation, as well as promote shared studying and consistency in applying the framework and steering documents to assist investors interested in victimisation real-world data (RWD) to develop RWE to facilitate Agency regulatory decisions.
- The Act requires FDA to release a model for developing the RWE System that describes the references of RWE, gaps in information collection and processing, guidelines, and research methods for collecting and analysing RWE, and thus the key initiatives, remaining challenges, and potential pilot challenges that the RWE programme can recognise.

CHAPTER 4: SIGNIFICANCE OF RWE IN INDIAN HEALTHCARE SYSTEM

4.1 Real World Evidence Council

- Indian Society for Clinical Research (ISCR) launched the Real World Evidence Council, so that all the stakeholders utilise it for improving patient health outcomes.
- There are many advancements in clinical research around the world, with the aim of making all research results more efficient and predictable. One of these developments is the essential role that RWE (Real World Evidence) plays in the development, development, and commercialization stages of new drugs.
- Unlike in the past, where RWE data was primarily used before or at the time of product launch, RWE is now refined throughout the product lifecycle as trends change.
- RWE is being used effectively not only in the early stages of drug development, but also in regulatory decisions concerning safety, effectiveness, and health technology.
- RWE also makes it easier to conduct effective clinical studies by simplifying the three-step process and expediting regulatory approval and post-market safety monitoring.
- Clinical research professionals, clinical research-related organisations, and other major participants in clinical research, such as ECs and researchers, are aware of this critical factor and use it to improve patient outcomes. The Real-World Evidence Council has been established by ISCR.
- The main goal of this council is to raise RWE awareness and acceptance in India, particularly in the following areas:

a. Working with government policy makers, especially senior officials linked to ICMR, Ministry of Health, CDSCO, etc.
b. Assisting healthcare providers to collect, and analyze policy frameworks for RWE research in India.
c. Conducting unique training programmes for professionals and investigators on critical components of RWE research across the country.
d. Use Real data to improve patient outcomes.
e. To raise awareness of methodologies, results, and product lifecycle support.

4.2 Indian Healthcare System and RWE

RWE studies are valuable across the product lifecycle and can provide multiple benefits such as product development, providing evidence to support health outcomes, reduction in resource use, detection of untreated or undiagnosed patients, generating hypotheses for prospective trials, identification of suboptimal dosing, characterizing appropriate treatment subgroups, monitoring safety especially uncommon or rare adverse reactions.
Various sources from which RWE may be gathered include additional information collected during RCT. Using clinical opinion and processes, including existing clinical trials, large- scale field trials to evaluate drug efficacy or treatment, administrative data fees, electronic health records, and detailed health. Investigation information collected primarily for reimbursement. The interpretation and application of RWE research in developing countries such as India presents many challenges. The open-ended, blind, and non-randomized designs used in the RWE study question their relevance. India has lost a large amount of RWD and the number of registrations and information stored there is still lagging behind. In terms of population size, medical expenses are not subsidized by the government. As a result, RWD registers, databases, medical records and other sources have not yet been developed in the country.

However, the country is now starting to take small steps towards collecting RWE. The International Society for Pharmacy Economics and Outcomes-ISPOR India Branch has developed a draft guidance for PE in India. EP analysis assists decision makers in healthcare systems. A clinician, hospital manager, health insurer or government provides a means to optimize health care resources and evaluate the cost and outcomes of all available drugs.

Government of India recently launched SEHAT - Social Endeavour for Health and Telemedicine. It empowers rural people through the use of digital technology to provide access to information technology and other services in a variety of areas, providing diagnostic treatment, free medicines, etc. costs and insurance for treatment of critical diseases within the framework of the National Health Assurance Mission. The government is also conducting an 'e-health initiative' as part of the Digital India campaign. It aims to provide economical and efficient healthcare to all citizens. The program uses eKYC data from Aadhaar numbers to help people maintain health records. With a practical framework for realizing universal health care for the masses, India has made positive progress in reconciling many fragmented health care systems.

CHAPTER 5: SWOT ANALYSIS OF RWE

STRENGTHS

- RWE helps in creative and scientific innovations which leads to reduction in cost of medicines.
- Accessibility to high quality data is increased, leading to more comprehensive research with more reliability.
- Identifying drug effectiveness leads to improvement in health outcomes.
- Solves the ethical and legal considerations faced by RCTs during patient interventions.
- RWE plays a role in in effective strategy formulation: identifying stakeholders, product development, best sources of RWD, events causing re-evaluation of strategy.
- RWE act as an essential element in deciding Coronavirus behavior in different populations.
- Others: Drug development, regulatory approval decisions, post-approval safety signal monitoring, making initial HTA and payer coverage decisions.

WEAKNESSES

- Data is voluminous, it becomes difficult to filter the required data.
- Intervention factor is still missing.
- Reliance on RCT trials associated lack of an applicable substitute study design.
- Regulatory limits to direct patient interactions.
- Data sources – accessibility and completeness might be difficult.
- Study design might not be relevant to the question.
- Confounding factors might play a huge role in determining results.

OPPORTUNITIES

- Value chain management.
- Partnership in biotech firms and experts in market access and data generation.
- Scope for future Research & Development.
- Offering new standard of care.
- Increase the quality and credibility of RWE studies.
- Establish effective governance arrangements that clarify how much data can be shared.
- Focus RWE efforts on the development of pragmatic clinical trials.

THREATS

- Payers security and aversion to high prices.
- Barriers to access set up by payers.
- Small patient population for rare diseases.
- Varying price regulations on medicines across US and European markets.
- Diversity in HTA (Health Technology Assessment) agencies value frameworks.
- Lack of comparators.
- Potential biases and concerns about external validity, i.e., generalizability of the results.

CHAPTER 6: ROLE OF RWE IN HEALTHCARE DECISION MAKING

6.1 Product Development

RWE is used in all the stages of Product lifecycle:

- Initiation stage
- Growth stage
- Maturity stage
- Decline stage

RWE Journey occurs from Planning till Communication in Product Development:

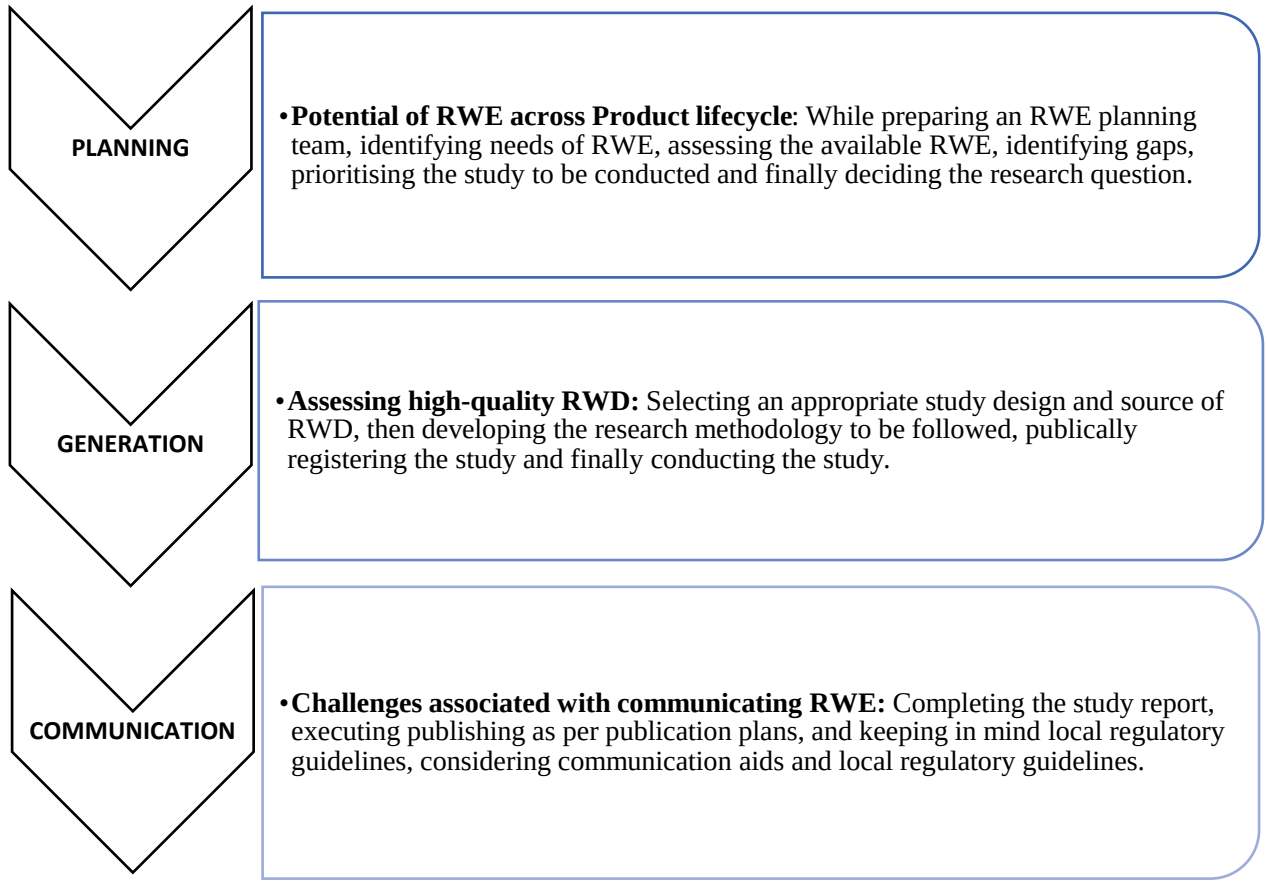


Fig 6.1: Role of RWE in Product Development

The study will help in:

a. Licensing of the product: RWE study will provide string evidence to support efficacy of the product i.e medical device, drug, or therapy.
b. Trials of the product: Trials are conducted before launching any product into the market. We cannot always use RCT studies for the same due to ethical and legal considerations. This makes RWE as a gold standard for conducting studies for product launching.

6.2 Providing Evidence to Support Health Outcomes

As the population is increasing, the age is advancing and as the cases of rare diseases and chronic diseases are increasing, there is an increase in studies conducted using RWE. These studies have led to improvement in health outcomes and will play a significant role in the coming future.

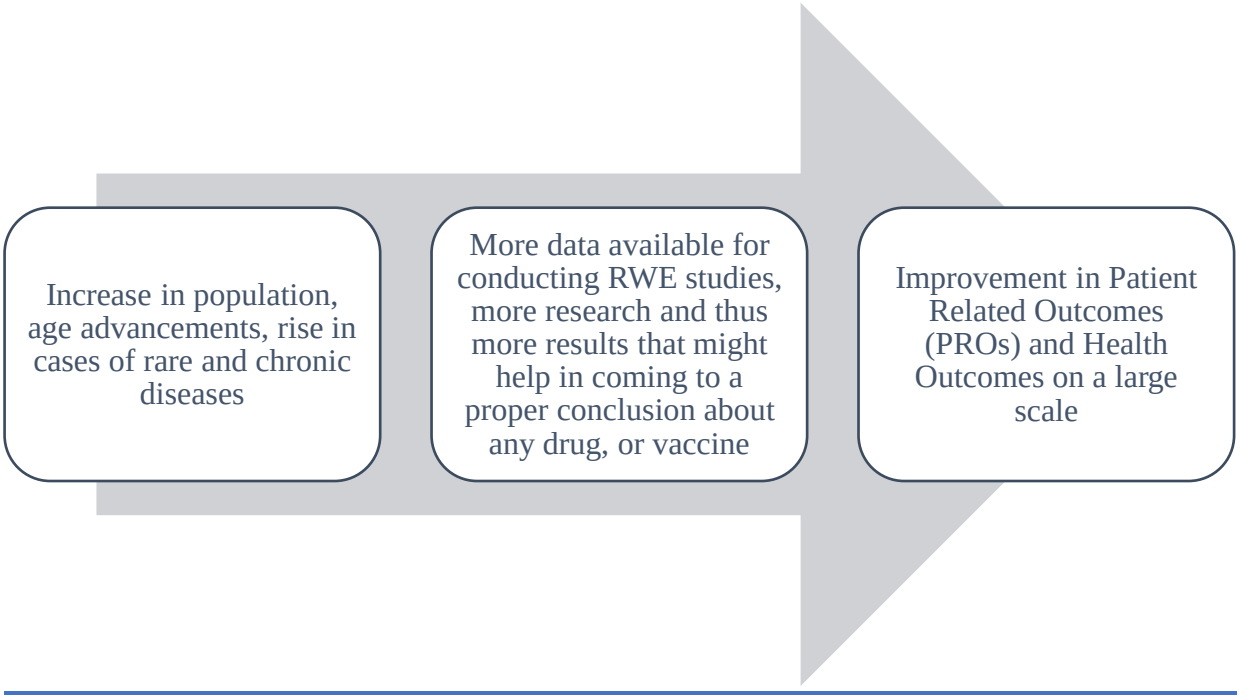


Fig 6.2: Role of RWE in providing evidence to support health outcomes

6.3 Changing the Treatment Protocols

RWE studies determine whether a particular treatment is effective, a particular drug is more effective than the other one or a particular medical device controls the condition better. This helps in changing the treatment protocol at the right time, so that life can be saved.

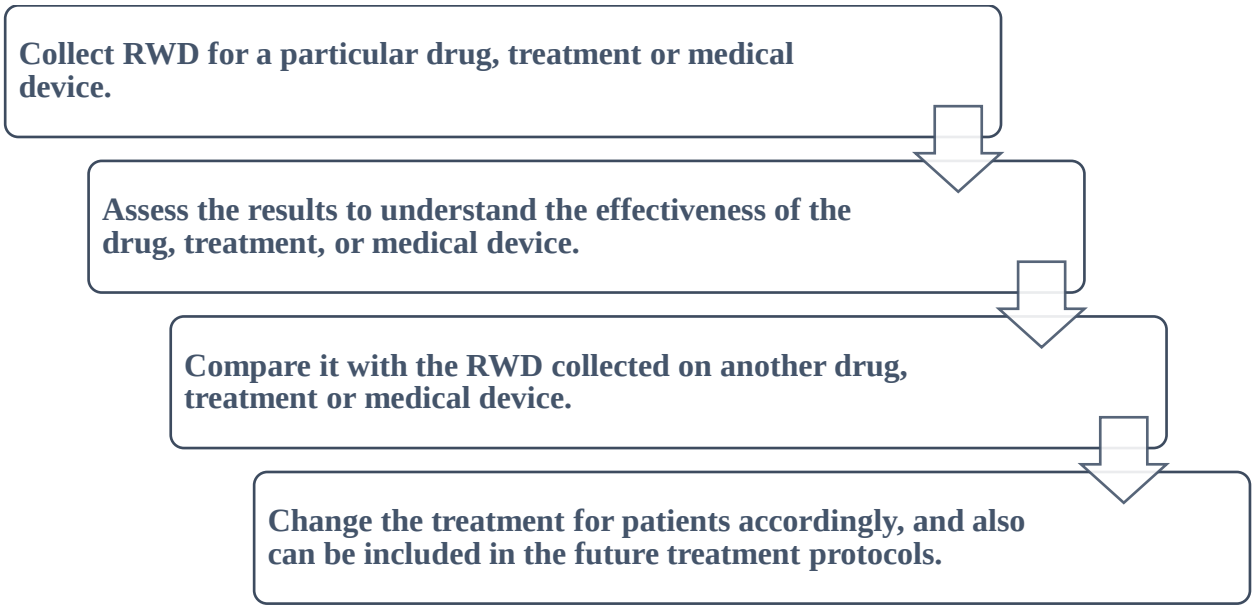


Fig 6.3: RWE in changing the treatment protocols

6.4 Healthcare Resource Utilization

RWE studies uses patient data which would have been otherwise of no use. These data are removed from the database after a few years, and there remains no evidence for studies. We can use this data for studies and determine future treatment protocols. This will help in proper resource utilization.

Fig 6.4: RWE in Healthcare Resource Utilization

6.5 Generating Hypothesis for Trials

We can conduct studies using RWD to reach to a particular hypothesis which can be used to conduct further trials and interventions based on it.

For eg: In context of COVID 19:

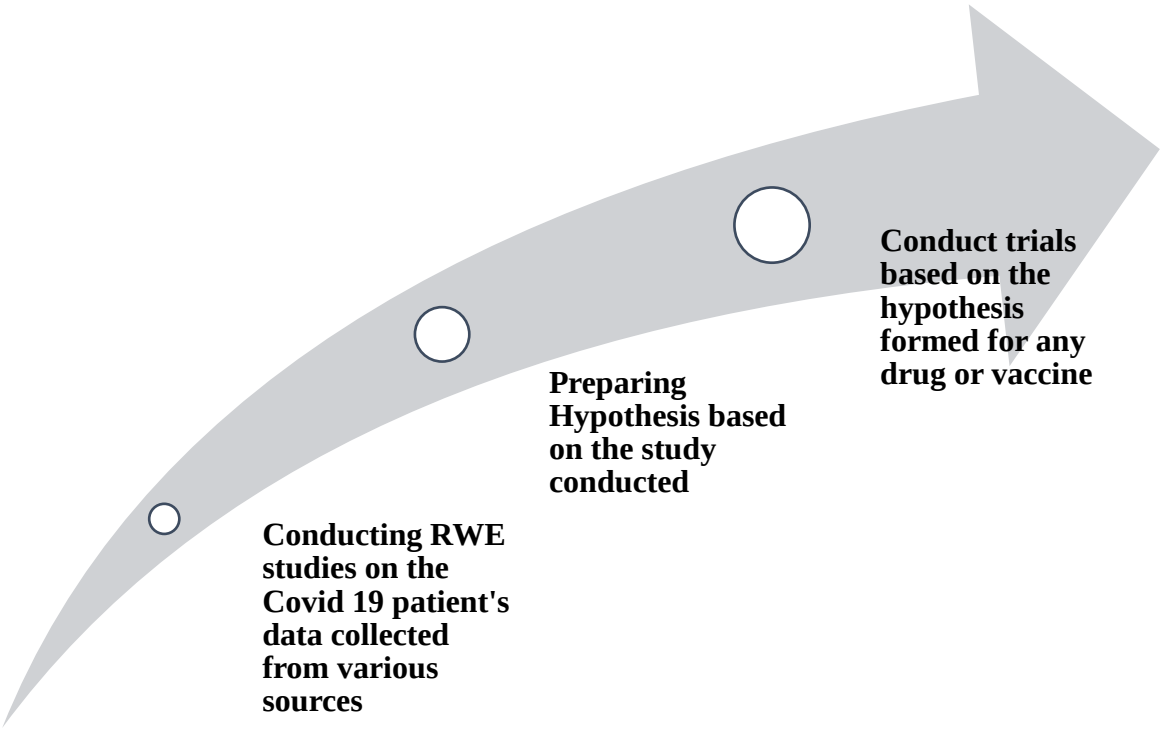


Fig 6.5: RWE in generating hypothesis for trials

6.6 To test Safety and Effectiveness of any drug, treatment, or medical device

Gather information on the safety and efficacy of all patients with specific devices implanted at participating institutions. The registry also uses a validated matching algorithm to match managed care claims with the registry as an additional dataset for capturing persistent results. Investigations using the registry's data collection and analysis infrastructure begin with an approved IDE application, or it may not have happened as part of your normal medical care. The FDA hopes that RWD will provide sufficient quality to address important safety concerns and potentially support label changes and other regulatory decisions on this device.

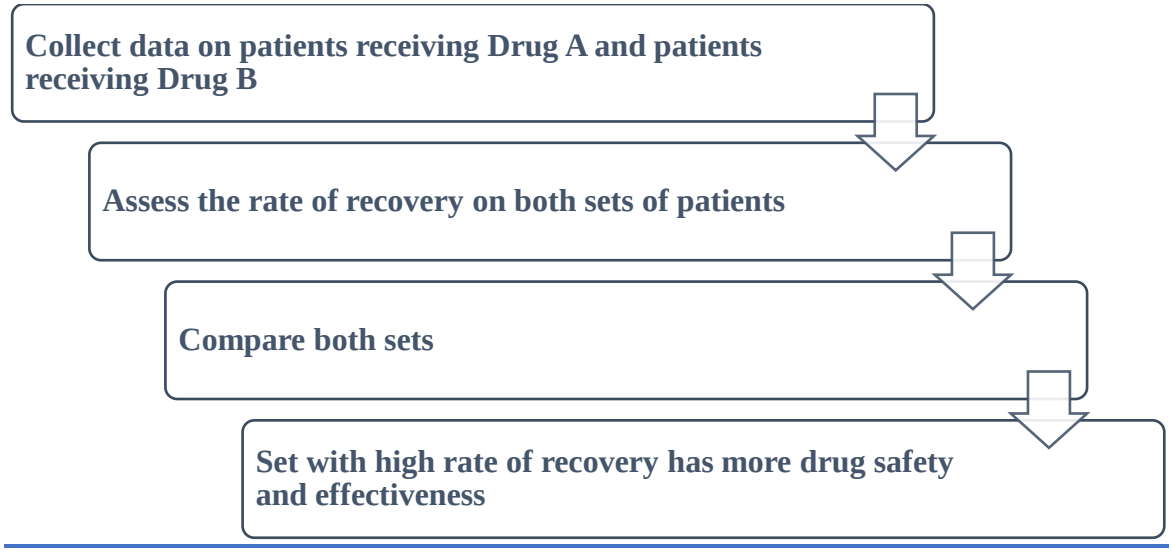


Fig 6.6: RWE in testing safety and effectiveness of any drug, treatment, or medical device

6.7 Acting as a Control Group

RWE can be used as a synthetic control group while conducting Randomized Controlled Trials when sufficient data or the required data is not available for the study. It will reduce the chances of bias as well as significantly decrease the ethical and legal issues.

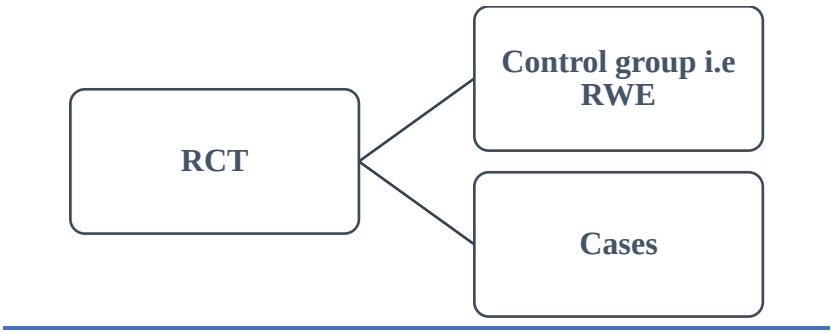


Fig 6.7: RWE as a control group

6.8 Measuring Objective Performance Criteria (OPC) and Performance Goals (PG)

RWD and RWE can be used to measure OPCs and PGs of a particular pharmaceutical or health organization. Study can be conducted to look for a particular drug, medical device, or a treatment to check whether the results are better than the previous time for performance assessment.

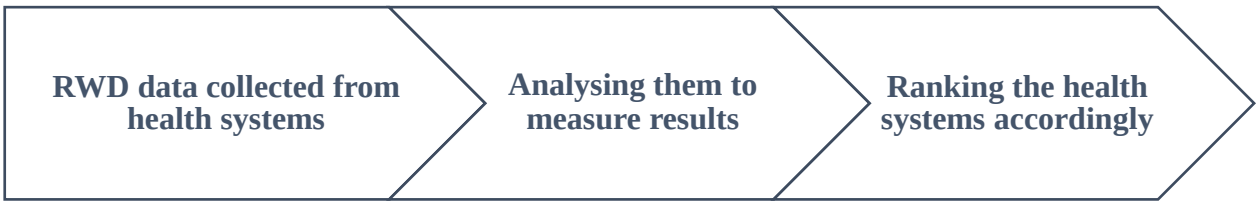
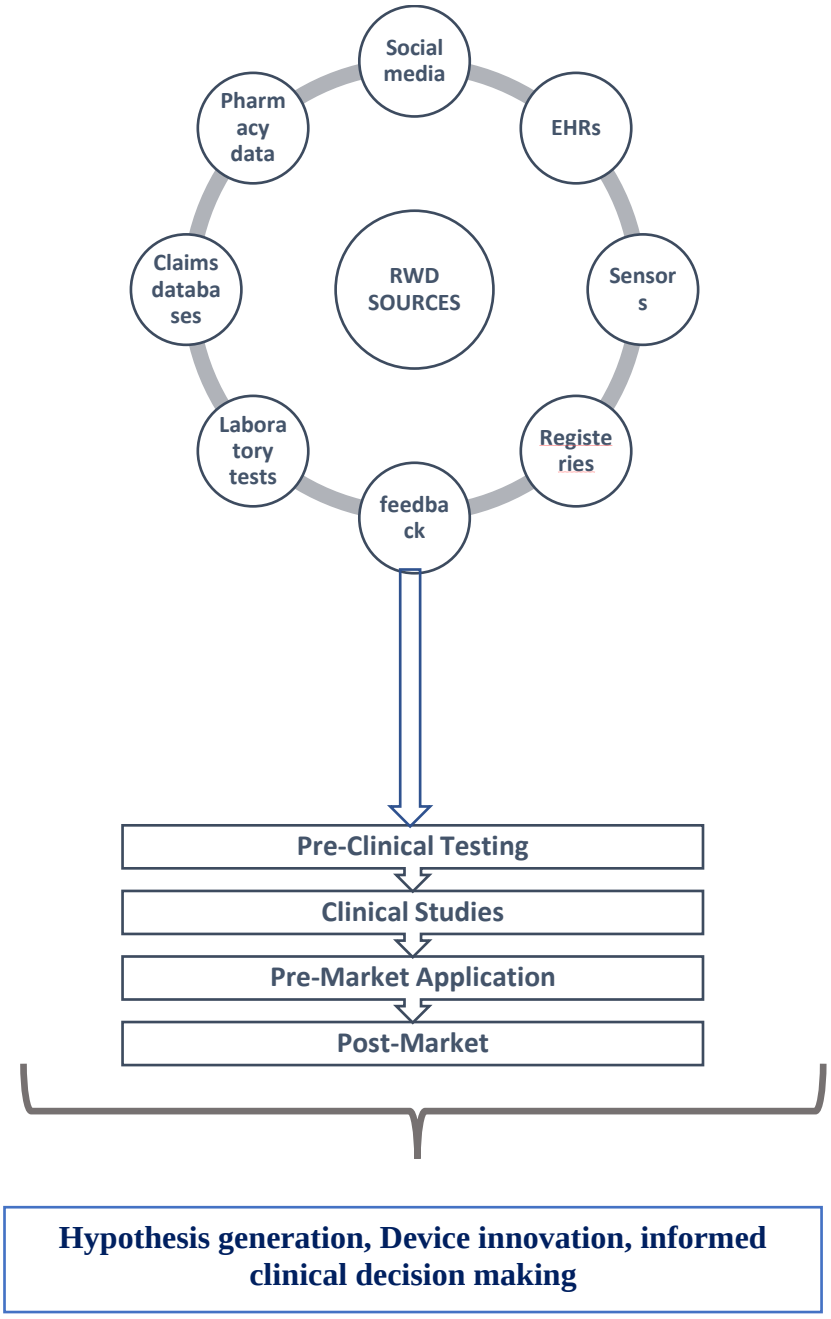


Fig 6.8: RWE in measuring Objective Performance Criteria and Performance Goals

CHAPTER 7: CONCLUSION

RWE has added a lot more value to the traditional clinical pathways for improving health outcomes. RWE is the future for health research and will do wonders in healthcare sector.



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Thank You