

ROLE OF REAL-WORLD EVIDENCE IN HEALTHCARE DECISION MAKING

Guided by:
Dr. Sunita Nigam

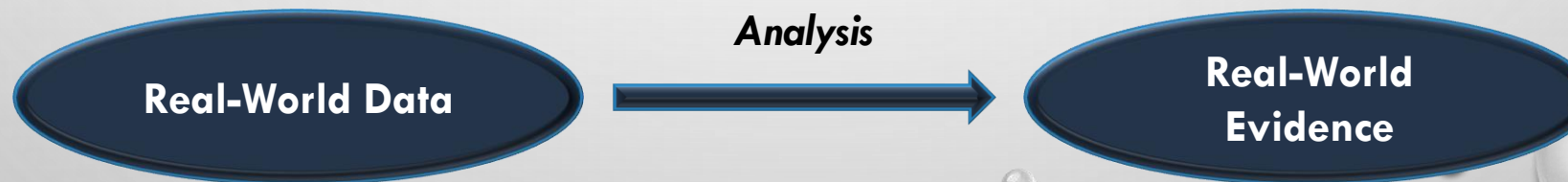
Presented by:
Dr. Astha Sharma
MBA HM 24 (Health)
Roll no. 0893

Introduction



Real-World Data: It is the data consisting of patient health status or the delivery of health care routine collected from multiple sources including Electronic Health Records (EHRs), Claims and billing activities, Product and disease registries, and patient generated data

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



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.*

Overview

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)

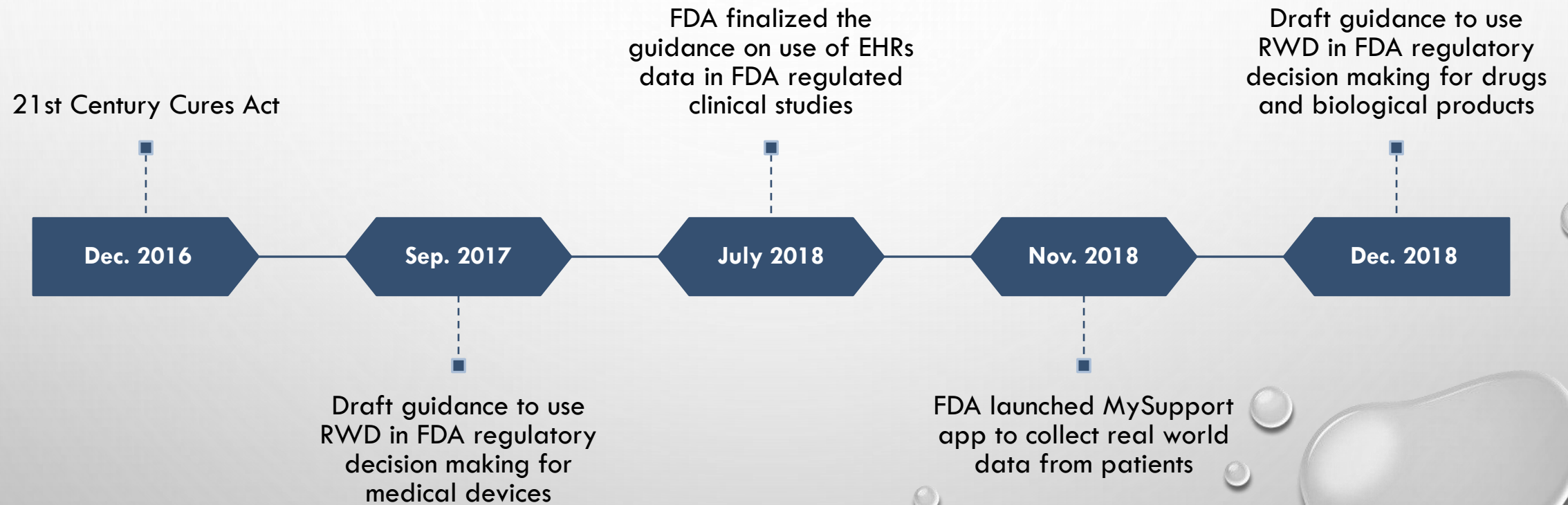
IMPLICATIONS OF THE RESERCH

My research will help in:

- 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.

Evolution of RWE in US

FDA(Food & Drug Administration) - The Regulatory Authority



Evolution of RWE in India

ISCR(Indian Society for Clinical Research) - The Regulatory Authority

Indian Society for Clinical Research (ISCR) launched the Real World Evidence Council. The objectives behind launching RWE Council were:

Working with government policy makers, especially senior officials linked to ICMR, Ministry of Health, CDSCO, etc

Assisting healthcare providers to collect, and analyse policy frameworks for RWE research in India

To conduct innovative training programs across the country for professionals and investigators on the key aspects of RWE research

To raise awareness of methodologies, results, and product lifecycle support

Use Real data to improve patient outcomes

Literature Review

TITLE	AUTHOR	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, comparing the effectiveness of various interventions, 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.

Literature Review

TITLE	AUTHOR	KEY LEARNINGS
Making Real-World Evidence More Useful for Decision Making	Sheldon Greenfield	- Following the given recommendations will help in making RWE useful in decision making: - Publication of the study. - Complete transparency of the data, including full sharing of patient information. - Confirmation of the findings from another data source. - 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.

Literature Review

TITLE	AUTHOR	KEY LEARNINGS
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: Drug development, Regulatory approval decisions, post-approval monitoring of safety signals, taking initial decisions for HTA assessments and payer coverage decisions, outcomes-based contracting. - Challenges in use of RWE: Bias & Confounding, incomplete data, data mining, access to data, lack of universally accepted methodological standards, lack of investigator expertise, obsolete evidence hierarchies. Opportunities: - 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. Additional opportunities in generation and use of RWE: - Real-time evidence-based medicine. - Real-time monitoring of patients. - Accelerated access to innovative therapies.

Literature Review

TITLE	AUTHOR	KEY LEARNINGS
• 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.

SWOT Analysis

STRENGTHS	WEAKNESSES
• 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 Randomised Controlled Trials 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 monitoring of safety signals, taking initial decisions for HTA assessments and payer coverage decisions, outcomes-based contracting.	• Data is voluminous, it becomes difficult to filter the required data. • Intervention factor is still missing • 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. • Reliance on RCT trials associated lack of an applicable substitute study design • Reliance on RCT trials associated lack of an applicable substitute study design

SWOT Analysis

OPPORTUNITIES	THREATS
• 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 • Establish effective governance arrangements that clarify how much data can be shared • Focus RWE efforts on the development of pragmatic clinical trials.	• 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

Role of RWE in Healthcare Decision Making

PRODUCT DEVELOPMENT

RWE Journey occurs from Planning till Communication in Product Development

PLANNING

- **Potential of RWE across Product lifecycle:** While preparing an RWE planning team, identifying needs of RWE, assessing the available RWE, identifying gaps, prioritising the study to be conducted and finally deciding the research question.

GENERATION

- **Assessing high-quality RWD:** Selecting an appropriate study design and source of RWD, then developing the research methodology to be followed, publicly registering the study and finally conducting the study.

COMMUNICATION

- **Challenges associated with communicating RWE:** Completing the study report, executing publishing as per publication plans, and keeping in mind local regulatory guidelines, considering communication aids and local regulatory guidelines.

Role of RWE in Healthcare Decision Making

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

Increase in population, age advancements, rise in cases of rare and chronic diseases

More data available for conducting RWE studies, more research and thus more results that might help in coming to a proper conclusion about any drug, or vaccine

Improvement in Patient Related Outcomes (PROs) and Health Outcomes on a large scale.

Role of RWE in Healthcare Decision Making

TESTING SAFETY AND EFFECTIVENESS OF ANY DRUG

RWE studies determine whether a particular treatment is effective, a medical device follows the safety standards and is safe, or a particular drug is safe to use or not.

Collect data on patients receiving Drug A and patients receiving Drug B

Assess the rate of recovery on both sets of patients

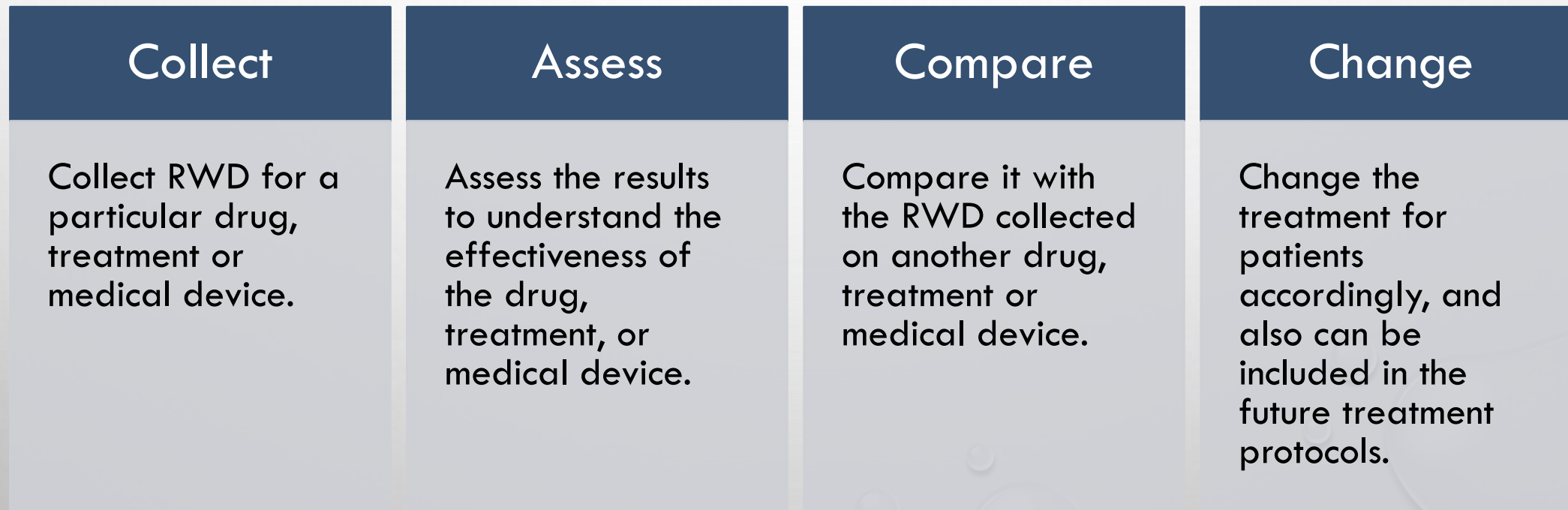
Compare both sets

Set with high rate of recovery has more drug safety and effectiveness

Role of RWE in Healthcare Decision Making

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.

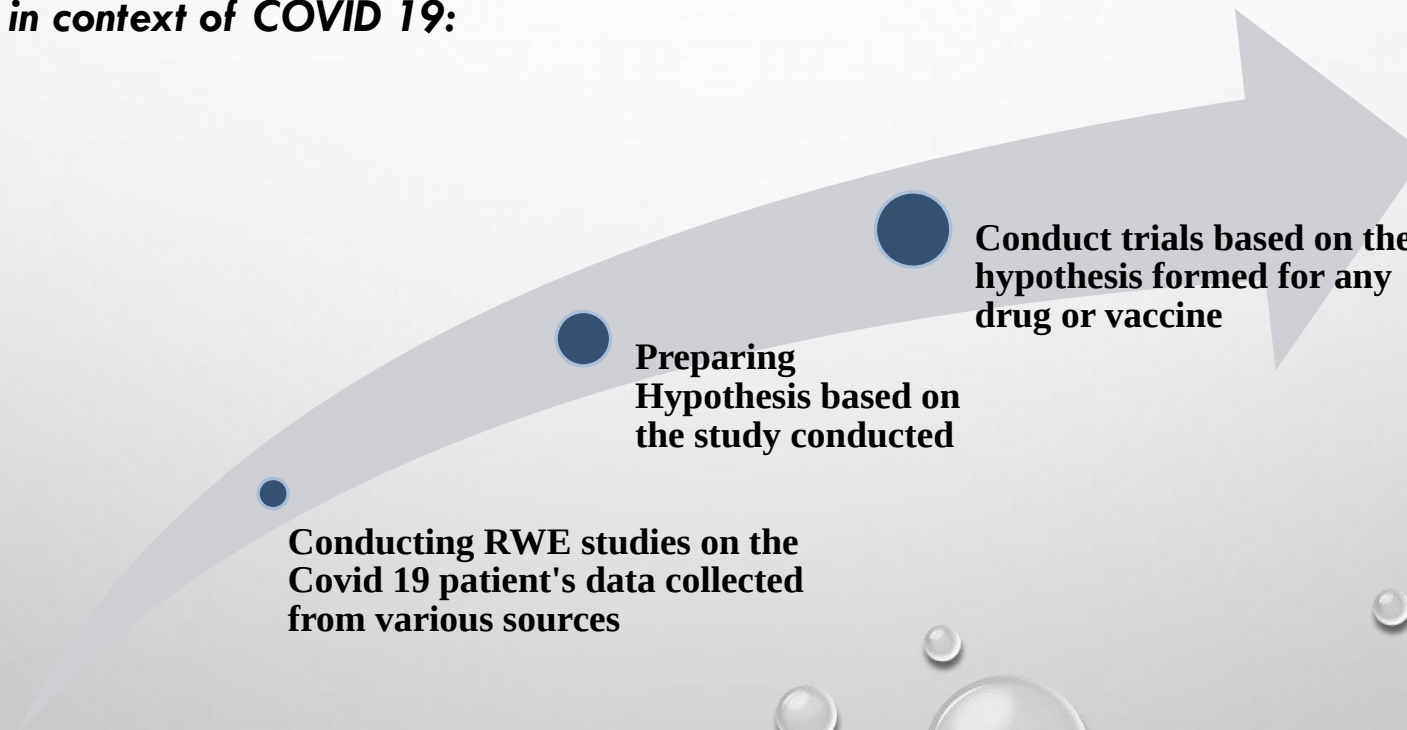


Role of RWE in Healthcare Decision Making

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

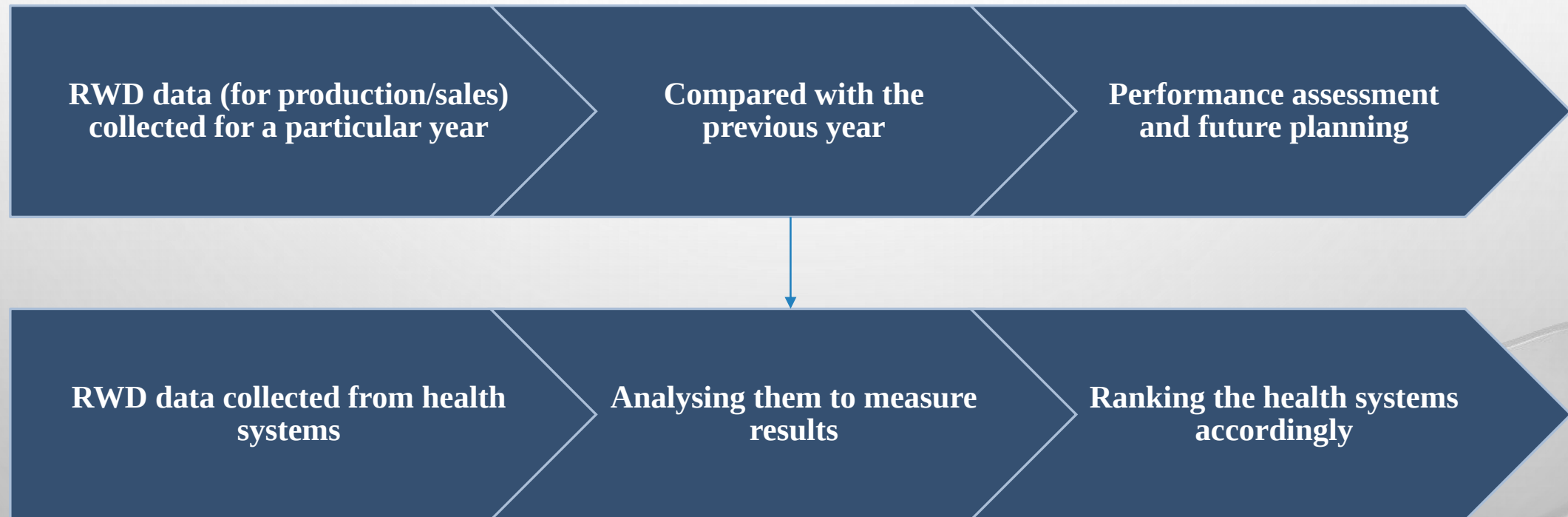
Let us take an example in context of COVID 19:



Role of RWE in Healthcare Decision Making

MEASURING OBJECTIVE PERFORMANCE CRITERIA AND PERFORMANCE GOALS

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



Role of RWE in Healthcare Decision Making

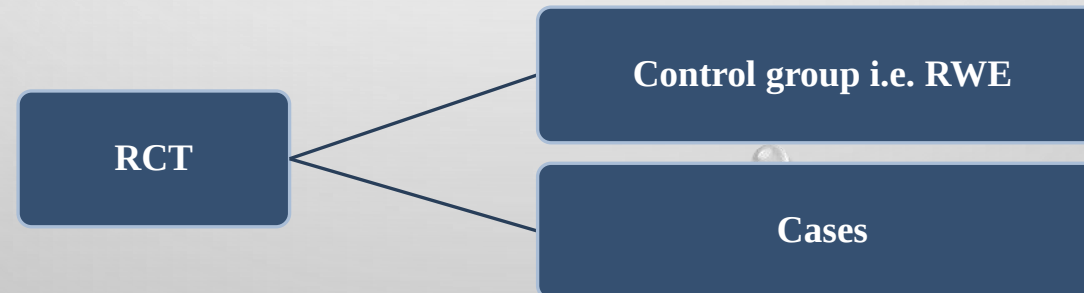
HEALTHCARE RESOURCE UTILIZATION

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. This will help in proper resource utilization



ACTING AS A CONTROL GROUP

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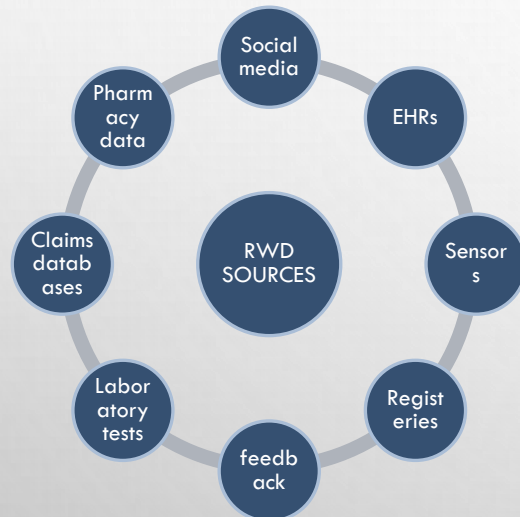


Conclusion

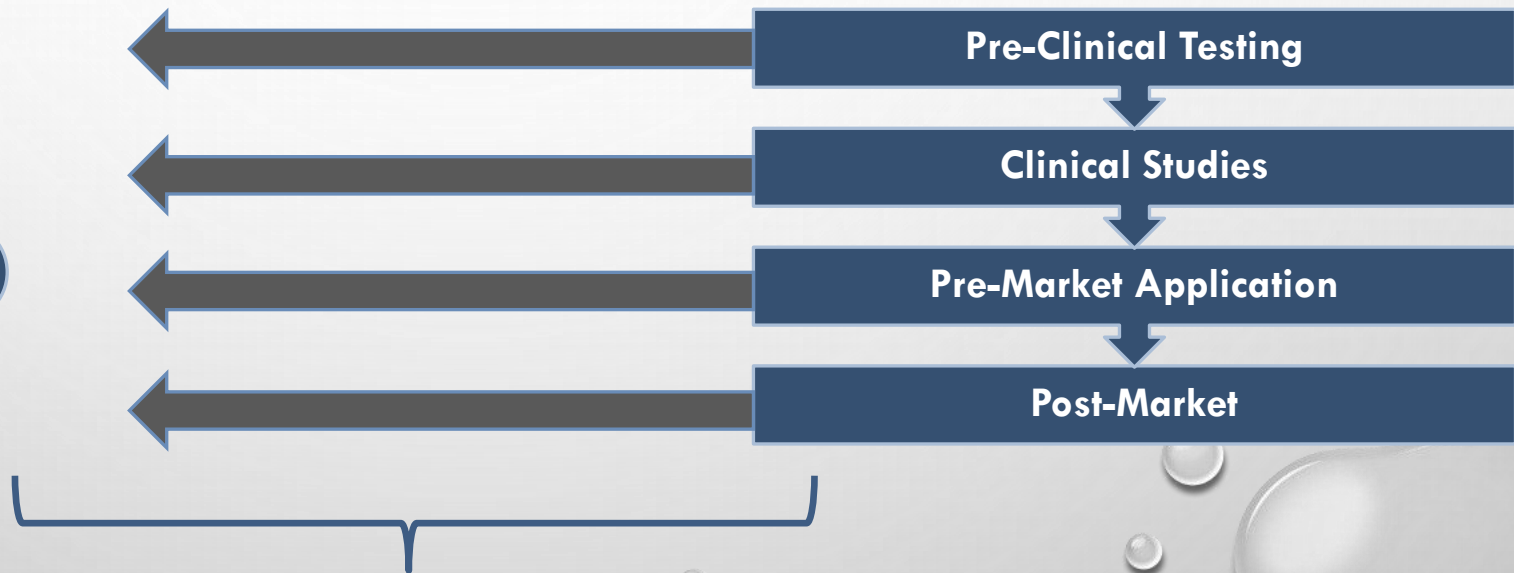
RWE: THE FUTURE OF HEALTHCARE SECTOR

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

Non-Traditional Clinical Data Generation



Traditional Regular Pathway



Hypothesis generation, Device innovation, Informed clinical decision making



THANK YOU