wjpmr, 2023, 9(12), 129-131

SJIF Impact Factor: 5.922

WORLD JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.wjpmr.com

Review Article

ISSN 2455-3301

WJPMR

REAL-LIFE TRIALS IN MOROCCO: BENEFITS AND LIMITATIONS

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Article Received on 21/10/2023 **Article Revised on 11/11/2023** **Article Accepted on 01/12/2023**

ABSTRACT

Introduction: cancer is a major cause of death worldwide, and its treatment requires a multidisciplinary approach based on evidence-based medicine. Recently, there has been growing interest in real-world data. These health data, collected outside controlled clinical trials, reflect the real population and provide concrete evidence (RWE). Real world data (RWD) is clinical evidence based on data collected in real-life practice. They are used by health authorities to assess the safety of health products. Increasingly integrated into oncology clinical research, RWD is seen as an alternative source of evidence to guide the decisions of regulators, payers and clinicians. However, their quality can be limited, requiring an approach that combines the strengths of randomized controlled trials and RWD studies. In Morocco, specific challenges exist for the collection and use of real data in oncology, requiring efforts to build research capacity. RWD enables resource-limited countries to conduct real-life studies and contribute to research by improving cancer management.

KEYWORDS: real-life data, cancer, phase IV, cancer clinical trial, oncology.

INTRODUCTION

A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (including a placebo or other control) in order to assess the effects of these interventions on health-related biomedical or behavioral outcomes, and to answer specific questions relating to innovative medical treatment (vaccines, new therapies or novel methods of administering already known treatments), diagnostic procedures and disease monitoring.

Clinical trials play a fundamental role in today's medicine, providing a scientifically rigorous means of validating and evaluating the full range of care and therapeutic strategies offered to patients.[1]

According to the FDA, traditional clinical trials are supported by a research infrastructure, and are generally randomized, double-blind trials in which the investigator and patient are both controls, and the investigator and patient do not know which treatment is being administered.

The results of clinical trials can have an impact on medical practice by providing scientific evidence to guide treatment decisions and the approval of new drugs or medical interventions. Clinical trials are generally overseen by ethics committees and regulatory agencies, which ensure that the rights and safety of participants are protected.[2]

Clinical trials offer patients access to new treatments and advanced, high-quality medical care, with close monitoring of their health by a multi-disciplinary research team, enabling patients to receive personalized advice throughout the study, and thus improve their condition.

On the other hand, they enable scientists and researchers to generate valuable data on the efficacy and safety of experimental treatments, and thus validate research hypotheses, in collaboration with other experts and institutions, in order to acquire new skills or influence treatment recommendations.

The final stage of clinical trials, or Phase IV, known as "post-approval surveillance", is referred to as Real World Data (RWD), defined as health data collected outside traditional randomized controlled trials (RCTs). In other words, RWDs are data relating to the patient's state of health and management, and which, unlike "research" data, are routinely collected in routine practice outside the constraints of randomized clinical trials.[3]

Phase IV aims to take advantage of more extensive experience in evaluating the efficacy and safety of the

new drug, by comparing the data and/or combining it with other existing treatments.

To assess the long-term effects of the drug, enabling less frequent side effects to be detected. Although the first three phases are carried out vigilantly, active monitoring of side-effects after a drug has been marketed is essential.

However, the focus is on safety of use (drug safety), prescribing procedures and assessment of drug interactions. In the case of vaccines, safety of use, potential vaccine strategies, improvements to the vaccination schedule and possible vaccine combinations to facilitate dissemination are documented.[2]

Phase IV is ultimately an observational phase, which serves as real world data of major interest in oncology, where the need for personalized medicine is very great (4). They will also help select the most promising drug candidates in terms of efficacy and cost. RWD will therefore play an important role in the orientation and management of the industry's product portfolio.[5]

Thanks to robust sources of RWD, more in-depth analyses can be carried out to contribute to better therapeutic decisions based on the follow-up of patients in everyday practice.

Sometimes, real-life studies can identify sub-populations that were not included or were under-represented in clinical trials, and for whom the drug is not providing the expected benefits. Real-life data can also reveal toxicity signals that could not be captured in clinical trials, leading in some cases to marketing authorization restrictions.

If analyzed appropriately, these data can generate real-world evidence (RWE), which provides insight into the benefits and risks of therapeutic interventions as observed in a real-world environment, as opposed to a trial setting.

Objective

The main objective of this literature review is to determine the interest and limitations of Real World Data in oncology in Morocco.

Real-life trials: interests and limits

- In the light of the literature, Real World Data studies have become increasingly popular in Morocco in recent years.
- The situation in Morocco with regard to clinical trials in oncology faces a number of limitations and particularities that impact on research in this field. Mainly due to financial resource constraints, clinical trials require substantial investment to conduct controlled studies with a control group, specific interventions and rigorous supervision.
- Real-life trials enable treatment protocols to be constantly adapted to the specific needs of Moroccan patients. Advances in data collection and analysis contribute to more personalized care.

- RWD Trials in Morocco offer several advantages:
  - Diversity of Populations: RWD trials make it possible to include more diverse patients, reflecting Moroccan clinical reality. This improves the generalizability of results to different populations and sub-populations.
  - Real-life clinical context: By using data from daily clinical practice, RWD trials capture the nuances of treatment in real-life situations. This provides a more complete picture of the challenges faced by patients and physicians in the local context.
  - Research acceleration: By leveraging existing data, RWD trials reduce patient recruitment times, speeding up the research process. This enables new therapies to be made available to patients more quickly.
  - Cost savings: Compared with conventional clinical trials, RWD trials are often more cost-effective, as they minimize the need to create specific infrastructures and recruit patient cohorts.

- Faced with these advantages, we note the following main obstacles:
  - Lack of financial resources.
  - Lack of a dedicated research ethics department and committee.
  - Lack of public awareness of the importance of clinical trials and their benefits, especially for participants.

- These challenges must be met by implementing solutions based on 2 pillars:
  - Data quality: Ensuring data quality is a major challenge. Rigorous data collection, validation and analysis measures are needed to guarantee reliable results.
  - Confidentiality and Ethics: Protecting patients' personal data is a priority. Implementing strict confidentiality and ethical protocols is essential to maintain the trust of participants.
- However, this does not mean that cancer research is absent or neglected in Morocco. The cancer research institute (IRC) aims to promote cancer research and improve available treatments.
- Thanks to this initiative, Morocco is increasingly positioning itself as a major player in the fight against cancer in Africa and internationally.
- In addition, we rely on Phase IV studies, which are correlated with real-world data, to conduct research and contribute to the advancement of oncology.
- Using an approach based on real-world data has enabled us to gain a more complete perspective and better represent clinical reality, unlike laboratory studies which take place under controlled conditions.

- The emergence of new technologies and data sources such as electronic medical records, national registries and surveillance databases provide rich access to comprehensive, longitudinal information on large patient populations, enabling in-depth analyses.
- It's important to stress that Phase IV studies and real-world data do not replace Phase III randomized controlled clinical trials, which remain the gold standard for assessing treatment efficacy. Nevertheless, given our financial constraints, it is essential to make the best possible use of available resources.
- Despite the challenges facing the national scientific oncology community, Morocco's contribution to cancer research through Phase IV studies based on real-world data is invaluable, taking into account cultural, demographic and genetic particularities that could influence results.
- This is a living example of the need to invest in RWD, especially in countries where there are no clinical trials, such as Morocco, where there are ethnic, genetic, dietary and climatic differences.
- We need to rely on phase IV trials to monitor the efficacy of standardized treatments based on post-marketing clinical trials, especially if they are carried out on a different population, which is the case most of the time.

CONCLUSION

- RWD studies in oncology have mainly relied on the collection and analysis of observational data, which can offer valuable information on the actual conditions under which antitumor treatments are applied.
- However, given the methodological limitations inherent in these data, their quality may sometimes be too low to produce a usable RWE.
- RWDs are very important, especially in oncology. However, they can never replace clinical trials, but are complementary to them.
- In Morocco, there may be specific challenges in collecting and using real data in oncology. These may include limitations in access to electronic medical records, uneven healthcare coverage, limited resources for research and less centralized healthcare systems.
- Hence the interest in building capacity in cancer research and real data collection in Morocco. This would enable us to better understand the characteristics of the disease, evaluate treatments and improve patient care.

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