

Patient Registries – New Gold Standard for Real-World Data

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Lavanya Peddibhotla Biography

Lavanya Peddibhotla, enjoys being part of Clinical Statistical programming industry. To her, Statistical programming is beyond datasets, TLF and Define packages...it is one step closer to bringing lifesaving drugs to patients. She has extensive experience building high performing Biometrics teams. In her current role as Director of Statistical Programming at Covance, she is responsible for leading global team of Biostatisticians and Statistical programmers. Over the last 18+ years, she has been in various roles at Pharmaceutical, CRO and Service industries learning and developing her skills. She is based in North Carolina, USA. Lavanya earned her Master's degree in Bioinformatics from Brandeis University in MA.

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Introduction

- ▶ A patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.
- ▶ Uses of patient registries
- ▶ Update on some programs initiated by regulatory authorities
- ▶ Key considerations on patient registries from the recent guidance published by EMA.
- ▶ Challenges and solutions in handling the patient registry data.

Why Patient Registries?

The Agency for Healthcare Research and Quality's registries guide identifies four primary use cases for patient registries:

- ▶ Determining clinical effectiveness
- ▶ Understanding natural history of a disease
- ▶ Safety surveillance
- ▶ Evaluating and improving quality of care
- ▶ Other purpose

Regulatory Agencies and Evolution of Registries

- ▶ FDA has created a framework to evaluate the potential use of real-world evidence (RWE).
- ▶ FDA has recognized patient registries as one of the sources of Real World Data (RWD) that could be extensively used to generate RWE.
- ▶ Patient-Centered Outcomes Research Institute (PCORI) has identified registries as an important potential source of data to support patient-centered outcomes research (PCOR).
- ▶ In 2015, EMA established a 'Patient Registries Initiative' to support a systematic and standardized approach for registry contribution to medicines assessment.

Considerations for Patient Registries

Following are some points of considerations as per the recent draft guidance launched by EMA:

Registry Population

- ▶ To clearly define the purpose of the registry and the corresponding target population.
- ▶ Translate the target population definition into a detailed description of when, where and how patients will be enrolled in practice.
- ▶ To establish processes allowing for enrolment of all eligible patients fulfilling the description of the target population definition.
- ▶ To create a system that best minimizes loss to follow-up and maximizes the completeness and accuracy of key information collected on each enrolled patient.

Considerations for Patient Registries

- ▶ **Data Elements** – Core and Optional data elements
- ▶ **Quality Management** – consistency, completeness, accuracy and timeliness
- ▶ **Governance** – effective collaborations between all parties for regulatory use of registries and follow the guidance from the appropriate Code of Conduct
- ▶ **Data sharing outside the context of registry-based studies** – Data sharing may require a contractual agreement between the registry coordinated network and the other concerned parties

Challenges in Handling Patient Registry Data

Source of Registry Data

- ▶ Routine patient care
- ▶ CRFs
- ▶ Secondary source of data: such as administrative claims data and Electronic Health Record data (HER)
- ▶ Patient-reported outcomes

Challenges in Handling Patient Registry Data

- ▶ **Routine Patient Care** – Diverse data due to difference in data documentation and frequency and types of assessments performed.
- ▶ **CRFs** – When collecting data via CRF in more than one language and/or culture, appropriate translation and linguistic validation of CRFs is critically important to maintain a high quality of systematic data collection.
 - CRF to be translated into the common language(s) of each study region.
 - The translated CRFs also should be linguistically valid in each study region.
 - Additionally, CRFs implemented in multiple countries must allow for variability in standard of care.

Challenges in Handling Patient Registry Data

- ▶ **Secondary Source of Data** – Linkage to secondary data sources is challenging due to inconsistent availability and requirements for access to source data.
 - A coordinated effort is needed to extract a common set of core data elements from each source of information, accounting for variations in data structure, coding conventions, format, language differences, standards of care and clinical care.
- ▶ **Patient-Reported Outcomes** – PRO instruments may not be available in all necessary languages.
 - If PRO instrument has not been linguistically validated, consider validating the instrument within the registry, as the study is running, or not collecting responses to that PRO instrument in the particular country.

Conclusion

Patient registries offer great potential to address many types of research questions. Registries face many challenges because of the variation across countries in terms of patient demographics, how and where clinical care is provided, differences in access to treatment and treatment patterns, and ethical, regulatory, and legal environments. While some of these factors, like variations in patient population and standard of care, are unlikely to change, increased harmonization of ethical and regulatory requirements would support the efficient use of registries to address a wide range of research questions. At present, sound planning and design, along with proactive risk management, are essential for developing and implementing a successful registry. Studies derived from well-designed and well-performed patient registries can provide a real-world view of clinical practice, patient outcomes, safety, and clinical, comparative, and cost-effectiveness, and can serve a number of evidence development and decision-making purposes

Questions?

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