ORACLE

Oracle Life Sciences Patient Registries and Cohort Studies

What is a patient registry?

A patient registry is defined as 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 stated scientific, clinical, or policy purposes."[1]

Registries serve many purposes including

Describing the natural history of disease

Determining clinical effectiveness or cost-effectiveness of healthcare products and services

Measuring or monitoring safety and harm

Measuring quality of care

As the value from a registry is broad and deep, data can be leveraged by various stakeholders across the industry. Whether your need is for a disease registry or a product registry, Oracle Life Sciences can support you.

Disease registries

They include patients suffering from or at risk of a disease and are a great way to describe the natural history of a disease.

These registries can help identify meaningful endpoints and potential patient populations to consider incorporating into clinical trials, generating supplementary evidence in the form of an external control arm and identifying patients for enrollment in clinical trials.

Product registries

They are focused on patients treated with a product or device and often fulfill post marketing authorization requirements focused on assessing safety, real-world effectiveness or harm.

Why is there value in having a registry?

Registries are driven and led by a variety of stakeholders including academia, government institutions, life sciences organizations and patient advocacy groups, to name a few. Over the last few years, the life sciences industry has experienced an acceleration in the focus on patient needs and patient relevant outcomes in registries as evidence from registries has become widely accepted as an industry standard.

Registries are increasingly moving away from studies designed to meet a single purpose to reusable data infrastructures that fulfill multiple purposes. These registries are the basis for the learning health system and include using data to improve patient outcomes, quality of care and life sciences research.

Health authorities and payers are increasingly making important approval and coverage decisions taking into consideration patient generated health data (PGHD) and patient reported outcomes (PROs). PGHD and PROs are often referenced in regulatory guidance and workshop materials and have become an accepted methodology and source of Real-World Data.

Our consultive and customized approach includes:

Depending on your needs, we can help you build a registry using the best existing data sources or create a new registry using primary data collection.

We start by identifying existing Real-World Data (RWD) which may be utilized to create registries also called cohort studies. We have exclusive access to Oracles Life Sciences EHR data via the Learning Health Network to leverage for registries. The Oracle Life Sciences EHR data has over 100 million patients over all venues of care. We also have access to other existing databases and registries.

When relevant Real-World Data doesn't exist, we can assist you in the design and creation of a new registry using primary data collection with direct to patient or site-based methodologies. A hybrid approach can also provide you with a more comprehensive answer if you need to combine primary prospective data with existing RWD.

Evidence generated by registries are often submitted to Health authorities like the FDA or EMEA, therefore it is imperative registries are designed to be regulatory grade. There is no formal alignment on what is considered regulatory grade, however, there are consistencies between guidance's provided by the FDA and the EMEA, for instance the use of certain technology platforms, a high-quality data management process and the registry being fit for purpose.

Why trust Oracle Life Sciences?

With more than 40 years' experience, Oracle Life Sciences is an expert in designing and executing regulatory-grade registries.

Whether your needs are focused on a specific disease and uncovering its natural history, or you are trying to meet your regulatory requirements, our expertise and flexibility will help you identify the best methodology and data to meet your needs.

40+

Registries using both primary research and existing RWD

1,000,000+

Patients enrolled in Oracle Life Sciences registries

Various types of data collected and analyzed: clinical information (including treatment, lab values, imaging), genetic information, PGHD, PROs, ObsROs (Observer-reported outcome), healthcare resource utilization (HRU), etc

Partner of choice for Patient Advocacy Groups including The International Gaucher Alliance (IGA) and The Cure and Action for Tay-Sachs (CATS) Foundation

Some examples

Therapy Area	Type	Source of data	Countries	Publications
Migraine	Disease	Primary Direct to patients	1	15+ posters and abstracts
Hepatocellular Carcinoma	Product	Primary Site based	39	2 manuscripts

Some examples *cont.*

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