CREATING LICENSABLE REAL-WORLD EVIDENCE DATASETS

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The Value

Real-World Evidence (RWE) is at the heart of value-based care, impactful medical research, new product development, and health equity. To have value, an RWE dataset must be clinically and statistically significant, longitudinal, and possess internal data integrity capable of validation.

The design and execution of an RWE dataset should be based on principles of good clinical practice (GCP). It must also be "fit for purpose"; that is, the protocol underlying the dataset must address a clearly articulated clinical/scientific hypothesis and one or more corresponding endpoints.

Thus, the elements of a licensable RWE dataset closely resemble those of a randomized controlled trial (RCT). The major difference is that the narrow inclusionary criteria of RCTs render them irrelevant to most real-world indications and patient populations. Moreover, the expense, delay, and administrative burden of RCTs generally limit their sponsorship and value to well-capitalized manufacturers seeking one-time regulatory approval for a specific product.

Real-world data – the building blocks of RWE datasets – are by definition plentiful. But the most powerful and therefore valuable RWD are to be found in everyday clinical interventions and correlated long-term outcomes.

Those RWE datasets are in great demand by product manufacturers, payers, generative AI learning models and other healthcare constituencies. They therefore represent substantial and sustained licensing and other monetization opportunities to those who develop and own them.

The Challenges

Creating a licensable RWE dataset requires several key components:

- A study design addressing a specific clinical and/or scientific issue of relevance in the current healthcare environment.
- A study protocol which is efficient, "fit-for-purpose", and will generate correlations reflecting statistical and clinical significance.
- Experienced and motivated investigators with access to the patient

populations relevant to the study design.

- Access to patient populations with a large n" specific to the study's endpoints.
- Processes which do not interrupt the normal clinical flow of the investigators and their staff.
- Long-term patient compliance with outcomes reporting.
- Support for scientific, statistical, legal/regulatory, publication and other study-related components.
- Often, an Institutional Review Board or Medical Ethics Committee.
- Funding.
- The technical platform(s) supporting, investigator recruitment and collaboration, patient outcomes capture, data reporting, patient consent form tracking, regulatory compliance (HIPAA, GDPR, Part 11, etc.) and other GCP elements.

These requirements can appear daunting. They can prevent smaller hospitals and provider groups from developing monetizable RWE databases.

However, this need and should not be the case, especially because clinical groups often represent the richest source of real-world evidence.

The Solution

Circles enable the cost efficient and minimally burdensome generation of monetizable RWE datasets. Through Circles, provider groups of any size can:

- Quickly set up one or more Observational Protocols underpinning a fit-for-purpose study design.
- Establish the elements of a study protocol which will lead to clinically and statistically significant endpoints, supported by validatable data and other GCP requirements.
- Identify and efficiently integrate scientific, statistical, laboratory personnel and other collaborators into the data generation process.
- Identify, recruit, and support sustained collaboration among clinical investigators, whether within or outside of institutional and national boundaries.
- Ensure no interruption of regular clinical activities for those investigators or their staff.

- Accommodate practice variations of each investigator without compromising data integrity.
- Support IRB/MEC requirements.
- Automatically enroll patients, obtain and record customizable patient consents, track long-term outcomes with high compliance rates, prepare and deliver ongoing patient education materials and progress reports.
- Attract funding.
- Data ownership and access at any time from any device.
- Generate reports, filtered against any Observational Protocol question.
- Meet legal and regulatory requirements.
- Continue and expand the RWE datasets after the attainment of original endpoints.
- Develop licensing and other monetization opportunities.
- A robust, compliant technical platform and associated processes integrating the foregoing into a single turnkey solution.

The creation of monetizable RWE datasets is generally hindered by cost, delay, complexity, multiple separately managed processes, and clinical burden.

Circles eliminate these challenges, allowing provider groups, regardless of specialty, to convert their everyday clinical data into substantial and sustained financial value.

Learn More

To learn more, please view client use cases here, or contact us.