RegenMed

Real-World Evidence Programs For Academic Medical Institutions

April 2024

Executive Summary

Real-world evidence (RWE) is arguably the most important healthcare data category of the 21st century. For academic medical institutions (AMCs), a well-structured RWE Program can be foundational to several strategic initiatives:

- Better clinical decision-making and evidence-based standards of care.
- Better-funded, more diverse, and more impactful research.
- Value-based care and health equity/SDOH programs.
- Meaningful engagement with employed physicians, as well as external medical practices.
- Proprietary highly correlated datasets available for licensing and other monetization opportunities.
- Lower-cost and more sustained IP development.
- Ethical industry funding.
- Deeper and sustained patient engagement

A Real-World Evidence Program based on Circles adds value to each department of an AMC, clinical or research. It imposes minimal clinical burden, is low-cost and modular, and represents a profit not a cost center.

About Real-World Evidence

What It Is

In principle, RWE can be developed from a variety of sources – EMRs, retrospective studies, and registries for example.
In practice, the most valuable RWE by far isbased on validated everyday clinical interventions, closely correlated to standardized long-term outcomes.

Importance

Policymakers, regulators, payers and private sector experts have all emphasized the importance of RWE for value-based care, clinical decision-making, efficient and impactful medical research and greater health equity. [1]

Institutional Value Categories

Value-Based Care

Value-based care is heavily dependent on RWE – standardized outcomes assessments closely correlated with specific relevant clinical data. This is what the FDA calls "fit-for-purpose" data.

Research

An RWE Program makes high quality, impactful research opportunities accessible to younger and the busiest of clinicians. It allows publishable and statistically significant research to be democratized. [2]

Industry Funding

As indicated, recent FDA guidance supports the use of RWE in regulatory decision-making. Most major device and pharmaceutical companies support investigator-initiated studies.

A Circles-based RWE Program enables substantial expansion of IIS and similar industry-sponsored studies.

Dataset Licensing

An RWE Program continuously generates validated, longitudinal, and proprietary datasets directly relevant to a specific clinical and/or scientific healthcare issue.

These datasets are both clinically and statistically significant, thus representing deep value to product manufacturers, AI training models and other licensees. [3]

Collaboration With External Provider Groups

Outpatient procedures across all specialties will continue to move to ASCs. There is likely to be a resurgence in regional physician-owned hospitals. Governmental and patient pressure to "bend the healthcare cost curve" will only intensify.

IP Development

The busy clinician is simultaneously a key source of RWE *and* intellectual property. A well-designed RWE Program will educate and incentivize each physician regarding IP potential of their everyday cases, as well as provide him/her the tools to capture the relevant data to support such IP without interrupting clinical flow.

Health Equity/SDOH

"Health equity" and "Social Determinants of Health" are increasingly important components of value-based payments. [4] An RWE Program develops datasets supporting standards of care for under-represented patient cohorts, "orphan" indications and other groups which often fall outside of quality, mainstream healthcare.

Expanded Access/Compassionate Use

Many newer treatment protocols and products are first administered to patients in the context of expanded access programs. [5] These are typically delivered in the context of clinical trials. Circles combine technical robustness with low cost

and efficiency, allowing AMCs to undertake many more EAP interventions.

Patient Engagement

A successful RWE Program drives high patient compliance in long-term outcomes reporting. Benchmarc™ delivers excellent patient UX, including educational materials, data-driven reports and other communications.

This positive patient engagement redounds to an AMC's overall branding value.

RWE PROGRAM ELEMENTS

Clinical Grade Technical Platform

A Circles-based RWE Program is founded on the patented inCytes™ (clinician-facing) and Benchmarc™ platforms. [6] It supports HIPAA, GDPR and Part 11 compliance. Its open API allows HL7 and other integrations.

As an encrypted cloud-based system, inCytes™ is customizable, scalable, multilingual, available in many languages, and accessible on any device 24/7.

Clinical User Experience

Uninterrupted Clinical Flow

Circles processes ensure efficient RWE generation while eliminating clinical and administrative burden. Physicians and researchers focus on what matters most to them – study design, generating causal correlations, and improving evidence-based patient care.

Collaboration

Circles break down the barriers among specialties, and between the laboratory and the clinic. They enable sustained and meaningful collaboration across institutional and national borders.

Education and Training

What are the clinically important data to capture for a particular indication? How best do I measure outcomes for this procedure and patient? How can I validate product claims? How do I measure my patients' outcomes against those of my peers? How do I develop an evidence-based standard of care for a particular patient cohort?

Asking and answering these and similar questions are at the heart of medicine, and of an RWE Program.

Clinician Support

Support for conference presentations, publication, statistical analysis, IRB submissions, grant proposals, and

clinical/scientific mentorship is an important part of a Circles-based RWE Program.

Sustained Clinician Engagement

Circle Academies are an example of regular communication channels inherent in an RWE Program enabling researchers and clinicians to discuss study designs, results, observations, and best practices.

Profit Center, Not A Cost Center

Cost-Efficiency

A Circles-based RWE Program is low cost and modular. SaaS pricing ensures complete control over expenditures, no commitments, full transparency, and the ability to scale as KPIs are met.

Monetization

An RWE Program will materially improve the quality and number of research and other grant proposals. Also, as indicated, RWE datasets represent significant value for product manufacturers, payers, and other healthcare constituencies.

Properly designed and executed, an RWE Program will represent a substantial financial, clinical, and scientific return on investment for an AMC.

Partner, Not A Vendor

RegenMed works as a long-term partner in the structuring and execution of an RWE Program. It provides the ongoing support needed to minimize clinical burden. At the same time, it works with AMC leadership to ensure that the Program meets pre-agreed KPIs.

To find out more, please contact us.

ENDNOTES

1 See for example FDA, Real World Evidence, FDA, Post-Market Surveillance Programs; The 21st Century Cures Act; NIH Grants Program For Real-World Studies; Expect To See More RWE-Based Regulatory Decisions, Robert Califf, FDA Commissioner; Use Of Real-World Evidence In Regulatory Decision Making, European Medicines Agency. Registries for Evaluating Patient Outcomes: A User's Guide: 4th Edition, Agency for Healthcare and Quality and Research, U.S. Department of Health and Human Services. Deloitte 2022 Study: *RWE's Evolution Into A True End-To-End Capability*. McKinsey: *Creating Value From Next-Generation Real-World Evidence*.

[2] See *Rediscovering and Re-Imagining Medical Research*.

[3] See *Healthcare Data: Ownership, Publication and Monetization*. *Getting Ready For The Generative AI Training Data Licensing Boom*.

[4] See for example *Social Determinants of Health*, https://health.gov/healthypeople/priority-areas/social-determinants-health; *FDA Office Of Minority Health and Health Equity*, https://www.fda.gov/about-fda/office-commissioner/office-minority-health-and-health-equity; *CMS Value Based Care*, https://www.cms.gov/priorities/innovation/key-concepts/value-based-care.

[5] *FDA Expanded Access*, https://www.fda.gov/news-events/public-health-focus/expanded-access. *Overview of FDA's Expanded Access Program for Investigational Drugs*, Jarow et al., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5443564/pdf/nihms863256.pdf. *CliicalTrials.gov data submissions for EAPs.* https://prsinfo.clinicaltrials.gov/expanded_access_definitions.html.

[6] U.S. Patent No. 11720567, Method and System For Processing Large Amounts of Real-World Evidence.