RegenMed

ARTICLE

External Circles For Academic Medical Institutions

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TABLE OF CONTENTS

INTRODUCTION

Physicians and researchers at academic medical centers can advance their professional objectives through real-world evidence.[1] However, structural barriers often hinder their ability to do so. Those barriers can include:

- RVU and other financial pressures.
- Funding constraints.
- Complex, lengthy IRB processes.
- Limited access to laboratory time, scientists, statisticians, and other experts.
- Inability to develop statistically significant population samples.
- Cumbersome or poorly suited internal IT platforms.

Circles address these challenges. On the one hand, their features comply with the objectives – transparency, consents, investigator credentials, HIPAA, etc. – underlying institutional policies. On the other hand, they offer the flexibility and user experience necessary to support collaboration across institutional and national borders.

Circles thus represent a powerful, efficient, and low-cost solution for designing and executing "external" yet impactful studies.

USE CASES AND BENEFITS

Circles use cases relevant to employed clinicians and researchers include the following.

Sustained Collaboration With Mentees

Department chairs and other mentors can continue meaningful relationships with fellows, residents and other mentees who have moved to other practice environments. They can build upon past work, as well as initiate new areas of inquiry.

Medical Society Influence

Institutional thought-leaders often serve as medical society board members or officers. These are excellent positions from which to develop research, registry, and other initiatives.

Properly structured and executed, such initiatives will lead to evidence-based clinical translation of medical advances. They will also drive value for and retention of society members, and increase the society's impact.

Support For Patient Groups

Alliances, advocacy groups, athletic conferences, veterans' organizations, and other groups coalesce strongly around

specific medical conditions. Diabetes, traumatic brain injury, cognitive impairment, IVF, and PTSD are but a few examples.

Institutional leaders can help such groups develop science-based recommendations for their constituencies.

Value-Based Care Registries

Value-based care is perhaps the dominant trend in 21st century healthcare delivery. Today, value means much more than lower readmission rates. Providers are expected to demonstrate long-term safety and efficacy for each category of clinical intervention. However, even the largest hospital groups rarely capture long term outcomes consistently.

The clinical grade inCytes™ and Benchmarc™ platforms capture two years or more of outcomes at only $5 per Case. Those data can easily be integrated into existing EMR platforms, and thus represent a strong clinical and financial return on investment for medical centers of any size. Circles typically reflect compliance rates of 70% or higher for patient outcomes reporting.

Private Studies

Younger physicians, as well as their more experienced colleagues, are often deterred from developing datasets which could support their clinical decision-making.

A study need not be expensive, burdensome, or time-consuming to be impactful. Institutions often permit observational and quality control studies without undue complications. Moreover, an institution-employed physician is always free to observe – and often participate in – an existing Circle which may be relevant to them.

Health Equity and SDOH

"Health equity" and "Social Determinants of Health" are increasingly important components of value-based payments. [2] Circle Members can include rural providers, practical nurses, social workers or even caregivers collaborating closely with those in academic medical centers.

Circle Observational Protocols can include social or other assessments and datasets in linked to more traditional clinical data.

Expanded Access (Compassionate Use)

Many newer treatment protocols and products are first administered to patients in the context of expanded access programs. [3] These are typically related to clinical trials.

Institutional policies can make it difficult for physicians or their patients to participate in such trials. Circles enable them to do so in a transparent manner.

EXECUTION

Pilot Study

Circles are highly flexible. A Circles-based initiative can be implemented for minimal cost and in a short amount of time. It can also be terminated quickly. [4] This allows a Circle Founder to begin conservatively and with a minimal budget, while benefitting from the full functionality and power of Circles.

Expansion

Circles are fully scalable in terms of complexity, dataset size, numbers of sites and investigators and other parameters. They can be rendered in a variety of languages without losing data integrity. Circles can accommodate -- and integrate data from – clinicians, patients, laboratories, consulting clinicians and other parties.

User Experience

Circles UX for clinicians, researchers and patients is excellent. Moreover, RegenMed's processes support sustained collaboration, investigator recruitment, patient enrollment, teaching, publication, and many other support elements. Circles protect clinicians' data ownership.

Funding

The real-world evidence generated by Circles is inherently valuable. RegenMed works closely with industry and physicians to develop investigator-initiated studies and associated compensation, honoraria and other reimbursement fairly reflecting that value.

To find out more, please contact us.

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1 See for example *FDA, Real World Evidence*, https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence; *McKinsey, Creating Value From Next-Generation Real-World Evidence*, https://www.mckinsey.com/industries/life-sciences/our-insights/creating-value-from-next-generation-real-world-evidence; *AHRQ (HHS), Registries For Evaluating Patient Outcomes, A User's Guide*, https://effectivehealthcare.ahrq.gov/products/registries-guide-4th-edition/users-guide.

2 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.

[3] *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. *ClinicalTrials.gov data submissions for EAPs.* https://prsinfo.clinicaltrials.gov/expanded_access_definitions.html.

[4] Summary pricing can be found at https://www.rgnmed.com/circles/what-is-a-circle. More detailed information on products, servicing and pricing can be found at https://kb.rgnmed.com/product/service-charges-and-payment-terms.