MULTICENTER STUDIES WITH CIRCLES

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"Impactful and professionally rewarding multicenter studies are well within reach for all clinicians."

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ILLUSTRATIVE MULTICENTER STUDY USE CASES

The efficiency with which multicenter studies can be designed and executed opens up a range of use cases. As but a few examples:

Improved Standards of Care

An orthopedic surgeon wishes to substantiate that his specific approach to minimally invasive shoulder reconstruction is superior in safety and efficacy to the standard approach currently utilized in his hospital.

Clinical Decision Making

A pain medicine doctor wishes to improve her ability to develop different treatment plans for a diverse patient population presenting with lower back pain. She wants to be able to segment her lower back pain patient panel in an evidence-based manner.

Reimbursement

An ambulatory surgery center wishes to support reimbursement for a particular procedure for which patients currently pay out-of-pocket. Reimbursement may come from traditional payers, or in the context of a narrow network established by the ASC with select partners.

Testing A Clinical/Scientific Hypothesis

A clinician, intrigued by peer-reviewed literature suggesting the value of certain biologics for a specific segment of her patient panel, wishes to validate their safety and efficacy for that segment.

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Registries

A regional medical society wishes to establish a registry which adds value to its members, attracts new members, attracts new industry funding in a product-agnostic manner, and simultaneously advances the mission of the society.

Sustained Involvement of Teaching Hospital Residents and Fellows

The maxillofacial department of a major hospital wishes to establish a research/clinical program which not only attracts promising fellows and residents, but maintains a relationship with them throughout their careers.

Extend Best Practices of Sports Medicine KOL's

A sports medicine thought leader establishes and encourages best practices among college level soccer trainers in the context of concussion protocols, by involving those trainers in his study.

FUNDING

Traditional studies are long, expensive and involve limited patient populations. Such studies will of course always have their place. However, as indicated above in footnote 1, there are equally legitimate, far less costly and often more impactful alternatives. Their modest budgets and clinical efficiency make funding much more accessible.

In larger hospitals and clinical groups, study funding is often available from research, education, training and even marketing budgets. Another approach is Investigator-Initiated Trials. These studies are financially supported by

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industry, but explicitly leave to the clinician/investigator all control over study design and execution. [1]

CIRCLES AS A COMPREHENSIVE SOLUTION

General

Circles represent an integrated approach to multi-center studies. A successful Circle comprises two closely integrated components:

- inCytes™ , the technical foundation for value-added registries, studies, trials and other forms of clinical data collection.
- Circle Academies, which enable the collaboration, education, discussion, publication, and the "network effect" needed to realize the full potential of correlations developed through inCytes™.

Circles thus represent a turnkey solution with excellent user experiences – and motivation -- for clinicians, patients, and other users. The burden on providers is minimal.

Identifying Peers and Experts

RegenMed plays an active role in identifying -- and supporting collaboration among -- practitioners sharing a common clinical/scientific interest. Those "Circle Members" can be found in the same hospital department, in study-relevant medical societies, as authors of articles and conference presentations, and among RegenMed's network.

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[1] See our Article of Investigator-Initiated Trials here.

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Circle Members often include scientific and clinical domain experts who can assist with study design, education and training. They also help identify and analyze useful correlations generated through aggregated datasets. A statistician can also be a valuable member of a Circle.

IRB and Other Approvals

As mentioned, many forms of clinically- and statistically significant studies do not require the involvement of an IRB. Examples are "observational" and "quality improvement" studies. [2]

Data Collection, Aggregation, Correlations

The statistic power and clinical value of most multicenter studies derive from their large population sizes. This also is the foundation for uncovering "serendipitous" correlations, as well as those envisioned in the original study design. The time needed to achieve that "n" is also significantly accelerated when multicenter studies are efficiently executed.

Circles enable the economical and efficient collection of real-world data within the clinical setting of each Circle Member. At the same time, Circle functionality aggregates those data in real time from all Circle Members, wherever located. That aggregated data is then available -- also in real-time and at any time -- to all Circle Members.

Importantly, aggregated is available through a powerful Report Builder allowing any Circle Member to:

- filter Circle data according to any study question, and compare it to patient report outcomes or other assessment scores established as part of the Study;
- compare his data against those of all Circle Members;

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[2] A good example is the extensive AAOS Registries. See here.

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- compare a particular patient's data against those of her broader patient panel;
- compare outcomes of two or more patient cohorts against the same outcomes score;
- export raw data; and
- more.

Circles accommodate variations in protocols and legal/regulatory environments across various practices, while preserving the "canonicity" of all data relevant to verifiable and useful correlations in the multi-center study's dataset. They also provide full multilingual functionality, allowing participation among like-minded members in any country. [3]

Patient Compliance And User Experience

Patient enrollment, and timely capture of their longitudinal outcomes against a standardized scoring algorithm, are essential to a successful study. The Benchmarc™ patient user experience drives consistently high compliance rates. In addition, RegenMed offers a cost-effective Service Provider Agreement, pursuant to which it handles enrollment and outcomes reporting follow-up on behalf of clinicians.

Ongoing Collaboration

For many clinicians, the opportunity to collaborate with peers in other institutions and countries is an attractive aspect of multicenter studies. Ideally that collaboration is meaningful and sustained throughout the full course of the

[3] While English is common to most clinicians around the world, most are more comfortable in their native language. More importantly, patient-reported outcomes reporting and other patient-engagement elements are essential to a successful study. That engagement should be in the patient's native language.

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study -- from the initial design through the joint generation of correlations. Circle Academies provide the secure, always-on environment allowing them to do so.

Publication and Influence

Clinicians and other healthcare constituencies around the world will be interested in one or more elements of multicenter studies – hypotheses, indications involved, study protocol, tentative correlations, methods of efficient execution. These elements are compelling data-driven content for conference presentations, articles, blog posts, training/education programs and patient materials. [4]

RegenMed works closely with Circle Members to develop the appropriate content, formats and distribution channels reflecting their work. [5]

CONCLUSION

Most clinicians are capable of designing and/or participating in a multicenter study. Doing so need not be expensive or burdensome. Properly executed, such studies are professionally rewarding, and result in genuine clinical and professional value.

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[4] Indeed, a common criticism of traditional trials is the secrecy with which they are conducted. It is often many years, if ever, before their methodologies and conclusions are published.

[5] See here for more information.

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Contact Us

If you have any questions about how multicenter Circles may benefit you or your institution, please contact us.

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