CIRCLES FOR HOSPITAL DEPARTMENTS

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INTRODUCTION

Circles Overview

Circles represent a powerful, flexible and cost-effective approach to outcomes capture, studies, registries, publication and other healthcare objectives. A single Circle unites clinicians, scientists, patients and industry in developing – and extracting value from – real-world evidence ("RWE") in the context of a specific medical condition or procedure. They enable sustained collaboration among stakeholders, and can be implemented within and across institutional and national borders. A Circle can be up and running in two weeks, can accommodate any budget and is highly scalable.

Circles utilize RegenMed's patent-pending inCytes™ and Benchmarc™ platforms. They integrate world-class technical infrastructure and excellent clinician and patient user experience. They offer powerful collaboration tools, 24/7 access, advanced reporting functions, data control/validation/security, and publication support.

Key to development of RWE is minimizing the clinical burden in developing foundational real-world data. RegenMed's platforms and processes do so by streamlining patient enrollment, long-term outcomes follow-up, Investigator and team member onboarding, and other tasks. This allows the busy clinician to focus on patient care.

Circles deliver continuous value for any healthcare stakeholder. In this Article, we summarize value categories for hospital departments.

Hospital Departments and Real-World Evidence

Modern medicine is characterized by hyper-specialization, rapidly advancing science, sophisticated devices and products, "informed" patients [1],

[1] The accuracy and completeness of information patients receive through advertisements, online resources and word-of-mouth are of course open to debate.

reimbursement codes, legal/regulatory complexity, literature "overload" and clinical burden (both patient care and administrative.)

In addition to these challenges, the hospital department chair must also deal with clinical and research revenue goals, talent acquisition and retention, budgetary constraints, training/education, publication and inter-departmental "co-opetition".

However, that chair has two major assets to help address those challenges:

1. A large volume of clinical interventions and laboratory analyses representing usable real-world data.
2. Accessible medical researchers and scientific equipment.

From these assets, Circles can generate several important categories of value, summarized below.

CIRCLE BENEFITS FOR HOSPITAL DEPARTMENTS

Clinical Decision-Support

The ability of clinicians to make evidence-based diagnoses and treatment protocol decisions is hampered by several factors. These include personalized/precision medicine, systemic effects of apparently localized medications or interventions, the lack of long-term outcomes data, incomplete patient histories, co-morbidities, no or poor evidence for many interventions, and time constraints.

By designing and executing large "n" Circles, a department can develop and continually improve evidence-based standards of care for specific interventions, patient cohorts, pre-and post- clinical care and products.

Patient Engagement

Today's patients have multiple provider choices, are savvier about their care, and have higher expectations. They are accustomed to personalized user experiences outside of the clinical environment. They want to understand their condition, the proposed treatment protocol, the likely outcomes. They want to participate in their care, and appreciate their provider helping them do so.

Circles provide an excellent user experience for patients pre-, peri- and post-clinically. This experience is customized for the treating physician, as well as the patient. It includes information on the condition, treatment protocol, expected outcomes, and outcomes of similar patient cohorts. Circles can include "digital front doors" and "outcomes pages" for the department's (or each clinician's) webpage, as well as data-rich content for blog posts.

All patient engagement processes are HIPAA and GDPR compliant.

New Service Lines

Borders among traditional medical specialties are blurring; new ones are forming. Plastic surgeons are utilizing adipose-based treatments for musculoskeletal conditions. Immunomodulation science is no longer relevant only to oncology or rheumatology. Sports medicine is fast becoming a branch separate from orthopedics. Leading hospitals have established regenerative medicine centers of excellence, and even academic curricular offerings. Clinicians, and payers, recognize the importance of evidence-based rehabilitation – and even pre-habilitation – as a distinct clinical specialty.

At the core of these trends is not only advancing medical science, but the results of registries, pragmatic studies and other real-world evidence sources. Circles help hospital departments identify and implement new service lines.

Reimbursement

The mix of governmental, private, and out-of-pocket reimbursement differ among hospital departments according to specialty and geographic locations. Some departments benefit significantly from research grants and donations, others less so. In the near future, narrow networks, accountable care organizations and other types of value-based medicine will become increasing important factors in reimbursement.

The collection of long-term outcomes, tightly correlated to specific diagnoses and interventional protocols, are becoming central to all forms of reimbursement. Circles are designed to identify and capture such real-world data, and aggregate it into statistically significant support for all forms of payers.

Exploiting Research Capabilities

Genuine clinical translation is unnecessarily slow and difficult. This has been widely recognized, including in national legislation such as the 21st Century Cures Act and "Right To Try" laws.

In theory, hospital departments with research capabilities should be ideal "incubators" for evidence-based clinical translation. In practice, however, there are many challenges. These include differing revenue incentives, operational environments, and legal/regulatory parameters. Busy clinicians are unable to keep up with sophisticated medical science. Researchers do not understand clinical realities.

Nevertheless, a hospital department can achieve the promise of regular evidence-based clinical translation by implementing Circles:

- Researchers can work with the department chair or other practitioners to develop a clinically efficient Observational Protocol (study design) focusing on the safety and efficacy specific condition or treatment protocol.
- Practitioners can collect the real-world data generated by their everyday cases, and corresponding to that Observational Protocol.

This would include longitudinal and standardized patient-reported outcomes.

- The research laboratory can assist with the collection of scientific data requiring laboratory equipment. [2]
- The researchers and clinicians can jointly analyze the resulting aggregated datasets for hypothesized or serendipitous correlations (real-world evidence).
- The researchers and clinicians can jointly prepare journal articles, conference presentations, education/training materials.

Circles provide the turnkey platforms and processes to achieve genuine clinical translation, with sustained value for both "sides": research and patient care.

Publication

The reputation and influence of a hospital department is closely related to its data-supported standards of care and outcomes. Those defining characteristics are traditionally propagated through peer-reviewed articles and conference presentations. In today's world, digital platforms, online education forums, and select social media are equally important.

Circles provide departments with the real-world evidence at the heart of any influential healthcare content. Circle Academies allow department members Circle Members to securely present and discuss individual cases, study designs, tentative observations, or publication content. RegenMed also supports social multi-media presentations, website outcomes pages, and digital front doors for efficient patient enrollment.

Education and Training

Hospital departments have various education and training components. These typically include from medical student internships, formal residents and fellows' programs, mortality and morbidity conferences, lecture series and grand rounds.

[2] As but one example, cell/tissue characterization. This might be done for each Case, or for a pre-determined percentage of similar Cases.

Circles can provide several valuable forms of education within any of these contexts:

- Developing real-world study designs.
- Executing real-world studies, from the informal to formal research assignments.
- Integrating modern medical science with everyday clinical care.
- Identifying key elements of interventions constituting real-world data.
- Determining statistical and clinical significance of aggregated datasets.
- Use of appropriate outcomes measures for specific indications.
- Developing evidence-based standards of care.
- Engaging with patients through longitudinal, personalized and data-driven conversations.

Industry And Other Funding Relationships

In today's complex and expensive healthcare environment, only industry has the resources necessary to develop, test and bring to market new products. Meanwhile, only the busy clinic can provide the data evidencing long-term safety and efficacy. Thus, medical advances, as well as the delivery of everyday care, rely on close collaboration between product manufacturers and clinicians. However, legal and institutional policies often pose obstacles to that collaboration.

Real-world studies provide a potent and ethical bridge between providers and industry enabling provider funding, product development and improved patient care. A common version of such studies is the "investigator-initiated trial", for which Circles are commonly used.

Circle-supported studies are also an effective way to demonstrate to corporate and private donors the real-world impact of their gifts.

GETTING STARTED

General

There are several ways, detailed here, to experience the functionality and value-creation of Circles. A major benefit of Circles is their broad flexibility. They can accommodate any real-world evidence goal, regardless of size or complexity, without forfeiting functionality. Moreover, it is easy to scale a Circle, or add new ones, at any time.

For hospital departments, Circles may need to be implemented in the context of a business associate agreement, internal system integration, IRB policies and other institutional requirements. RegenMed is able to do so.