RegenMed

WHITEPAPER

Establishing an Impactful Clinical Registry

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1. Key Considerations

Most clinical registry Sponsors seek to play a leadership role in developing evidence-based standards for specific classes of clinical interventions. As part of that goal, the Sponsor often attempts to establish one or more "registries". The reach and impact of the Sponsor's mission will be greatly amplified to the extent it is able properly to design and execute its registries.

To achieve reach and impact, the Sponsor should address several important elements in designing and executing its registry program:

- What type of data will lead to correlations which are genuinely useful in the clinic?
- What registry structure is most likely to capture such data?
- How does the Sponsor motivate busy clinicians — the primary source of the most important data — to participate?
- What are the policies regarding data control and ownership?
- How can the Sponsor, within its personnel and budgetary constraints, execute and grow a registry in a sustained manner?

Key Considerations

1.1 Data Quality

The legitimacy and impact of a registry of course depend on the nature and quality of its data. Those data should be:

- Based on reasonable and clearly articulated scientific hypotheses.
- Contextualized within a well identified indication, treatment plan and patient-cohort.
- Longitudinal and integrated across clinical cases.
- Fully auditable as to source, date/time and other parameters.
- Submitted and subsequently accessible in consistent and standardized formats.
- Submitted and subsequently available in a manner compliant with HIPAA, GDPR and other patient and personal privacy laws and institutional policies.

Without sustained submission to a registry of integrated datasets corresponding to the foregoing criteria, the ability to achieve and defend correlations will always be highly compromised.

Key Considerations

1.2 Registry Structure

A registry may be as simple as an online spreadsheet, or as complex as a large claims database. It may be an amalgamation of several other databases. It may focus on prospective, or retrospective, data. It may include only or principally outcomes data. However, whatever their form, most registries fail to achieve their intended impact, usually after significant expenditures of time and money by their sponsors.

For a registry to be impactful, it should be designed from the beginning to generate the types of correlations which are useful to busy clinicians within the targeted medical/scientific field. Most such fields encompass numerous treatment plans, products, clinical settings, legal/regulatory environments, and patient cohorts. Consequently, no single form of pre-defined registry can adequately predict or capture the datapoints which will end up being important for a specific indication, patient group or clinical environment.

Yet, the Sponsor must somehow design a structure which gathers and organizes enough datasets capable of yielding useful correlations for practitioners seeking to provide superior, predictable outcomes.

Key Considerations

1.3 Clinician Motivation

Gathering, properly characterizing, and submitting meaningful clinical data on a continual basis require time, commitment, and consistency from already over-burdened healthcare professionals. The inability to motivate practitioners to submit quality data is thus another major reason for the failure of registries to achieve desired impact. It is simply not enough that a ***very few*** clinicians submit ***some*** data, ***some*** of the time, which is ***partial*** and ***unverifiable***.

Despite this, Sponsors -- while requesting the busy clinician constantly to submit information -- typically offer little if anything in return. (Urging participants to “help advance medicine” may occasionally provide some temporary incentive. But it has proved to be insufficient to develop a meaningful registry on a sustained basis.)

Key Considerations

1.4 Data Ownership and Control

Governmental (HIPAA, other) and institutional policies regarding patient privacy are frequently impediments to registry participation by many clinicians. In addition, other data ownership and control issues deter clinicians. These include the desire to embargo useful datasets for articles and conference presentations, hospital policies, and unattractive or unclear registry policies regarding realizing value from data.

1.5 Personnel and Budget

Most Sponsors are medical societies and other not-for-profit organizations with part-time management, multiple stakeholders occasionally with conflicting agendas, limited budget and other constraints. (This often described the vendors to such Sponsors as well.)

These factors can result in slow and inefficient decision-making processes, inflexibility in correcting registry structural issues, and inability meaningfully to promote, sustain and grow the reach and impact of the registry.

2. CIRCLES

2.1 General

Most clinical registry Sponsors seek to play a leadership role in developing evidence-based standards for specific classes of clinical interventions. As part of that goal, the Sponsor often attempts to establish one or more "registries". The reach and impact of the Sponsor's mission will be greatly amplified to the extent it is able properly to design and execute its registries.

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- How can the Sponsor, within its personnel and budgetary constraints, execute and grow a registry in a sustained manner?

CIRCLES

2.2 Solutions

Circles, powered by our proprietary inCytes™ technology, are collaborative communities of practitioners aggregating, correlating and disseminating real-world evidence around specific clinical topics. Circles address the following pain points comprehensively, thus representing a turn-key solution for the management and growth.

PAIN POINT	SOLUTIONS INCLUDE
POLITICS	Each Society, Institution and/or Individual of the BA manages their own "Circle'. **See Appendix A: Figure 1**
	Each Circle determines their membership, protocol localized privacy settings, including server locations, data de-identification and sharing rules, patient consent language, and more. **See Appendix A: Figure 2**
	Circle Members can see Circle data. Members of multiple Circles can see multiple Circles' data. BA authorized representatives, as default members of all Circles, could aggregate all Circles' data.
	Root Protocols ensure consistent data aggregation even among user-customized protocol versions. **See Appendix A: Figure 3**

CIRCLES

2.2 Solutions Continued

PAIN POINT	SOLUTIONS INCLUDE
THE RIGHT DATA	Custom eCRF builder with flexible question creation, modification, gamification. **See Appendix A: Figure 4**
	Dozens of musculoskeletal PROMs. Ability to cost-effectively upload, configure and use any new PROM, ClinRo or other custom Assessment (E.G. PRP Classification System)
	Immediate correlation of any custom question(s) against standard assessments. (E.G. PLTs Greater than X to KOOS outcomes) **See Appendix A: Figure 5**
	Hl7/FHIR standard relational database, robust user verification, action tracking and various other audit trails.

CIRCLES

2.2 Solutions Continued

PAIN POINT	SOLUTIONS INCLUDE
PATIENT ENGAGEMENT AND COMPLIANCE	Custom, practice-branded, interactive Patient Portal, Benchmarc™ **See Appendix A: Figure 6**
	Live patient benchmarks, against themselves and others, earn and engage follow up reporting. **See Appendix A: Figure 7**
	Seamless registration experience, including custom eConsent for each Circle. **See Appendix A: Figure 8**
	Before/After Images, Content and Case Data makes Patient active participant and beneficiary of their follow up regimen.

CIRCLES

2.2 Solutions Continued

PAIN POINT	SOLUTIONS INCLUDE
PRACTITIONER BUY-IN	Smaller, targeted, personalized Circles preferable for Clinicians to large, monolithic registries. **See Appendix A: Figure 9**
	Robust, automated patient engagement through Benchmarc™
	Delegate to staff, laboratories, external call centers.
	Simple, visual and effective data aggregation and visualization. **See Appendix A: Figure 10**

CIRCLES

2.2 Solutions Continued

PAIN POINT	SOLUTIONS INCLUDE
HUMAN CAPITAL SUPPORT	Earn revenues, without tarnishing BA registries, through independent, industry sponsored Circles . **See Appendix A: Figure 11**
	RegenMed handles all training, service and support of inCytes™ users.
	Circles allow uploading of historical cases, and RegenMed could handle in bulk for new members or those using redundant systems.
	RegenMed promotes Circles Founders, helping nurture and grow Circle memberships and results. **See Appendix A: Figure 12**

3. Execution and Support

Regen Med's full-time business is the design, support and implementation of product-agnostic Circles. It provides to a Sponsor the following capabilities:

Execution and Support

3.1 Expertise

In addition to the Company's business, medical and scientific leadership, the RegenMed network includes leading independent thought leaders and academic medical institutions from around the world in many therapeutic areas. These resources can supplement existing Sponsor expertise and extend the geographic reach of registries. It can also extend the applicability of the registry to other medical specialties, as clinical diagnoses and interventions become increasingly systemic.

EXECUTION AND SUPPORT

3.2 Turnkey, Integrated and Customizable Processes

The involvement of multiple vendors, platforms and partial solutions in the design, curation and promotion of a clinical registry usually leads to unnecessary costs, delays, participant frustration and substantial underperformance. Regen Med's processes and platforms are designed and executed from the ground up to support Circles in a turn-key, clinically-efficient, integrated and sustained manner.

The focus is on adding value to clinicians through the power of real-world evidence. These processes are highly scalable, from smaller practices to large hospital systems. As a result, Circles not only allow a Sponsor to provide "mini registry" capabilities, but also to generate multiple impactful correlations from large aggregated datasets contained in a master registry.

Moreover, all Circles are highly customizable – and may be "white-labelled – at the individual clinician, hospital and Sponsor levels.

EXECUTION AND SUPPORT

3.3 Next Steps

A typical registry Sponsor already has board or other members which can represent the initial Circle, capable of generating relatively quickly a corresponding “mini-registry”. Seeing is believing, and by promoting these early Observational Protocols and preliminary real-world datasets, the Sponsor will be able to attract additional Circle members and Circles. In this way, it will have created a sustainable, attractive and self-scaling process for developing a master registry with substantial impact. Through its existing processes and platforms, RegenMed is able to handle all elements of this process each step of the way on behalf of the Sponsor.

We welcome a conversation to discuss further.

4. RegenMed

The Evidence-Based Network

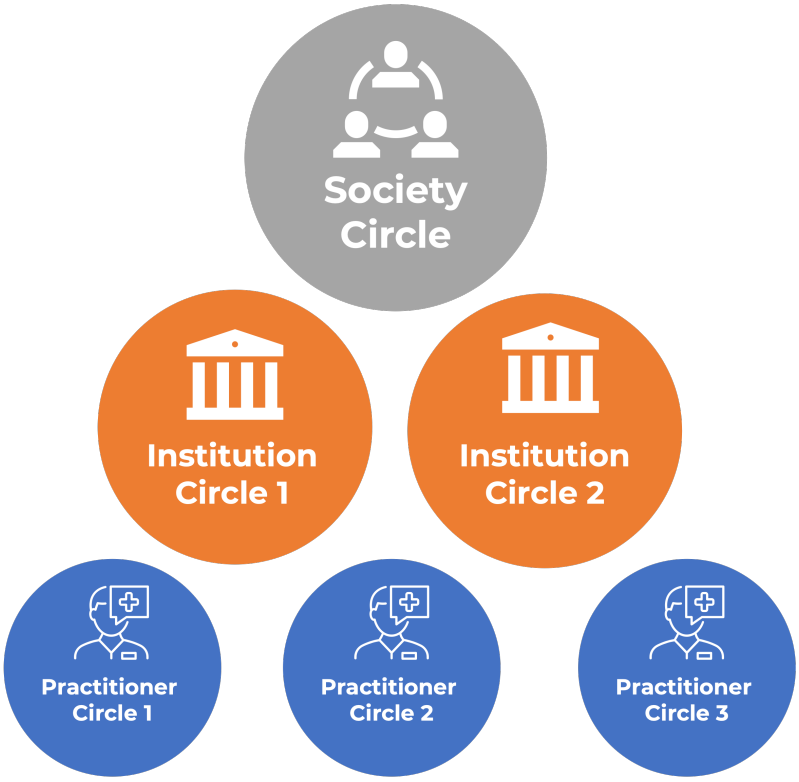
Regen Med's offers the leadership, systems and professionalism required to help materially improve medical product sales revenues and margins by generating and exploiting real-world evidence.

The Company works in most regions around the world, and with large hospital systems as well as individual clinicians and medical scientists. Through Circles, it and its clients are generating – and developing demonstrable value from – real world evidence in a variety of therapeutic areas. See the Company's Latest page for examples.

Visit www.rgnmed.com to learn more.

Appendix A Figures

Figure 1



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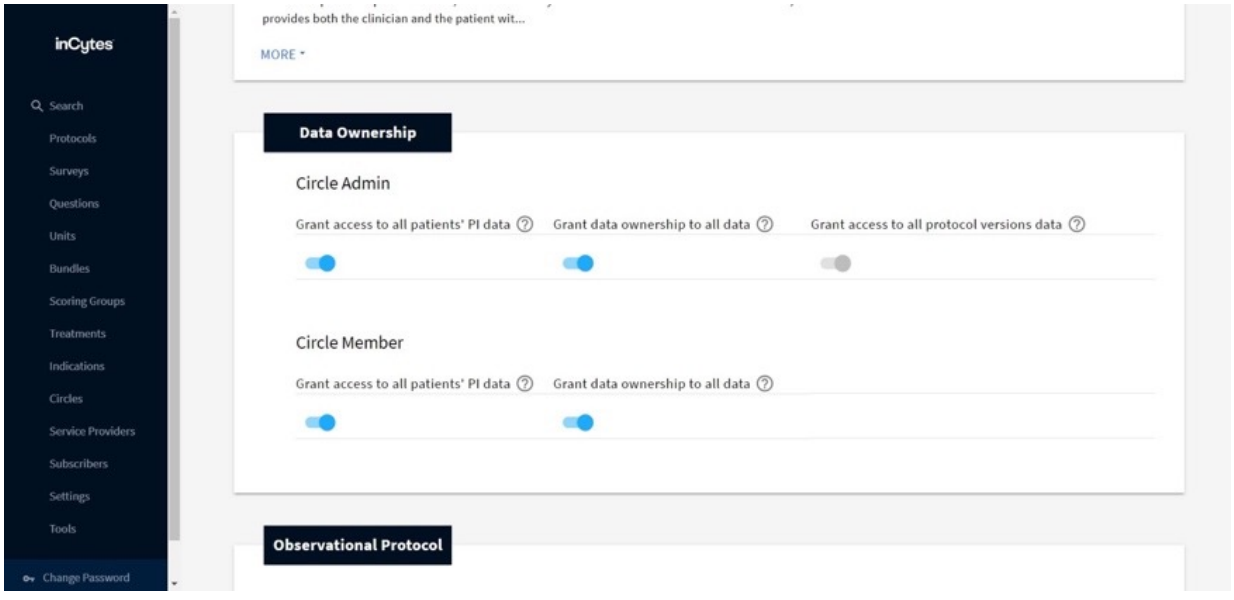
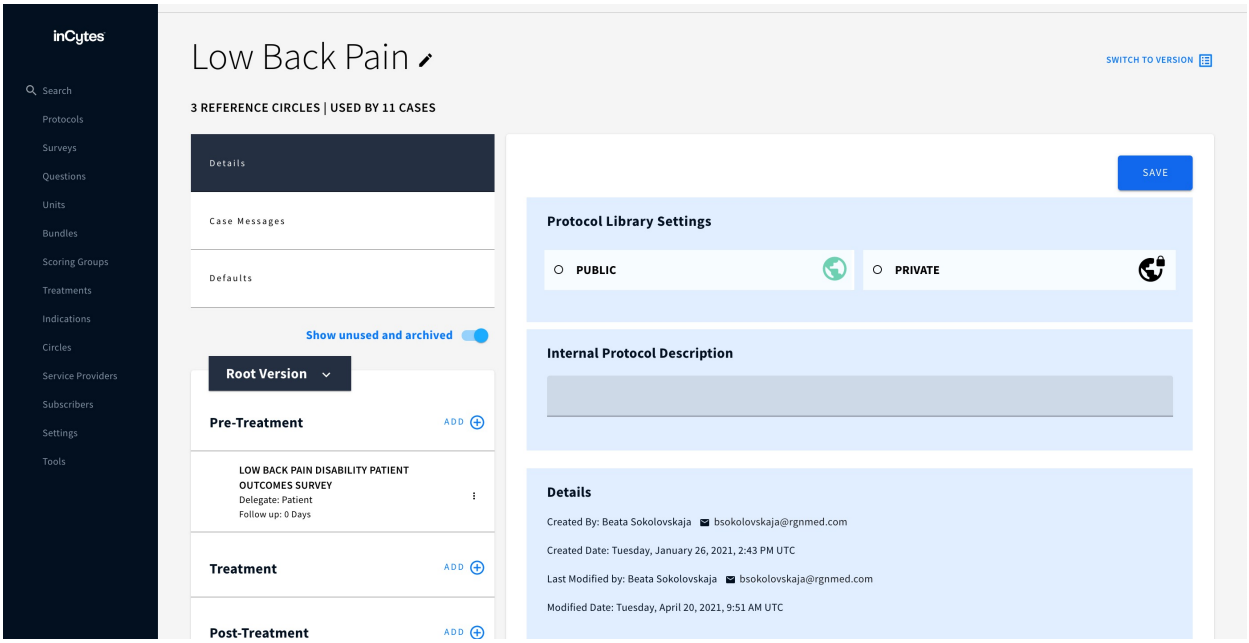


Appendix A Figures

Figure 3



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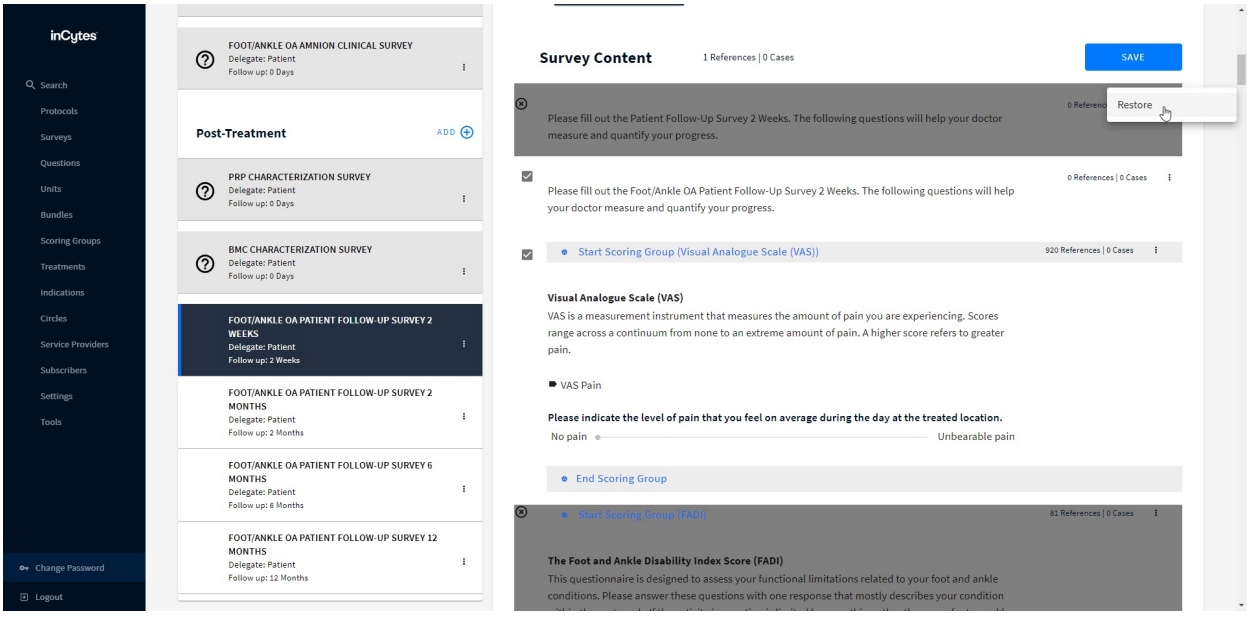
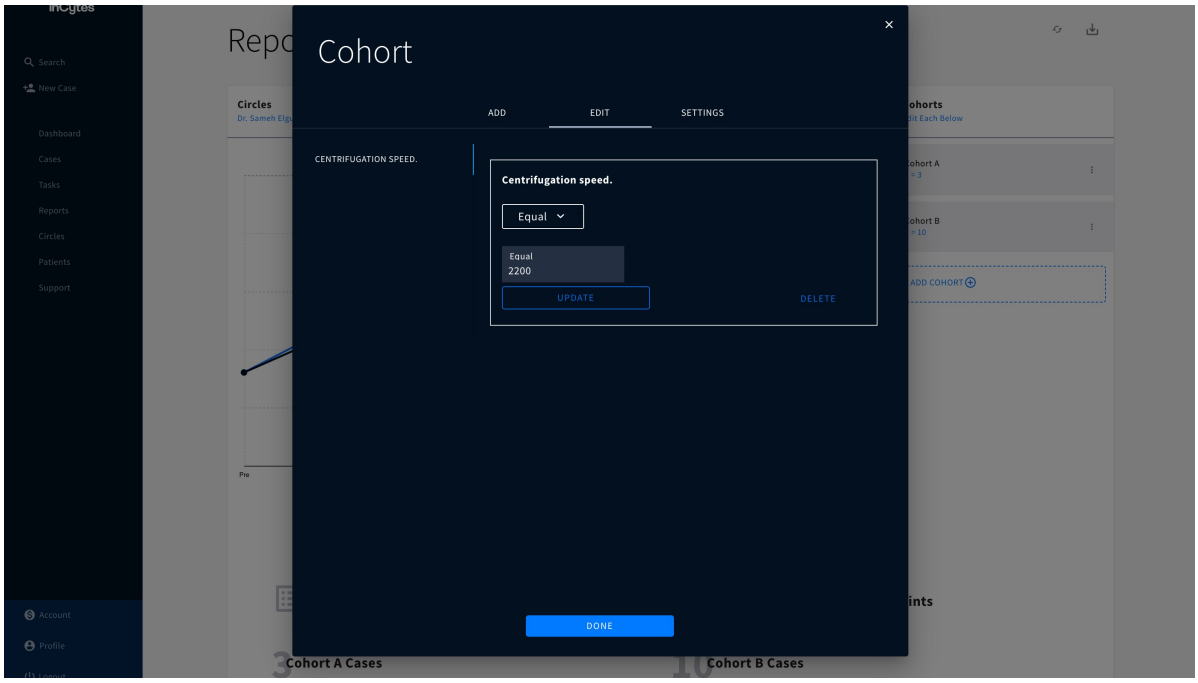


Appendix A Figures

Figure 5



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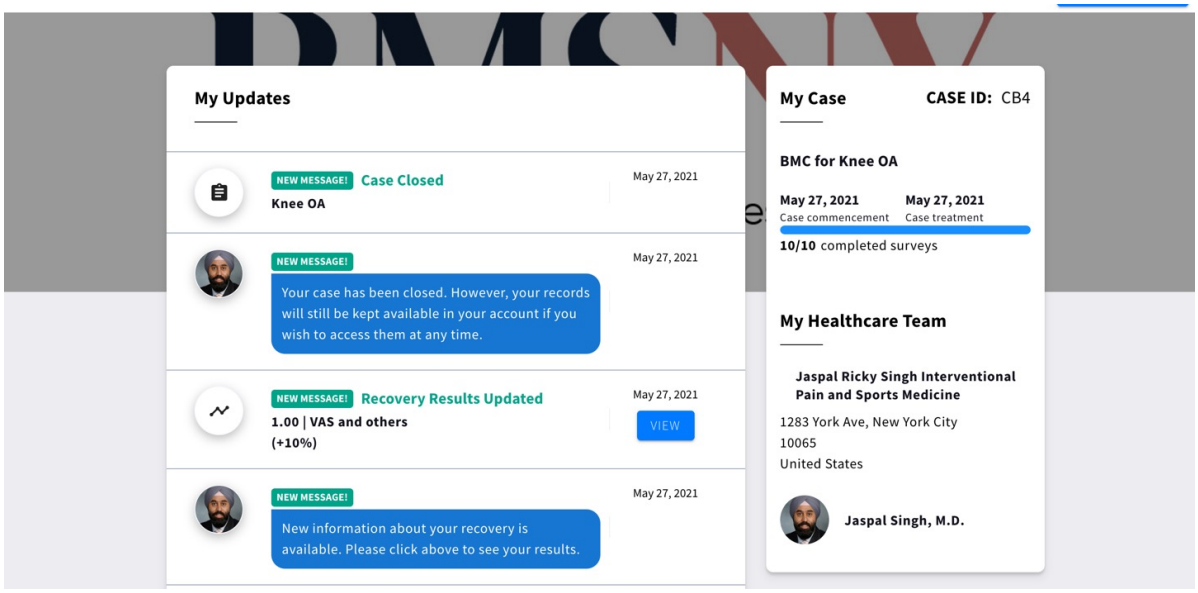
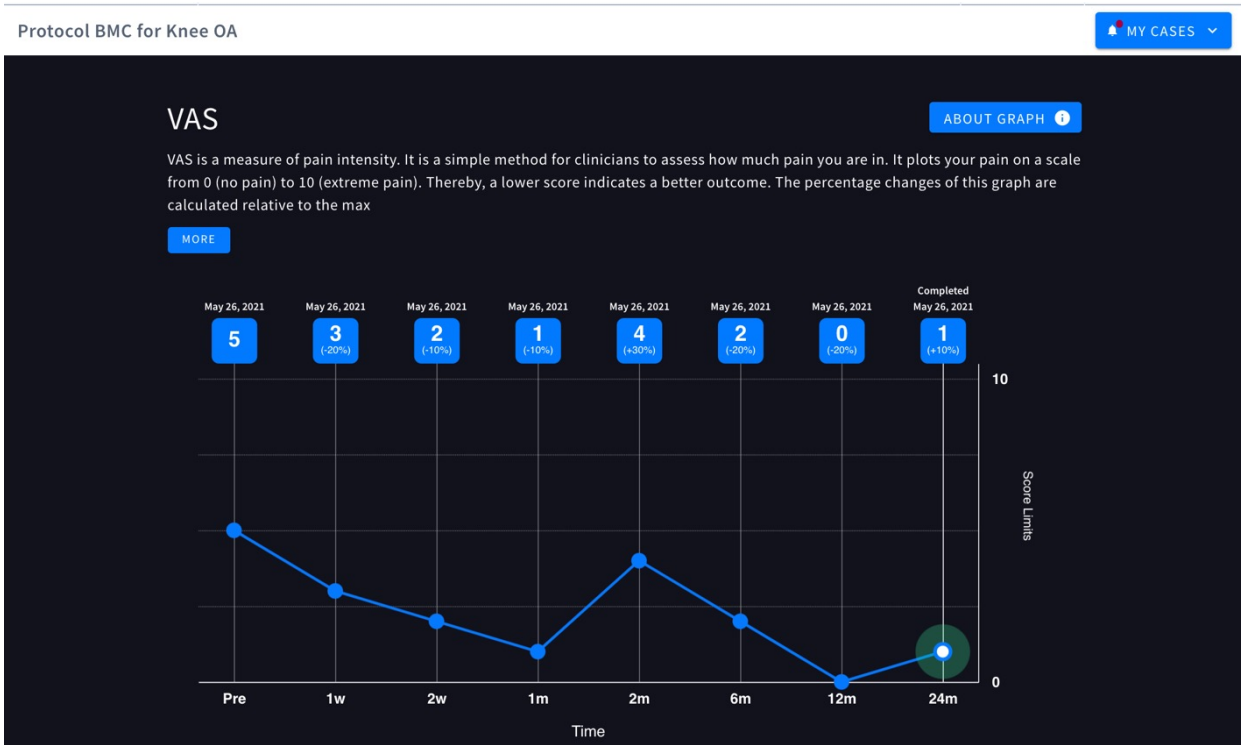


Appendix A Figures

Figure 7



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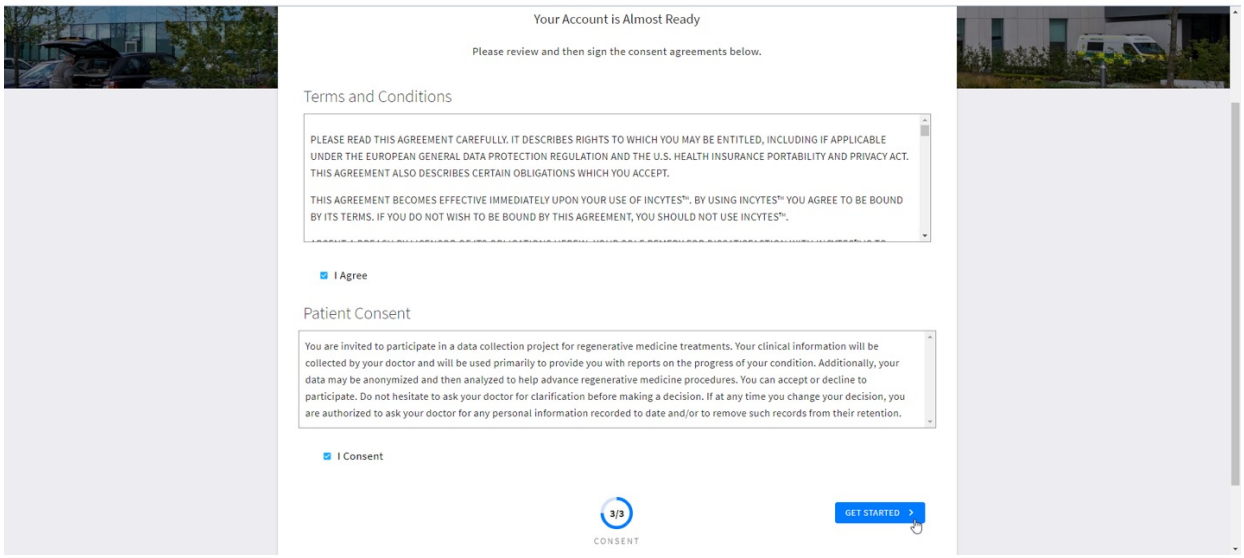
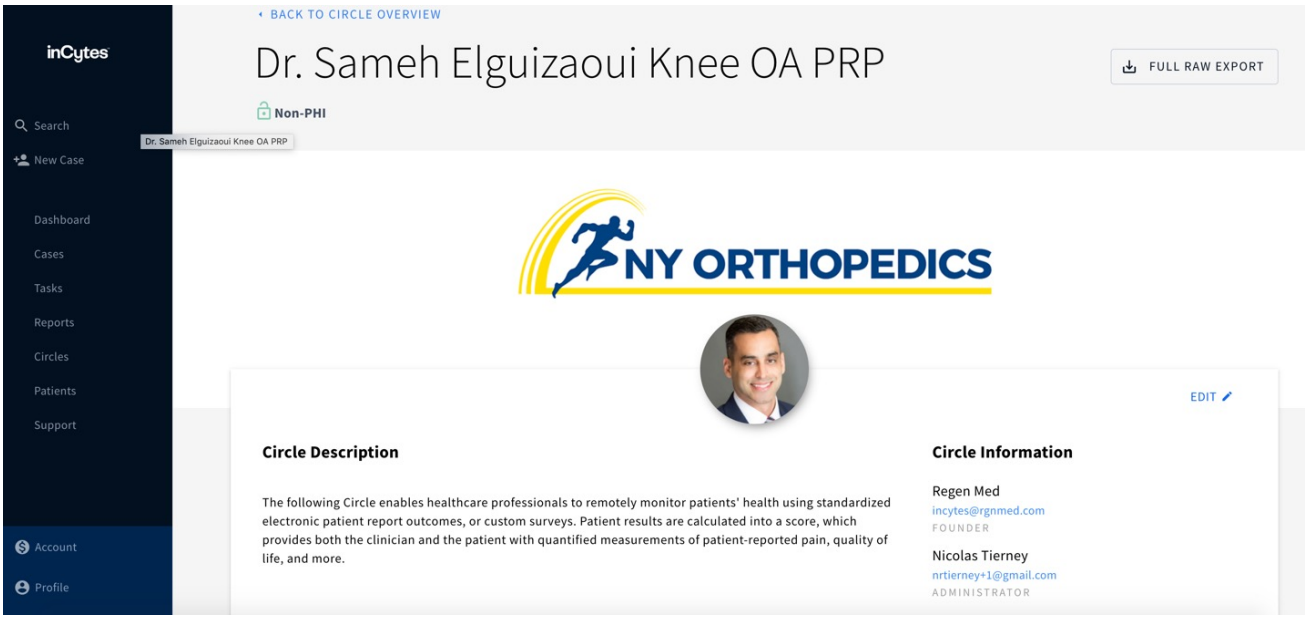


Appendix A Figures

Figure 9



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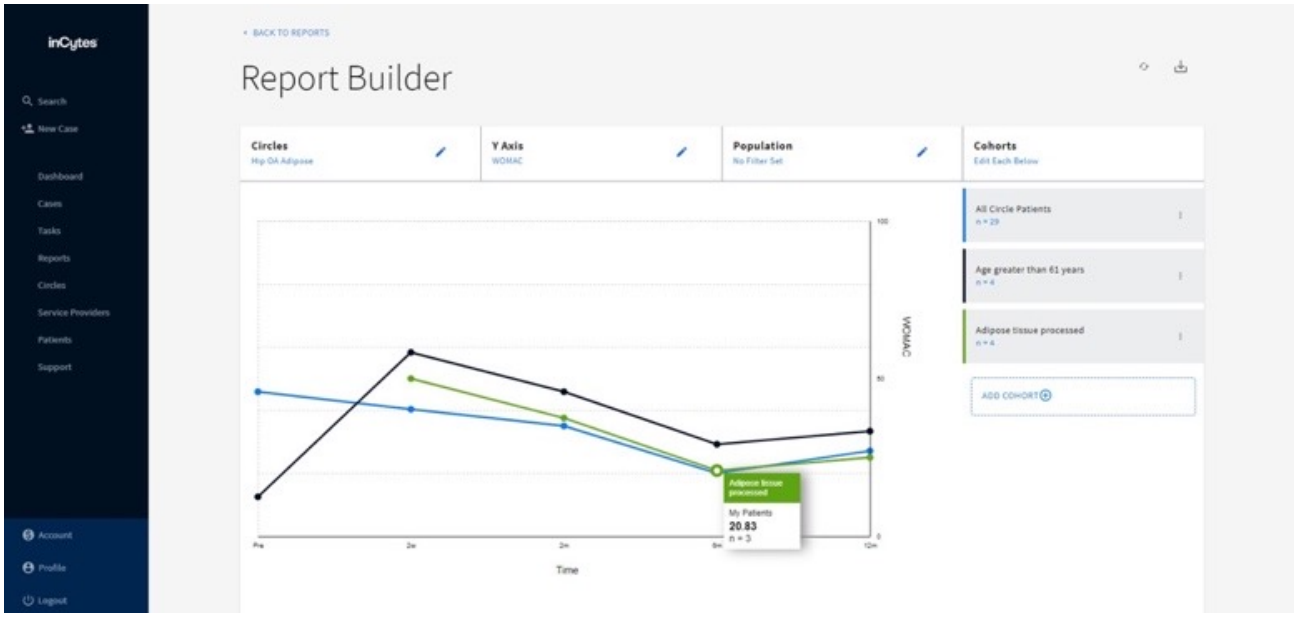
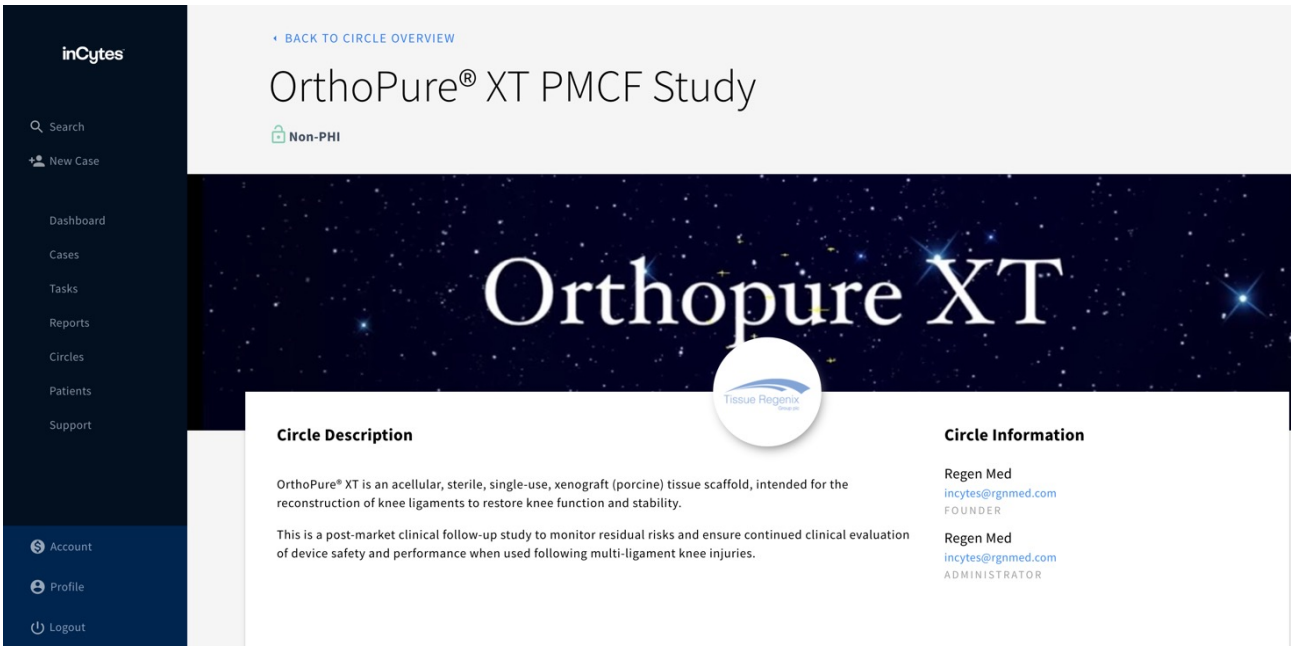


Appendix A Figures

Figure 11



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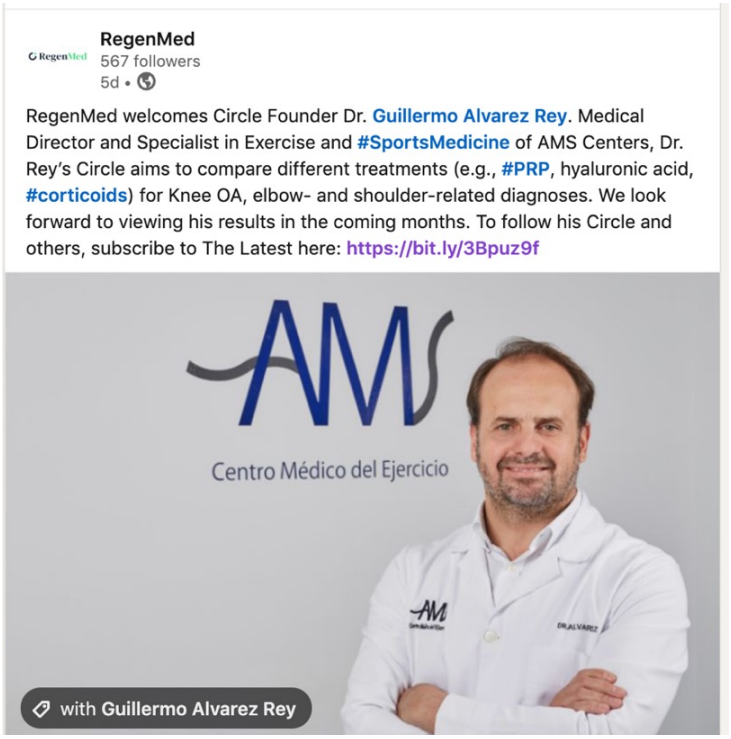

RegenMed

Get Started with Circles

Interested in starting a clinical registry with RegenMed's Circles?

Contact Us Today