



# WHITEPAPER

## Establishing an Impactful Clinical Registry



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# 1. Key Considerations

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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?

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# Key Considerations

## 1.1 Data Quality

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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.

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# Key Considerations

## 1.2 Registry Structure

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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.

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# Key Considerations

## 1.3 Clinician Motivation

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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.)

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# Key Considerations

## 1.4 Data Ownership and Control

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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.

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## 1.5 Personnel and Budget

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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.

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# 2. CIRCLES

## 2.1 General

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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?



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# CIRCLES

## 2.2 Solutions

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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
<b>POLITICS</b>	Each Society, Institution and/or Individual of the BA manages their own “Circle”. <b>See Appendix A: Figure 1</b>
	Each Circle determines their membership, protocol localized privacy settings, including server locations, data de-identification and sharing rules, patient consent language, and more. <b>See Appendix A: Figure 2</b>
	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. <b>See Appendix A: Figure 3</b>

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# CIRCLES

## 2.2 Solutions Continued

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PAIN POINT	SOLUTIONS INCLUDE
<b>THE RIGHT DATA</b>	<p>Custom eCRF builder with flexible question creation, modification, gamification. <b>See Appendix A: Figure 4</b></p>
	<p>Dozens of musculoskeletal PROMs. Ability to cost-effectively upload, configure and use any new PROM, ClinRo or other custom Assessment (E.G. <a href="#">PRP Classification System</a>)</p>
	<p>Immediate correlation of any custom question(s) against standard assessments. (E.G. PLTs Greater than X to KOOS outcomes) <b>See Appendix A: Figure 5</b></p>
	<p>HI7/FHIR standard relational database, robust user verification, action tracking and various other audit trails.</p>

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# CIRCLES

## 2.2 Solutions Continued

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

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# CIRCLES

## 2.2 Solutions Continued

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

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# CIRCLES

## 2.2 Solutions Continued

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

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# 3. Execution and Support

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

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## Execution and Support

### 3.1 Expertise

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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.

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# EXECUTION AND SUPPORT

## 3.2 Turnkey, Integrated and Customizable Processes

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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.

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# EXECUTION AND SUPPORT

## 3.3 Next Steps

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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.



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# 4. RegenMed

## The Evidence-Based Network

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[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](http://www.rgnmed.com) to learn more.

# Appendix A Figures

Figure 1

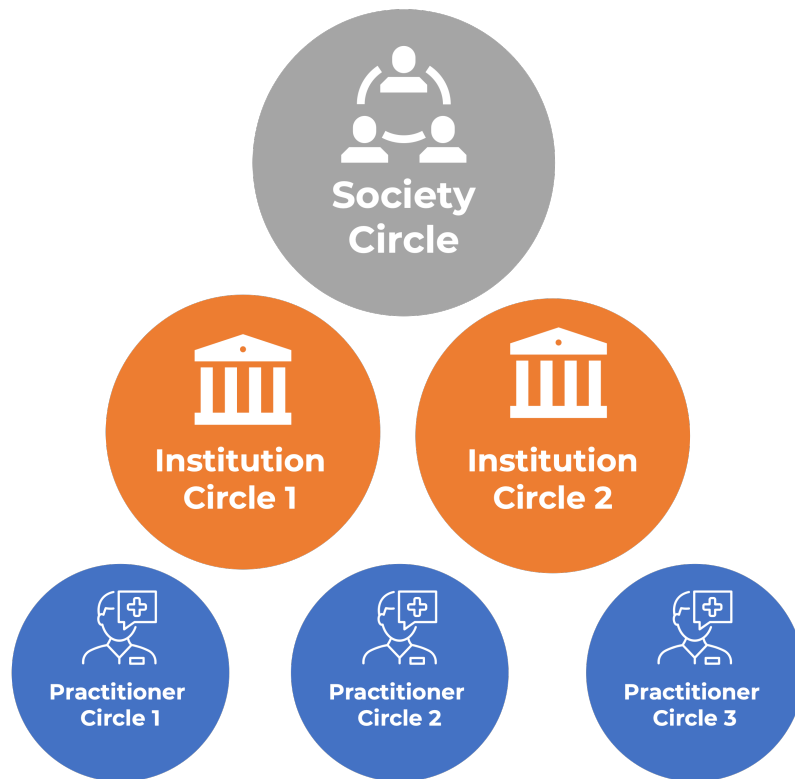


Figure 2

The screenshot shows the inCytos user interface. On the left is a dark sidebar with a search bar and a list of navigation items: Protocols, Surveys, Questions, Units, Bundles, Scoring Groups, Treatments, Indications, Circles, Service Providers, Subscribers, Settings, and Tools. At the bottom of the sidebar is a 'Change Password' link. The main content area shows a section for 'Data Ownership' with two sub-sections: 'Circle Admin' and 'Circle Member'. Each sub-section has three toggle switches for different data access permissions, each with a help icon. The 'Circle Admin' section has three toggles: 'Grant access to all patients' PI data' (checked), 'Grant data ownership to all data' (checked), and 'Grant access to all protocol versions data' (unchecked). The 'Circle Member' section has two toggles: 'Grant access to all patients' PI data' (checked) and 'Grant data ownership to all data' (checked). Below the 'Data Ownership' section is a section for 'Observational Protocol'.

# Appendix A Figures

Figure 3

The screenshot shows the 'Low Back Pain' protocol settings in the inCytes system. The interface includes a sidebar with navigation options like Search, Protocols, Surveys, Questions, Units, Bundles, Scoring Groups, Treatments, Indications, Circles, Service Providers, Subscribers, Settings, and Tools. The main content area is titled 'Low Back Pain' and shows '3 REFERENCE CIRCLES | USED BY 11 CASES'. It features a 'Details' section with 'Case Messages' and 'Defaults'. A 'Show unused and archived' toggle is visible. Below this is a 'Root Version' dropdown and sections for 'Pre-Treatment', 'Treatment', and 'Post-Treatment', each with an 'ADD +' button. The 'Pre-Treatment' section lists 'LOW BACK PAIN DISABILITY PATIENT OUTCOMES SURVEY' with delegate and follow-up information. The right-hand side contains 'Protocol Library Settings' with 'PUBLIC' and 'PRIVATE' radio buttons, an 'Internal Protocol Description' text area, and a 'Details' section with creation and modification metadata.

Figure 4

The screenshot displays the 'Survey Content' configuration page in the inCytes system. The sidebar is consistent with Figure 3. The main content area is titled 'Survey Content' and shows '1 References | 0 Cases'. It features a 'SAVE' button and a 'Restore' button. The content is organized into sections: 'Post-Treatment' with an 'ADD +' button, and a list of surveys including 'FOOT/ANKLE OA AMNION CLINICAL SURVEY', 'PRP CHARACTERIZATION SURVEY', 'BMC CHARACTERIZATION SURVEY', and 'FOOT/ANKLE OA PATIENT FOLLOW-UP SURVEY 2 WEEKS' (which is highlighted). Below this, there are sections for 'Visual Analogue Scale (VAS)' and 'The Foot and Ankle Disability Index Score (FADI)'. The VAS section includes a visual scale from 'No pain' to 'Unbearable pain'. The FADI section includes a 'Start Scoring Group (FADI)' button and a description of the questionnaire.

# Appendix A Figures

Figure 5

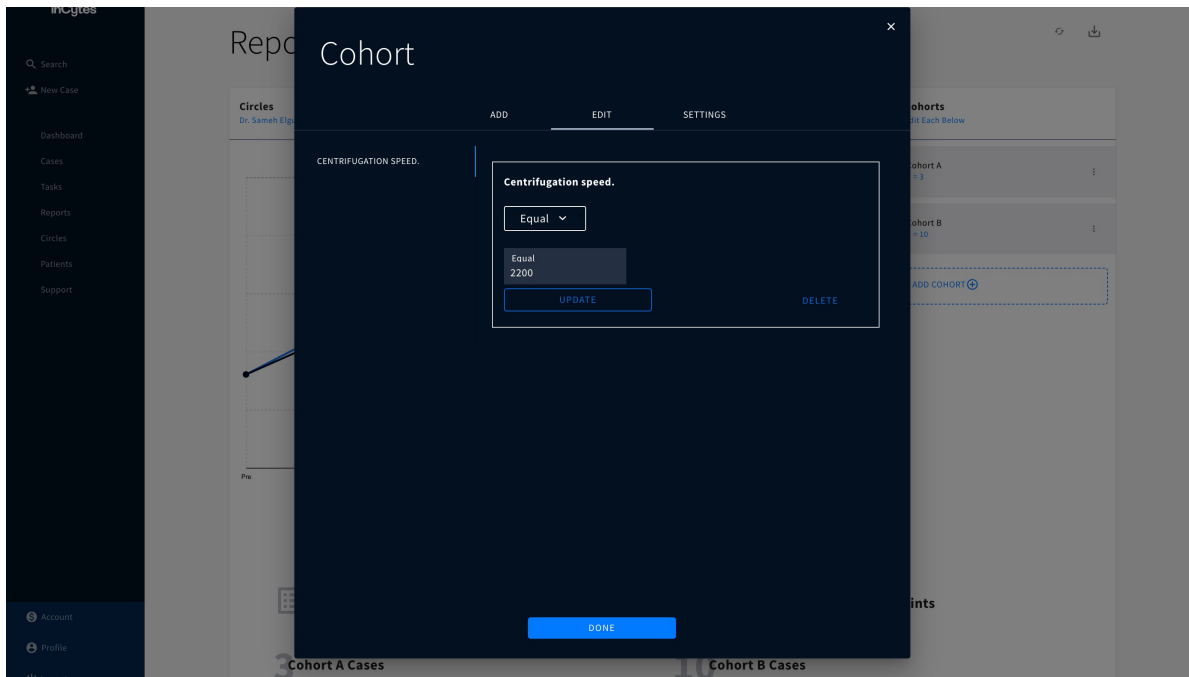
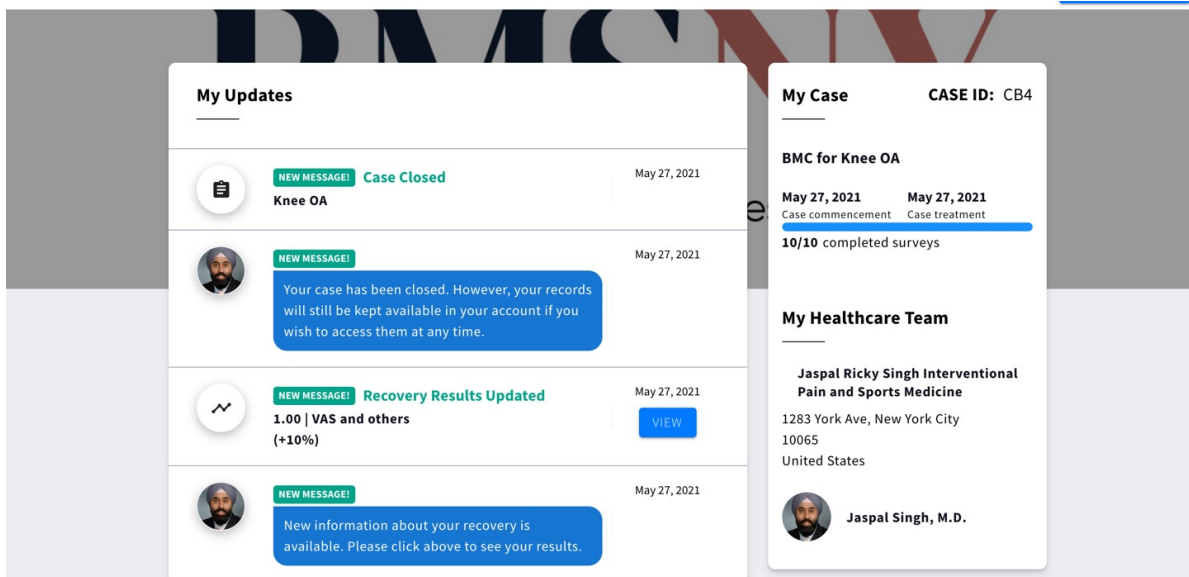
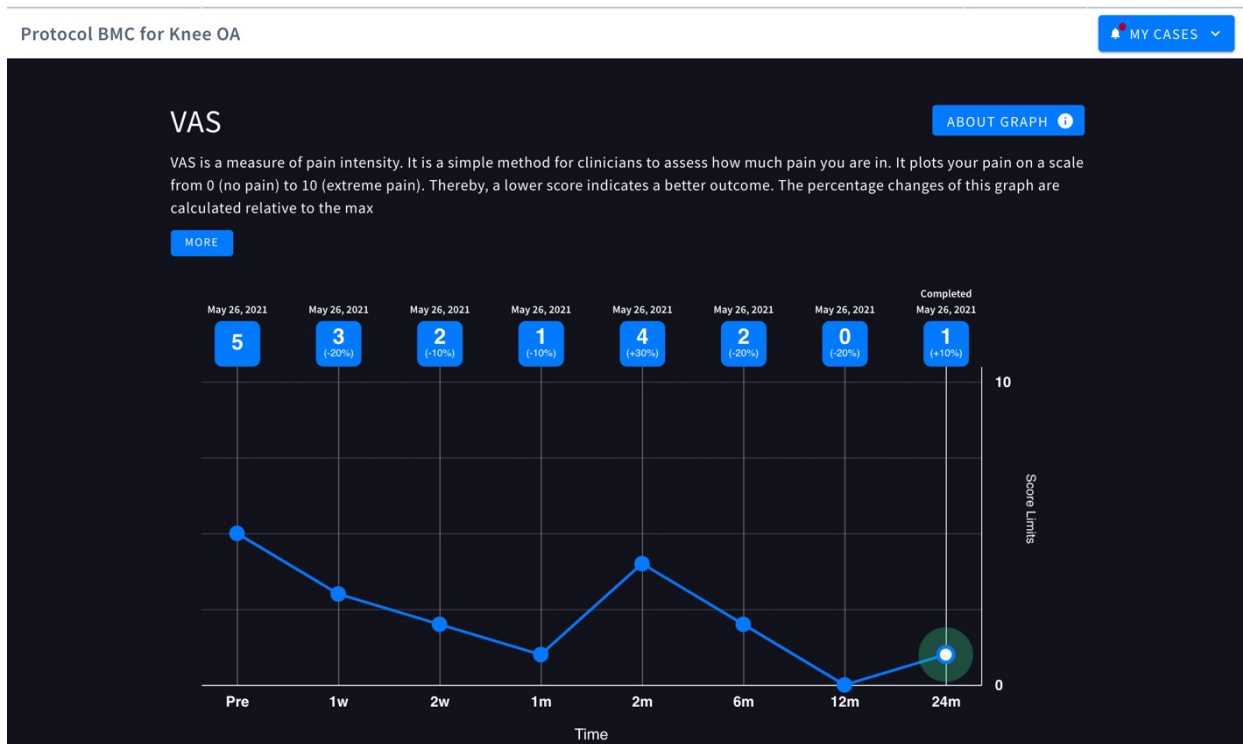


Figure 6



# Appendix A Figures

## Figure 7



## Figure 8

Your Account is Almost Ready

Please review and then sign the consent agreements below.

### Terms and Conditions

PLEASE READ THIS AGREEMENT CAREFULLY. IT DESCRIBES RIGHTS TO WHICH YOU MAY BE ENTITLED, INCLUDING IF APPLICABLE UNDER THE EUROPEAN GENERAL DATA PROTECTION REGULATION AND THE U.S. HEALTH INSURANCE PORTABILITY AND PRIVACY ACT. THIS AGREEMENT ALSO DESCRIBES CERTAIN OBLIGATIONS WHICH YOU ACCEPT.

THIS AGREEMENT BECOMES EFFECTIVE IMMEDIATELY UPON YOUR USE OF INCYTES™. BY USING INCYTES™ YOU AGREE TO BE BOUND BY ITS TERMS. IF YOU DO NOT WISH TO BE BOUND BY THIS AGREEMENT, YOU SHOULD NOT USE INCYTES™.

I Agree

### Patient Consent

You are invited to participate in a data collection project for regenerative medicine treatments. Your clinical information will be collected by your doctor and will be used primarily to provide you with reports on the progress of your condition. Additionally, your data may be anonymized and then analyzed to help advance regenerative medicine procedures. You can accept or decline to participate. Do not hesitate to ask your doctor for clarification before making a decision. If at any time you change your decision, you are authorized to ask your doctor for any personal information recorded to date and/or to remove such records from their retention.

I Consent

3/3 CONSENT GET STARTED

# Appendix A Figures

Figure 9

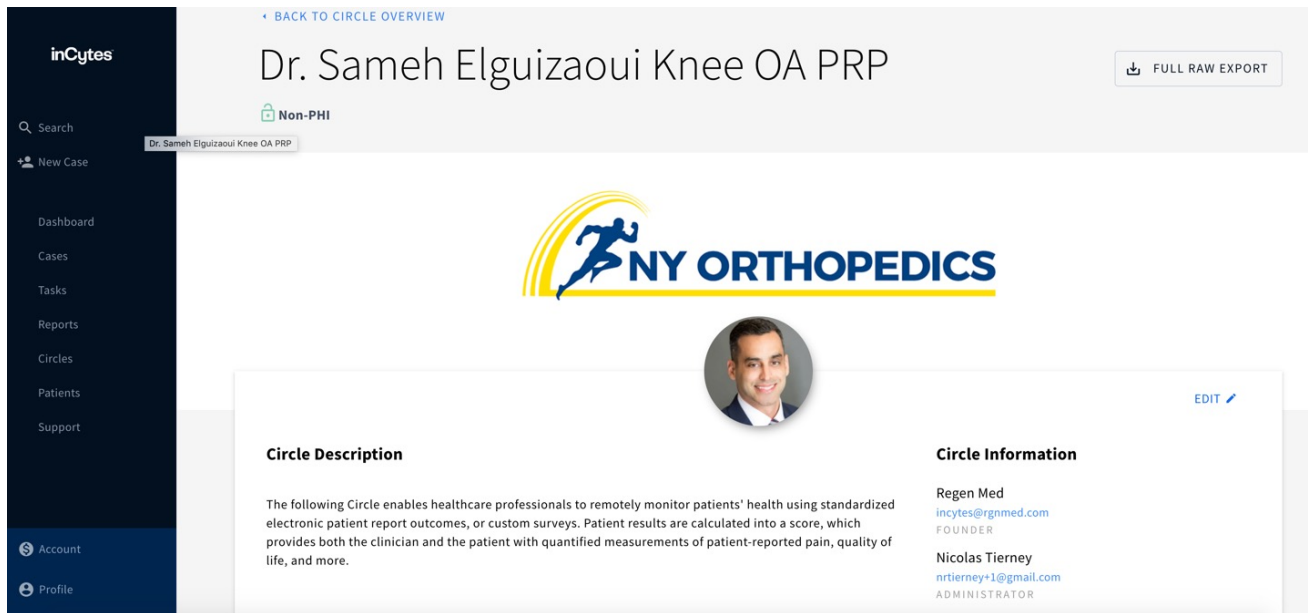
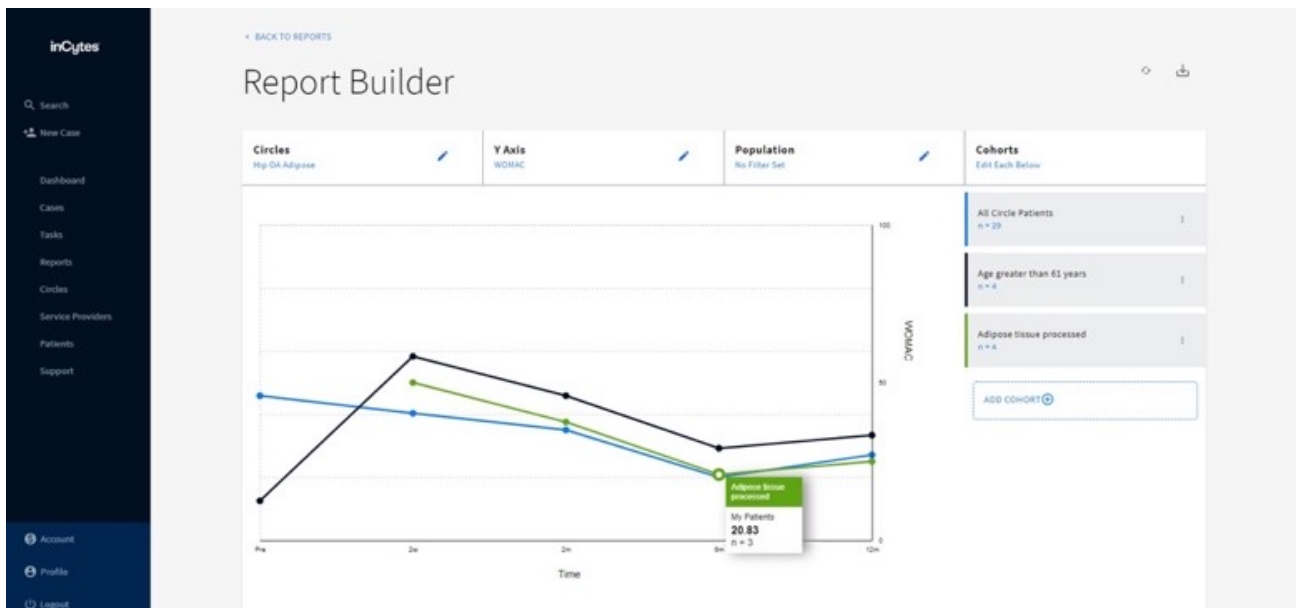


Figure 10



# Appendix A Figures

Figure 11

inCytes

• BACK TO CIRCLE OVERVIEW

## OrthoPure® XT PMCF Study

Non-PHI

# Orthopure XT

Tissue Regenix

**Circle Description**

OrthoPure® XT is an acellular, sterile, single-use, xenograft (porcine) tissue scaffold, intended for the reconstruction of knee ligaments to restore knee function and stability.

This is a post-market clinical follow-up study to monitor residual risks and ensure continued clinical evaluation of device safety and performance when used following multi-ligament knee injuries.

**Circle Information**

Regen Med  
incytes@rgnmed.com  
FOUNDER

Regen Med  
incytes@rgnmed.com  
ADMINISTRATOR

Figure 12

RegenMed  
567 followers  
5d • 🌐

RegenMed welcomes Circle Founder Dr. [Guillermo Alvarez Rey](#). Medical Director and Specialist in Exercise and [#SportsMedicine](#) of AMS Centers, Dr. Rey's Circle aims to compare different treatments (e.g., [#PRP](#), hyaluronic acid, [#corticoids](#)) for Knee OA, elbow- and shoulder-related diagnoses. We look forward to viewing his results in the coming months. To follow his Circle and others, subscribe to The Latest here: <https://bit.ly/3Bpuz9f>

AMS  
Centro Médico del Ejercicio

with Guillermo Alvarez Rey

# Get Started with Circles

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

[Contact Us Today](#)