

**TABLE OF CONTENTS**

<b>2</b>	<b>WELCOME</b>
<b>2</b>	<b>SELECT CLIENT ACTIVITIES</b>
2	SINGAPORE GENERAL HOSPITAL
3	PAGDIN HEALTH
3	APEX BIOLOGIX
4	GULF COAST BIOLOGICS
4	JOINTECHLABS
5	DR. GUILLERMO ÁLVAREZ REY
5	DR. JOSÉ MIGUEL CATALÁN
<b>6</b>	<b>THE WORLD OF REAL-WORLD EVIDENCE</b>
6	AAOS REAL-WORLD EVIDENCE REGISTRY
6	SUNSETTING OF ARTHREX'S SURGICAL OUTCOMES SYSTEM
6	MANDATES, BEST PRACTICES, REFERENCES
<b>7</b>	<b>COMPANY NEWS</b>
7	NEW WEBSITE
7	CIRCLE ACADEMIES
8	EVENTS
<b>9</b>	<b>SUBSCRIBE, FOLLOW</b>

Welcome to RegenMed's January 2023 Newsletter. Here, we summarize client activities of interest, events and upcoming activities. Find out more on our [Latest](#) and [Circle Academies](#) pages.

## SELECT CLIENT ACTIVITIES

Healthcare providers and medical device manufacturers around the world are using [Circles](#) to advance their clinical, scientific and commercial objectives. Following are some recent examples.

More information on each Circle can be found by clicking on the Circle Academy link provided after each entry. This will allow interested clinicians to get in touch with Circle Founders for permission to follow, or join, their Circles.

Get started with [your own Circle](#).

### Singapore General Hospital



Together with his colleagues, Professor [Tay Boon Keng](#), head of orthopedics at the prestigious [Singapore General Hospital](#), is completing a twelve month study comparing the safety and efficacy of hyaluronic acid alone with HA plus PRP for knee osteoarthritis patients. Outcomes data using the [WOMAC](#) scoring system have been collected for 118 patients. Those data suggest improved scores for the HA+PRP group, compared with that of HA alone and this group is finishing the long-term follow-up for this project.

[Visit Dr. Tay Boon Keng's Knee OA and PRP Circle Academy Space](#) →

## Pagdin Health



In 2020 [Health Canada](#) issued a [Policy Position Paper](#) regarding autologous cell therapy products. The paper emphasized the importance of practitioners working with Health Canada in helping to develop evidence-based standards of care for such interventions in the context of specific indications.

[Dr. Grant Pagdin](#) in British Columbia is among the leading clinicians closely following Health Canada's policy goals.

Working with RegenMed, Dr. Pagdin has designed and implemented multiple Circles covering the use of PRP for various urological and musculoskeletal indications. He has established a dedicated [Outcomes Page](#) on his website, allowing patients to follow their progress over time against standardized benchmarks.

[Visit Dr. Pagdin's Circles Academies Space](#) →

## Apex Biologix



[Apex Biologix](#) has funded 4 initial Circles to support its key opinion leaders, including [Dr. George Chang Chien](#), in the establishment and growth of quality improvement registries around the use of PRP, BMC, A2M and more.

Circle design and clinical/scientific hypotheses undergirding the Circle will be discussed on the [EVOLVE Conference](#) hosted by the [Advanced Regenerative Medicine Institute](#) February 3 - 5, 2023 in Salt Lake City.

[Visit Dr. George Chang Chien's Circle Academy Space](#) →

## Gulf Coast Biologics



Under the leadership of [Peter Everts, Ph.D., FRSM, Gulf Coast Biologics](#) is organizing a clinically-sophisticated Circle for knee treatments utilizing PRP. Long-term outcomes utilizing the IKDC and WOMAC scoring measures will generate correlations against key pathoanatomic real-world datapoints, including PRP preparation, dosing and specific injection locations.

Respected interventional practitioners from around the country are participating, including Doctors [Luga Podesta](#), [Glenn Flanagan](#), [Donald Buford](#), [Timothy Mazzola](#), [Ariana Demers](#), [Imran Siddiqui](#), [Alberto Panero](#), [Gayan Poovendran](#) and more. In addition, [Christine Mahoney, Ph.D.](#) is providing statistical analysis support.

Gulf Coast Biologics expects at least 50 patients to be enrolled each month for a minimum of six months. In addition, GCB will host monthly “Circle Hours” – LiveStream discussions on Circle Academies among Circle Members and registered participants reviewing early observations. Dr. Everts and RegenMed’s Scientific Director, [Seve dos Anjos, Ph.D.](#), will moderate the LiveStream event, as well as subsequent on-line Circle Academy discussions.

[Visit Dr. Peter Everts’s Circle Academy Space](#) →

## JoinTechLabs



Working with [Doctors Mitchell Sheinkop, John Ferrell, III, Imran Siddiqui, Ariana DeMers](#) and [Janet Pearl](#), RegenMed has designed and implemented Circles to facilitate two studies for the delivery of micronized adipose for knee and shoulder pathologies. Endpoints will be measured using both patient-reported and clinically-assessed outcomes measures. The Circles are funded by [JoinTechLabs](#), and will enroll over 30 patients. They will be overseen by the [IRCM IRB](#).

[Visit Dr. Mitchell Sheinkop’s Circle Academy Space](#) →

**Dr. Guillermo Álvarez Rey**



[Guillermo Álvarez Rey, M.D.](#) (sports medicine specialist) and Carlos Ferrer Señorans M.D. (orthopedic surgeon) from [AMS Sonosurgery center](#) - located in Málaga, Spain- have created several real-world studies using Circles out of their own clinical practice. As one relevant example for Knee Osteoarthritis, they are capturing patient outcomes up to a year using KOOS, and correlating those outcomes to various clinical factors, such as biological treatments used, and the Kellgren-Lawrence (KL) grade of each of their patients.

They are capturing Real World Clinical Data for many other musculoskeletal indications such as Achilles tendinopathy, epicondylitis or shoulder pathologies. They have reached the landmark of 180 cases in all their Circles, many of which have already achieved the 12-months follow-up.

[Visit Dr. Guillermo Álvarez Rey's Circle Academy Space](#) →

**Dr. José Miguel Catalán**



[Dr. José Miguel Catalán](#), orthopedic surgeon expert in the use of biological therapies for different indications, but particularly on PRP and BMC, is one of the pioneers in the use of Circles and the inCytes platform for Real World Data Collection since 2019.

Dr Catalán has already collected PRP characterization data from near 300 clinical cases, including platelet dose and other variables, that he is now correlating against the long-term patient-reported outcomes using WOMAC scale. He is presenting these updated Real World Data at OrtoBioMSK specialized course in Seville on February this year, and also at the next TOBI Conference.

[Visit Dr. Catalan's Knee PRP Circle Academy Space](#) →

[Visit Dr. Catalan's Bone Marrow Aspirate, Knee and Hip Circle Academy Space](#) →

## THE WORLD OF REAL-WORLD EVIDENCE

### AAOS Real-World Evidence Registry

The [AAOS registries](#) cover several traditional orthopedic interventions. The Academy is now discussing how to collect real-world evidence to deliver efficacious, safe orthobiologic therapies, as well as the elements for biologics registries and bio-repository systems.

RegenMed attended a small conference held in November of 2022 in Washington D.C. by AAOS. Other invitees included representatives from the FDA, HHS, the [Biologic Association](#) and clinicians from around the country.

For more information on approaches to and benefits of biologics registries, this RegenMed [Article](#) may be useful.

### Sunsetting of Arthrex's Surgical Outcomes Center

About ten years ago, [Arthrex](#) introduced its [Surgical Outcomes System](#) ("SOS") to help customers collect outcomes data against particular orthopedic interventions. Arthrex has announced the discontinuation of SOS effective August 1, 2023. RegenMed is working with former SOS users to transition their existing data and outcomes capture programs to Circles.

### Mandates, Best Practices, References

The concepts of "real-world" data and evidence have existed in the literature for many years. They are now playing important roles for providers, payers, manufacturers and other healthcare stakeholders due to legal/regulatory mandates, value-based medicine, and patient expectations.

A good summary of references, as well as clinically efficient approaches to generating value from real-world data and evidence, can be found in this [publication](#) by the Agency For Healthcare Research and Quality, part of the U.S. Department of Health and Human Services.

## COMPANY NEWS

### New Website



RegenMed's [website](#) has been thoroughly reorganized. We hope it will help healthcare stakeholders more easily find information on [PROMs](#), [Studies](#), [Registries](#), [Publication](#) and other solutions to developing and generating value from real-world clinical data.

The site makes it easy to [get started](#) in generating value from Circles in a number of ways. These include free [Demo Circles](#), as well as [Open Outcomes Circles](#) and [Open Registry Circles](#). These allow providers to be up and running with value-added Circles in a matter of minutes, and at minimum cost.

### Circle Academies



**Welcome to the Real-World Evidence Circle Academy**



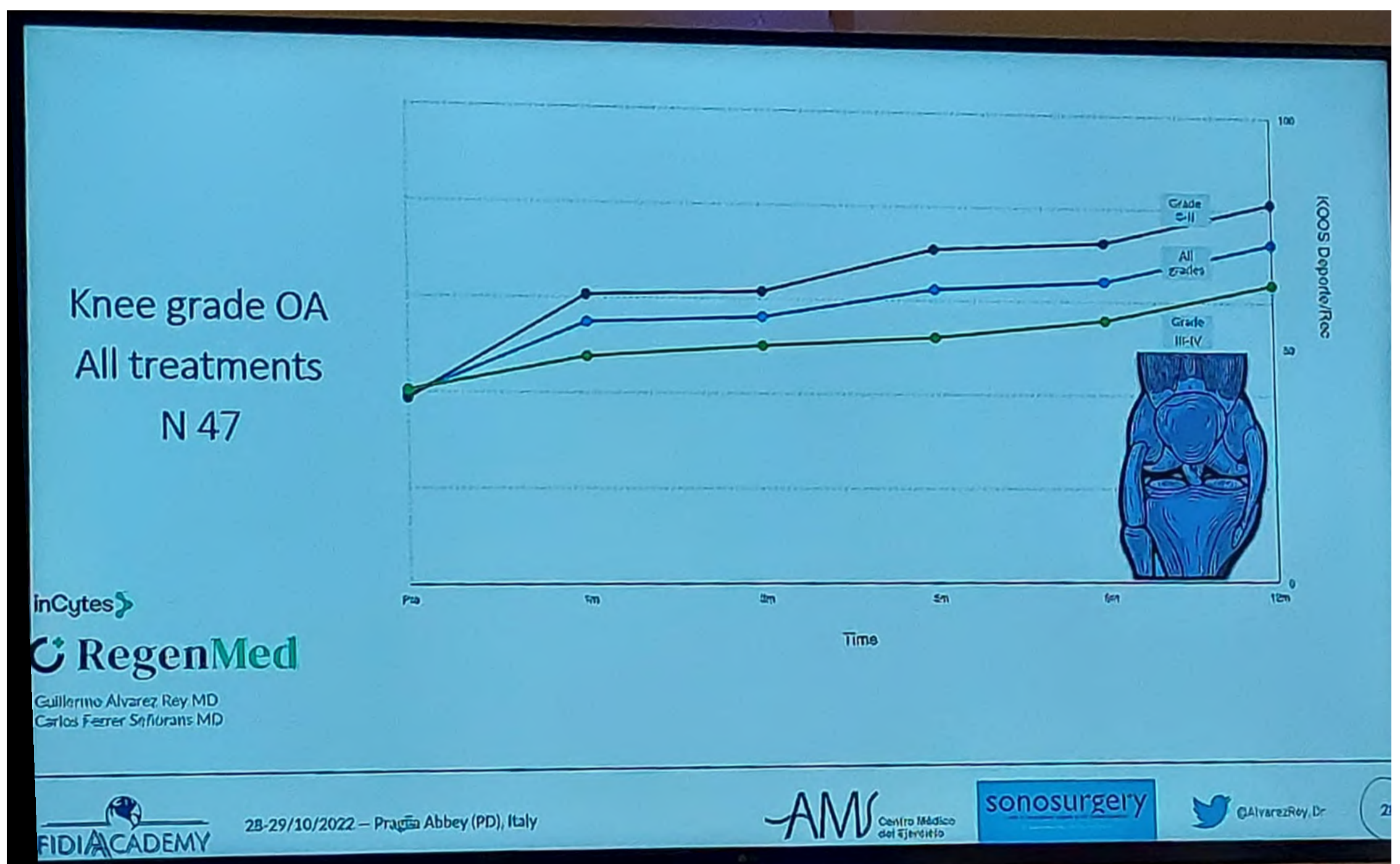
RegenMed has now launched [Circle Academies](#) in two versions. The [Open Academy](#) is

available to anyone in the healthcare field.

The [Members Only Academy](#) is accessible only to clinicians who register. It provides a secure, moderated forum to clinicians to teach, learn and observe in the context of real-world data pertaining to specific clinical conditions and procedures.

Circle Academies provide all of the functionality of modern social media platforms, without the multiple disadvantages.

**Events**



Circle Members and RegenMed regularly present their study designs and observations at medical and scientific conferences around the world. Recent and upcoming events include:

[CASEM](#), Quebec City September 2022

[EVOLVE](#), Salt Lake City, February 3- 5, 2023



[IOF Max Experience](#), Scottsdale, February 16 – 19, 2023

TOBI 2022, June 2022, Hollywood Fl.

[OrthoBioMSK](#), February 9 – 11, Seville, Spain

[Sport AMS Ultrasound](#), April 20-22 2023, Malaga Spain

Fidia Academy, October 28 – 29, 2022, Praglia Abbey, Italy

[Gulf Coast Biologics](#)

## FOLLOW US

