

CIRCLES

INFLUENCE THROUGH EVIDENCE

NEWSLETTER

December 2023

Select Client Activities

Investigator Initiated Studies



Major product manufacturers make funding available for research through investigator-initiated trials.

RegenMed is supporting Dr. Ariana Demers, President of the Interventional Orthobiologics Foundation, in obtaining such funding from a major orthopedic device manufacturer to study output characteristics of the manufacturer's biologics processing system.

In their Circles-based *in-vitro* study design, Dr. Demers and her co-investigators have determined the endpoints which they consider most clinically relevant.

Depending on the results of the initial study, a second *in-vivo* Circle will support the approval of one or more additional indications.

Surgical and Non-Surgical Orthopedics

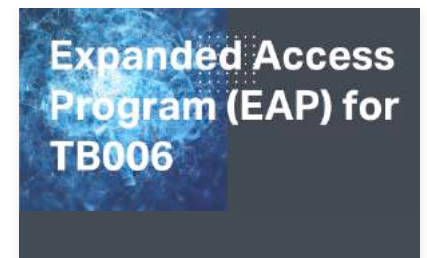
RegenMed has successfully migrated onto Circles over 5,000 Cases previously captured by Professor Gordon Mackay on the Arthrex Surgical Outcomes System.



All data collected through six separate SOS modules – Knee Arthroscopy, Knee Arthroplasty, Shoulder Arthroscopy, Foot and Ankle, Elbow Procedures and Shoulder Non-Operative – remain fully accessible for analysis in corresponding Circles.

Expanded Access Programs

Also referred to as compassionate use, Expanded Access Programs are often used by providers for patients whose conditions are not responding to alternative therapies.



The FDA specifies the circumstances when an investigational medical product (drug, biologic, or medical device) may be used for treatment outside of clinical trials.

RegenMed is developing a Circle for TrueBinding's monoclonal antibody, TB006, which has been approved for EAP use.

TB006 targets a wide range of dementias. The EAP TB006 Circle incorporates remote cognitive

impairment testing through the [Folstein Mini-Mental State Examination](#), and captures adverse and serious adverse events.

Rapamycin for Cognitive Impairment

[Dr. Sheldon Jordan](#) as Principal Investigator has launched a [Cognitive Optimization Circle](#). In his keynote address at the recent [A4M Longevity](#) conference, he discussed his study to the over 1,000 clinicians in attendance.



Cognitive Optimization,
MoCA Assessment

Through the company's [MoCA](#)-certified employees, RegenMed is assisting

[Dr. Jordan](#) and his

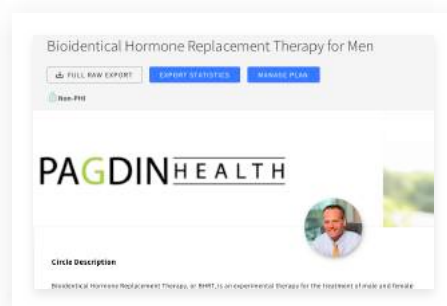
staff in the collection and analysis of key clinical, laboratory and patient reported dementia data in the context of [Sirolimus \(rapamycin\)](#).

The accessible [Benchmark™](#) user experience has been an important element of successful patient and caregiver reporting compliance.

Qualified clinicians are invited by [Dr. Jordan](#) to join his [Circle](#).

Endocrinology: BHRT Treatments

Bio-identical hormone replacement therapies are [increasingly common](#) for men and women.



[Dr. Grant Pagdin](#) is utilizing Circles to monitor longitudinal safety and efficacy in the context of BHRT treatment paths.

RegenMed is also preparing Circles for compounding pharmacies, which face increased regulatory and patient focus regarding their hormone products.

Qualified clinicians are invited by [Dr. Pagdin](#) to join his [BHRT Circles](#).

Select Company Activities

Claude T. Moorman, M.D. Joins RegenMed Clinical/Scientific Advisory Board



[Dr. Moorman](#) is the Chair of the Department of Orthopaedic Surgery, and presides over the Musculoskeletal Institute, at Atrium Health. Atrium is a major part of [Advocate Health](#), the fifth-largest nonprofit integrated health system in the United States.

[Dr. Moorman](#) joins [Ken Zaslav](#) and [Bert Mandelbaum](#) on RegenMed's C/SAB.

New Website

RegenMed's new website makes it easier for visitors to [Join Circles](#) of interest, review relevant [Value Propositions](#), search for [client use cases](#), and easily find tutorials and other [support](#).

Join/A Circle

Join A Circle Library

Search by Status, Circle Name, Outcome Measure

Status	Circle Name	Outcome Measure	
🔒	Erectile Dysfunction Founded by RegenMed Funded by RegenMed	IEF	PREVIEW
🔒	General Health Assessment Founded by RegenMed Funded by RegenMed	SF-12	PREVIEW
🔒	Greater Trochanteric Pain Syndrome Assessment Founded by RegenMed Funded by RegenMed	VISA-G	PREVIEW
🔒	Hamstring Tendinopathy Outcomes Founded by RegenMed Funded by RegenMed	VISA-H	PREVIEW
🔒	Dr. Luis Gallego - Shoulder Circle Founded by Luis Gallego, M.D. Funded by Luis Gallego, M.D.	SSQ12	PREVIEW

RegenMed has a fast-growing library of Circles. They comprise a wide variety of medical specialties,

standardized assessments, clinical surveys, languages and other parameters, across multiple medical specialties.

Our [Join/Start A Circle](#) page now allows clinicians easily to find, review and, if qualified, join a Circle. For those preferring to control data ownership and other Circle parameters, it is now simpler than ever to [Start a Circle](#).

Case Data Migration

On behalf of many Clients, RegenMed technology now supports the lossless migration of large amounts of complex case data from a variety of sources onto Circles. See [here](#) for more information.

Import your data to InCytex

DOWNLOAD ERRORS

Your import was finished.

TOTAL ROWS	PATIENTS CREATED	PATIENT CREATION FAILED
1,938	1,938	10
CELLS WITH NO ATTRIBUTES	IMPORTED CELLS	CELLS WITH FAILED VALIDATION
125	3.5 MILLION	15

Conference Participation

At the June Bio-Illuminate Conference sponsored by [Gulf Coast Biologics](#), RegenMed conducted a series of seminars for clinicians around the country on Real World Data &



Bio-Illuminate III International CME Conference

Evidence Based Treatment Protocol Development.

RegenMed also participated at the December [A4M Longevity Conference](#) in Las Vegas.



FDA Draft Guidance On Real-World Evidence

The FDA has recently [released](#) for public comment guidance on the “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices”.

As the FDA points out, real-world evidence “may provide an efficient means of generating the necessary clinical evidence to support regulatory decisions”. However, the guidance also emphasizes that data quality, good clinical practice, proper study design, longitudinal outcomes data and other traditional methodological considerations remain critical.

The [technology](#) and [processes](#) underlying Circles comply with the FDA’s guidance. Circles are purpose built to generate clinical, scientific, and financial value from real-world evidence. And to do so in a minimally burdensome and cost-effective manner.

Additional Activities

See the RegenMed [Latest](#) page to read about relevant value propositions and use cases.

Contact Information



How Can We Help You?

Request a Demo

Join a Circle

Request a Circle

Customer support

Other

Whether you are a provider, industry participant, medical society, or payer, please [contact us](#) to learn

how Circles can generate clinical, professional, and financial value for you.