

CIRCLES

ORTHOBIOLOGICS PROGRAM FOR MEDICAL SOCIETIES

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Abstract

A Circles Orthobiologics Program (COP) provides sustained value and increased relevance for orthopedic societies. It maintains current members, attracts new ones, and distinguishes a society from other alternatives available to its members.

A COP fulfills a society's mission to educate, advocate and advance evidence-based patient care. It supports impactful research initiatives, generates fresh publishable content for society meetings, and productively engages with members between meetings.

A COP is self-funding; indeed, it creates multiple new revenue sources for the society. It is evidence-based, efficient and turnkey.

Each COP is based on regenerative medicine and real-world evidence, two critical trends in modern healthcare. As such, it has direct relevance to members' everyday clinical decision-making, patient engagement, and professional advancement.

Relevance Of Orthobiologics

Orthobiologics are increasingly used as alternatives to, or to defer, surgical interventions. Regenerative rehabilitation and "prehabilitation" underscore the importance of orthobiologics as adjunct therapies.

The fast-growing orthobiologics market is valued in excess of \$8 billion. Leading orthopedic medical centers such as Hospital For Special Surgery, Northwell, and Mayo Clinic operate dedicated orthobiologics centers of excellence.

ClinicalTrials.gov lists hundreds of studies focusing on biologics and other regenerative medicine approaches for musculoskeletal indications.

Smith & Nephew, Stryker, Arthrex and other orthopedic product manufacturers actively develop and market orthobiologics products. Journals and other medical literature focusing on orthobiologics are common. ¹

The [AAOS Biologics Initiative](#), [AO Foundation Osteobiologics](#), and the [Biologic](#)

[Association](#) represent but a few orthopedic society activities focusing on orthobiologics.

The Relevance of Real-World Evidence

Supporting research is a major objective of most medical societies. However, the cost, delay, and exclusionary criteria of traditional clinical trials have become serious obstacles to genuine clinical translation for most indications and patient populations.

[Pragmatic](#), “[n of 1](#)”, properly curated registries ², and other modern study designs based on RWE provide critical support for, and often alternatives to, traditional RCTs. Recent FDA draft guidance states that RWE

“may provide an efficient means of generating the necessary clinical evidence to support regulatory decisions”. ³

Three of the most important trends in healthcare are [value-based care](#), [health equity/SDOH](#), and [controlling costs](#). RWE is an essential element of each of these. ⁴

RWE study designs are particularly important in the field of orthobiologics, which often involve autologous and/or systemic datapoints.

Program Elements

A society can design a COP to be modest or comprehensive. It is modular, flexible, and scalable. A typical COP comprises the following sequence and elements:

- ❖ Development of two to three [Circles](#) targeting clinical/scientific endpoints with particular relevance to society members. Principal investigators are identified from among society leadership or member thought leaders.
- ❖ Recruitment of five or more society members as Circle co-investigators.
- ❖ Link to an actively promoted [Join-A-Circle](#) page to enhance recruitment of

additional society members as co-investigators.

- ❖ Establishment of a dedicated society website research page, which is also actively promoted. This page describes Circles protocols, endpoints, principal and co-investigators, and developing real-world data.
- ❖ Communications through the society newsletter and other suitable communication channels of preliminary aggregated data and related observations.

- ❖ Use of Circle Academies to host periodic “Circle Hours” among society members. These private discussions among society members, moderated by principal investigators, cover learnings from ongoing Circle activities to date.
- ❖ Circle Academies also support secure 24/7 interaction among Circle members and, if desired, other society members.
- ❖ Engagement with industry and donor organizations to support investigator-initiated trials, training and education sessions, society meeting break-out sessions, and other society initiatives derived from the COP.
- ❖ Publication of select COP activities or results by the society and/or principal investigators through internal and external conferences, articles, and social media.
- ❖ Scaling of Circles to include provider groups and/or other societies outside of society membership. Design and implementation of additional Circles addressing specific member research or clinical interests.
- ❖ Development of COP monetization opportunities resulting from product development, conference sponsorship, data licensing and other pathways.

Execution And Pricing

The inCytes™ and Benchmarc™ platforms, and accompanying physician processes, ensure that RegenMed can handle all COP elements on a turnkey basis on behalf of a society.

A COP can begin modestly, allowing members to join one or more of the dozens of orthobiologics Circles already available. The corresponding cost is only \$5 per Case, and \$35 per month per subscriber.

As a society wishes to scale its COP, pricing remains low and flexible. Any COP program can be terminated at any time. ⁵

RegenMed engages with industry and donors to develop financial support for the COP. Properly designed and executed, a society COP can represent a significant source of revenues to support its mission.

RegenMed works as a long-term partner to ensure that each COP is tailored to a society’s objectives, mission, and membership.

Learn More

[Leadership](#)

[History and Principles](#)

[How Circles Work](#)

[Circles Value Propositions](#)

[Circle Academies](#)

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Endnotes

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- ¹ See for example, [Biologic Orthopedics](#); [MDPI Biologics](#) (Open Access); [Biologics In Orthopaedic Surgery](#); Science Direct, 2019; [Orthobiologics A Comprehensive Review of the Current Evidence and Use in Orthopedic Subspecialties](#), ResearchGate, 2018; [Orthobiologics: A Review](#), ResearchGate, 2023.
 - ² See AHRQ Registries Users Guide, cited above in footnote 1.
 - ³ *Use of Real-World Evidence to Support Regulatory Decision-Making For Medical Devices*, FDA, December 2023, <https://www.fda.gov/media/174819/download>.
 - ⁴ *Real World Evidence*, FDA, February 2023. <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>. *Registries for Evaluating Patient Outcomes: A User's Guide*, HHS/AHRQ, September 2020, <https://www.ncbi.nlm.nih.gov/books/NBK562575/>. *Creating Value From Next-Generation Real-World Evidence*, McKinsey July 2020.
 - ⁵ Further information on pricing can be found [here](#).