



REGENERATIVE MEDICINE CENTERS OF EXCELLENCE
REGEN MED CO-INVESTMENT CATEGORIES

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THE RMCE CONCEPT

A regenerative medicine center of excellence (“RMCE”) supports the delivery of evidence-based, regulatorily-compliant regenerative medicine procedures (“RMP’s”). The concept of an RMCE is flexible. It can be as basic as a segregated space no larger than 50 square meters dedicated to cell/tissue processing and characterization, device calibration, data collection/ reporting and other support for clinicians providing RMP’s. Or, it can represent the entire clinical experience of RMP’s, including procedure rooms, bio-banking, patient concierge, a dedicated conference room for training and educational seminars, and other components. ¹

REGEN MED PARTNERSHIP IN RMCE’S

INTRODUCTION

Regen Med typically co-invests with its clinical partners (“Affiliates”) in one of two ways in the design, operation and scaling of an RMCE:

- As a minority shareholder in a separate legal entity owning the RMCE. In this model, the Affiliate remains the majority shareholder, and each shareholder funds the capital requirements of the RMCE, and allocates profits, in accordance with its share ownership.
- As a non-shareholder in the RMCE. In this case, the Affiliate owns the entire RMCE and Regen Med contributes the capital and services stipulated in the RMCE business plan. In consideration therefor, it receives an agreed percentage of RMCE revenues.

Whether Regen Med co-invests as a shareholder, or separately allocates its own capital against a revenue share arrangement, it succeeds only to the extent that the RMCE, and therefore the Affiliate, succeeds. The objective of both parties is the creation of long-term equity value in the RMCE.

The practice, business and other realities of Affiliates vary; as do their objectives in regenerative medicine. Some categories of Regen Med co-investment are more suitable for larger clinics, and others for smaller settings. Generally, however, Regen Med provides several types of investments

¹ The document, “*Regenerative Medicine Centers of Excellence: Building Long-Term Equity Value*” describes the clinical and financial advantages of an RMCE; it also outlines a conservative step-by-step approach to doing so. That document should be read prior to, or in conjunction with, the present document.

simultaneously, and on an ongoing basis. Some investments are pertinent during the early stages of an RMCE, and others later on.

Regen Med's investments into an RMCE can be divided into three broad categories: business, scientific and clinical. The remainder of this document identifies specific examples in each of those categories.²

BUSINESS

Legal

Structuring and Initial Documentation

Creation of long-term equity value for an RMCE begins with careful analysis of the current legal, regulatory, tax and other considerations relevant to potential partnership structures. Having chosen the most sensible structure, conforming documentation must be prepared. This may include term sheets, operating agreements, article of incorporation, shareholders agreements, by-laws.

Entity Formation and Registration

Depending on the nature of the partnership entity chosen for the RMCE, filings with various authorities, on an initial and ongoing basis, will be required.

Miscellaneous Legal Documentation

During the course of its activities, the RMCE will generally need to draft or negotiate non-compete, confidentiality, patient consent, employment, clinical trial, purchase/sale and other legal documents.

Regulatory

The regulatory environment for regenerative medicine is complex and dynamic. In Europe and the United States, it is governed by federal, regional and often local bodies. Definitions of "minimal manipulation", homologous versus non-homologous, ATMP's, same surgical procedures and other concepts differ from jurisdiction to jurisdiction. Communications with relevant

² For each of the investments identified below, Regen Med may use its own resources and personnel, or it may engage outside experts. The final nature of Regen Med investments for any RMCE is defined in the binding partnership documents executed between Regen Med and the Affiliate.

governmental ethics committees are important, as is clinical documentation establishing conformance to applicable regulations.

Corporate Governance

Having a board of qualified management or directors, and regular substantive meetings among them, are important in developing long-term value for any entity, including an RMCE. This requires selection of and communications with value-added board members, preparing meeting agendas, resolutions and related matters.

Business Plans

RMCE Cash Flow Break-Even

The first several months of an RMCE's activities are critical, and the best metric of financial success is achieving cash-flow breakeven. The components involved in this goal are set out in the Initial Business Plan.

Annual Business Plans

After cashflow breakeven has been achieved, the RMCE will operate according to an Annual Business Plan, agreed to by the partners at least one month prior to the commencement of the upcoming fiscal year. With respect to both the Initial and Annual Business Plans, Regen Med will also track key performance metrics to indicate in advance when corrective action should be taken.

Marketing and Communications ³

RMCE Website

Regen Med will design, code and provide the hosting of a RMCE-specific website. This will include the creation of fresh blog, newsletter and other content, patient testimonials, and other editorial

³ "Branding and Marketing" are important parts of building enduring equity value for the RMCE. This means far more than a website or a logo on the door; it means conveying at every opportunity the messages of clinical excellence, scientific legitimacy and patient engagement.

items as desired by the Affiliate.⁴ Also, for example, access to Patient Reports can be designed into the RMCE's website.

HCP-Oriented

Materials prepared for healthcare professionals explaining the scientific legitimacy, and clinical and financial benefits, of the RMCE's activities are important drivers of increased usage. This is true for clinicians within the clinical environment surrounding the RCME, as well as those outside of it who may want to avail themselves of the RMCE's capabilities.

Patient-Oriented

Properly designed and delivered communications with patients – existing and potential – is important for many reasons. These include (i) attraction of new patients and retention of existing ones, (ii) improved diagnosis and compliance, (iii) positive word-of-mouth, and (iv) support of influential patient-advocacy groups.

Regulatory- and Payer-Oriented

As mentioned, regular communications with regulatory bodies can be a major advantage for the RCME as it grows. Proper protocol design, patient consent forms and outcomes registries can establish the RCME as the model for RMP's. Government and private payers also value such documentation and registries in evaluating the applicability of RMP's as reimbursable standards of care.

Destination Medicine

Regenerative medicine represents one of the larger sectors of destination medicine.⁵ Depending on its regulatory jurisdiction and RMP's offered, the RMCE may be in a strong position to capitalize on this trend. An important approach in doing so is developing relationships with physicians and clinics in the "referring" regions. Small seminars in those regions, coupled with longitudinal RMP's involving referring clinicians in pre- and post- RMP consults, can establish a strong base from which to benefit from destination medicine.

⁴ See [here](#) for an example. The RMCE website can be prepared in any language chosen by the Affiliate.

⁵ The destination medicine market is conservatively forecast to be worth US\$130 bn. by 2025.

Financial

Projections and Statements

A proper chart of accounts, and regularly-issued financial forecasts and statements ⁶ are closely tied to the concept of Business Plans. These documents provide the RMCE's partners, and potential outside investors, with the transparency necessary to evaluate the entity's performance, and value.

Invoicing and Collections

Examples include sponsored studies, paid seminars and conferences, in-center nutraceutical and similar sales, honoraria and similar revenue sources for the RMCE.

Tax

This can include income and VAT or other sales tax documentation and filing.

Bank Accounts

For an RMCE formed as a separate legal entity, the establishment and maintenance of a registered bank account is often necessary, as is monthly reconciliation of its balances to the entity's financial statements.

Third-Party Capital

In many cases, an RMCE may seek outside capital – in the form of bank loans or additional investors, to fund growth and/or acquire some or all of the existing shareholders' financial interests.

Operational

Education and Training

Initial and ongoing video-conferenced and in-person sessions for RMCE personnel, corresponding to the specific RMP's being offered.

⁶ RMCE financial statements typically comprise the balance sheet, profit and loss and statement of cash flows.

Seminar and Conference Logistics

Designing, marketing and oversight of RMCE-based seminars for external HCP's and patients. ⁷

Product Selection and Negotiation

Identification of products and devices corresponding to RMP's to be performed by the RMCE. Consultation on clinical, scientific and regulatory claims made by manufacturers. Negotiation with distributors on pricing, training, maintenance and other terms. ⁸

Staffing

Assistance in identification, selection and training of RMCE technician, patient concierge and other personnel.

SCIENTIFIC**Medical Ethics Committee**

Assistance in selection of members and processes for committee to evaluate RMP's, studies, registries and other RCME activities.

Evidence-Based RMP's***Literature References***

Identification, and linking in marketing materials, of peer-reviewed medical literature supporting RMP's offered by the RCME.

⁷ See for example Regen Med's [CELL™ Conferences](#).

⁸ Regen Med earns no commission or other benefit relating to any device or consumable purchase by the Affiliate.

Treatment Paths

Assistance in the design and encoding for clinical evidence collection and reporting of RMP protocols.⁹

Consultation

Availability of clinicians and scientists in Regen Med Network to discuss potential RMP's.

Collaboration***Studies and Presentations***

Support for data collection, chart and slide presentation, coordination with other study centers or collaborators.¹⁰

Conferences and Seminars

Organization of "bio-breakfasts", wet-labs and similar meetings highlighting the scientific activities of the RCME.

CLINICAL**Procedures*****Multi-Disciplinary***

Development of RMP's through which other clinical units can utilize RMCE capabilities.

⁹ Each HCP in an RMCE is entitled to a royalty-free license to [inCytes™](#). However, there is no requirement for an RMCE to utilize inCytes if it prefers another clinical evidence collection/reporting platform.

¹⁰ See [here](#) and [here](#) for more information on inCytes™ Circles.

Clinical Training

Offer RCME HCP's training in clinical procedures outside the normal scope of their practices. ¹¹

Study Designs

Assistance in design, data collection/reporting, consent forms, IRB communications and industry sponsorship (if desired).

Patient Engagement

Educational Materials

Treatment plans and associated materials customized to the patient, treating clinician and indication.

Outreach

RMCE sponsored presentations, webinars for specific patient groups. ¹²

Patient reports

Design and encoding of existing or modified PROM's, compliance support tools, and graphically-powerful and understandable reports for patients customized for the specific indication, RMP and outcomes history.

Data Registries

Design of registry structure. Preparation of materials for registry data collection and reporting. Maintenance of registry databases consistent with patient privacy regulations.

¹¹ Examples are lipo-harvests for musculoskeletal healthcare professionals, bone-marrow aspiration for plastic surgeons, PRP procedures for primary care physicians, ultrasound imaging indicating angiogenesis for RMCE technicians.

¹² An example is oncology patients suffering loss of function or mobility from radiation-induced fibrosis, where the angiogenic effects of properly performed adipose grafts may provide demonstrable benefits.