



**THE REGENERATIVE MEDICINE CENTER OF EXCELLENCE:  
BUILDING LONG-TERM EQUITY VALUE**

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## SUMMARY

Regenerative medicine, broadly defined, is one of this century's major medical trends. <sup>1</sup> Its "value" is estimated conservatively in excess of \$100 billion, with substantial growth forecast for many decades. Much of this value will inevitably accrue to product manufacturers and other non-practitioners. However, it should also accrue to those clinicians delivering evidence-based and regulatorily-compliant regenerative medicine procedures ("RMP's"). A regenerative medicine center of excellence ("RMCE") allows clinicians to capture and grow enduring equity value through the delivery of RMP's and related services.

Hematology, radiology, oncology, immunology and many other medical disciplines were once emergent with limited clinical applicability. Today, these of course represent major and indispensable elements of diagnosis, therapies and medical science. Regenerative medicine is no different; an RMCE is a flexible, efficient approach to the design, delivery and characterization of RMP's across virtually all indications. <sup>2</sup>

Regen Med is a product-agnostic company which co-invests with clinical groups ("Affiliates") <sup>3</sup> to design, operate and expand RMCE's. This document details why an RMCE is a powerful approach to participating in one of the most exciting fields of healthcare, while building inherent equity value for its

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<sup>1</sup> For purposes of this paper, "[regenerative](#)", "[personalized](#)" and "[precision](#)" medicine can be used interchangeably. Related categories include [regenerative rehabilitation](#), "[omics](#)", [biologics](#) and [tissue engineering](#).

<sup>2</sup> An RMCE 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. See the companion document, ***Regen Med Co-Investment Categories***, for more detail.

<sup>3</sup> An Affiliate is a hospital, clinical department or individual clinician with which Regen Med partners in designing and operating an RMCE. The form of that partnership is detailed in the companion document, ***Regen Med Co-Investment Categories***. In all cases, the financial and other interests of Regen Med and the Affiliate are aligned for the long term success of the RMCE.

owners. The companion document, *Regen Med Co-Investment Categories*, describes concretely how Regen Med partners with its Affiliates in achieving that equity value. <sup>4</sup>

## WHY A REGENERATIVE MEDICINE CENTER OF EXCELLENCE?

### GENERAL

Regenerative medicine is applicable to virtual all specialties and indications. It is relevant as a primary and/or adjunct procedure, and is used pre-, peri- and post-operatively. It harnesses, by definition, the body's innate healing, angiogenic and immunomodulatory processes, and therefore typically does not require expensive equipment.

Each year, the scientific understanding of those processes leads to broader opportunities for genuine clinical translation. As a result, regenerative medicine will continue to move from the "new and interesting" category to a fundamental part of most standards of care. Establishing competency at this early stage in such a large medical trend presents a strong clinical and financial opportunity for the Affiliate.

### SUPPORTING TRENDS IN CONTEMPORARY HEALTHCARE DELIVERY

The revenue and practice models for clinicians are changing in fundamental ways. Not preparing for those changes is a risky strategy – professionally and financially. This is no less true for hospitals, ASC's and large clinics than for smaller practices.

A properly designed and operated RMCE is not an additional burden on the already over-worked clinician. To the contrary, it will support that clinician in addressing several related and important trends in modern healthcare delivery.

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<sup>4</sup> An overview of how Regen Med is partnering with a major European hospital group in developing an RMCE can be found [here](#).

### **Personalized/Precision Medicine**

Current medical literature makes clear that proper diagnoses, treatment plans and predictable, successful outcomes do not derive from a one-time, one-size-fits-all clinical approach. Rather, they depend on the specific, longitudinal patient story -- including relevant “omics”, co-morbidities and treatment history – as well as the patient’s willingness and ability to comply with pre-and post-treatment regimens.

### **Value-Based Medicine**

The traditional fee-for-service model is under attack from all sides. Ministries of health, industry associations, health insurance companies and private-pay patients are all seeking to correlate reimbursement to outcomes and other “value” metrics. Various approaches – accountable care organizations, patient-satisfaction scores, monitoring of re-admission rates among them – reflect this trend.

### **Ambulatory Procedures**

Technology, reimbursement policies, patient expectations and a focus on clinical specializations are leading to an increasing variety and volume of out-patient procedures. This, and the plethora of third-party support services, have allowed smaller groups to establish successful practices outside the traditional hospital model.

This trend is reflected in the establishment by large companies of their own health clinics; in the movement of major pharmacies into ambulatory procedures; and in “executive health” and similar facilities opened by hospitals and luxury resorts alike. <sup>5</sup>

### **PROFESSIONAL FULFILLMENT**

Physician “burn-out” is a widely discussed and important issue. The automation of many medical procedures, hyper-specialization, the burdens of non-medical responsibilities, less time spent with

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<sup>5</sup> See [Health Transformation Alliance](#); [Berkshire Hathaway/JPMorgan/Amazon](#); [Apple and Amazon, Walgreens/Boots Alliance](#) and [CVS](#) for a few examples.

patients, legal/regulatory requirements and the “corporatization” of medicine all leave many clinicians disillusioned with the realities of modern healthcare delivery.

However, healthcare professionals affiliated with a properly designed and executed RMCE can focus on patient care, and rediscover their initial attraction to the noble profession of medicine.

### **Education**

Even years ago, fifty percent of what was learned in medical school soon became outdated. That “educational gap” is only increasing given the dynamic advances in cell-based therapies, tissue engineering, genomics and other “omics”, immunomodulation and similar disciplines – all of which are relevant to most indications. Becoming involved in regenerative medicine in an evidence-based, collaborative manner provides the busy clinician with a sound and practical grounding in these exciting, medically essential areas.

### **Collaboration**

Clinical and scientific advances result from collaboration among clinicians and bench scientists. An RMCE provides the practicing healthcare professional many opportunities to work with peers and thought-leaders on studies, papers, presentations and consultations in the dynamic field of regenerative medicine.

### **Patient Engagement**

Patients today have ever-higher expectations of their clinicians. This is due to on-line resources, patient advocacy groups, increased out-of-pocket payments, and patient-satisfaction reimbursement incentives. Properly designed and delivered, personalized/ regenerative medicine provides a foundation for deep and long-lasting patient relationships.<sup>6</sup>

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<sup>6</sup> An RMCE is designed to provide superior patient satisfaction, thereby attracting new patients, and reducing patient “leakage”.

## REAL WORLD DATA; REAL WORLD EVIDENCE

The concepts of Real World Data (“RWD”) and Real World Evidence (“RWE”) are now recognized by regulatory agencies, providers, payers and patients as essential to determining the safety and efficacy of medical products, devices and procedures. <sup>7</sup> RWD most importantly comprise clinical procedure and outcomes data collected *outside* of the traditional clinical trial structure. <sup>8</sup> RWE in turn results from the application of sound scientific and clinical judgement to those RWD, which then leads to medical evidence supporting standards of care.

Defining and delivering standards of care for all medical procedures – regenerative and other – therefore depend on the identification and analysis of “real world” clinical data. Providing the capabilities to do so -- without adding to the clinician’s workload, but instead increasing professional satisfaction -- is an integral part of each RMCE.

## BUILDING RMCE EQUITY VALUE

### GENERAL

Typically, the financial value of any professional practice, including medical, is strongly linked to their founders/owners. The inevitable consequence is the destruction of this value upon retirement or death of those founders. However, this need not be the case – integrating business competence with clinical excellence will provide the foundation for practice value which will grow during, and survive, the founders’ lifetimes.

Business competence involves legal structuring, branding and marketing, disciplined business plan design and execution, engagement and motivation of the right personnel, and other operational considerations. It is the rare clinician who has the background, interest or time properly to handle

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<sup>7</sup> See here and here for introductory materials provided by the European Medicines Agency and the U.S. Food and Drug Administration.

<sup>8</sup> The limitations of traditional clinical trials are increasingly recognized. Among these are sole focus on regulatory approval<sup>8</sup>, narrow inclusionary criteria, irrelevance of trial research structure to clinical practice, high cost and duration. Industry expenditures on clinical trials exceed the entire U.S. National Institutes of Health budget.

these often complex items. Regen Med provides those competencies at a high level in its capacity as a co-investing partner alongside with – and not a vendor to -- its Affiliates. <sup>9</sup>

## BUILDING BLOCKS

There are many similarities among most clinical practices; at the same time, there are important differences. In designing an RMCE, Regen Med recommends building slowly upon the Affiliate's current clinical platform. This results in minimum cost and disruption, and enables the Affiliate to proceed at its own pace within budgetary, institutional and other constraints. As the benefits of any given stage become evident, the RMCE can increase its capabilities and opportunities.

The following sections summarize major "building blocks" involved in designing, operating and expanding a successful RMCE.

### A Business Plan

No business, and therefore no medical practice, can build meaningful value for its owners without a business plan. Documents illustrating the process of co-developing an RMCE business plan with an Affiliate include:

- The [agenda](#) for the initial meeting between the clinical, scientific and business representatives of the Affiliate on the one hand, and their counterparts at Regen Med on the other hand.
- Principal [elements](#) of a business plan.
- A top-level [Gantt Chart](#) showing a typical schedule for implementing those components.
- A sample [pro-forma consolidated profit and loss statement](#) for an RMCE.

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<sup>9</sup> **Regen Med Co-Investment Categories** describes in more detail the types of co-investments Regen Med makes in the context of these and other elements of an RMCE.

## Marketing and Communications

Building equity value in any business, including a medical practice, requires the establishment of a clear “brand” and competitive advantage. The ability to deliver RMP’s can be a strong differentiator. At the core of an RMCE “brand” -- in contrast to many “stem-cell” centers -- is a commitment to peer-reviewed science, clinical evidence, regulatory compliance and meaningful patient engagement.

This brand is established through proper marketing and communications to all relevant stakeholders.<sup>10</sup> That of course includes (but is not limited to) the design and “curation” of a website -- not merely an online brochure, but a portal for stakeholder communications, search engine optimization and regularly refreshed RMCE content.<sup>11</sup>

## Execution

Developing a realistic business plan is essential; executing upon it equally so. Personnel selection and training, space lay-out, equipment sourcing, patient and HCP communications, financial and legal documentation, regulatory communications, data collection/reporting – all of these and other components of the business plan need to be thought through and properly executed.

Setting up the processes to do in a consistent and professional manner is what builds long-term equity value. This is where Regen Med plays a major and valuable partnership role in the success of the RMCE, allowing the Affiliate to focus on the clinical practice of regenerative medicine.

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<sup>10</sup> Stakeholders typically include, in addition to patients, referring HCP’s, regulators, payers, patient advocacy groups, industry manufacturers and distributors, and medical societies.

<sup>11</sup> See [here](#) for an example of such a website.



## INTERNAL SCALING

Having successfully designed and executed upon the initial business plan <sup>12</sup>, an RMCE is now in a position to capitalize on its inherent potential for expansion. Typical areas of expansion include:

- New clinical (including multi-disciplinary) procedures.
- New diagnostic offerings (genomics and other “omics”; specialized blood and adipose analyses specific to individual indications and procedures, advanced ultrasound imaging, etc.).
- Participating in, or leading, industry-sponsored studies and trials.
- HCP- and patient-oriented education and training seminars.
- Ancillary services, such as bio-banking, rehab and “pre-hab”.
- Product sales (e.g., regenerative creams, nutraceuticals.)
- Destination medicine.
- Participation in ACO’s, narrow-networks and similar groups.
- Product incubation.

## EXTERNAL SCALING

An RMCE need not limit itself to internal expansion. Depending on its objectives and resources, it can build externally upon what it has established. For example, it can provide services in the fields of personalized and regenerative medicine to other healthcare professionals. Similarly, it can license or otherwise monetize all or portions of its capabilities to other healthcare providers.

Another powerful RMCE expansion opportunity is “product incubation”. Many advancements in medical science and processes are discovered by clinicians “in the operating room”. An RMCE, with its data collection capabilities, is in a strong position to establish initial commercial viability of such

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<sup>12</sup> Typically, an initial business plan takes the RMCE through cash-flow breakeven.

inventions, and preserve much more of the long-term value of such commercialization for the clinician.

## WHY REGEN MED?

### INTEGRATED OFFERINGS

Regen Med brings to its Affiliates an integrated set of offerings combining all components needed to build a clinically and financially successful RMCE. These offerings include legal and financial structuring, HCP and patient-focused education and communications,<sup>13</sup> clinical evidence collection and reporting<sup>14</sup> and many others.

### INDEPENDENT AND EXPERIENCED

[Regen Med](#) is a product-agnostic company which partners with Affiliates to exploit the powerful trends of personalized and regenerative medicine. Regen Med balances deep expertise in peer-reviewed medical science, the realities of clinical practice and applicable business elements. Summary information on the Company can be found [here](#) and [here](#).

### LONG TERM PARTNERSHIP

Regen Med establishes relationships with its Affiliates for the long-term. Those relationships are ones in which the parties' interests are transparent and closely aligned. This is contrary to the opaque, one-time approach taken by many vendors to clinical practices.

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<sup>13</sup> See for example [here](#), [here](#) and [here](#).

<sup>14</sup> See for example [here](#), [here](#) and [here](#).