

# A Global Leader in Regenerative and Advanced Therapies



## Challenge

Value demonstration and commercial success for most emerging technologies are substantially different from conventional products. Precision and transformative life science technologies face unique challenges for value demonstration and access, requiring special expertise to optimize product potential.

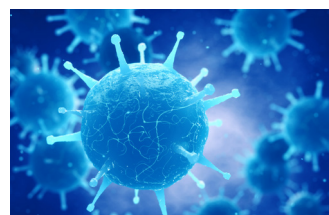
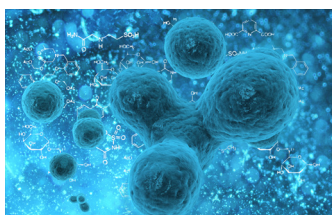
## Why Evidera for the Solution?

Evidera recognizes that precision and transformative life science technologies are different. We therefore channel our considerable expertise in this area to provide solutions tailored to the specific needs of these types of products.

- Dedicated Center of Excellence in Precision and Transformative Medicine including experts from across all practice areas
- Involved in development, access, and launch preparation for 75% of the transformative therapies marketed since 2016
- Partnered on development, value demonstration, and access support for >200 regenerative and advanced therapy assets
- Recognized global thought leadership in regenerative and advanced therapies, including leadership committee roles with the Alliance for Regenerative Medicine and International Society for Cellular Therapy
- Deep innovative technology expertise integrated with our proven capabilities in health economics and outcomes research (HEOR) and market access
- Global company with an end-to-end, full suite of capabilities, including clinical and market access services, allowing us to be a true partner and extension of your team from early development through commercialization

## We Understand the Core Challenges of Value Demonstration in Regenerative Medicines and Can Help You Address Them from a Practical, Business Perspective

1. Advanced therapies are truly novel: there is significant stakeholder uncertainty about benefits and harms
2. Therapies have potential for transformative or curative effect, but you must prove it to stakeholders
3. Magnitude and duration of effect: plans must balance short-term vs. longer-term evidence and anticipate market entry agreements
4. There are different success factors for regenerative and advanced therapies based on site of care, complexity, and other factors
5. Reimbursement and payment systems did not anticipate transformative or potentially curative therapies: success requires special planning and preparation



## Highlighted Areas of Expertise

### Cell, Gene, and Regenerative Medicine Therapies

Out-of-the-box thinking is required to successfully navigate regenerative therapies through global systems that have not anticipated these types of interventions. Regenerative medicines have limited precedent, challenging reimbursement “fit,” in addition to requiring novel value considerations, such as the potential to cure disease. Evidera has significant expertise in value demonstration and reimbursement strategy for regenerative medicines.

### Orphan, Rare Disease, and Specialty Treatments

Orphan, rare disease, and specialty treatments face special value demonstration challenges. These include uncertainty around supporting evidence, evolving Health Technology Assessment (HTA) scrutiny, and growing commercial and policy hurdles. Evidera has partnered with orphan drug manufacturers on more than 100 projects per year to optimize their value proposition. We have helped align access and commercial efforts to changing requirements for this growing category.

### Immunotherapies, Novel Biologics, and Therapeutic Vaccines

Immunotherapies and advanced biologics offer great promise for improving outcomes by leveraging the body’s own capacity to heal. Unique attributes such as prolonged duration of therapeutic effect and novel administration regimens can also make their value demonstration more complex and stretch current reimbursement mechanisms. Evidera has significant experience in emerging immunotherapies and novel biologics. We understand that greater manufacturer diligence in market access and commercial planning is key for their success and have conducted approximately 200 projects for immuno-targeting biologicals, including novel cell-based approaches.

## Select References and Conference Presentations

**Faulkner E**, Spinner D, and **Ringo M**. Out of the Box: Health Ecosystem Effects of Therapies with Transformative or Curative Intent. Value in Health 2018. (publication in press)

**Faulkner E**, Werner MJ, Slocomb T, Han D. Ensuring Patient Access to Regenerative and Advanced Therapies in Managed Care: How Do We Get There? Glen Allen, VA: ARM Monograph (Journal of Managed Care), 2018.

**Faulkner E**, Powell R, Goldenring J, Cross J, Tolley K. Navigating regenerative medicine technology assessment and reimbursement in North America and Europe. Alliance for Regenerative Medicine Meeting on the Mesa. La Jolla, CA. October 2017.

**Faulkner E**, Ransom J, Renbaum A, Briggs G. Is Managed Care Prepared for Regenerative Medicine? Early Landscape and Reimbursement Considerations. Journal of Managed Care Medicine. 2017;20:1.

**Faulkner E**. Addressing Uncertainty in Regenerative Medicine Value Demonstration: What is Mission Critical vs. Mission Impossible? Meeting on the Mesa. Alliance for Regenerative Medicine. La Jolla, CA. October 2016.