Alliance for Regenerative Medicine

ARM Advisory Groups

Introduction

Advisory groups (AGs) consist of select ARM members who collaborate to influence ARM's policy and advocacy agenda and strategic initiatives.

Group members represent diverse perspectives and expertise to ensure the adoption of comprehensive and effective strategies that align with ARM's mission and values.

Together, advisory groups drive innovation, improve patient outcomes, and work to navigate the challenges and opportunities in the regenerative medicine space.

Terms

Advisory group members serve two- or three-year terms, depending on the group. AG terms run from July 1 to June 30, except for those noted below with an asterisk. Terms for those AGs run from January 1 to December 31.

AGs with 2-Year Terms

EU Leadership	Medicare Policy*
EU Market Access	Patient
EU Government Relations	US Government Relations
Medicaid Policy*	US Value Workstream and Narrative

AGs with 3-Year Terms

Cell Therapy*	Tissue Engineering*
EU Regulatory	US Regulatory Policy
Gene Therapy*	
Regulatory CMC	

Member Expectations

- Demonstrate commitment to ARM, the strategic agenda, and ARM mission
- Attend and participate in all AG meetings (AGs meet as frequently as monthly)
- Offer guidance on strategy
- Support (or align member organization efforts) on implementation
- Influence ARM policy and political position decision-making

*Please contact the Membership Team at **member@alliancerm.org** with questions.*

Policy & Regulatory Advisory Groups

EU Leadership Advisory Group:
Consists of industry leaders who actively contribute to and promote ARM's priorities throughout Europe, offering advice and direction for ARM's advocacy strategy, as well as its plans for political and allied stakeholder engagement.

EU Government Relations Advisory Group:
Supports ARM's EU advocacy by providing targeted input on legislative and policy developments impacting the ATMP sector. Bringing together members active in Brussels, the group helps inform ARM's positioning on specific policy files and supports alignment and coordination in engagement with EU institutions, working in complement to the EU Leadership Advisory Group.

EU Market Access Advisory Group:
Addresses European-specific issues and topics related to HTA, pricing, reimbursement, and market access of ATMPS.

EU Regulatory Advisory Group:
Coordinates ARM's European regulatory strategy, aligning stakeholder input to address key region-specific policy issues and guiding coordinated engagement with EMA and MHRA to support fit-for-purpose, innovation-enabling frameworks.

Medicaid Policy Advisory Group:
Addresses Medicaid-specific issues and topics which have implications on patient access and reimbursement for cell and gene therapies.

Medicare Policy Advisory Group:
Addresses Medicare-specific issues and topics which have implications on patient access and reimbursement for cell and gene therapies.

Patient Advocacy Advisory Group:
Provides important perspectives that help ensure patients' interests are at the center of ARM's advocacy and policy positions. The Patient Advisory Group allows ARM staff to get timely feedback on policy proposals that impact access to cell and gene therapies, as well as amplify ARM's positions among key audiences. *Open only to patient advocacy organizations who are voting members of ARM.*

Regulatory CMC Advisory Group:
Provides commentary on draft CMC guidance, works to identify outdated CMC guidance, and proactively identifies guidance gaps.

US Government Relations Advisory Group:
Provides strategic counsel and guidance on ARM'S advocacy strategy and political and allied stakeholder engagement plans and contributes to the execution of ARM's lobbying campaigns. *Membership is limited to individuals who are based in the Washington, DC area or who frequent DC to meet with Congress and federal agencies as part of their responsibilities.*

US Regulatory Policy Advisory Group:
Oversees the development and execution of ARM's U.S. regulatory policy strategy. Aligns industry perspectives to define policy priorities and advance actionable solutions, while guiding coordinated engagement with FDA to improve regulatory clarity, consistency, and predictability, including through formal and informal scientific exchange.

Cell and Gene Therapy Value Narrative Advisory Group
Creates a transformational value narrative for approved and emerging CGTs to educate policymakers and the public about the impact of these therapies on patients and the healthcare system, based on data about the diseases being treated, the unmet need being addressed, and the potential savings provided to the healthcare system from durable treatments.

CGT Advisory Groups

Cell Therapy Advisory Group:
Providesexpert input onemergingareas, challenges, and trends affecting the cell therapy field, including scientific advancements, CMC issues, regulatory, and payment & reimbursement for cell therapies.

Gene Therapy Advisory Group:
Providesexpert input onemergingareas,challenges, and trends affecting the gene therapy field, including scientific advancements, CMC issues, regulatory, and payment & reimbursement for gene therapies.

Tissue Engineering Advisory Group:
Providesexpert input on emerging areas,challenges, and trends affecting the tissue engineering field, including scientific advancements, CMC issues, regulatory, and payment & reimbursement for tissue engineered therapies, also referred to as tissue therapeutics. This group will also discuss aspects related to tissues engineering for xenotransplantation and other related areas in which gene editing techniques are used to enhance engraftment of tissue engineered products into patients.