

# FAQ for Overall Governance Process

Mark Battaglini, Chief Strategy Officer

# **Chairs/Vice-Chairs Advisory Groups**

#### **Medicaid AG**

Scott McGoohan, Vertex (Chair) Mary Lacey Reuther, CSL Behring (Vice-Chair)

#### **Medicare AG**

Brent Rice, Autolus (Chair) Laura Okpala, Kite Gilead (Vice-Chair)

#### Value AG

Dan Kirby, Orca Bio (Chair) Clark Paramore, bluebird bio (Vice-Chair)

**US GR Advisory Group** Jay Greissing, BioMarin (Chair)

#### US Intel & Regulatory Policy Robert Pietrusko, Vor BioPharma

Robert Pietrusko, Vor BioPharma (Chair) Nimi Chhina, Biomarin (Vice-Chair)

#### EU Regulatory (incl. Hospital Exemption)

Sybille Herzer, Kite Gilead (Chair) Jacquelyn Awigena-Cook, BMS (Vice-Chair)

#### **European Leadership Advisory Group**

Chris Vann, Autolus (Chair) Miguel Forte, Kiji Therapeutics (Vice-Chair)

### **EU MA & Value Recognition** Francis Pang, Orchard Therapeutics (Chair) Stephen Connell, Pfizer (Vice-Chair)

#### **Regulatory CMC**

Mike Mendicino, Hybrid Concepts (Chair) Mia Wang, Novartis (Vice-Chair

#### **Cell Therapy**

Rupa Pike, Thermo Fisher (Chair) Kristi Jones, NexImmune (Vice-Chair) Adrienne Farid, Century Therapeutics (Vice-Chair)

#### **Tissue Engineering**

Jordan Lancaster, Avery Therapeutics (Chair) Eric Roos, Aspect Biosystems (Vice-Chair) Geoff Hamilton, Stemson Therapeutics (Vice-Chair)

#### **Gene Therapy**

Sven Kili, Antion Biosciences (Chair) Khandan Baradaran, Ultragenyx (Vice-Chair)

What credentials are necessary to join an Advisory Group? What are the specific guidelines for the election, tenure, and duration of member involvement in an AG?

We look to Advisory Group Chairs and ARM Staff to decide the optimal size and composition. We envision these groups to be nimble decision-making bodies. ARM seeks to rotate individuals on-and-off Advisory Groups to ensure the optimal mix shaping and implementing a sector-wide public affairs agenda. In general, Advisory Group participants will demonstrate leadership in the specific field of focus. Advisory Group leaders will start with a two-year term as Vice-chair, then a two-year term as Chair to preserve institutional memory.

Is there a cap on the number of participants in an Advisory Group? How often will these groups meet?

We recommend an Advisory Group size of 8-15 individuals. When we have more volunteers than available spots, we will preserve a waitlist ("bench pool") for interested members. The Chairs will work with ARM Staff to determine the size, composition and tenure of participants for each Advisory Group. Cadence of meetings will be decided by the Chairs and ARM Staff.

## Are Advisory Group members automatically assigned from previous Committees?

No. While there is likely some overlap between Committee and Advisory Group membership, ARM's boardapproved 2023-2025 strategy has specific areas of focus that require focused and diverse perspectives. As such, we ask individuals and member-organizations interested to contact the relevant ARM Staff member.

### What does a Forum do?

A Forum keeps members abreast on the latest developments in a specific topic area, for example US reimbursement. It also serves as an opportunity for similarly-focused colleagues to build relationships within their specialty. While Forums are not decision-making bodies, there may be opportunities to provide input into ARM's ongoing public affairs and S&I activities. Reasonable attempts will be made to allow for Hybrid sessions. ARM staff and relevant topical Advisory Group Chairs may draw from the Forum participants for Task & Finish projects.

### Who is eligible for Forum membership?

All members are welcome to participate in a Forum of interest. There is no ceiling on the number of participants from a member organization.

Who has responsibility for cross-cutting issues (e.g., a coupled reimbursement-and-regulatory challenge)?

Some issues overlap with the mandate of multiple membership groups. In such instances, ARM will either 1) create a new Working Group/Task & Finish Group to ensure the appropriate perspectives are represented, or 2) introduce a coordinating mechanism to ensure alignment and public affairs cohesion.

# How do I stay abreast of the activities of an Advisory Group if not directly involved?

ARM will create ample opportunities to transparently share developments from Advisory Groups. All members will have access to a summary of each Advisory Group meeting via ARM's Member Portal, and membership Forums will retain, as a standing agenda item, a review of the work of relevant Advisory Groups.

My institution has a public affairs challenge that we believe is relevant to the broader CGT sector. How do I elevate this issue for consideration in future ARM public affairs efforts?

Please contact the Chairs / Vice-Chairs and of the relevant Advisory Group in parallel with ARM staff. They will confer with other members and ARM staff to see if this issue is a significant shared challenge where ARM can play a legitimate role advancing policy. We acknowledge that a focused public affairs agenda does not allow ARM to address every sector-wide challenge. For issues with significant budget and resource implications, ARM's board will review and approve prior to evolving existing priorities.

### Will meetings be in-person, virtual, or hybrid?

- Forums, as large bodies, should be in-person events to effectively share information and build relationships. ARM will leverage well-attended events such as Meeting on the Mesa / Med to lower the barrier to in-person participation. A virtual link will also be provided.
- Advisory Groups and Working Groups, as smaller focused bodies, will still retain high levels of effectiveness as virtual gatherings.

### I'm a new member. What groups should I join?

We recommend joining each Forum that is linked to your institution's interests. The membership team will help connect you to the right Forums. We will look to pull you into Working Groups/Task & Finish Groups and Advisory Groups over time if there is interest.

