ARM × GENOTHER WORKSHOP

From Platform to Patient

Defining Market Readiness for Genetic Medicines

19 June 2026 · Institut Imagine, 24 Bd du Montparnasse, 75015 Paris · *Hybrid format*

MEETING AGENDA

Friday, 19 June 2026

8:00 – 9:00	**Registration & Breakfast**
9:00 – 9:20	OPENING REMARKS · 20 MIN **Welcome** **Sharon Anderson** — *Vice President, Scientific Affairs, Alliance for Regenerative Medicine* **Marco Pintore** — *Director General, GenoTher*
9:20 – 9:40	KEYNOTE · 20 MIN **Extending the successes of Gene Therapy: challenges and perspectives** This keynote will examine the current state and future trajectory of gene therapy development, exploring what it takes to transition platform technologies from academic proof-of-concept to robust, industrial-scale production capable of reliably delivering therapies to patients. **Frédéric Revah** — *Chief Executive Officer, Généthon*

SESSION 1

The Integrated Translational Ecosystem

How integrated ecosystems including academic research, clinical development and manufacturing accelerate the path to patient access. Collaboration models, public-private partnerships, and lessons from established hubs.

9:40 – 10:00	PRESENTATION · 20 MIN **Institut Imagine: Bridging Patients, Research & Clinical Development** How Institut Imagine's patient-centered model connects rare disease research directly to clinical programs; a blueprint for translational success in genetic medicine. **Prof. Bana Jabri** — *Director General, Institut Imagine*
10:00 – 10:30	PANEL DISCUSSION · 30 MIN **Translational Ecosystems as Accelerators** Panelists: **Miguel Forte** — *Chief Executive Officer, Kiji Therapeutics* ***(moderator)*** **Thomas Carlsen** — *Chief Executive Officer, Novo Nordisk Foundation Cellerator* **Stephen Ward** — *Chief Technology Officer, Cell & Gene Therapy Catapult* **Marco Pintore** — *Director General, GenoTher* **Marion Hitchcock** — *Managing Director, Gene & Cell Therapies Incubator Berlin and R&D Strategy & Portfolio Manager, Bayer*

10:30 – 10:45	**Morning Break**

SESSION 2

Defining Control Strategy in Platform Genetic Medicines

Analytical and quality control challenges unique to platform-based genetic medicines: multi-attribute potency, NGS-based identity and impurity profiling, and a fit-for-purpose control strategy across the lifecycle.

10:45 – 11:05

PRESENTATION · 20 MIN

Addressing Analytical Challenges: Multi-Attribute Potency & Beyond

This presentation will address the different methods used as potency assays along the development phase of Gene Therapy products and their challenges. A case study on AAV vectors will be presented.

Christine Le Bec — *Deputy CTO, Head of Analytical Development & QC, Sensorion*

11:05 – 11:25

PRESENTATION · 20 MIN

Identity, Impurities & Genome Integrity — NGS and Beyond

Advanced characterization tools, including NGS, for vector identity, residual impurities and genome integrity across manufacturing campaigns.

Matthew Hewitt — *Vice President, CTO Manufacturing Business Division, Charles River Laboratories*

11:25 – 11:55

PANEL DISCUSSION · 30 MIN

What Constitutes a "Sufficient" Control Strategy?

Panelists:

Patrick Santambien — *Director of Technological Development, Généthon* ***(moderator)***
Matthew Hewitt — *Vice President, CTO Manufacturing Business Division, Charles River Laboratories*
Romain Fragnoud — *Head of Analytical Development, CMC, Généthon*
Christine Le Bec — *Deputy CTO, Head of Analytical Development & QC, Sensorion*

SESSION 3

Achieving Manufacturing Robustness Across Modalities

Manufacturing reproducibility as platforms scale across product variants and production sites: process characterization, technology transfer, and consistency in viral vector production at commercial scale.

11:55 – 12:15

PRESENTATION · 20 MIN

Reproducibility at Scale & Platform Expansion

Real-world challenges of maintaining process consistency as gene therapy platforms expand to new products, sites and commercial-scale operations.

John Tomtishen — *Global Head, Cell Therapy Field Application Scientists & Strategic Alliances, Catalent*

12:15 – 12:25	**Short Q&A / Transition**
12:25 – 1:25	**Lunch**

SESSION 4

Regulatory Convergence: Platform Thinking in Practice

Aligning regulators and industry on risk-based frameworks for platform-manufactured genetic medicines: platform comparability, the EU regulatory landscape, and streamlining submissions while safeguarding patients.

1:25 – 1:45

REGULATORY PRESENTATION · 20 MIN

EMA Perspective on Platforms and Prior Knowledge

How the EMA is approaching platform-based development, such as comparability data expectations, platform master files, and balancing flexibility and rigor in ATMP regulation.

Marcel Hoefnagel — *Senior Assessor & Chair, EMA Quality Innovation Group, Dutch Medicines Evaluation Board (MEB-CBG)*

1:45 – 2:25	PANEL DISCUSSION · 40 MIN **Risk-Based Regulatory Frameworks** Panelists: **Rehma Chandaria** — *Head of Regulatory Affairs, Cell & Gene Therapy Catapult* ***(moderator)*** **Sibylle Herzer** — *Senior Director, Regulatory CMC, Kite* **Andrea Braun** — *Senior Vice President, Regulatory Affairs, Autolus* **Marcel Hoefnagel** — *Senior Assessor & Chair, EMA Quality Innovation Group, Dutch Medicines Evaluation Board (MEB-CBG)* **Janet Glassford** — *Quality Assessor, Biological Products Unit, MHRA*

SESSION 5

Market Access & Accelerating Speed to Market for ATMPs

Policy and commercial pathways shaping ATMP availability in Europe: the EU Biotech Act, reimbursement and access models, and cross-stakeholder collaboration to reach patients faster.

2:25 – 2:45	PRESENTATION · 20 MIN **EU Biotech Act & Speed to Market** How the EU Biotech Act and related policy initiatives are reshaping the regulatory and commercial landscape for advanced therapies, and what it means for the timeline from approval to patient access. **Caterina Giovagnoni** — *Policy Analyst, European Commission, DG SANTÉ*
2:45 – 3:25	PANEL DISCUSSION · 40 MIN **Accelerating ATMP Access in Europe** Panelists: **Lydia Shotton** — *Associate Director, EU Government Affairs, ARM* ***(moderator)*** **Adam Parnaby** — *Lead, Global Policy & Access, Bristol Myers Squibb* **Dilip Patel** — *SVP, Global Pricing & Market Access Strategy, Autolus* **Melanie Yammine** — *Lead Policy & Government Affairs, Established Markets, Astellas Pharma*
3:25 – 3:50	**Afternoon Break**

SESSION 6

Technical Maturity & Capital Formation

The link between manufacturing readiness and investor confidence: the technical milestones investors look for, how manufacturing maturity de-risks programs, and what it takes to attract growth-stage capital today.

3:50 – 4:50	PANEL DISCUSSION · 60 MIN **What Technical Maturity Unlocks Capital?** Panelists: **Sven Kili** — *Partner, Saisei Ventures* ***(moderator)*** **Charles-Édouard Escurat** — *Director General, Agence de l'Innovation en Santé (AIS)* **Mathieu Losguardi** — *Chief Financial & Corporate Development Officer, WhiteLab Genomics* **Yann Echelard** — *President and Managing Partner, ORI Capital*
4:50 – 5:10	CLOSING REMARKS · 20 MIN **Reflections & Path Forward** **Sharon Anderson** — *Vice President, Scientific Affairs, Alliance for Regenerative Medicine* **Maria Grazia Biferi** — *Chief Scientific Officer, GenoTher*
5:20 – 7:00	**Networking Reception** Rooftop, Institut Imagine

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