



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2026
EMA/53023/2026

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Agenda – 1st EMA-ISCT (International Society for Cell and Gene Therapy) bilateral meeting

5 October 2026, 15:30-17:30 CEST, meeting room 0A and Teams

Chair: Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

Item	Preliminary draft agenda	Mins
1.	Welcome and Introductions	15'
2.	Clinical trial regulation for advanced therapy medicinal products (ATMPs)	20'
3.	Classification of ATMPs under new legislation	20'
4.	Divergence of specifications in cell and gene therapy products	20'
5.	Patient access and market integration	15'
6.	Other technical topics: • Monographs for cell and gene therapies • Decentralised vs. Centralised Manufacturing Models and Boundaries of "Minimal Manipulation"	25'
7.	Conclusions and next steps Close of meeting	5'

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