

# EU Regulatory Update

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# Disclaimer

- **EMA:** “The views expressed in this presentation are my personal views and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.”
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# EU Regulatory activities

2024

- Ongoing work on Pharma Revision  
[https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation\\_en](https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en)
- New Regulation on substances of human origin  
← starting materials for cell based ATMPs  
[https://health.ec.europa.eu/blood-tissues-cells-and-organs/overview/new-eu-rules-substances-human-origin\\_en](https://health.ec.europa.eu/blood-tissues-cells-and-organs/overview/new-eu-rules-substances-human-origin_en)
- Ongoing activities on the interfaces of medicines with medical devices and in vitro diagnostics
  - COMBINE project (clinical trials)  
[https://health.ec.europa.eu/medical-devices-topics-interest/combined-studies\\_en](https://health.ec.europa.eu/medical-devices-topics-interest/combined-studies_en)
  - Focus group on joint scientific advice
- Updates on the implementation of the Medical device and In vitro diagnostics Regulations  
[https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance\\_en](https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en)

# CAT Workplan 2024

<b>1. Evaluation activities for human medicines .....</b>	<b>2</b>
1.1. Pre-authorisation activities .....	2
1.1.1. Guideline on requirements for investigational ATMPs in clinical trials .....	2
1.1.2. Revision of the Questions and Answers on Gene Therapy .....	3
1.2. Initial evaluation activities .....	3
1.2.1. Benefit/Risk methodology and communication .....	3
1.2.2. Real World Data (RWD) in regulatory decision making of ATMPs .....	4
1.2.3. Improve interactions with Health Technology Assessment (HTA) bodies to optimise clinical evidence generation .....	5
1.2.4. Implementation of the medical device regulation and strengthening of the assessment of Companion Diagnostics .....	6
1.3. Post-authorisation activities .....	6
1.3.1. Post-authorisation safety and efficacy follow-up and RMP for ATMPs .....	6
<b>2. Horizontal activities and other areas .....</b>	<b>7</b>
2.1. Partners and stakeholders .....	7
2.1.1. Interaction with Stakeholders .....	7
2.1.2. Scientific symposium on the future of ATMPs .....	8
2.1.3. International Regulatory Science Collaboration .....	8



# 15 Years of EMA Committee for Advanced Therapies

## Scientific symposium on the work of the CAT and the future of ATMPs



- Contributions from experts in the field
- CAT stakeholders and previous CAT chairs
- Communicate on the work and achievements of CAT
- *Contribution – Evolution - Revolution*
- Hybrid meeting

**Thank you to the members of the drafting groups!!!!**

**Questions?**

