COST ACTION CA23140 – ESENBURN

Workshop Characterisation WG1 & WG2

16 September 2026 — Lyon, France

AGENDA

Location:

Edouard Herriot Hospital. 5 Pl. d'Arsonval, 69003 Lyon, France

September 16, 2026

10:00 – 10:10—Welcome & Opening (10 min)

10:10 – 10:40. Session 1 — *Introduction to Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials (EMA/CAT/22473/2025)*. Gloria Carmona Sánchez

The purpose of session is to introduce the specifics aspects including in the EMA/CAT/22473/2025 about characterisation

Expected Output:

- ✓ *Knowledge about regulatory guideline in order to be use to characterise the products to be use in severe burnt patients according to regulatory bodies*

Purpose: *To review the specific characterisation requirements described in EMA/CAT/22473/2025 and identify the critical quality attributes (CQAs) and characterisation parameters applicable to ATMPs intended for the treatment of severe burn patients.*

Particular focus will be given to:

- *Identity.*
- *Purity and impurities.*
- *Cellular composition.*
- *Viability.*
- *Biological activity and potency.*
- *Structural and functional characterisation.*
- *Product heterogeneity.*
- *Comparability considerations.*

Expected Output:

- *Shared understanding of current EMA characterisation expectations.*

10:40–11:10 —Coffee Break

11:10–13:00. Session 2 – Characterisation Methods Implemented by Authorised Manufacturers of ATMPs for Severe Burn Patients

Purpose: To review and compare the characterisation methods implemented by manufacturers of authorised ATMPs for the treatment of severe burn patients.

Topics to be reviewed:

- Characterisation methods applied to the active substance.
- Characterisation methods applied to the final product.
- Challenges and limitations encountered during product characterisation.

Expected Output:

- Summary of characterisation methods applied to active substances and final products.
- Identification of areas where harmonisation may be feasible within ESENBURN

13:00 – 14:30. Lunch break

14:30 – 16:00. Session 3 — Challenges observed during regulatory assessments for ATMPS products

- Examples of regulatory assessments developed for different ATMP products
- Review of characterisation-related questions raised by regulatory authorities.
- Discussion of lessons learned from authorised products.

Expected Output:

- List of key regulatory challenges related to ATMP characterisation.
- Lessons learned from regulatory assessments of authorised products.

16:00 – 16:30. Closing session

- Conclusions of the different characterisation methods presented.
- Identification of common and product-specific approaches.
- Action Plan & Next Steps.

Expected output: *Draft White Paper comparing characterisation approaches for ATMPs intended for the treatment of severe burn patients across European countries, highlighting similarities, differences and opportunities for harmonisation.*