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► To cite this version:

Auxane Delage, Luc-Sylvain Gilbert, Hsin-Yu Kuo, Jennifer Lorigan, Clare Blackburn, et al.. Bringing gene and cell therapies from lab to patients: the EuroGCT research pathways. European Society for Gene & Cell Therapy Congress 2022, Oct 2022, Edinburgh, United Kingdom. halshs-03901227

HAL Id: halshs-03901227

<https://shs.hal.science/halshs-03901227v1>

Submitted on 15 Dec 2022

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Bringing gene and cell therapies from lab to patients: the EuroGCT research pathways

Auxane Delage¹, Luc-Sylvain Gilbert², Hsin-Yu Kuo³, Jennifer Lorigan⁴, Clare Blackburn⁵, Anna Couturier⁶, Amanda Waite⁷, Aurélie Mahalatchimy⁸

¹EuroGCT Information Officer on Ethical, Legal & Societal issues (ELSI), Research Engineer and PhD student in law, Law Faculty, UMR 7318 International, Comparative and European laws, UMR 7318 DICE CERIC, CNRS, Aix Marseille Univ., Toulon Univ., Aix-en-Provence, France; ²EuroGCT Information Officer on ELSI, Research Engineer in law, Law Faculty, UMR 7318 International, Comparative and European laws, UMR 7318 DICE CERIC, CNRS, Aix Marseille Univ., Toulon Univ., Aix-en-Provence, France; ³EuroGCT Information Officer on ATMP Product Development Pathway, Centre for Regenerative Medicine, Institute for Regeneration and Repair, Edinburgh Univ., UK; ⁴EuroGCT Information Officer on Gene and Cell Therapy, Centre for Regenerative Medicine, Institute for Regeneration and Repair, Edinburgh Univ., UK; ⁵EuroGCT Project Coordinator, Centre for Regenerative Medicine, Institute for Regeneration and Repair, Edinburgh Univ., UK; ⁶EuroGCT Project Manager – Digital and Technical, Centre for Regenerative Medicine, Institute for Regeneration and Repair, Edinburgh Univ., UK; ⁷EuroGCT Project Manager – Information and Networks, Centre for Regenerative Medicine, Institute for Regeneration and Repair, Edinburgh Univ., UK; ⁸EuroGCT Deputy coordinator and WP4 leader, Permanent Researcher in law at the French National Centre for Scientific Research (CNRS, CR), Law Faculty, UMR 7318 International, Comparative and European laws, UMR 7318 DICE CERIC, CNRS, Aix Marseille Univ., Toulon Univ., Aix-en-Provence, France. Acknowledgement: This work has been supported by Horizon 2020 funded EuroGCT project (GA N° 965241, PI: C. Blackburn).

INTRODUCTION & AIM

Bringing gene and cell therapies from lab to patients raises challenges from the development of these therapies to patient access. Therapy development must comply with many regulatory requirements in order to ensure patient safety. These requirements have been established throughout the life cycle of these therapies from fundamental research to post-administration vigilance, through manufacturing, clinical trials, marketing authorisation, patentability, or pricing & reimbursement.

The **EuroGCT** website aims to provide accessible and reliable information on therapy development and regulatory pathways.

METHODOLOGY



Legal and scientific watch



Collection and organisation of ATMPs legal acts and guidance



Dissemination of information to EuroGCT partners



Review of research pathways main entries drafts by partners & external collaborators

GENERAL CHALLENGES RAISED & RESEARCH PATHWAYS TREE

Temporality

Variety of Actors

Legal Complexity

Binding texts vs. guidelines

European Union law vs. national laws

Legal classification leading to different pathways

5

Actors & Networks

Stakeholders mapping in Europe and beyond

6

Public Involvement & Data

Best practices for public involvement & health data handling

1

Research & Innovation

Translating discoveries from basic research

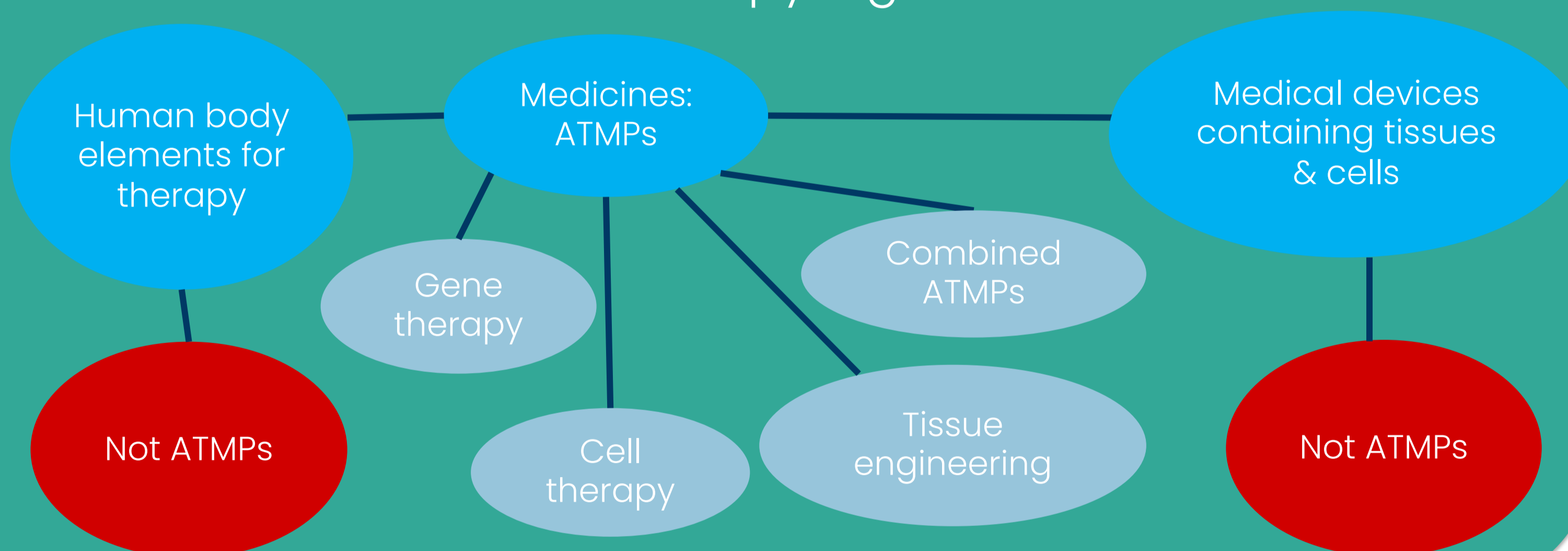
- Fundamental research
- Clinical research
- Funding
- Incentives
- Early interactions with regulators

2

Therapy Classification

Gene & cell therapy legal classification

Determining legal mechanisms for gene & cell therapies



3

Manufacturing

Overview of ATMPs manufacturing processes

- Manufacturing Authorisation
- Good Manufacturing Practice
- Investigational ATMP Dossier
- Capability
- Scalability
- Packaging & Labelling

4

Commercialisation

Enabling timely patient access to ATMPs

- Market access for ATMPs
- Standard & expediting Marketing Authorisation
- Good Distribution Practice
- Good Pharmacovigilance Practice
- Pricing & Reimbursement

CONCLUSION

Research Pathways content should be written in lay language and regularly updated to provide reliable and accessible information. Key content will be translated and available in seven European languages: English, French, German, Italian, Polish, Spanish, and Portuguese.

CONTRIBUTE

Contribution and participation is warmly welcome!

Join the EuroGCT ELSI Network of Expertise:

- To provide drafts content of entries
- To provide lay summaries of your research papers
- To translate existing entries
- To review draft entries
- To provide useful updated resources

All contributions will be credited on the EuroGCT website: www.eurogct.org
To get involved in this collaborative work, please contact the EuroGCT information officers on ELSI
 Auxane Delage: auxane.delage@univ-amu.fr
 Luc-Sylvain Gilbert: luc.gilbert@univ-amu.fr