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Illustrating regulatory requirements for the development of Gene and Cell therapy products with the EuroGCT Research Pathways

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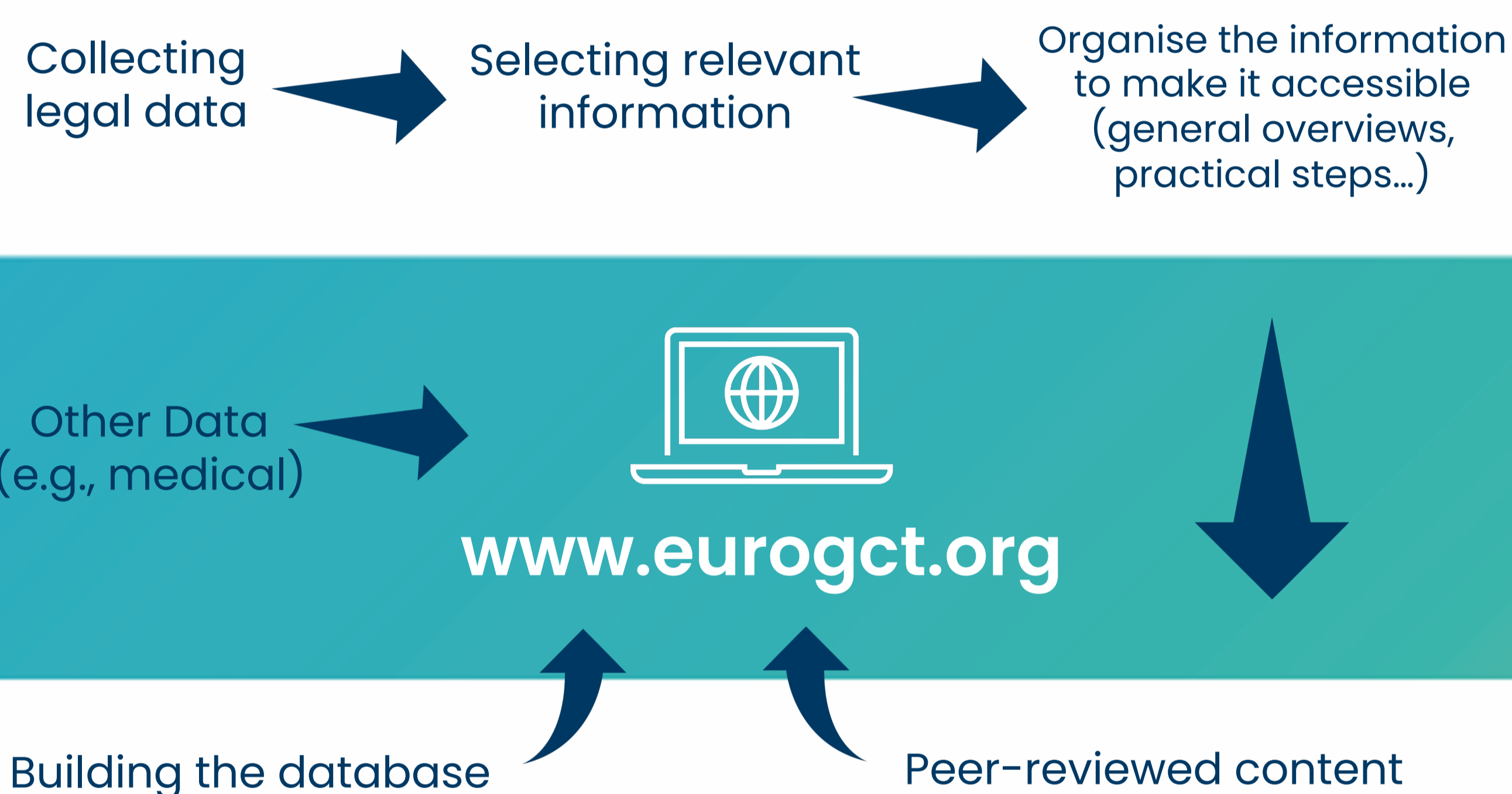
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BACKGROUND

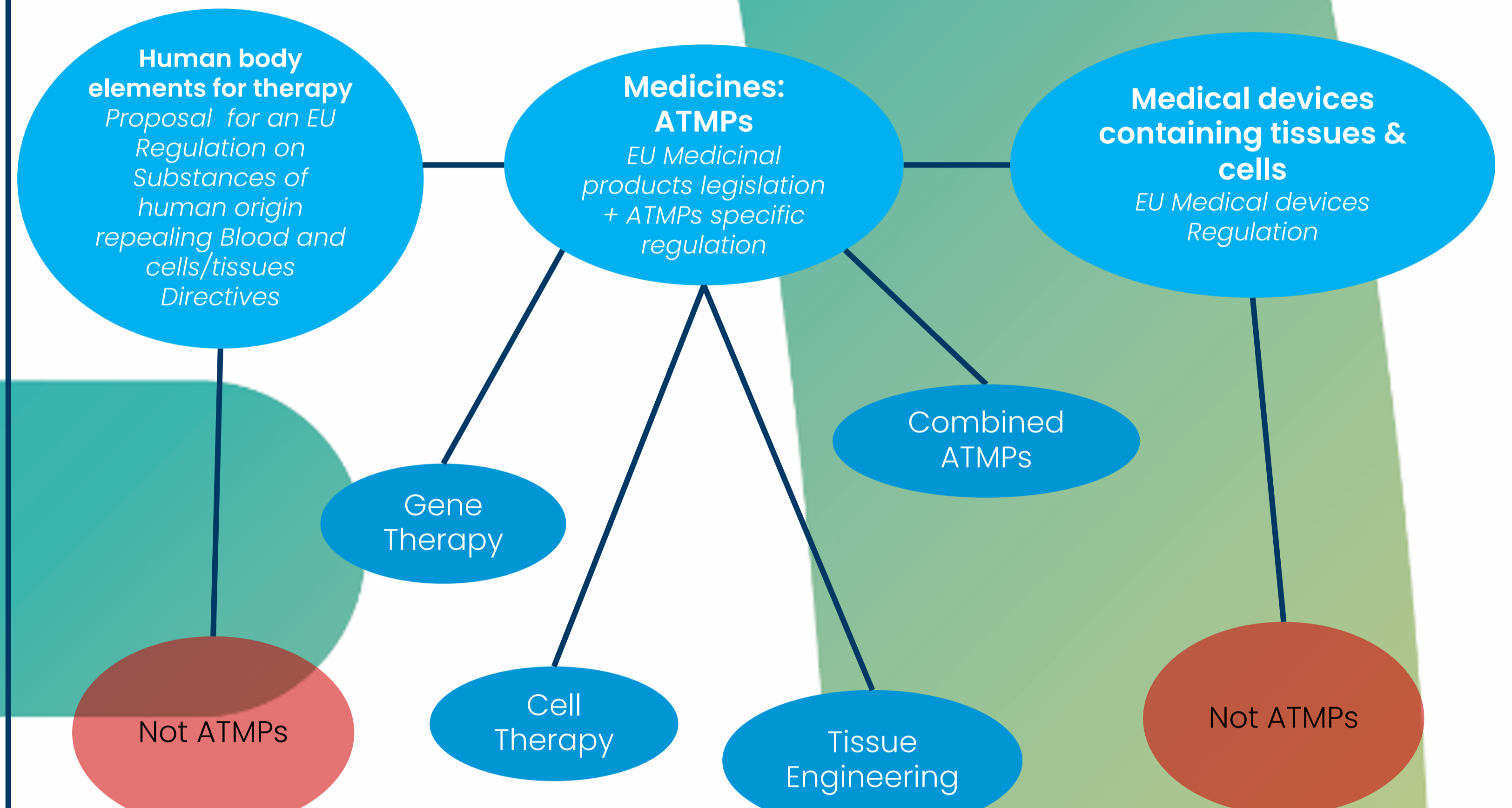
Communicating information on the regulatory framework applicable to gene and cell therapies, at every stage of development and towards every actor involved, is a challenge. Therapy development needs to comply with several regulatory requirements mostly to ensure patients' safety. The complexity comes from the diversity of the regulatory landscape. Some requirements are binding, others are guidance only. Most aspects are governed by European Union law, but some remain regulated on a national scale. The regulatory landscape is a combination of general and specific rules and guidance depending on competent institutions, legal classifications of the products, and steps of their developments.

Methodology

Communicating information on GCT with an online tool



Legal Classification of Gene & Cell Therapy



CHALLENGES

- TEMPORALITY**
- Changes in regulation or legislation
 - Scientific discoveries

- DIVERSITY OF ACTORS**
- European Medicines Agency
 - National Medicines Agencies
 - HTA Bodies
 - Ethics committees
 - GMO authorities

- LEGAL COMPLEXITY**
- European Union law vs. national laws
 - Binding texts vs. guidance
 - Legal classification leading to different pathways

Addressing the challenges in finding information with EuroGCT Research Pathways

Research & Innovation | Therapy Classification | Manufacturing | Commercialisation | Public Involvement & Data

- Fundamental Research
- Clinical Research
- Translational Science
- Incentives
- Early Interactions with Regulators
- See figure above
- Manufacturing Authorisation
- Good Manufacturing Practice
- Investigation Medicinal Product Dossier
- Capability
- Scalability
- Packaging and Labelling
- Market Access for ATMPs
- Distribution
- Advertising
- Pharmacovigilance
- Pricing and Reimbursement
- Data Protection
- Data storage
- Data collection, processing, controlling
- Data sharing and Open Data
- Mission creep and Data Misuse

CONCLUSION

The EuroGCT Research Pathway resources facilitates better decision-making at key points in development of new therapies and thus enable improved product development, by providing the research community, regulatory and healthcare authorities with an information source on the practical steps needed for cell and gene therapy development.

Creating and documenting this process adds value to the community as a whole as we navigate bringing novel treatments responsibly from the lab to the clinic.

CONTRIBUTE

Interested in contributing your insight? We welcome involvement in the further development of the EuroGCT Research Pathways Resource.

- 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
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