

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



EC & EDQM Collaboration: Towards the future in the organs, tissues and cells field

Keeping up with Reality and Quality: A Challenge for European Blood Establishments
27-29 October 2020

Marta López Fraga, PhD

European Committee on Organ Transplantation (CD-P-TO)

99 representatives coming from 34 member states and 19 observer states and institutions (including the EC, WHO, CoE Committee on Bioethics and the main professional societies in the field)



- Development of quality, safety and ethical standards
- Promotion and non-commercialisation of organ donation
- Fight against organ trafficking

Dual Chairmanship to address distinct areas of work:

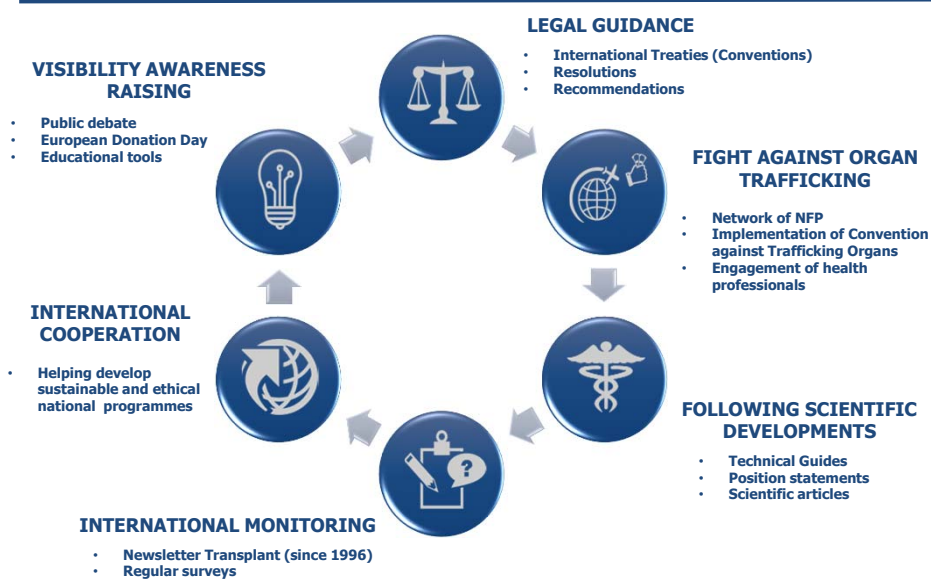
- Chair (**organs**)
- Vice-Chair (**tissues & cells**)

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Activities of the COE in the Field of Transplantation

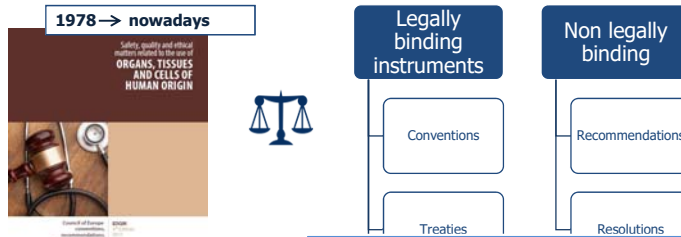


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Legal Guidance at Council of Europe Level



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- Recommendation CM/Rec(2020)6 on establishing harmonised measures for the protection of haematopoietic progenitor cell donors
- Recommendation CM/Rec(2020)4 on the quality and safety of organs for transplantation
- Recommendation CM/Rec(2020)5 on the quality and safety of tissues and cells for human application
- Resolution CM/Res(2017)2 on establishing procedures for the management of patients having received an organ transplant abroad upon return to their home country to receive follow-up care
- Resolution CM/Res(2017)1 on principles for the selection, evaluation, donation and follow-up of the non-resident living organ donors
- Resolution CM/Res(2015)11 on establishing harmonised national living donor registries with a view to facilitating international data sharing and its Explanatory Memorandum
- Resolution CM/Res(2015)10 on the role and training of critical care professionals in deceased donation
- Resolution CM/Res(2013)56 on the development and optimisation of live kidney donation programmes and its Explanatory memorandum
- Resolution CM/Res(2013)55 on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system
- And many more!

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Council of Europe Technical Guidance



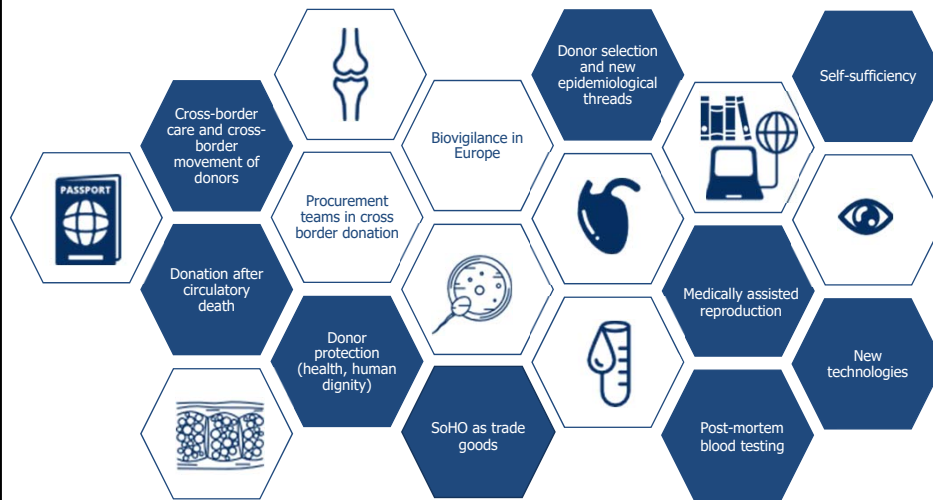
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CD-P-TO's comprehensive work programme addressing changing state-of-the-art and challenges in the field



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International Monitoring at the EDQM/CoE



Editing

- Annual – since 1996
- Edited by EDQM - ONT

Content

- International figures on D&T activities (organs / tissues / HPC) , wait lists, and tx centres
- Resolutions/Recommendations & other documents delivered by CD-P-TO or CoE
- International ethical & legal standards, other documents of interest

Setting

- CoE Member States, Observers & Others (MTN, RCIDT)

Increasingly comprehensive

- More countries: 16 (1996) → 71 (2020)
- More variables (and gender disaggregation)

Reference

- Only international official data source for many years
- Feeds other data bases



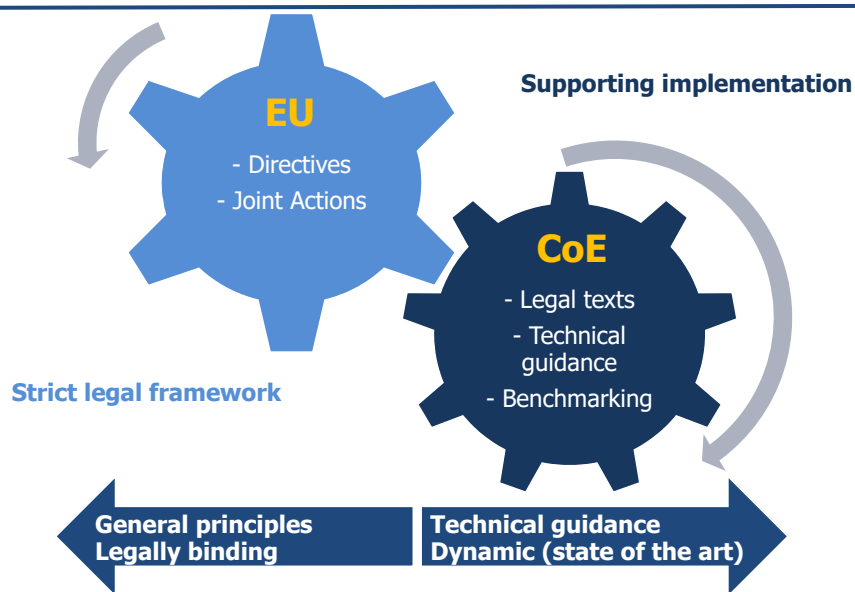
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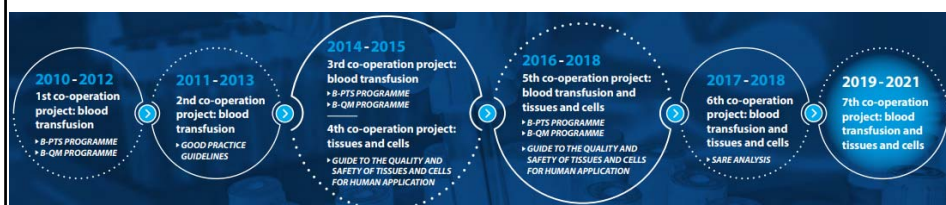
Complementary Role of the EU and the CoE



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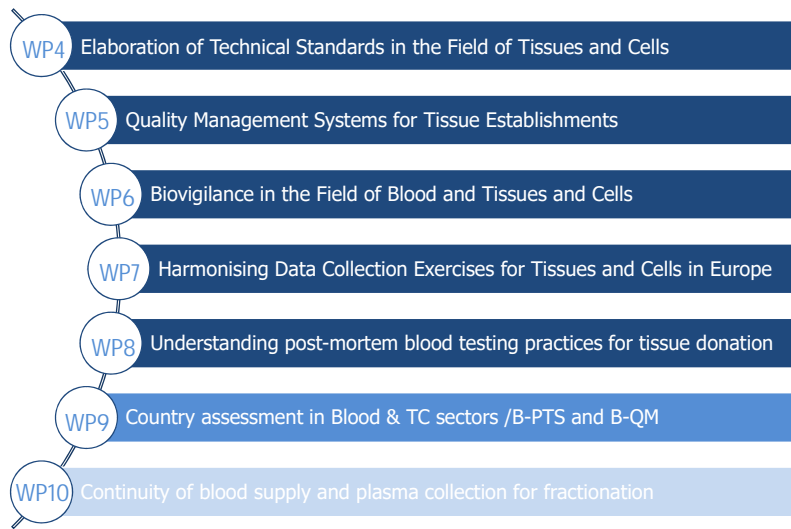
Past and Ongoing Cooperation Agreements



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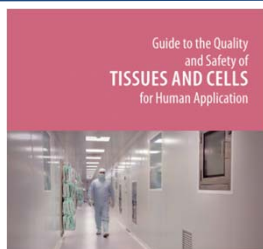
EU GRANT AGREEMENT 2018 53 01 (2019-2021)



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Elaboration of technical standards in the field of T&C



www.edqm.eu
Address: rue de la Loi 17
1049 Brussels

EDQM
4th Edition
2019



Endorsed by the European Union and the Council of Europe

Co-ordinated by the Council of Europe

Implemented by the Council of Europe

Target audience

- Professionals involved in identifying potential donors
- Transplant coordinators managing the process of donation after death
- Testing laboratories
- Bone marrow and cord blood collection centres
- Tissue establishments processing and storing tissues and cells
- Fertility clinics
- Inspectors auditing the establishments and organisations responsible for human application
- Health Authorities responsible for tissues and cells

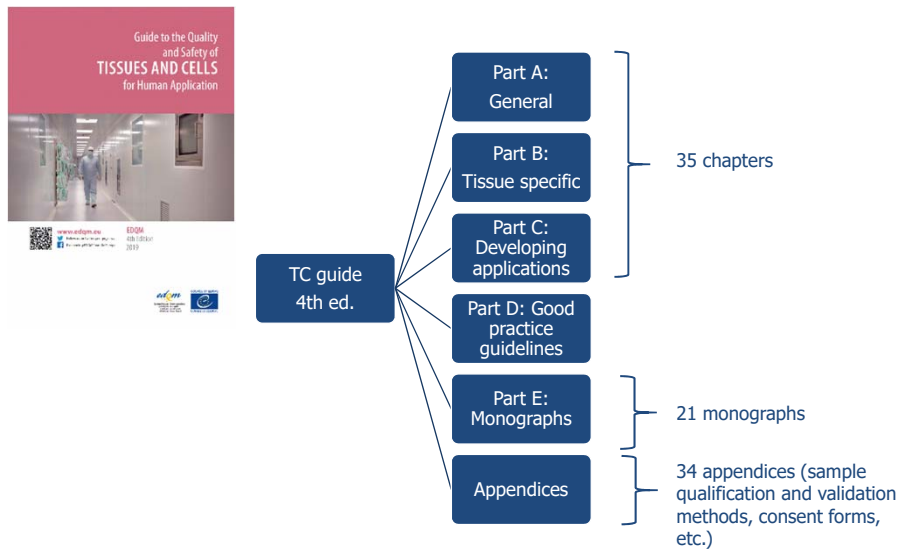
In collaboration with:



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Contents and Structure



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Synergies and Multiplier Effect

With professional associations



With EU-funded projects

- The Guides compile the best available knowledge, including that produced thanks to EU-funded projects, to elaborate their recommendations
 - **Dissemination**
 - **Sustainability**
 - Ensures **future and continuous update** and maintenance
- The Guides provide themselves source material for EU-funded projects
 - Best available and up-to-date information to **built on**
 - **Training** material (e.g. T&C Guide used in EUSTITE Training for inspectors)

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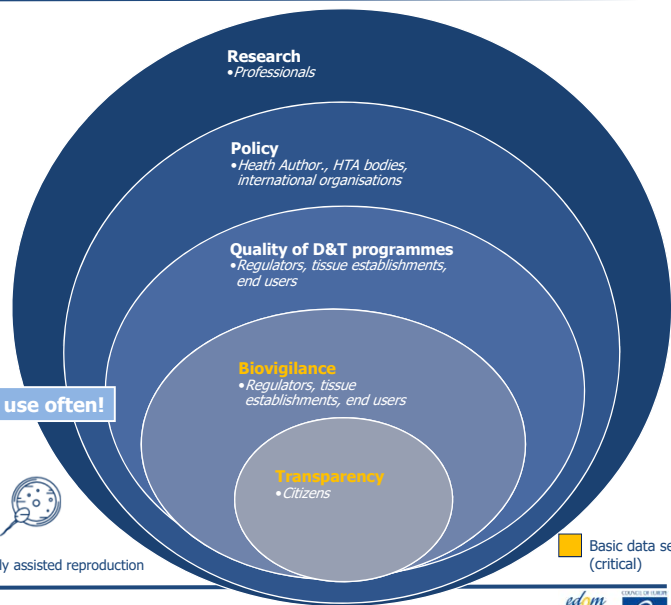
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Activity data reporting as an essential tool to adapt and appropriately fund donation programmes

A realistic assessment of how many tissues and cells are available and how many are required are fundamental for governments to **ensure a rational, fair, and effective distribution** of tissues and cells and to **avoid overreliance** on 3rd countries (outside the EU) or on a few EU countries with the final goal of **achieving European self-sufficiency**.

Mantra: Collect once and use often!

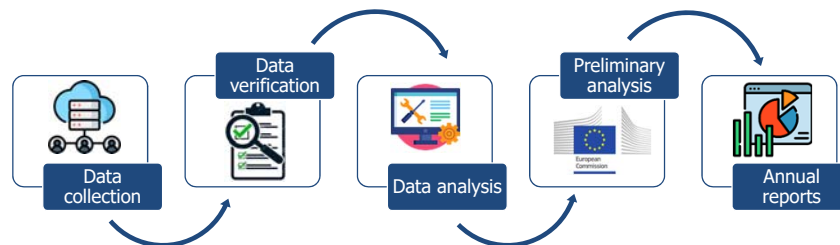


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Serious Adverse Reactions Events (SARE) TC and Blood



Activities involved:

- 1 exercise per field per year

Funded by the European Union and the Council of Europe

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EU Grant Agreement 2018 53 01

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Trainings on QM in TE and biovigilance

Quality Management Systems for Tissue Establishments

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- ✓ European tissue establishments (all kinds);
- ✓ Procurement organisations (e.g. HPC collection centres);
- ✓ European professional associations (e.g. EATB, EBMT, ESHRE, EBA);
- ✓ National regulatory bodies/national Health Authorities, including inspectorates;
- ✓ Suppliers of equipment and materials.

Biovigilance and Good Reporting Practices



- ✓ National biovigilance officers;
- ✓ National regulatory bodies/ national Health Authorities.



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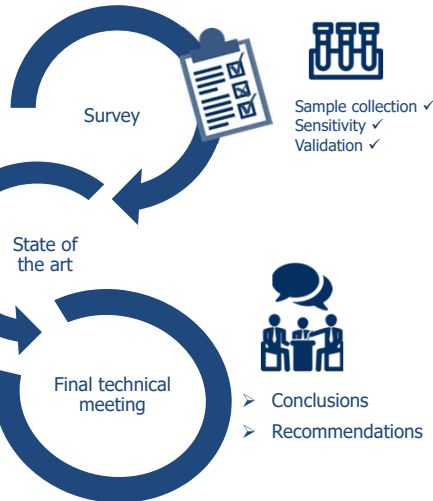
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Understanding post-mortem blood testing practices for tissue donation



- ✓ European Commission/ DG-SANTE team responsible for the field of substances of human origin;
- ✓ European Centre for Disease Prevention and Control (ECDC);
- ✓ National regulatory bodies/national Competent Authorities;
- ✓ European professional associations (e.g. EATB, EEBA, EBA, Medtech Europe);
- ✓ European tissue establishments;
- ✓ Experts in microbiology testing and post-mortem blood testing.



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Conclusions

- The Council of Europe, through the CD-P-TO and its working groups, has been a **pioneer in establishing quality, safety and ethical guidelines for organ, tissue and cell donation and transplantation in Europe.**
- It has implemented an effective approach of adopting the relevant **EU directives as minimum requirements** for safety and quality, while adding value by defining **ethical principles** and providing **detailed and constantly updated technical guidance.**
- This work is valuable to:
 - **Professionals, transplantation centres and tissues establishments** in EU MS because it provides practical information in guidance documents;
 - to **regulators and inspectors** by defining best practice for the implementation of the relevant EU directives that support inspection activities;
 - to **policy-makers** by revealing where future modifications and enhancements of this legislation may be made.
- Perhaps even more importantly, the work of the Council of Europe provides a **comprehensive framework for MS beyond the EU.**
- The results of the cooperation between the EU and the COE contributes to **achieving the shared objective of exchanging knowledge and contributing to the development and improvement of national donation and transplantation programmes**, leading to the successful and safe transplantation of human organs, tissues and cells, offering immense savings to the national health budgets and, ultimately, saving and improving thousands of lives.

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