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Strasbourg, July 2025

EUROPEAN COMMITTEE (PARTIAL AGREEMENT) ON ORGAN TRANSPLANTATION (CD-P-TO)

Harmonising Activity Data Collection Exercises in the Field of Tissues and Cells in Europe (TO111)

PROCEEDINGS

Final meeting
Thursday 10 December 2020, 09h00 - 13h00
Videoconference

EDQM Responsible Scientific Administrator: Jaime MARCO

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For information :
TO111-WG - HPC Hematopoietic Progenitor Cells
TO111-WG - MAR Medically Assisted Reproduction
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HARMONISING ACTIVITY DATA COLLECTION EXERCISES IN THE FIELD OF TISSUES AND CELLS IN EUROPE

PA/PH/TO (21) 7 DEF

PROCEEDINGS OF THE FINAL MEETING

10 December 2020

Videoconference

This technical meeting was organised by the EDQM in the frame of the Grant Agreement 2018 53 01, an activity carried out with funding from the European Union and the Council of Europe. The views expressed herein can in no way be taken to reflect the official opinion of the European Union.

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INTRODUCTION

Founded in 1949, the Council of Europe is the oldest and largest European institution, currently comprising 46 member states. One of its core principles is to enhance cooperation among member states to improve the quality of life for all Europeans. Transplantation activities within the Council of Europe are coordinated by the European Directorate for the Quality of Medicines and HealthCare (EDQM) through its European Committee on Organ Transplantation (CD-P-TO).

Since 1987, the EDQM has actively contributed to the development and implementation of quality, safety, and ethical standards in the field of organs, tissues, and cells. This has been achieved through various initiatives, programmes, and legal instruments, facilitating knowledge exchange between countries and institutions. Within this context of intergovernmental cooperation in the field of health, the EDQM regularly identifies and investigates technical challenges.

The EDQM also maintains strong and fruitful cooperation with the European Union (EU) on a range of health-related issues. This collaboration supports the harmonised implementation of high standards for quality and safety in healthcare across Europe and beyond, while also aiding the enforcement of EU legislation. Moreover, the outcomes of these activities provide valuable data to inform evidence-based policymaking.

Under recent grant agreements between the European Commission and the EDQM, the EDQM has examined national and EU-level practices for collecting and reporting tissue and cell activity data. The goal was to harmonise methodologies, reduce the reporting burden on institutions, and ensure the collection of accurate and meaningful data to assess the availability and needs of tissues and cells across Europe.

Achieving self-sufficiency based on voluntary, unpaid donation, ensuring supply security, and guaranteeing timely and equitable access to safe transplantation are key national and European objectives. A realistic assessment of needs is essential for the fair and efficient distribution of tissues and cells and, most importantly, to avoid overdependence on third countries or a few EU countries. Accurate activity data is also critical for contextualising figures related to serious adverse events and reactions involving the use of tissues and cells of human origin.

However, at the time of the meeting, data on tissue and cell activity remained fragmented and incomplete. This applied not only to national procurement and distribution but also to cross-border exchanges within the EU and internationally. Despite efforts by various stakeholders—including some Member States and professional societies—to collect such data, reporting bodies such as tissue establishments and clinical users faced significant burdens. These efforts were often

hindered by inconsistent terminology, varying units of measurement, unclear data requirements, and the absence of a legal mandate at the EU level.

To address these challenges, representatives from Member States, professional societies, the European Commission, and the Council of Europe have collaborated to improve the coherence, accuracy, and granularity of data collection.

For this purpose, three working groups participated in the project—comprising experts in the fields of replacement tissues, haematopoietic progenitor cells (HPC), and medically assisted reproduction (MAR). They developed a core dataset designed to streamline and harmonise data collection across the EU. This dataset aims to improve the quality, consistency, and accuracy of collected data, ensuring the level of detail required for transparency, biovigilance, and the needs of all relevant stakeholders.

The groups also agreed on a unified methodology and terminology to ensure data accuracy and completeness. These elements were incorporated into both a glossary of definitions and the dataset itself for clarity. Additionally, they issued recommendations on the coordination and implementation of data collection, including its frequency and key measures to support its effectiveness.

The purpose of this meeting was to present the outcomes of this work to all stakeholders—particularly the proposed datasets—and to finalise the conclusions and recommendations to be submitted to the European Commission for consideration in the upcoming revision of EU legislation in this field.

PROGRAMME OF THE TECHNICAL MEETING

AGENDA

1. Welcome and opening remarks (EC and EDQM)
2. Background introduction: The importance of data in the future EU SoHO Framework (EC)
3. Background introduction: State-of-the-art in tissue and cell activity data reporting and methodology used during this project (EDQM)
4. Presentation of the developed minimum datasets: replacement tissues, haematopoietic progenitor cells and medically assisted reproduction (representatives of each subgroup)
5. Results of the pilot tests (EDQM)
6. Conclusions and recommendations (EDQM)
7. Next actions (EC)

DATASETS

REPLACEMENT TISSUES ACTIVITY DATA

COUNTRY		Year	

	DONORS (COLLECTED AT NATIONAL LEVEL)	NUMBERS	UNITS/EXPLANATIONS
DD	Deceased donors		# of deceased tissue/cell donors at national level
LD	Living donors		# of living tissue/cell donors at national level

		OCULAR TISSUE	NUMBERS	UNITS/EXPLANATIONS
OCULAR	OC 1	Donors: Living donors		# of living ocular tissue/cell donors at national level
	OC 2	Donors: Deceased donors		# of deceased ocular tissue/cell donors at national level
	OC 3	Donations: Ocular tissue donations		# of donation events from one donor, may include 1 or 2 eyes/corneas
	OC 4	Releases for clinical application, whether distributed or not: Cornea, full thickness (high endothelial cell density)		# of corneas with endothelial cell density ≥ 2000 cells per mm2
	OC 5	Releases for clinical application, whether distributed or not: Cornea, full thickness (low endothelial cell density)		# of corneas with endothelial cell density < 2000 cells per mm2
	OC 6	Releases for clinical application, whether distributed or not: Cornea for Endothelial Keratoplasty (precut/peeled in the Tissue Establishment)		# of corneas
	OC 7	Releases for clinical application, whether distributed or not: Sclera		# of containers
	OC 8	Releases for clinical application, whether distributed or not: Other ocular		# of containers
	OC 9	Distributed to end user in the country: Cornea, full thickness (high endothelial cell density)		# of corneas with endothelial cell density ≥ 2000 cells per mm2
	OC 10	Distributed to end user in the country: Cornea, full thickness (low endothelial cell density)		# of corneas with endothelial cell density < 2000 cells per mm2
	OC 11	Distributed to end user in the country: Cornea for Endothelial Keratoplasty (precut/peeled in the Tissue Establishment)		# of corneas
	OC 12	Distributed to end user in the country: Sclera		# of containers
	OC 13	Distributed to end user in the country: Other ocular		# of containers
	OC 14	Distributed to end user in another EU country: Cornea, full thickness (high endothelial cell density)		# of corneas with endothelial cell density ≥ 2000 cells per mm2
	OC 15	Distributed to end user in another EU country: Cornea, full thickness (low endothelial cell density)		# of corneas with endothelial cell density < 2000 cells per mm2
	OC 16	Distributed to end user in another EU country: Cornea for Endothelial Keratoplasty (precut/peeled in the Tissue Establishment)		# of corneas
	OC 17	Distributed to end user in another EU country: Sclera		# of containers
	OC 18	Distributed to end user in another EU country: Other ocular		# of containers
	OC 19	Sent to a tissue establishment (transport) in another EU country: Cornea, full thickness (high endothelial cell density)		# of corneas with endothelial cell density ≥ 2000 cells per mm2
	OC 20	Sent to a tissue establishment (transport) in another EU country: Cornea, full thickness (low endothelial cell density)		# of corneas with endothelial cell density < 2000 cells per mm2
	OC 21	Sent to a tissue establishment (transport) in another EU country: Cornea for Endothelial Keratoplasty (precut/peeled in the Tissue Establishment)		# of corneas
	OC 22	Sent to a tissue establishment (transport) in another EU country: Sclera		# of containers
	OC 23	Sent to a tissue establishment (transport) in another EU country: Other ocular		# of containers
	OC 24	Received from a tissue establishment (transport) in another EU country: Cornea, full thickness (high endothelial cell density)		# of corneas with endothelial cell density ≥ 2000 cells per mm2
	OC 25	Received from a tissue establishment (transport) in another EU country: Cornea, full thickness (low endothelial cell density)		# of corneas with endothelial cell density < 2000 cells per mm2
	OC 26	Received from a tissue establishment (transport) in another EU country: Cornea for Endothelial Keratoplasty (precut/peeled in the Tissue Establishment)		# of corneas
	OC 27	Received from a tissue establishment (transport) in another EU country: Sclera		# of containers
	OC 28	Received from a tissue establishment (transport) in another EU country: Other ocular		# of containers
	OC 29	Exports (non EU): Cornea, full thickness (high endothelial cell density)		# of corneas with endothelial cell density ≥ 2000 cells per mm2
	OC 30	Exports (non EU): Cornea, full thickness (low endothelial cell density)		# of corneas with endothelial cell density < 2000 cells per mm2
	OC 31	Exports (non EU): Cornea for Endothelial Keratoplasty (precut/peeled in the Tissue Establishment)		# of corneas
	OC 32	Exports (non EU): Sclera		# of containers
	OC 33	Exports (non EU): Other ocular		# of containers

	OC 34	Imports (non EU)	Cornea, full thickness (high endothelial cell density)		# of corneas with endothelial cell density ≥ 2000 cells per mm2
	OC 35		Cornea, full thickness (low endothelial cell density)		# of corneas with endothelial cell density < 2000 cells per mm2
	OC 36		Cornea for Endothelial Keratoplasty (precut/peeled in the Tissue Establishment)		# of corneas
	OC 37		Sclera		# of containers
	OC 38		Other ocular		# of containers
	OC 39	Application procedures	Applications for Penetrating Keratoplasty		# of applications (one surgical procedure, regardless of the # of grafts used)
	OC 40		Applications for Anterior Lamellar Keratoplasty		# of applications (one surgical procedure, regardless of the # of grafts used)
	OC 41		Applications for Endothelial Keratoplasty		# of applications (one surgical procedure, regardless of the # of grafts used)
	OC 42		Applications for scleral reconstruction		# of applications (one surgical procedure, regardless of the # of grafts used)
	OC 43		Applications for other ocular treatments (only use if the application does not fit into one of the above categories)		# of applications (one surgical procedure, regardless of the # of grafts used)

		PLACENTAL TISSUE		NUMBERS	UNITS/EXPLANATIONS
PLACENTAL	PL 1	Donors	Living donors		# of living placental tissue donors at national level
	PL 2		Deceased donors		# of deceased placental tissue donors at national level
	PL 3	Donations	Placental membrane donations		# of donation events from one delivery, including multiple births
	PL 4	Releases for clinical application, whether distributed or not	Amniotic membrane		# of containers
	PL 5		Amniotic membrane eyedrops		# of batches prepared for a single patient
	PL 6		Other placental		# of containers
	PL 7	Distributed to end user in the country	Amniotic membrane		# of containers
	PL 8		Amniotic membrane eyedrops		# of batches prepared for a single patient
	PL 9		Other placental		# of containers
	PL 10	Distributed to end user in another EU country	Amniotic membrane		# of containers
	PL 11		Amniotic membrane eyedrops		# of batches prepared for a single patient
	PL 12		Other placental		# of containers
	PL 13	Sent to a tissue establishment (transport) in another EU country	Amniotic membrane		# of containers
	PL 14		Amniotic membrane eyedrops		# of batches prepared for a single patient
	PL 15		Other placental		# of containers
	PL 16	Received from a tissue establishment (transport) in another EU country	Amniotic membrane		# of containers
	PL 17		Amniotic membrane eyedrops		# of batches prepared for a single patient
	PL 18		Other placental		# of containers
	PL 19	Exports (non EU)	Amniotic membrane		# of containers
	PL 20		Amniotic membrane eyedrops		# of batches prepared for a single patient
	PL 21		Other placental		# of containers
	PL 22	Imports (non EU)	Amniotic membrane		# of containers
	PL 23		Amniotic membrane eyedrops		# of batches prepared for a single patient
	PL 24		Other placental		# of containers
	PL 25	Application procedures	Amniotic membrane applications for ocular treatment (excluding amniotic eye drops)		# of applications (one surgical procedure, regardless of the # of grafts used)
	PL 26		Amniotic membrane applications for ocular treatment (amniotic eye drops)		# of batches prepared for a single patient
	PL 27		Amniotic membrane applications for non-ocular burn/wound healing		# of applications (one surgical procedure, regardless of the # of grafts used)
	PL 28		Amniotic membrane applications for other treatments		# of applications (one surgical procedure, regardless of the # of grafts used)
	PL 29		Other placental tissue applications (only use if the application does not fit into one of the above categories)		# of applications (one surgical procedure, regardless of the # of grafts used)

CUTANEOUS

	CUTANEOUS TISSUE		NUMBERS	UNITS/EXPLANATIONS
CU 1	Donors	Living donors		# of living cutaneous tissue donors at national level
CU 2		Deceased donors		# of deceased cutaneous tissue donors at national level
CU 3	Donations	Skin donations		# of donation events from one donor, regardless of the number of tissues obtained
CU 4	Releases for clinical application, whether distributed or not	Skin		cm2
CU 5		Acellular dermal matrix		cm2
CU 6		Keratinocytes/melanocytes		# of containers
CU 7		Other cutaneous tissues		# of containers
CU 8	Distributed to end user in the country	Skin		cm2
CU 9		Acellular dermal matrix		cm2
CU 10		Keratinocytes/melanocytes		# of containers
CU 11		Other cutaneous tissues		# of containers
CU 12	Distributed to end user in another EU country	Skin		cm2
CU 13		Acellular dermal matrix		cm2
CU 14		Keratinocytes/melanocytes		# of containers
CU 15		Other cutaneous tissues		# of containers
CU 16	Sent to a tissue establishment (transport) in another EU country	Skin		cm2
CU 17		Acellular dermal matrix		cm2
CU 18		Keratinocytes/melanocytes		# of containers
CU 19		Other cutaneous tissues		# of containers
CU 20	Received from a tissue establishment (transport) in another EU country	Skin		cm2
CU 21		Acellular dermal matrix		cm2
CU 22		Keratinocytes/melanocytes		# of containers
CU 23		Other cutaneous tissues		# of containers
CU 24	Exports (non EU)	Skin		cm2
CU 25		Acellular dermal matrix		cm2
CU 26		Keratinocytes/melanocytes		# of containers
CU 27		Other cutaneous tissues		# of containers
CU 28	Imports (non EU)	Skin		cm2
CU 29		Acellular dermal matrix		cm2
CU 30		Keratinocytes/melanocytes		# of containers
CU 31		Other cutaneous tissues		# of containers
CU 32	Application procedures	Applications for burns/wound healing		# of applications (one surgical procedure, regardless of the # of grafts used)
CU 33		Applications for reconstructive surgery		# of applications (one surgical procedure, regardless of the # of grafts used)
CU 34		Applications for other treatments (only use if the application does not fit into one of the above categories)		# of applications (one surgical procedure, regardless of the # of grafts used)

	CARDIAC TISSUE		NUMBERS	UNITS/EXPLANATIONS
CA 1	Donors	Living donors		# of living cardiac tissue donors at national level
CA 2		Deceased donors		# of deceased cardiac tissue donors at national level
CA 3	Donations	Cardiac tissue donations		# of donation events from one donor, regardless of the number of tissues obtained
CA 4	Releases for clinical application, whether distributed or not	HV, aortic		# of HV
CA 5		HV, pulmonary		# of HV
CA 6		HV, aortic decellularised		# of HV
CA 7		HV, pulmonary decellularised		# of HV
CA 8		Non-valved patches and conduits		# of containers
CA 9		Pericardium		# of containers
CA 10		Other heart tissues		# of containers

CARDIAC	CA 11	Distributed to end user in the country	HV, aortic	# of HV
	CA 12		HV, pulmonary	# of HV
	CA 13		HV, aortic decellularised	# of HV
	CA 14		HV, pulmonary decellularised	# of HV
	CA 15		Non-valved patches and conduits	# of containers
	CA 16		Pericardium	# of containers
	CA 17		Other heart tissues	# of containers
	CA 18	Distributed to end user in another EU country	HV, aortic	# of HV
	CA 19		HV, pulmonary	# of HV
	CA 20		HV, aortic decellularised	# of HV
	CA 21		HV, pulmonary decellularised	# of HV
	CA 22		Non-valved patches and conduits	# of containers
	CA 23		Pericardium	# of containers
	CA 24		Other heart tissues	# of containers
	CA 25	Sent to a tissue establishment (transport) in another EU country	HV, aortic	# of HV
	CA 26		HV, pulmonary	# of HV
	CA 27		HV, aortic decellularised	# of HV
	CA 28		HV, pulmonary decellularised	# of HV
	CA 29		Non-valved patches and conduits	# of containers
	CA 30		Pericardium	# of containers
	CA 31		Other heart tissues	# of containers
	CA 32	Received from a tissue establishment (transport) in another EU country	HV, aortic	# of HV
	CA 33		HV, pulmonary	# of HV
	CA 34		HV, aortic decellularised	# of HV
	CA 35		HV, pulmonary decellularised	# of HV
	CA 36		Non-valved patches and conduits	# of containers
	CA 37		Pericardium	# of containers
	CA 38		Other heart tissues	# of containers
	CA 39	Exports (non EU)	HV, aortic	# of HV
	CA 40		HV, pulmonary	# of HV
	CA 41		HV, aortic decellularised	# of HV
	CA 42		HV, pulmonary decellularised	# of HV
	CA 43		Non-valved patches and conduits	# of containers
	CA 44		Pericardium	# of containers
	CA 45		Other heart tissues	# of containers
	CA 46	Imports (non EU)	HV, aortic	# HV
	CA 47		HV, pulmonary	# HV
	CA 48		HV, aortic decellularised	# HV
	CA 49		HV, pulmonary decellularised	# HV
	CA 50		Non-valved patches and conduits	# of containers
	CA 51		Pericardium	# of containers
	CA 52		Other heart tissues	# of containers
	CA 53	Application procedures	Applications for HV replacement	# of applications (one surgical procedure, regardless of the # of grafts used)
	CA 54		Applications for cardiac reconstruction	# of applications (one surgical procedure, regardless of the # of grafts used)
	CA 55		Applications for other treatments (only use if the application does not fit into one of the above categories)	# of applications (one surgical procedure, regardless of the # of grafts used)

	VESSELS			NUMBERS	UNITS/EXPLANATIONS
VESSELS	VE 1	Donors	Living donors		# of living vessel donors at national level
	VE 2		Deceased donors		# of deceased vessel donors at national level
	VE 3	Donations	Vessel donations		# of donation events from one donor, regardless of the number of tissues obtained
	VE 4	Releases for clinical application, whether distributed or not	Vessels, arteries		# of containers
	VE 5		Vessels, veins		# of containers
	VE 6	Distributed to end user in the country	Vessels, arteries		# of containers
	VE 7		Vessels, veins		# of containers
	VE 8	Distributed to end user in another EU country	Vessels, arteries		# of containers
	VE 9		Vessels, veins		# of containers
	VE 10	Sent to a tissue establishment (transport) in another EU country	Vessels, arteries		# of containers
	VE 11		Vessels, veins		# of containers
	VE 12	Received from a tissue establishment (transport) in another EU country	Vessels, arteries		# of containers
	VE 13		Vessels, veins		# of containers
	VE 14	Exports (non EU)	Vessels, arteries		# of containers
	VE 15		Vessels, veins		# of containers
	VE 16	Imports (non EU)	Vessels, arteries		# of containers
	VE 17		Vessels, veins		# of containers
	VE 18	Application procedures	Applications		# of applications (one surgical procedure, regardless of the # of grafts used)

	MUSCULOSKELETAL TISSUE			NUMBERS	UNITS/EXPLANATIONS
	MU 1	Donors	Living donors		# of living musculoskeletal tissue donors at national level (including for autologous use of cranial bone and cartilage)
	MU 2		Deceased donors		# of deceased musculoskeletal tissue donors at national level
	MU 3	Donations	Musculoskeletal tissue donations		# of donation events from one donor, regardless of the number of tissues obtained (including for autologous use of cranial bone and cartilage)
	MU 4	Releases for clinical application, whether distributed or not	Whole or part of structural/supporting bone		# of pieces
	MU 5		Tendons (including with bony attachments)/ligaments/fascia		# of pieces
	MU 6		Osteochondral grafts		# of pieces
	MU 7		Bone filling material (excluding femoral heads)		# of containers
	MU 8		Femoral heads		# of containers
	MU 9		Demineralised bone matrix (including combined with a carrier)		# of containers
	MU 10		Meniscus		# of pieces
	MU 11		Other musculoskeletal (e.g. ear ossicles, cranial bone, cartilage)		# of containers
	MU 12	Distributed to end user in the country	Whole or part of structural/supporting bone		# of pieces
	MU 13		Tendons (including with bony attachments)/ligaments/fascia		# of pieces
	MU 14		Osteochondral grafts		# of pieces
	MU 15		Bone filling material (excluding femoral heads)		# of containers
	MU 16		Femoral heads		# of containers
	MU 17		Demineralised bone matrix (including combined with a carrier)		# of containers
	MU 18		Meniscus		# of pieces
	MU 19		Other musculoskeletal (e.g. ear ossicles, cranial bone, cartilage)		# of containers

MUSKULOSKELETAL	MU 20	Distributed to end user in another EU country	Whole or part of structural/supporting bone		# of pieces
	MU 21		Tendons (including with bony attachments)/ligaments/fascia		# of pieces
	MU 22		Osteochondral grafts		# of pieces
	MU 23		Bone filling material (excluding femoral heads)		# of containers
	MU 24		Femoral heads		# of containers
	MU 25		Demineralised bone matrix (including combined with a carrier)		# of containers
	MU 26		Meniscus		# of pieces
	MU 27		Other musculoskeletal (e.g. ear ossicles, cranial bone, cartilage)		# of containers
	MU 28	Sent to a tissue establishment (transport) in another EU country	Whole or part of structural/supporting bone		# of pieces
	MU 29		Tendons (including with bony attachments)/ligaments/fascia		# of pieces
	MU 30		Osteochondral grafts		# of pieces
	MU 31		Bone filling material (excluding femoral heads)		# of containers
	MU 32		Femoral heads		# of containers
	MU 33		Demineralised bone matrix (including combined with a carrier)		# of containers
	MU 34		Meniscus		# of pieces
	MU 35		Other musculoskeletal (e.g. ear ossicles, cranial bone, cartilage)		# of containers
	MU 36	Received from a tissue establishment (transport) in another EU country	Whole or part of structural/supporting bone		# of pieces
	MU 37		Tendons (including with bony attachments)/ligaments/fascia		# of pieces
	MU 38		Osteochondral grafts		# of pieces
	MU 39		Bone filling material (excluding femoral heads)		# of containers
	MU 40		Femoral heads		# of containers
	MU 41		Demineralised bone matrix (including combined with a carrier)		# of containers
	MU 42		Meniscus		# of pieces
	MU 43		Other musculoskeletal (e.g. ear ossicles, cranial bone, cartilage)		# of containers
	MU 44	Exports (non EU)	Whole or part of structural/supporting bone		# of pieces
	MU 45		Tendons (including with bony attachments)/ligaments/fascia		# of pieces
	MU 46		Osteochondral grafts		# of pieces
	MU 47		Bone filling material (excluding femoral heads)		# of containers
	MU 48		Femoral heads		# of containers
	MU 49		Demineralised bone matrix (including combined with a carrier)		# of containers
	MU 50		Meniscus		# of pieces
	MU 51		Other musculoskeletal (e.g. ear ossicles, cranial bone, cartilage)		# of containers
	MU 52	Imports (non EU)	Whole or part of structural/supporting bone		# of pieces
	MU 53		Tendons (including with bony attachments)/ligaments/fascia		# of pieces
	MU 54		Osteochondral grafts		# of pieces
	MU 55		Bone filling material (excluding femoral heads)		# of containers
	MU 56		Femoral heads		# of containers
	MU 57		Demineralised bone matrix (including combined with a carrier)		# of containers
	MU 58		Meniscus		# of pieces
	MU 59		Other musculoskeletal (e.g. ear ossicles, cranial bone, cartilage)		# of containers
	MU 60	Application procedures	Application for orthopaedic/maxillofacial surgery		# of applications (one surgical procedure, regardless of the # of grafts used)
	MU 61		Application for dental procedures		# of applications (one surgical procedure, regardless of the # of grafts used)
	MU 62		Applications for other treatments (only use if the application does not fit into one of the above categories)		# of applications (one surgical procedure, regardless of the # of grafts used)

		NEURONAL TISSUE		NUMBERS	UNITS/EXPLANATIONS
NEURONAL	NE 1	Donors	Living donors		# of living neuronal tissue donors at national level
	NE 2		Deceased donors		# of deceased neuronal tissue donors at national level
	NE 3	Donations	Nerve donations		# of donation events from one donor, regardless of the number of tissues obtained
	NE 4	Releases for clinical application, whether distributed or not	Nerves		# of containers
	NE 5	Distributed to end user in the country	Nerves		# of containers
	NE 6	Distributed to end user in another EU country	Nerves		# of containers
	NE 7	Sent to a tissue establishment (transport) in another EU country	Nerves		# of containers
	NE 8	Received from a tissue establishment (transport) in another EU country	Nerves		# of containers
	NE 9	Exports (non EU)	Nerves		# of containers
	NE 10	Imports (non EU)	Nerves		# of containers
	NE 11	Application procedures	Applications		# of applications (one surgical procedure, regardless of the # of grafts used)

		ADIPOSE TISSUE		NUMBERS	UNITS/EXPLANATIONS
	AD 1	Donors	Living donors		# of living adipose tissue donors at national level
	AD 2		Deceased donors		# of deceased adipose tissue donors at national level
	AD 3	Donations	Adipose tissue donations		# of donation events from one donor, regardless of the number of tissues obtained
ADIPOSE	AD 4	Releases for clinical application, whether distributed or not	Adipose tissue		# of containers
	AD 5	Distributed to end user in the country	Adipose tissue		# of containers
	AD 6	Distributed to end user in another EU country	Adipose tissue		# of containers
	AD 7	Sent to a tissue establishment (transport) in another EU country	Adipose tissue		# of containers
	AD 8	Received from a tissue establishment (transport) in another EU country	Adipose tissue		# of containers
	AD 9	Exports (non EU)	Adipose tissue		# of containers

AD 10	**Imports (non EU)**	Adipose tissue		# of containers
AD 11	**Application procedures**	Applications for reconstructive surgery		# of applications (one surgical procedure, regardless of the # of grafts used)
AD 12		Applications for aesthetic surgery		# of applications (one surgical procedure, regardless of the # of grafts used)
AD 13		Applications for other treatments (only use if the application does not fit into one of the above categories)		# of applications (one surgical procedure, regardless of the # of grafts used)

PANCREATIC

	PANCREATIC TISSUE		NUMBERS	UNITS/EXPLANATIONS
PA 1	**Donors**	Living donors		# of living pancreatic tissue donors at national level
PA 2		Deceased donors		# of deceased pancreatic tissue donors at national level
PA 3	**Donations**	Pancreatic tissue donations		# of donation events from one donor, regardless of the number of tissues obtained
PA 4	**Releases for clinical application, whether distributed or not**	Pancreatic islets		# of containers
PA 5	**Distributed to end user in the country**	Pancreatic islets		# of containers
PA 6	**Distributed to end user in another EU country**	Pancreatic islets		# of containers
PA 7	**Sent to a tissue establishment (transport) in another EU country**	Pancreatic islets		# of containers
PA 8	**Received from a tissue establishment (transport) in another EU country**	Pancreatic islets		# of containers
PA 9	**Exports (non EU)**	Pancreatic islets		# of containers
PA 10	**Imports (non EU)**	Pancreatic islets		# of containers
PA 11	**Application procedures**	Applications		# of applications (one single procedure, regardless of the # of grafts used)

	HEPATIC TISSUE		NUMBERS	UNITS/EXPLANATIONS
HE 1	**Donors**	Living donors		# of living hepatic tissue donors at national level
HE 2		Deceased donors		# of deceased hepatic tissue donors at national level
HE 3	**Donations**	Hepatic tissue donations		# of donation events from one donor, regardless of the number of tissues obtained
HE 4	**Releases for clinical application, whether distributed or not**	Hepatocytes		# of containers
HE 5	**Distributed to end user in the country**	Hepatocytes		# of containers

HEPATIC	HE 6	**Distributed to end user in another EU country**	Hepatocytes		# of containers
	HE 7	**Sent to a tissue establishment (transport) in another EU country**	Hepatocytes		# of containers
	HE 8	**Received from a tissue establishment (transport) in another EU country**	Hepatocytes		# of containers
	HE 9	**Exports (non EU)**	Hepatocytes		# of containers
	HE 10	**Imports (non EU)**	Hepatocytes		# of containers
	HE 11	**Application procedures**	Applications		# of applications (one procedure, regardless of the # of grafts used)

		PARATHYROID TISSUE		NUMBERS	UNITS/EXPLANATIONS
PARATHYROID	PR 1	**Donors**	Living donors		# of living parathyroid tissue donors at national level
	PR 2		Deceased donors		# of deceased parathyroid tissue donors at national level
	PR 3	**Donations**	Parathyroid tissue donations		# of donation events from one donor, regardless of the number of tissues obtained
	PR 4	**Releases for clinical application, whether distributed or not**	Parathyroid tissue		# of containers
	PR 5	**Distributed to end user in the country**	Parathyroid tissue		# of containers
	PR 6	**Distributed to end user in another EU country**	Parathyroid tissue		# of containers
	PR 7	**Sent to a tissue establishment (transport) in another EU country**	Parathyroid tissue		# of containers
	PR 8	**Received from a tissue establishment (transport) in another EU country**	Parathyroid tissue		# of containers
	PR 9	**Exports (non EU)**	Parathyroid tissue		# of containers
	PR 10	**Imports (non EU)**	Parathyroid tissue		# of containers
	PR 11	**Application procedures**	Applications		# of applications (one surgical procedure, regardless of the # of grafts used)

HAEMATOPOIETIC CELLS ACTIVITY DATA

COUNTRY | YEAR

SELF-SUFFICIENCY

	POTENTIAL FOR ALLOGENEIC DONATION	Registered at 01/01 00:00
SS a 1	# of registered and typed HPC donors	
SS a 2	# of registered and typed cord blood units available for transplantation of unrelated patients	

	DISTRIBUTION AND EXCHANGE # of unrelated (unit: Cell product from one donor, regardless of the number of donations/containers)	DISTRIBUTED			IMPORT	EXPORT
		Nationally	From EU countries	To EU countries	From non-EU countries	To non-EU countries
SS b 1	HPC from bone marrow for transplantation					
SS b 2	HPC from peripheral blood for transplantation					
SS b 3	Peripheral blood mononuclear cells for transplant support (e.g. donor lymphocytes for infusion)					
SS b 4	Peripheral blood mononuclear cells for other purposes, excluding ATMP (e.g. production of CAR-T cells, NK cells)					
SS b 5	HPC from cord blood for transplantation					

DONATION CENTRE

	DONATION/COLLECTION # of donations (unit: Cell product collected from one donor in one donation procedure - may encompass more than one apheresis session)	AUTOLOGOUS	ALLOGENEIC		
			Related donor		Unrelated registry donor
			Paediatric (<18 yr.)	Adult	
DC a 1	HPC from bone marrow for transplantation				
DC a 2	HPC from peripheral blood for transplantation				
DC a 3	Peripheral blood mononuclear cells for transplant support (e.g. donor lymphocytes for infusion)				
DC a 4	Peripheral blood mononuclear cells for other purposes, excluding ATMP (e.g. production of CAR-T cells, NK cells)				
DC a 5	HPC from cord blood				
DC a 6	Other cells (e.g. bone marrow for other purposes), excluding ATMP				

TISSUE ESTABLISHEMENT

	RELEASED FOR CLINICAL APPLICATION # released for clinical application, whether distributed or not (unit: Cell product collected from one donor in one donation procedure - may encompass more than one apheresis session)	AUTOLOGOUS	ALLOGENEIC	
			Related donor	Unrelated registry donor
TE a 1	HPC from bone marrow for transplantation			
TE a 2	HPC from peripheral blood for transplantation			
TE a 3	Peripheral blood mononuclear cells for transplant support (e.g. donor lymphocytes for infusion)			
TE a 4	Peripheral blood mononuclear cells for other purposes, excluding ATMP (e.g. production of CAR-T cells, NK cells)			
TE a 5	HPC from cord blood for transplantation			
TE a 6	Cord blood for other purposes, excluding ATMP (e.g. production of NK cells, mesenchymals)			
TE a 7	Other cells (e.g. bone marrow for other purposes), excluding ATMP			

TRANSPLANT CENTRES

	TRANSPLANT PROCEDURES ASSOCIATED WITH CLINICAL APPLICATION	AUTOLOGOUS	ALLOGENEIC	
			Related donor	Unrelated registry donor
TC a 1	# of transplants (unit: One transplant procedure with cells obtained from one or more donors)			
TC a 2	# of recipients (unit: One patient who had at least one transplant procedure during the year concerned)			
TC a 3	HPC from bone marrow for transplantation			
TC a 4	HPC from peripheral blood for transplantation			
TC a 5	HPC from cord blood for transplantation			

	OTHER PROCEDURES ASSOCIATED WITH CLINICAL APPLICATION	AUTOLOGOUS	ALLOGENEIC	
			Related donor	Unrelated registry donor
TC b 1	# of procedures (unit: One application with cells obtained from one or more donors)			
TC b 2	# of recipients (unit: One patient who had at least one procedure during the year concerned)			
TC b 3	Peripheral blood mononuclear cells for transplant support (e.g. donor lymphocytes for infusion)			
TC b 4	Peripheral blood mononuclear cells for other purposes (e.g. NK cells, Tregs, virus-specific cells), excluding ATMP			
TC b 5	Other cells for other purposes, excluding ATMP			

MAR ACTIVITY DATA

COUNTRY		YEAR	

PARTNER PROCEDURES

	MAR PARTNER ACTIVITIES	Treatment type			UNITS/EXPLANATIONS
		IUI	IVF/ICSI	Frozen/ergo embryo transfers (FET)	
PA a 1	# of couples treated				# of couples that had at least one treatment cycle intervention (IUI, IVF/ICSI and/or FET) completed
PA a 2	# of treatment cycles without stimulation				# of cycles without ovarian stimulation (includes hormone substituted cycles) that ended up with one of the interventions
PA a 3	# of treatment cycles with stimulation				# of cycles with ovarian stimulation (excludes hormone substituted cycles) that ended up with one of the interventions

	PARTNER GAMETES/EMBRYOS	Numbers (regardless of treatment type)	UNITS/EXPLANATIONS
PA b 1	# of oocyte retrievals		# of retrieval procedures where at least one oocyte was retrieved
PA b 2	# of oocytes retrieved		# of oocytes retrieved in total
PA b 3	# of oocytes cryopreserved		# oocytes cryopreserved in total
PA b 4	# of sperm collections (including MESA, PESA and TESE)		# of collections, regardless of number of straws and method of collection used
PA b 5	# of sperm units cryopreserved		# of straws/vials
PA b 6	# of embryos cryopreserved		# of embryos
PA b 7	# of embryo transfers (fresh or cryo)		# of procedures, regardless of the number of embryos transferred
PA b 8	# of embryos transferred (fresh or cryo)		# of embryos
PA b 9	# of embryos transferred (fresh or cryo) from donated sperm and partner oocytes		# of embryos
PA b 10	# of embryos transferred (fresh or cryo) from donated oocytes and partner sperm		# of embryos

	DISTRIBUTION AND EXCHANGE OF PARTNER GAMETES/TISSUES/EMBRYOS (ACCESS TO CARE)	TRANSPORT/DISTRIBUTION		IMPORT	EXPORT	UNITS/EXPLANATIONS
		From other EU countries	To other EU countries	From non-EU countries	To non-EU countries	
PA c 1	# of oocytes					# of oocytes
PA c 2	# of sperm units					# of straws/vials
PA c 3	# of embryos					# of embryos
PA c 4	# of ovarian tissues					# of vials/containers
PA c 5	# of testicular tissues (including MESA, PESA and TESE)					# of vials/containers

	DELIVERIES AND LIVE BORN CHILDREN (born during the reporting year regardless of when conceived)	Treatment type		UNITS/EXPLANATIONS
		IUI	IVF/ICSI (fresh or cryo)	
PA d 1	# of deliveries			# of deliveries regardless of the number of children born (including stillborn)
PA d 2	# of live born children			# of infants with any vital signs

	NON-PARTNER GAMETES/EMBRYOS	Numbers (regardless of treatment type)	UNITS/EXPLANATIONS
NP a 1	# of oocyte donors for dedicated and split donation cycles		# of donors (recruited for the specific purpose of donation), regardless of the number of donations
NP a 2	# of oocyte donors of supernumerary oocytes (from partner procedures)		# of donors of supernumerary oocytes from partner procedures, regardless of the number of donations
NP a 3	# of oocyte retrievals intended for donation (dedicated or split)		# of retrieval procedures where at least one oocyte was retrieved
NP a 4	# of oocytes donated (dedicated, split or supernumerary)		# of oocytes
NP a 5	# of oocytes cryopreserved (dedicated, split or supernumerary)		# of oocytes
NP a 6	# of sperm donors		# of donors who provided at least one sample during the year
NP a 7	# of sperm collections		# of collections, regardless of the number of straws
NP a 8	# of sperm units cryopreserved		# of straws/vials
NP a 9	# of embryos donated		# of embryos (supernumerary after partner and non-partner treatments)

	DISTRIBUTION AND EXCHANGE OF NON-PARTNER GAMETES/EMBRYOS (COMMERCIALISATION)	TRANSPORT/DISTRIBUTION		IMPORT	EXPORT	UNITS/EXPLANATIONS
		From other EU countries	To other EU countries	From non-EU countries	To non-EU countries	
NP b 1	# of sperm units					# of straws/vials
NP b 2	# of donated embryos					# of embryos

NON-PARTNER PROCEDURES

	MAR with non partner SPERM donation	Treatment type		UNITS/EXPLANATIONS
		IUI	IVF/ICSI	
NP c 1	# of recipients			# women who underwent IUI and/or an embryo transfer involving donated sperm (in the reporting country)
NP c 2	# of treatment cycles with donated sperm			# of cycles, with or without ovarian stimulation, where donated sperm was used
NP c 3	# of partner oocyte retrievals			# of retrieval procedures where at least one oocyte was retrieved
NP c 4	# of embryos cryopreserved			# of embryos (cryopreserved) from donated sperm
NP c 5	# of embryo transfers (fresh or cryo)			# of transfer procedures involving donated sperm, regardless of the number of embryos transferred
NP c 6	# of embryos transferred (fresh or cryo)			# of embryos (transferred) from donated sperm

	MAR with non partner OOCYTE donation	IVF/ICSI	UNITS/EXPLANATIONS
NP d 1	# of recipients		# women who underwent at least one embryo transfer involving donated oocytes (in the reporting country)
NP d 2	# of treatment cycles with donated oocytes		# of cycles, stimulated or non-stimulated, where donated oocytes were used
NP d 3	# of partner sperm collections		# of collections, regardless of the number of straws
NP d 4	# of embryos cryopreserved		# of embryos (cryopreserved) from donated oocytes
NP d 5	# of embryo transfers (fresh or cryo)		# of procedures involving donated oocytes, regardless of the number of embryos transferred
NP d 6	# of embryos transferred (fresh or cryo)		# of embryos (transferred) from donated oocytes

	MAR with non partner OOCYTES AND SPERM donation (double donation)	IVF/ICSI	UNITS/EXPLANATIONS
NP e 1	# of recipients		# women who underwent at least one embryo transfer involving donated oocytes and sperm (in the reporting country)
NP e 2	# of treatment cycles with donated oocytes and sperm		# of cycles, stimulated or non-stimulated, where donated oocytes and sperm were used
NP e 3	# of embryos cryopreserved		# of embryos (cryopreserved) from donated oocytes and sperm
NP e 4	# of embryo transfers (fresh or cryo)		# of procedures involving donated oocytes and sperm, regardless of the number of embryos transferred
NP e 5	# of embryos transferred (fresh or cryo)		# of embryos (transferred) from donated oocytes and sperm

	MAR with EMBRYO donation (supernumerary from partner or non-partner treatments)	IVF/ICSI	UNITS/EXPLANATIONS
NP f 1	# of recipients		# women who underwent at least one embryo transfer involving donated supernumerary embryos (in the reporting country)
NP f 2	# of treatment cycles with donated embryos		# of cycles, stimulated or non-stimulated, where donated supernumerary embryos were used
NP f 3	# of embryo transfers (fresh or cryo)		# of procedures involving donated supernumerary embryos regardless of the number of embryos transferred
NP f 4	# of embryos transferred (fresh or cryo)		# of embryos (transferred) from donated supernumerary embryos

	DELIVERIES AND LIVE BORN CHILDREN (during the reporting year regardless of when conceived)	Treatment type		UNITS/EXPLANATIONS
		IUI	IVF/ICSI (fresh or cryo)	
NP g 1	# of deliveries			# of deliveries, regardless of the number of children born (including stillborn)
NP g 2	# of live born children			# of infants with any vital signs

FERTILITY PRESERVATION		FERTILITY PRESERVATION	Numbers	UNITS/EXPLANATIONS
	FP a 1	# of patients who underwent one or more oocyte retrievals		# of patients who underwent at least one oocyte retrieval procedure, regardless of the number of oocytes retrieved
	FP a 2	# of oocyte retrieval procedures		# of oocyte retrieval procedures, regardless of the number of oocytes retrieved
	FP a 3	# of patients who underwent one or more sperm collections (including MESA, PESA and TESE)		# of patients who underwent at least one sperm collection procedure (including MESA, PESA and TESE with mature sperm extracted), regardless of the amount of straws/vials obtained
	FP a 4	# of sperm collection procedures (including MESA, PESA and TESE)		# of sperm collection procedures (including MESA, PESA and TESE with mature sperm extracted), regardless of the amount of straws/vials obtained
	FP a 5	# of patients who underwent an ovarian tissue collection		# of patients who underwent an ovarian tissue collection procedure, regardless of the amount of tissue collected
	FP a 6	# of ovarian tissue collection procedures		# of ovarian tissue collection procedures, regardless of the amount of tissue collected
	FP a 7	# of patients who underwent a collection of immature testicular tissue		# of patients who underwent a collection procedure of immature testicular tissue (i.e. not containing sperm), regardless of the amount of tissue collected
	FP a 8	# of immature testicular tissue collection procedures		# of immature testicular tissue collection procedures, regardless of the amount of tissue collected
	FP a 9	# of patients who underwent an ovarian tissue transplantation		# of patients who underwent an ovarian tissue transplantation, regardless of the number of tissue fragments transplanted

GLOSSARY OF DEFINITIONS FOR DATA COLLECTION ON ACTIVITY OF TISSUES AND CELLS IN EUROPE

This glossary of definitions is intended to facilitate the completion of the activity data collection exercise for tissues and cells, as per document Harmonisation of activity data collection exercises in the field of tissues and cells in Europe: Dataset for activity data reporting, PA/PH/TO (21) 2 *In some cases, the definitions included might not be suitable for other purposes (e.g. clinical practice). If a definition is not found among the terms included in this glossary, please refer to the Council of Europe Guide to the quality and safety of tissues and cells for human application.*

Application procedure: Clinical application of tissues/cells in a recipient, regardless of the number of grafts used.

Batch: A defined quantity of starting material, packaging material or product processed in one process (or series of processes) so that it can be considered to be homogeneous.

Cell product from one donor (referring to haematopoietic progenitor cells)**:** Product obtained from one donor in the amount/dosage of haematopoietic progenitor cells needed for one patient for one transplantation procedure/episode/treatment course.

Container: Receptacle used to store tissues or cells as provided for clinical application.

Examples:

Musculoskeletal Tissue	One individually packaged or contained graft (e.g. one femoral head, one unit of demineralised bone, one container of bone chips, one femoral strut, one osteochondral allograft, one tendon or part of a tendon).
Ocular Tissue	One individually packaged or contained graft (e.g. one cornea, one piece of sclera).
Cardiac Tissues	One individually packaged or contained graft (e.g. one valve).
Vessels	One individually packaged or contained graft (e.g. one package containing one or more lengths of vessel).
Amniotic Membrane	One container of tissue, regardless of the area of tissue it contains.

Couple: Two individuals who declare that they have an intimate physical relationship.

Cycle: The process (including medication or not) that leads to a unique collection of gametes (for donation or own use), to the single (at a unique time) use of gametes or to the transfer of one or more embryos in a single procedure.

Dedicated oocyte donation: A type of oocyte donation in which a specific donor is assigned to a specific recipient, who receives all of the donor's oocytes for a medically assisted reproduction treatment.

Delivery: The complete expulsion or extraction from a woman of one or more foetuses, after at least 22 completed weeks of gestational age, irrespective of whether they are live births or stillbirths. A delivery of either a single or multiple newborn is considered as one delivery. If more than one newborn is delivered, it is often recognised as a delivery with multiple births.

Distribution: Transportation and delivery of tissues, cells and/or embryos to an organisation responsible for human application in the EU.

Donor: An individual, living or deceased, who is a source of tissue, cells or embryos for human application and for other purposes including research, from whom tissues, cells and/or embryos have been retrieved.

Embryo donation: The process by which a woman (or couple) donates embryos to enable another woman (or couple) to conceive.

End user: Person or organisation responsible for the human application of tissues and cells.

Export: Transportation and delivery of tissues and cells intended for human application to tissue establishments or organisations responsible for human application outside the EU (i.e. in a third country).

Fertility preservation: The process of saving or protecting a person's oocytes, sperm and/or, reproductive (ovarian/testicular) tissue so they can use them to try to have biological children later in life.

Import: The act of bringing tissues or cells into an EU member state from a country outside the EU (i.e. a third country) for the purpose of human application, further processing or storage.

Intra-uterine insemination (IUI): Procedure in which processed sperm cells are transferred transcervically into the uterine cavity.

Intracytoplasmic sperm injection (ICSI): A procedure in which a single spermatozoon is injected into the oocyte cytoplasm.

***In vitro* fertilisation (IVF):** MAR procedure that involves extracorporeal fertilisation. It includes conventional *in vitro* insemination and intracytoplasmic sperm injection.

Live birth: The complete expulsion or extraction from a woman of a product of fertilisation, after 22 completed weeks of gestational age which, after such separation, breathes or shows any other evidence of life, such as heart beat, umbilical cord pulsation or definite movement of voluntary muscles, irrespective of whether the umbilical cord has been cut or the placenta is attached. A birth weight of 500 grams or more can be used if gestational age is unknown. Live births refer to the individual newborn; for example, a twin delivery represents two live births.

Medically assisted reproduction (MAR): Reproduction brought about through various interventions that include *in vitro* handling of both human oocytes and sperm, or of embryos, for the purpose of

treating different forms of fertility impairment and infertility. These include, but are not limited to, ovulation induction, ovarian stimulation, ovulation triggering, intra-uterine, intracervical and intravaginal insemination with semen of husband/partner or donor, *in vitro* fertilisation, embryo transfer and intracytoplasmic sperm injection.

Non-partner procedures: Any medically assisted reproduction method that involves procurement, processing, testing and/or storage of donated human gametes, zygotes, embryos and/or reproductive tissues of donors. Whenever donated gametes are used in a medically assisted reproduction procedure, all cycles, collection procedures and gamete units of both members of the couple should be reported under non-partner procedures.

Oocyte donation: The process by which a woman (the donor) donates oocytes to enable another woman (the recipient) to conceive as part of a medically assisted reproduction treatment.

Ovarian stimulation: Pharmacological treatment with the intention of inducing the development of ovarian follicles. Its purpose is to obtain multiple oocytes at follicular aspiration.

Partner procedures: Any medically assisted reproduction method that involves procurement, processing, testing and/or storage of human gametes, zygotes, embryos and/or reproductive tissues of couples that have an intimate physical relationship. It does not include medically assisted reproduction procedures involving any donated oocytes and/or sperm, i.e. whenever donated gametes are used in a medically assisted reproduction procedure, all cycles, collection procedures and gamete units of both members of the couple should be reported under non-partner procedures.

Release for clinical application: The act of certifying compliance of a specific tissue or cells or batch of tissues or cells with the requirements and specifications before storage.

Sperm donation: The process by which a man (the donor) donates sperm to enable a woman (the recipient) to conceive as part of a medically assisted reproduction treatment.

Split oocyte donation: A type of oocyte donation in which all the oocytes from one donor are donated for medically assisted reproduction procedures in more than one recipient.

Supernumerary oocyte (egg sharing)/supernumerary embryo donation: A type of oocyte/embryo donation in which a woman who is undergoing a medically assisted reproduction procedure donates some of her oocytes/embryos to the clinic where she is having treatment, so they can be used by another woman (or couple) for medically assisted reproduction.

Transport: The act of transferring or conveying of tissues and cells from one place to another within one organisation or between facilities. It may include transport between tissue establishments within the same country or to another EU member state for further processing or storage.

CONCLUSIONS AND RECOMMENDATIONS

The following conclusion and recommendations were agreed by the working group and made publicly available for consideration by the European Commission during the revision of the EU legislation in the field.

I. Objective and scope of the data collection

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
1. Member states must establish and maintain (a) national registry(ies) that is/are able to collect, at least, the identified minimum dataset.		
2. The mandatory collection of the identified minimum data set as per document 'Harmonising activity data collection exercises in the field of tissues and cells in Europe: Dataset for activity data reporting, PA/PH/TO (21) 02', will require legislative changes at EU level. However, if adopted, it would lead to important improvements in the data available both at national and EU level for transparency and biovigilance purposes, as well as to support policy decisions in relation to supply and sufficiency.		

II. Governance, responsibilities and authorisation

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
3. Governance and data collection and curation should be under the responsibility of the national Competent Authority(ies) (CA) or designated bodies.		
4. Activity data should be collected for the previous calendar year, ideally in parallel/together with the SARE exercise.		
5a. Tissue establishments must be authorised by their CA, and their authorisation be conditional, among other factors, on activity and biovigilance data reporting. This would ensure accurate and complete data reporting. Tissue establishments must report activity and biovigilance data to their CA on a yearly basis (or more frequently if so decided by the CA).	5a. Donation/collection centres must be authorised by their CA, and their authorisation be conditional, among other factors, on activity and biovigilance data reporting. This would ensure accurate and complete data reporting. Any tissue establishment collecting or storing units in a different country (e.g. cord blood units being collected in one country and processed and/or stored[1] in a different one)	5a. MAR clinics, tissue establishments handling reproductive tissues and/or cells and independent professionals/practices performing any MAR procedures must have an authorisation, issued by the CA, to perform MAR procedures, and their authorisation be conditional, among other factors, on activity and biovigilance data reporting. Activities that must not be done outside an authorised tissue establishment are processing (including washing of sperm), preservation, storage,

[1] This would not include units temporarily stored in the receiving centre for a specific patient

In third party contracts, data reporting obligations should be included and specified. End users must ensure traceability and report data on clinical applications. Each country can decide how to organise this reporting (through tissue establishments [the same as the SARE exercise], through an established registry [e.g. ECCTR] and/or directly to the CA) and its frequency.	must be authorised by their CA to do so, including the possibility of inspecting their collection and storage sites. Transplant centres must report activity and biovigilance data. Each country can decide how to organise this reporting (e.g. via EBMT and/or directly to the CA national registry(ies)) and its frequency. The CAs taking part in this exercise believed it would be easier to obtain this information by having direct reporting from transplantation centres to professional societies (e.g. EBMT), instead of to the CA.	transport/distribution and import/export of human tissues and cells. Data must be sent by MAR clinics, tissue establishments handling reproductive tissues and/or cells and independent professionals/practices performing any MAR procedures to their CA on a yearly basis. Each country can decide how to organise this reporting (through tissue establishments, through (an) established registry(ies) and/or directly to the CA) and its frequency. This would ensure accurate and complete data reporting. In third party contracts, data reporting obligations should be included and specified. End users [2] must ensure traceability and report all clinical applications and SARE. Each country can decide how to organise this reporting (through tissue establishments, through (an) established registry(ies) and/or directly to the CA) and its frequency.
5b. CA must be accountable for data collection. However, the CA participating in this exercise agreed that data collection by professional societies was very valuable and could maximise the accuracy of the data. Thus, should some of the identified data be collected by professional registries, CA would have to enforce rules to ensure adequate and mandatory transmission of data from these registries to them (i.e. to their national registry(ies)) in good quality and in a timely manner. CA must qualify those registries providing data to them. This could be done through inspections. In the case of international registries, inspections could be performed by one CA (mutual recognition by other CA) or by multinational groups of inspectors, or alternatively CA could rely on qualifications performed by EU authorities.		

[2] To be understood as a healthcare practitioner who undertakes human application procedures

		5c. Clinics/healthcare professionals must be authorised by the CA to perform any of the following activities outside of a tissue establishment: • Ovarian stimulation for IUI or IVF/ICSI • Procurement of oocytes, sperm and reproductive tissues These authorisations must be conditional on reporting activity data and biovigilance (SARE) data.
		5d. MAR clinics, tissue establishments handling reproductive tissues and/or cells and independent professionals/practices performing any MAR procedures must have contracts/written agreements in place with all couples or individuals receiving MAR treatments establishing their obligation to promptly report back information about deliveries, live born children and the occurrence of any SAR (including genetic disorders in offspring when non-partner donor gametes were used). Collecting data on deliveries and live born children (as proposed in the minimum dataset) would allow assessment of the number of children born from MAR procedures in each country.
		5e. Legislation must enforce single cycle data recording.

III. Transport, distribution and import/export

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
6. When transport/distribution activities involve third parties these must be done within the framework of a SLA with a tissue establishment. It would be the responsibility of the tissue establishment to report these transport/distribution activities to the CA as part of their reporting duties. Distribution of tissues/cells to any end user must be done within the framework of a SLA that specifies the obligation of the end user to ensure traceability and report clinical applications and SARE. In the case of distribution to an end user in another EU country, in addition to the national reporting requirements, the tissue establishment which distributed the tissues/cells must be informed of any serious adverse reactions.		6. When transport/distribution activities of gametes, embryos or reproductive tissues involve third parties these must be done within the framework of a SLA with a tissue establishment. End users must report the reception of any gametes/embryos/reproductive tissues (distribution from another EU country). Transport and distribution data should be collected without making any differentiation between both types of exchanges, as the tissue establishment sending the tissues/cells cannot foresee if they will be used for clinical application (distribution) or stored or sent to a different location (transport). The interest in collecting data on distribution/transport and import/export of reproductive tissues and cells is different in the case of partner and non-partner gametes/embryos. In the case of partner gametes/embryos, these may travel in response to differences in access to care (e.g. travel to access techniques not legal or available in the country of origin), while the movement of non-partner gametes/embryos across borders is probably mainly driven by commercialisation. Having information about both types of gametes/embryos would be valuable to meet the objectives of transparency (including self-sufficiency and overreliance on certain countries) and biovigilance.

IV. Data collection for other purposes

<table>
<tr><th>Replacement tissues</th><th>Haematopoietic cells</th><th>Medically assisted reproduction</th></tr>
<tr><td colspan="2">7a. The collection of outcome data is very complex and requires extensive resources.

Additional legislative changes should encourage detailed expanded data collection and reporting for other purposes (e.g. assessing the quality of donation and transplantation programmes, policy decisions, research), as well as detailed outcome data collection. However, this would be beyond the scope of the EU mandatory data collection exercise.

On the other hand, certain registries already collect this type of data (e.g. EBMT, ECCTR). In order to improve the quality of the data and coverage of reporting bodies (i.e. to have 100% of centres reporting their outcome data), the legislation should mention the need to record outcome data, e.g. in existing registries at national level and/or registries from professional societies.</td><td>7a. The collection of detailed outcome data (including efficacy, efficiency and long-term follow-up of offspring) is very complex and requires extensive resources.
Further legislative changes should encourage additional data collection and reporting for other purposes (e.g. assessing the quality of donation and transplantation programmes, policy decisions, research), as well as detailed outcome data collection. However, this would be beyond the scope of the EU mandatory data collection exercise.

On the other hand, certain registries already collect this type of data (e.g. ESHRE’s IVF Monitoring Programme). In order to improve the quality of the data and coverage of reporting bodies (i.e. to have 100% of centres reporting their outcome data), the legislation should mention the need to record outcome data, e.g. in existing registries at national level and/or registries from professional societies.

Nonetheless, basic information on outcomes (e.g. deliveries, live births from MAR procedures) is necessary for transparency and as denominators for SARE and should be collected through the mandatory dataset.</td></tr>
<tr><td></td><td>7b. Donor centres/registries should follow up related and unrelated HPC donors. WMDA has standards for the follow-up of unrelated donors and these could be extended to related donors.</td><td></td></tr>
</table>

V. Data protection and data traceability

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
8. In accordance with GDPR, patients and living donors must be informed that activity data, including at least that of the minimum dataset, will be recorded in relevant registry(ies).		
		9. Individuals undergoing MAR procedures must have a unique ID number at national level. Furthermore, couples undergoing partner procedures must be assigned a couple ID number at national level, and this couple ID number must be used for all future treatments involving the same partners.

VI. Data reporting to the EU

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
10. Following all the above specifications, the complete minimum dataset would be available from national registry(ies) and CA could therefore provide aggregated anonymised data to the EC on an annual basis, in parallel/together with the SARE exercise.		

VII. Sustainability

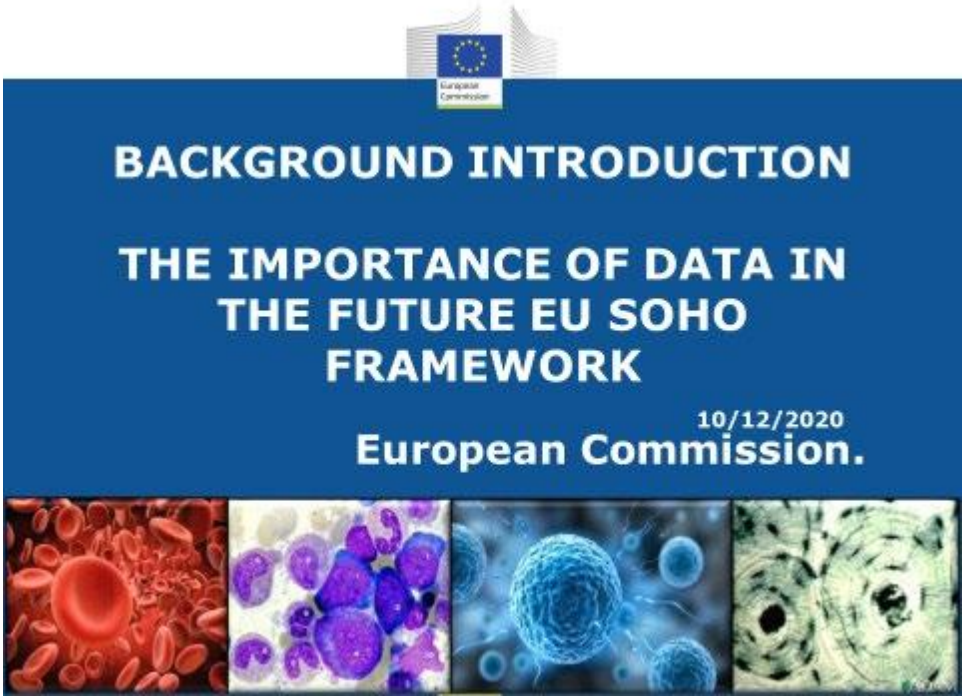
Replacement tissues	Haematopoietic cells	Medically assisted reproduction
11. Collecting the information identified in the minimum dataset will involve costs and the need for additional resources at tissue establishment, national and EU levels. Thus, policy makers should provide sufficient resources to enable implementation and sustained/continued operation.		

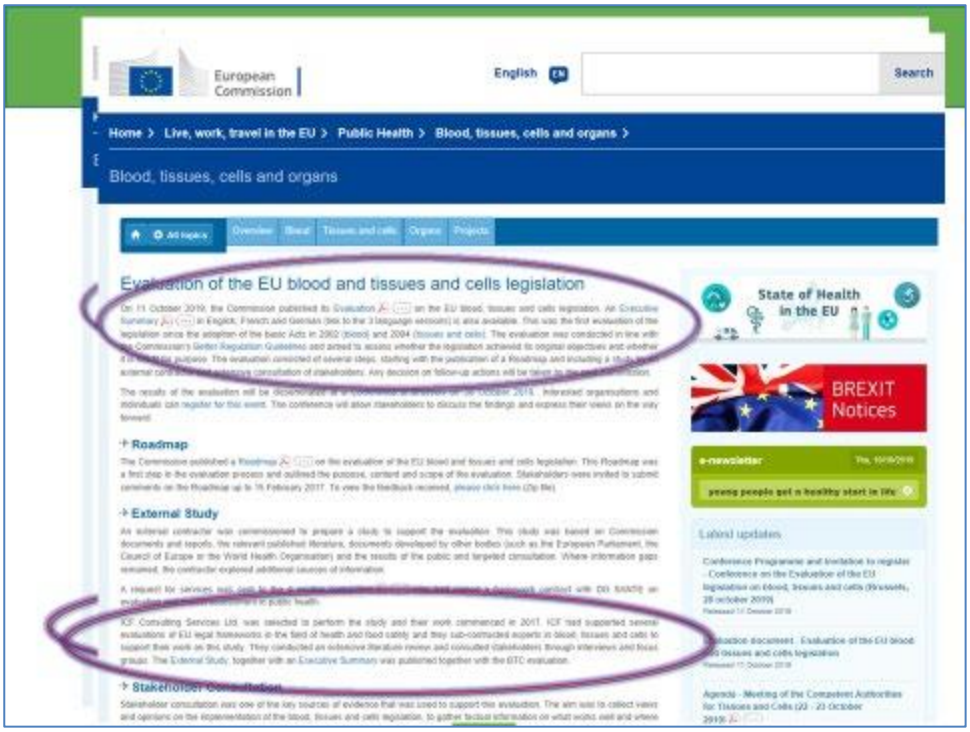
VIII. Data dissemination at national and EU level

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
12. Member states must be accountable for the data collection and its dissemination 13. This minimum data set should be made publicly available by the EC for transparency purposes, ideally disaggregated by country.		

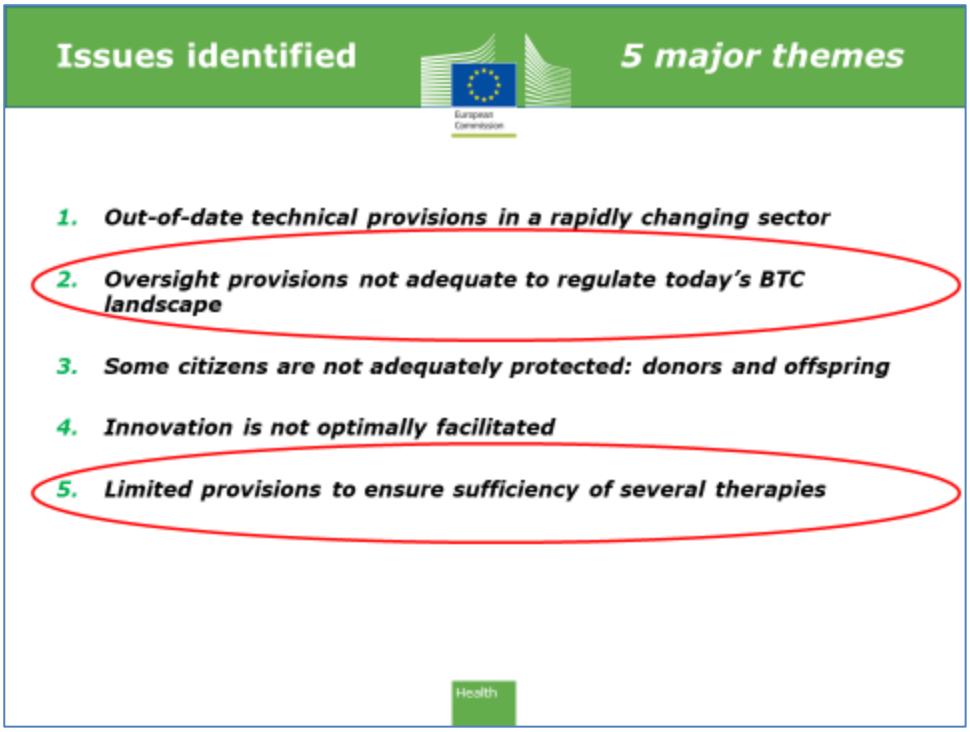
PRESENTATIONS

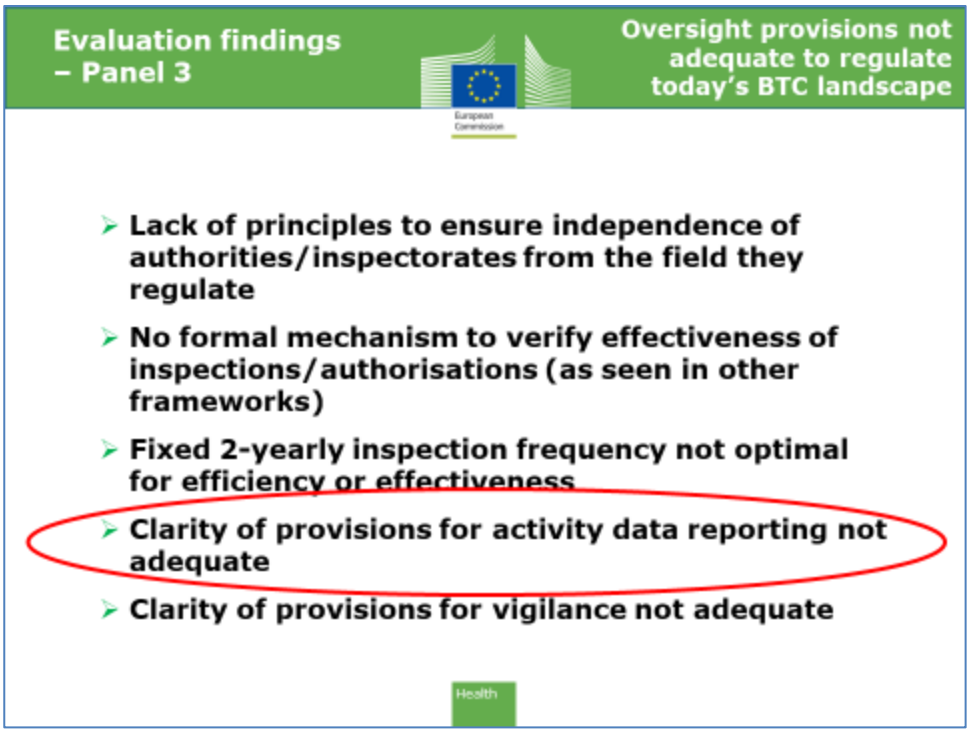
❖ **The importance of data in the future EU SoHO Framework by the DG-SANTE**
Deirdre Fehily (European Commission)

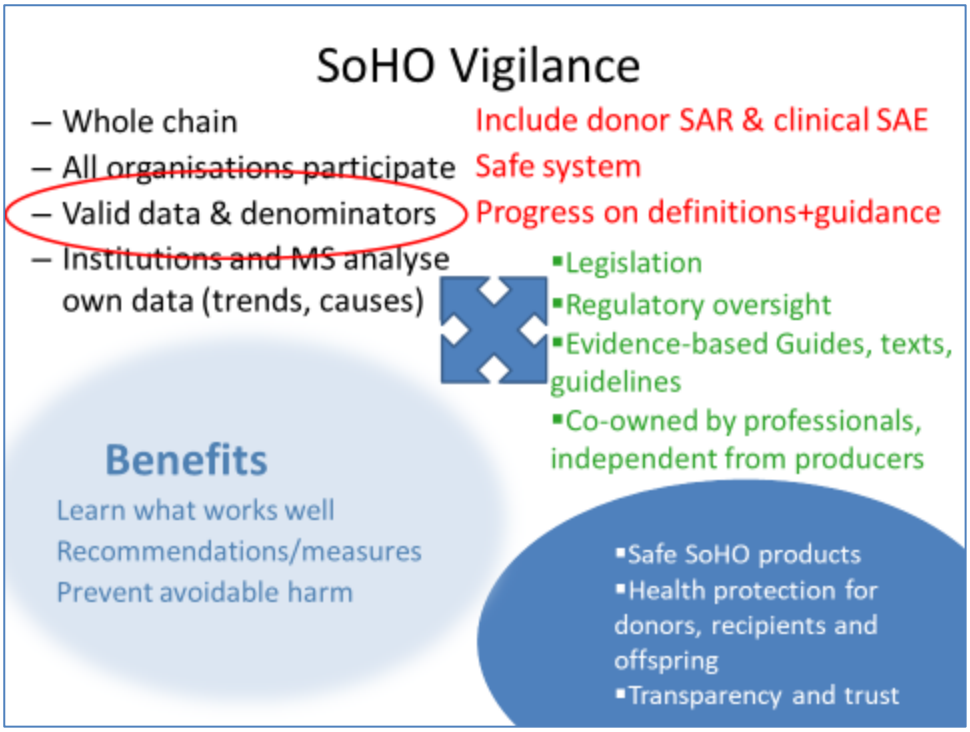


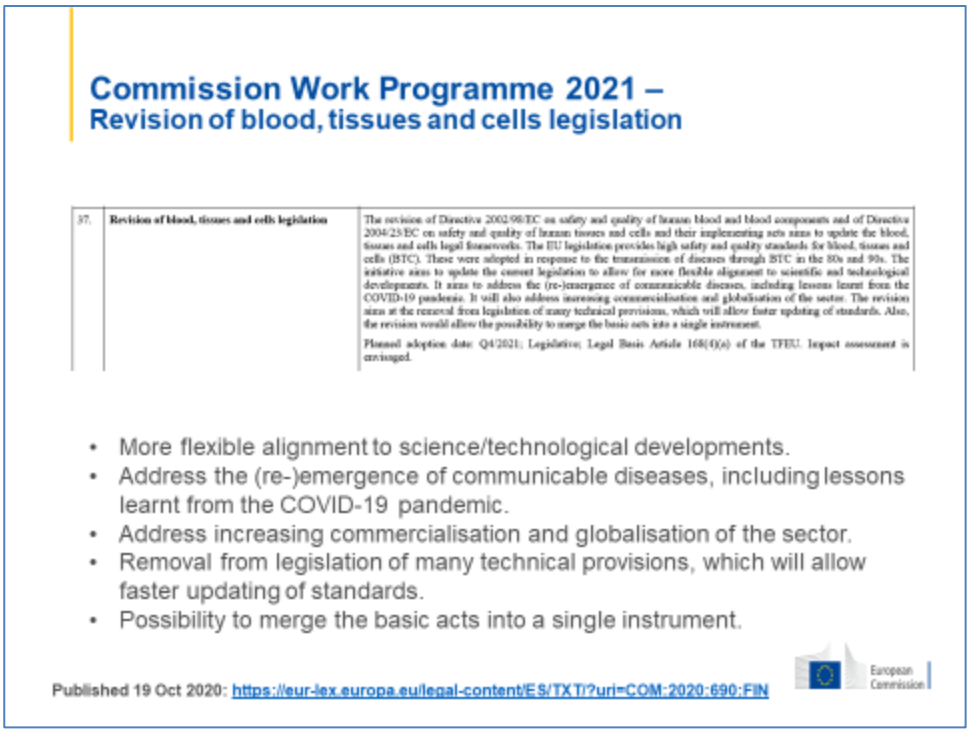

European Commission
English EN
Search
Home > Live, work, travel in the EU > Public Health > Blood, tissues, cells and organs >
Blood, tissues, cells and organs
Evaluation of the EU blood and tissues and cells legislation
State of Health in the EU
BREXIT Notices
Roadmap
External Study
Stakeholder Consultation


Conference on the BTC Evaluation – October 28 2019
European Commission


Issues identified
5 major themes
1. Out-of-date technical provisions in a rapidly changing sector
2. Oversight provisions not adequate to regulate today's BTC landscape
3. Some citizens are not adequately protected: donors and offspring
4. Innovation is not optimally facilitated
5. Limited provisions to ensure sufficiency of several therapies
Health


Evaluation findings – Panel 3
Oversight provisions not adequate to regulate today's BTC landscape
Lack of principles to ensure independence of authorities/inspectorates from the field they regulate
No formal mechanism to verify effectiveness of inspections/authorisations (as seen in other frameworks)
Fixed 2-yearly inspection frequency not optimal for efficiency or effectiveness
Clarity of provisions for activity data reporting not adequate
Clarity of provisions for vigilance not adequate
Health


SoHO Vigilance
– Whole chain
– All organisations participate
– Valid data & denominators
– Institutions and MS analyse own data (trends, causes)
Include donor SAR & clinical SAE
Safe system
Progress on definitions+guidance
▪Legislation
▪Regulatory oversight
▪Evidence-based Guides, texts, guidelines
▪Co-owned by professionals, independent from producers
Benefits
Learn what works well
Recommendations/measures
Prevent avoidable harm
▪Safe SoHO products
▪Health protection for donors, recipients and offspring
▪Transparency and trust


Commission Work Programme 2021 –
Revision of blood, tissues and cells legislation
37. Revision of blood, tissues and cells legislation
The revision of Directive 2002/98/EC on safety and quality of human blood and blood components and of Directive 2004/23/EC on safety and quality of human tissues and cells and their implementing acts aims to update the blood, tissues and cells legal frameworks. The EU legislation provides high safety and quality standards for blood, tissues and cells (BTC). These were adopted in response to the transmission of diseases through BTC in the 80s and 90s. The initiative aims to update the current legislation to allow for more flexible alignment to scientific and technological developments. It aims to address the (re-)emergence of communicable diseases, including lessons learnt from the COVID-19 pandemic. It will also address increasing commercialisation and globalisation of the sector. The revision aims at the removal from legislation of many technical provisions, which will allow faster updating of standards. Also, the revision would allow the possibility to merge the basic acts into a single instrument.
Planned adoption date: Q4/2021; Legislative; Legal Basis: Article 168(4)(a) of the TFEU. Impact assessment is envisaged.
• More flexible alignment to science/technological developments.
• Address the (re-)emergence of communicable diseases, including lessons learnt from the COVID-19 pandemic.
• Address increasing commercialisation and globalisation of the sector.
• Removal from legislation of many technical provisions, which will allow faster updating of standards.
• Possibility to merge the basic acts into a single instrument.
Published 19 Oct 2020: https://eur-lex.europa.eu/legal-content/ES/TXT/?uri=COM:2020:690:FIN
European Commission

Revision must follow Better Regulation Guidelines

- Inception Impact Assessment (Roadmap)
- Impact Assessment

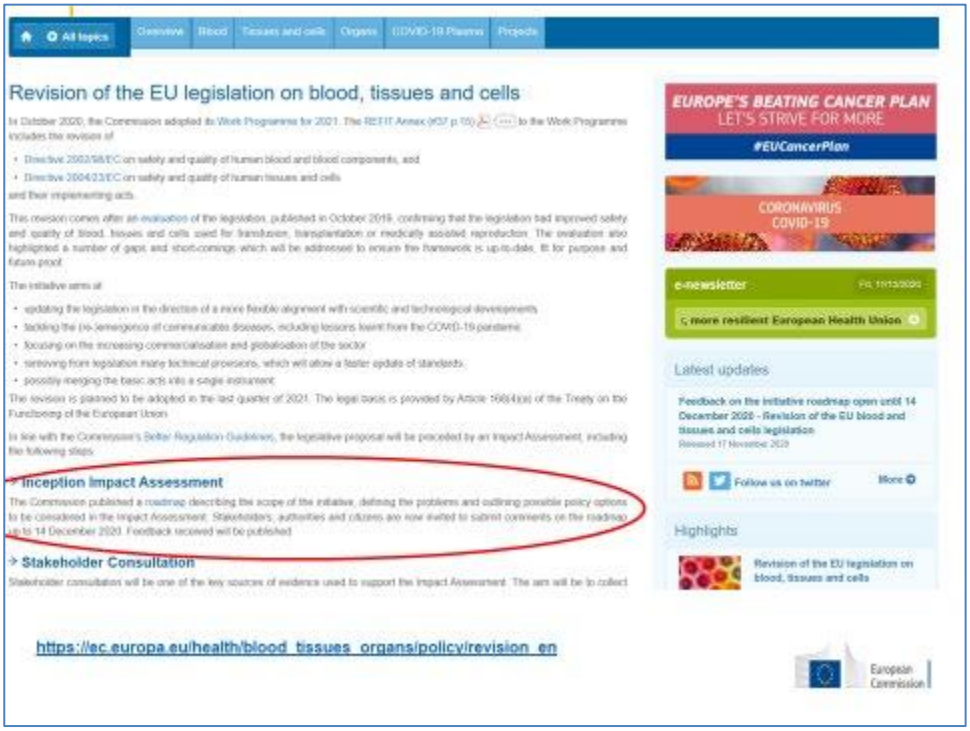
analyze the impacts of the policy options on social, economic, environmental impacts on all stakeholders while achieving the objectives

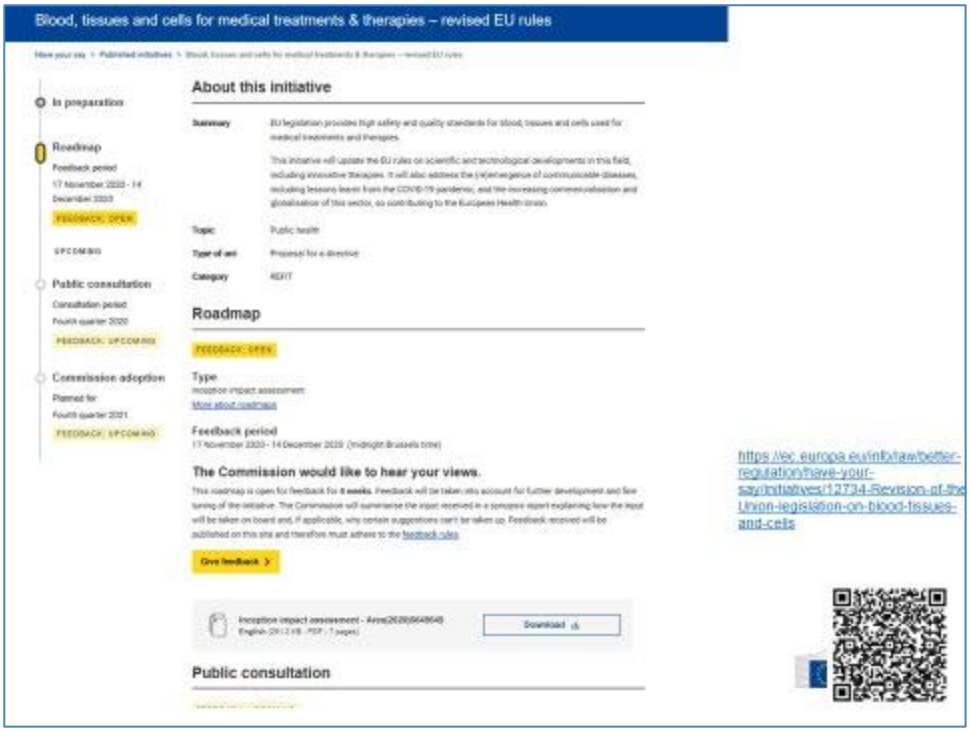
  - Open Public Consultation
  - External study (ies)

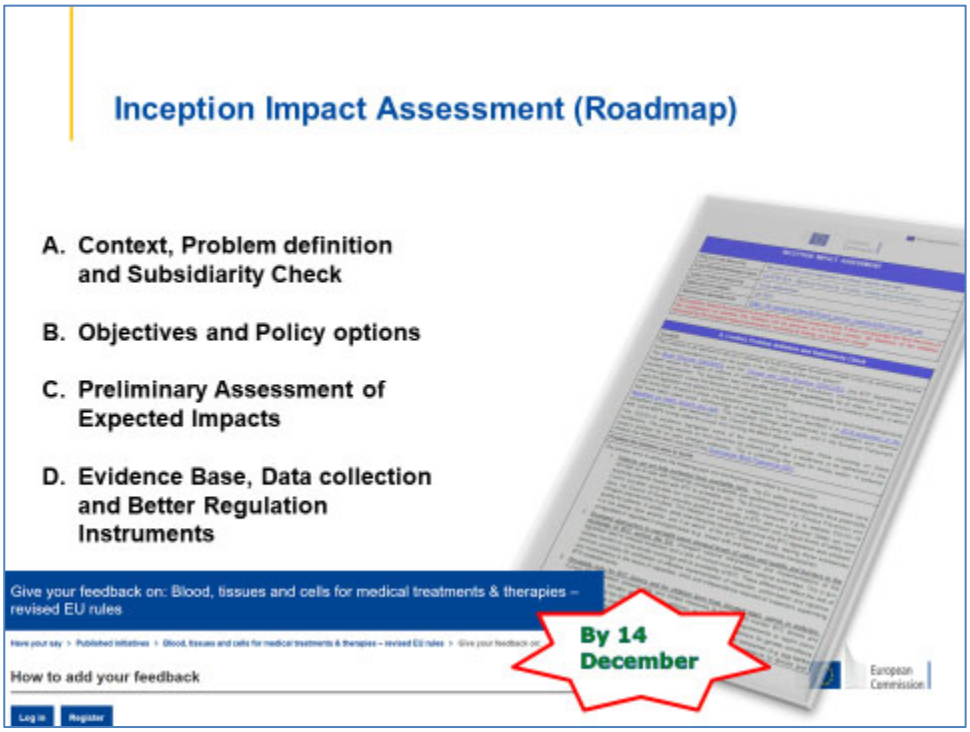
- Legal proposal

- Planned Commission adoption date: **Q4/2021**

https://ec.europa.eu/health/blood_tissues_organs/policy/revision_en




Blood, tissues and cells for medical treatments & therapies – revised EU rules
In preparation
Roadmap
Public consultation
Commission adoption
About this initiative
Roadmap
Type
Feedback period
The Commission would like to hear your views.
Give feedback
Public consultation
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12734-Revision-of-the-Union-legislation-on-blood-tissues-and-cells


Inception Impact Assessment (Roadmap)
A. Context, Problem definition and Subsidiarity Check
B. Objectives and Policy options
C. Preliminary Assessment of Expected Impacts
D. Evidence Base, Data collection and Better Regulation Instruments
Give your feedback on: Blood, tissues and cells for medical treatments & therapies – revised EU rules
How to add your feedback
Log in
Register
By 14 December
European Commission

B. Objectives

- The overall objectives of this initiative are to ensure a high level of health protection for EU citizens. The EU legal framework should therefore:

- 1. **Ensure safety and quality** for patients treated with BTC therapies, for donors and for children born from in vitro fertilization, and enforcement of safety and quality requirements.
  - Up-to-date with science, technology and epidemiology
  - Flexible and responsive
  - Protecting all affected citizens
- 2. **Optimize access to, and avoid shortages of, BTC therapies.**
  - Trusted oversight that facilitates exchanges
  - Supply monitoring
  - Emergency planning and preparedness
- 3. Ensure the framework is **future-proof and facilitates the development of innovative BTC therapies**.
  - Robust authorization of novel processes and use
  - Clear borderlines with other frameworks

European Commission

B. Policy options -

3 policy options – key differences (gaps 1, 2 and 3)

Policy option 1:
Strengthened quality & safety requirements defined by blood and tissue establishments with strengthened national inspection, EU audits of national control systems (self-regulation)

Policy option 2:
EU-level safety and quality requirements defined by European Expert Bodies (ECDC, EDQM,…) and strengthened national inspection, EU audits of national control systems (co-regulation)

Policy option 3:
EU-level safety and quality requirements laid down in the BTC legislation with improved national inspection systems

European Commission

B. Policy options - commonalities

Strengthen oversight (gap 3) through:

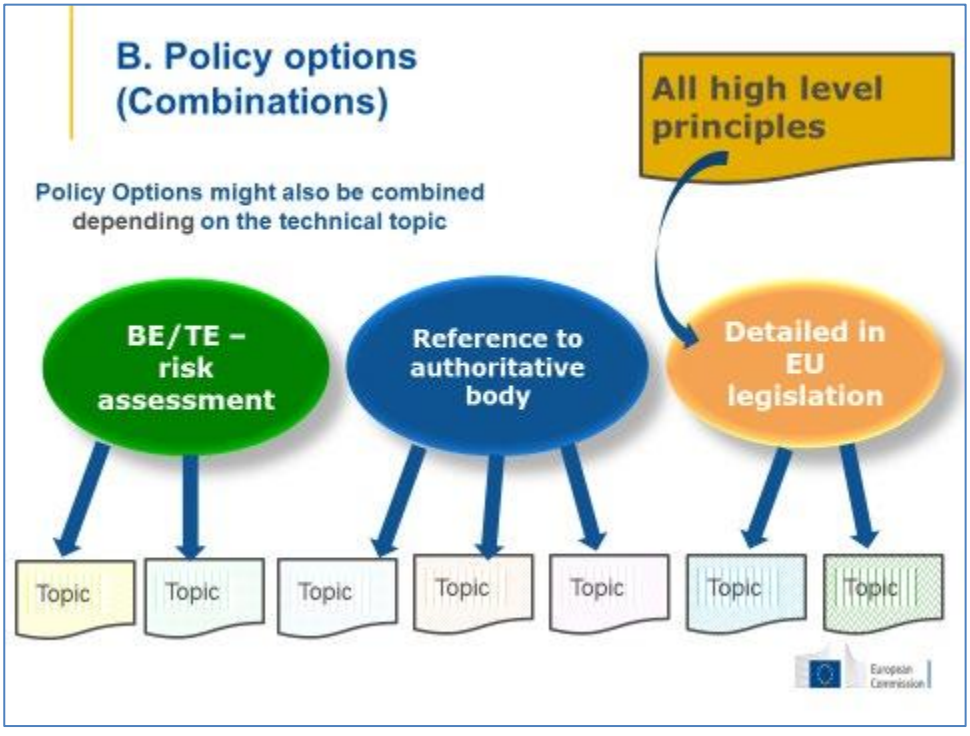
stronger principles in EU legislation,
combined with mutual peer audits, training and guidance

Facilitate innovation (gap 4) by:

Clarifying the BTC scope and provide advice to Member States on scope
Introduce risk assessments and proportionate collection of clinical data to allow for (prior) authorisations of innovative BTC

Manage supply issues (gap 5) through:

strengthening supply monitoring
emergency supply measures

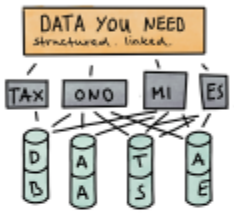


C. Preliminary assessment of expected impacts

- Likely **economic** impacts – on BEs, TEs, CAs, healthcare providers/systems, industry, researchers
- Likely **social** impacts – on donors, patients, children born from MAR
- Likely **environmental** impacts – none expected
- Likely impacts on **fundamental rights** – no significant impact expected
- Likely impacts on **simplification** and **administrative** burden - on BEs, TEs, CAs, healthcare providers/health system, industry

D. Evidence Base, Data collection and Better Regulation

Studies



Stakeholder consultation

Public Consultaiton

	Comments on Inception Impact Assessment	Online Public Consultation -PUBLIC	Online Public Consultation - TARTGETED	Targeted bilateral or multilateral stakeholder meetings
Aim	Gather stakeholders **views**			
topics	Problems Policy Objectives Policy Options Impacts			
	Feedback on document	lay language – high level topics - translated	more technical – selected topics – English only	Meetings with published summaries
Time period	**4 weeks** 17/10- 14/12/2020	**12 weeks** **Q1 2021**	**12 weeks** **Q1 2021**	continous
Where to go	https://tinyurl.com/y2mpodke			Contact the SOHO team

Evidence Gathering

	Impact Assessment Study	Feasibility Study (SOHO-X)
Aim	Research and analysis to **assess the costs, impacts and effectiveness** of policy options. Complement evaluation.	**Design the data system** to support the implementation
topics	Borderlines Costs of actions Impacts	Digital aspects
Involvement of the sector	**Senior experts** overseeing and steering on the IA study Dedicated **meeting** with NCAs and BE/TEs and stakeholders to understand key issues	**Participatory meeting to co-design the system with** NCAs, BE/TEs (and other stakeholders)
How will you be informed?	NCAs (and other stakeholders) will receive invitation	NCAs (and other stakeholders) will receive invitation

Why a feasibility study? What is SOHO-X?

The **feasibility study** complements the Impact Assessment study in the process of revising the legislation on the BTC sector blood, tissues and cells. Focus: design a data system and prepare implementation.

SOHO-X is used to describe the idea of an EU-wide data system in the SOHO sector to support the use of best available evidence and data for the public authorities, health providers, innovators and other stakeholders.

Timeline Q1-Q4 2021

Mapping – build on existing processes and databases

Oversight Data for Authorities

1. **Compendia of authorised Blood Establishments and activities** – also to support inspections
2. **Vigilance**. The rapid alert platforms for blood (RAB) and for tissues and cells (RATC) annual Serious Adverse Events Report (SARE) is compiled by the Council of Europe.
3. **Compendia on authorised Tissues and Cells**. (The on-going joint action GAPP has developed the data structure for the authorisation of new substances)
4. **Activity Data by EDQM** – on import and export of BTC, monitoring. Dataset already defined.
5. **Seroepidemiological Data by ECDC** – on prevalence of diseases in the donor base
6. + Coding System ISBT for BTC and processing

Clinical Data for Professionals

- registries developed and maintained by/for clinicians
- In the SOHO sector, there are a number of well advanced real world data platforms (EUCCP, EBMT, ESHRE, ECCTR, etc.)
- The EUCCP platform is the first prototype of the EU supporting such activities.

Ambition: Safety and outcome data from clinicians to feed into authorities data systems.
Interoperability supported by coding, taxonomies.

Existing. Under development. Preparatory work/datasets defined.

Activities

Map users of the SOHO-X (NCA, BE/TE, stakeholders, EU, policy makers) needs

Co-design system

Interoperable Oversight Systems

Link datasets (RAB, RATC, SARE, activity reporting), use EU coding, taxonomies (e.g., ATC, WHO-ICD etc.)

Tools for Clinical Data

Technical support, tools, prototype development for RWD platforms, data analytics etc.

Prepare for implementation under new MFF/new legal framework

European Commission

Revision of the Blood Tissues and Cells legislation

Inception Impact Assessment
published for consultation 17/11/2020

Open for comments on Commission **Have Your Say** portal

Open public consultation
(EU Survey) – early 2021

General questionnaire for the public - Technical questionnaire for professionals

Studies to gather evidence
(Impact assessment, SOHO-X)

Dedicated workshops on key issues

Impact Assessment of various policy options

Proposal for revised legislation
adopted by EC
Q4 2021

Follow the process at: https://ec.europa.eu/health/blood_tissues_organs/policy/revision_en

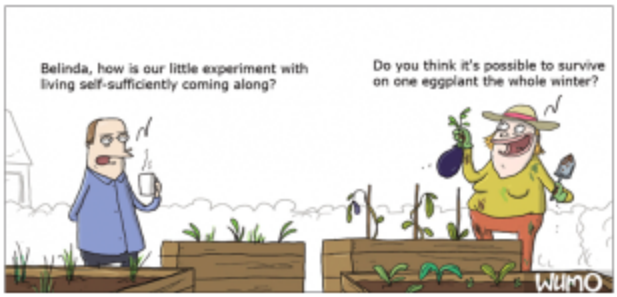
European Commission

❖ **State-of-the-art in tissue and cell activity data reporting and methodology used during this project**

Jaime Marco (European Directorate for the Quality of Medicines and Healthcare)

National and European Self-sufficiency

- Achieving self-sufficiency based on voluntary non-remunerated donation and achieving security of supply are important national (and European) goals to prevent shortages and meet the transplantation requirements of the patient population.
- To ensure timely and equitable access to safe transplantation, governments need to know how many tissues and cells are available and how many are required for their populations so the transplantation requirements can be consistently met and an appropriate level of funding to support donation programmes is maintained.
- A realistic assessment of requirements is fundamental for the rational, fair, and effective distribution of tissues and cells. It is also essential in order to avoid overreliance on 3rd countries (outside the EU) or on a few EU countries.



3

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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) — 69 (2019)
- More variables (and gender disaggregation)

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

EUROCET

- **Free download:** https://register.edqm.eu/freepub
- **Order free paper copies:** https://store.edqm.eu

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Activity Monitoring – Other Organisations

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Technical Meeting on National and EU-Level Tissue and Cell Activity Data Collection and Reporting

March 2018

- European regulatory bodies (EC, EDQM)
- National regulatory bodies/national competent authorities
- Professionals societies involved in activity data collection

EU Grant Agreement 2014 SI 401

Review, analyse and compare on-going data collected exercise and draw conclusions based on years of practical and technical experience

Discuss role of CA/EDQM/professional associations in this kind of data reporting and publication and if is there scope for collaborative work

Discuss data availability to evaluate self-sufficiency in Europe and dependence on third countries or supply from certain member States (concern about overreliance on few member States)

Discuss current fitness and adequacy of EU Directive legal requirements (are they clear and adequate and, if not, what should be recommended or mandated at a national/EU level?)

Recommendations to support possible future regulatory and technical decisions

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Findings and conclusions

- A realistic assessment of tissue and cell availability and requirements are fundamental for the rational, fair, and effective distribution of tissues and cells.
- It would be essential in order to strive for self-sufficiency and to avoid overreliance on 3rd countries (outside the EU) or on a few EU countries.
- This information would also be needed to provide adequate context for the national and European biovigilance figures (i.e. as denominators)
- However, at present we only have a fragmented and incomplete picture of the tissue and cell activity. This applies not only to the tissues and cells procured and distributed in individual countries but also at European level.
- Paradoxically, many stakeholders are trying to collect activity data in the field of tissues and cells but their efforts are undermined by the lack of: consensus and clarity on the data needed for different purposes, harmonisation of the terminology used and a legal mandate to collect this type of data.

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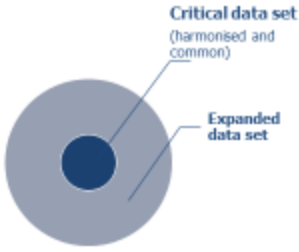
Recommendations



1. A basic data set should be mandated* at EU level. This data set would serve the purpose of transparency for citizens and as denominators for vigilance exercises.
2. The basic data set should be common for Health Authorities and professional societies.
3. The Health Authorities should be responsible for the collection of the basic data set and for reporting it to the EC.
4. There should be interaction between the EU (Health Authorities) and data-collecting professional societies and registries (e.g. ESHRE, EBMT, WMDA, Eurocet) for the definition of the common data set. This interaction could be facilitated by the EDQM based on existing experience (e.g. elaboration of technical guides, SARE exercise analysis).
5. There should be interaction between the Health Authorities and the data-collecting professional societies and registries for the validation of the collected data (health insurance companies could also contribute to the validation of data)
6. The EC should annually publish separate activity and vigilance reports.* This could be delegated to other bodies (e.g. EDQM, EUROCET)

**This would require legislative changes.*

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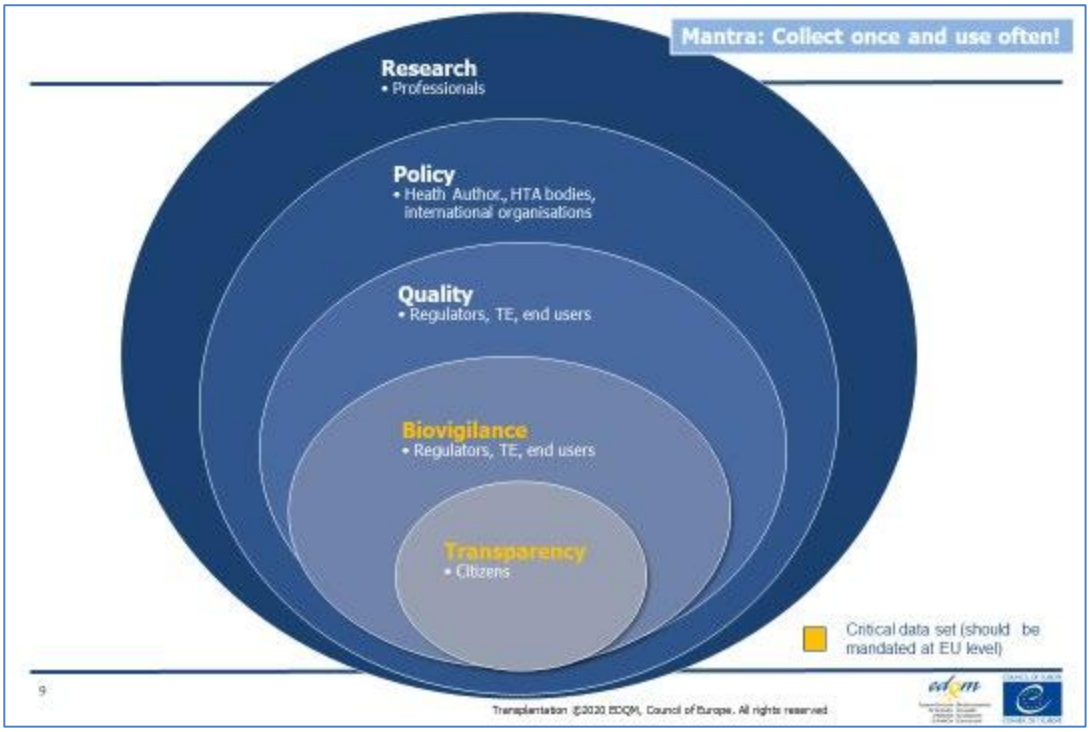
Mantra: Collect once and use often!
Research
• Professionals
Policy
• Heath Author., HTA bodies, international organisations
Quality
• Regulators, TE, end users
Biovigilance
• Regulators, TE, end users
Transparency
• Citizens
Critical data set (should be mandated at EU level)
9
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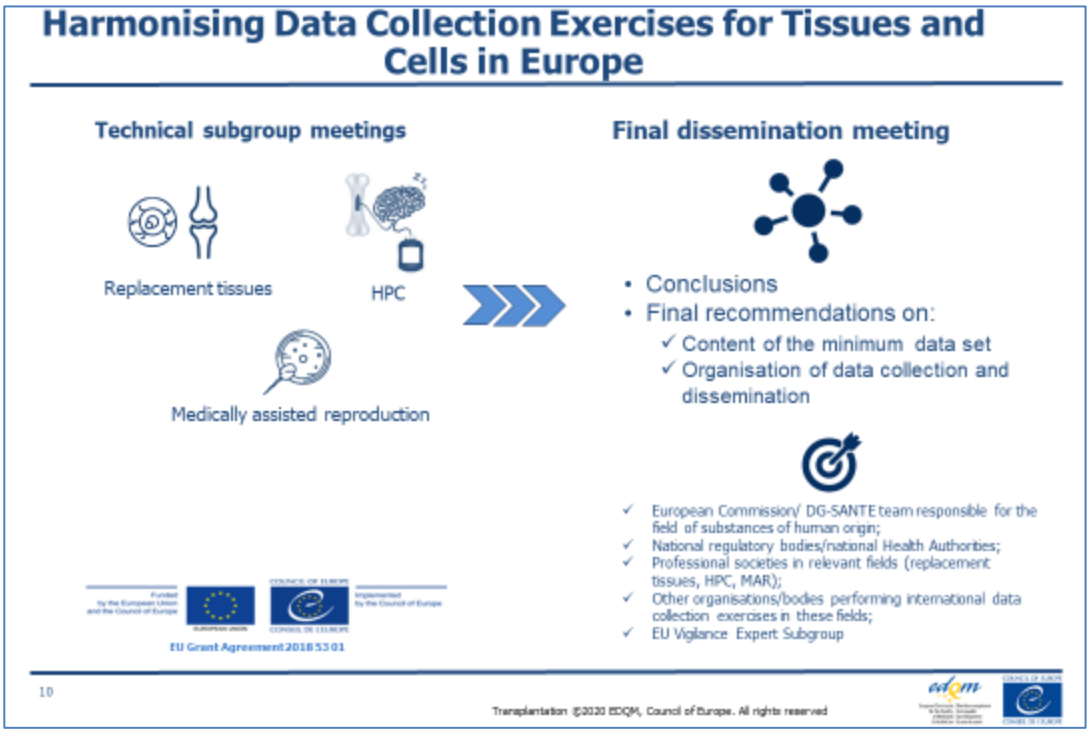
Harmonising Data Collection Exercises for Tissues and Cells in Europe
Technical subgroup meetings
Replacement tissues
HPC
Medically assisted reproduction
Final dissemination meeting
• Conclusions
• Final recommendations on:
✓ Content of the minimum data set
✓ Organisation of data collection and dissemination
✓ European Commission/ DG-SANTE team responsible for the field of substances of human origin;
✓ National regulatory bodies/national Health Authorities;
✓ Professional societies in relevant fields (replacement tissues, HPC, MAR);
✓ Other organisations/bodies performing international data collection exercises in these fields;
✓ EU Vigilance Expert Subgroup
EU Grant Agreement 20185301
10
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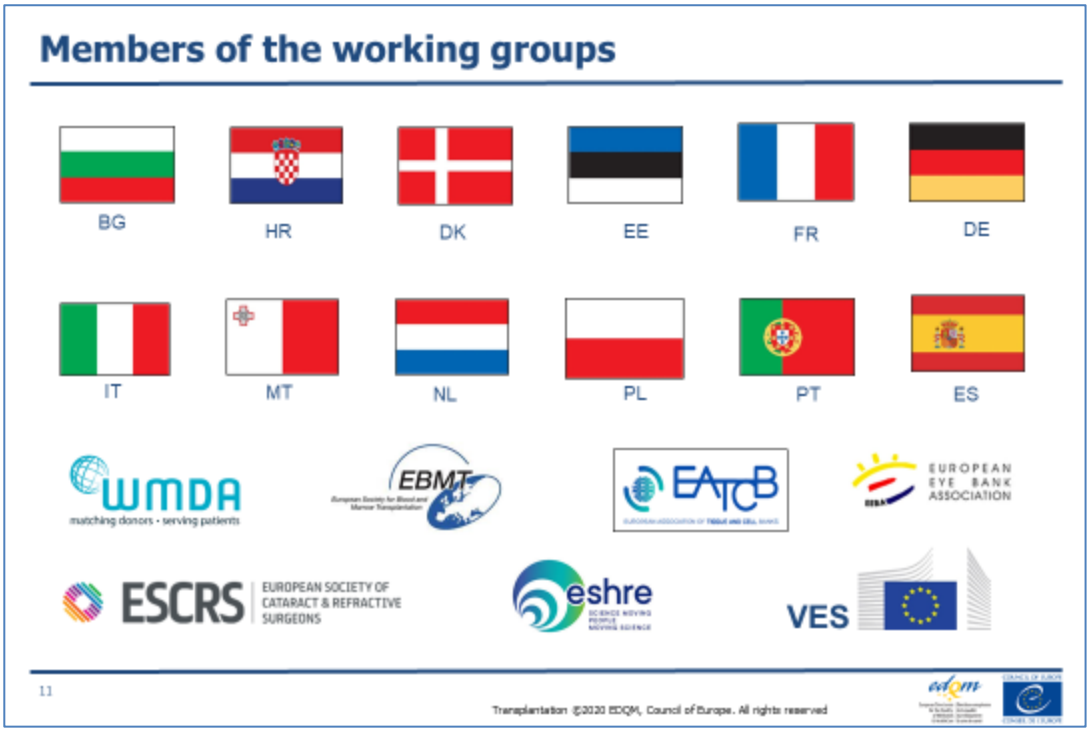
Members of the working groups
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PL
PT
ES
WMDA
matching donors • serving patients
EBMT
EATCB
EUROPEAN EYE BANK ASSOCIATION
ESCRS
EUROPEAN SOCIETY OF CATARACT & REFRACTIVE SURGEONS
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VES
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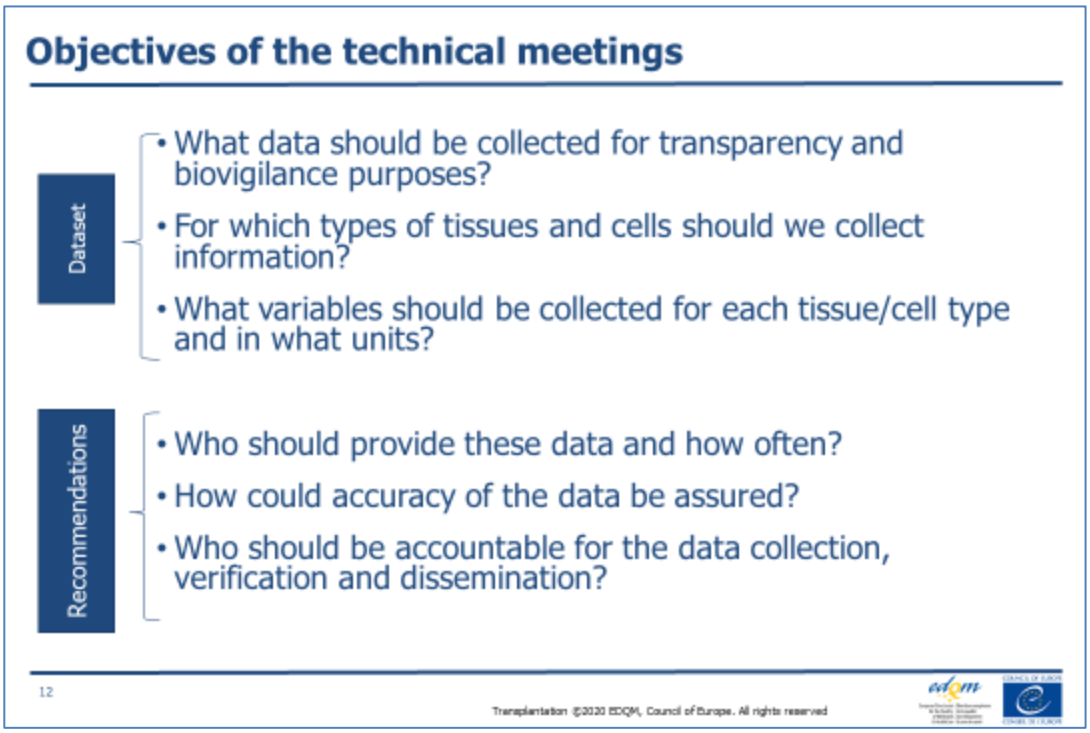
Objectives of the technical meetings
Dataset
• What data should be collected for transparency and biovigilance purposes?
• For which types of tissues and cells should we collect information?
• What variables should be collected for each tissue/cell type and in what units?
Recommendations
• Who should provide these data and how often?
• How could accuracy of the data be assured?
• Who should be accountable for the data collection, verification and dissemination?
12
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Designing the dataset

- ✓ Objectives: Transparency for citizens, biovigilance denominators and assess self-sufficiency
- ✓ Based on the EU coding platform categories
- ✓ Variables that were not aligned with the objectives were not considered
- ✓ With detailed explanations of the units to facilitate comprehension

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Objectives of the technical meetings

Dataset

- What data should be collected for transparency and biovigilance purposes?
- For which types of tissues and cells should we collect information?
- What variables should be collected for each tissue/cell type and in what units?

Recommendations

- Who should provide these data and how often?
- How could accuracy of the data be assured?
- Who should be accountable for the data collection, verification and dissemination?

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Additional elements to fine-tune and support datasets

Glossary of definitions:

- Providing clarity to the terms used in the datasets

Pilot tests:

- Participating member States and professional societies tested the datasets by sending them to national tissue establishments and clinics or by completing the data from their national registries
- Feedback was used to validate the datasets and glossary of definitions and adjust them, as needed

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Jaime.MARCO@edqm.eu

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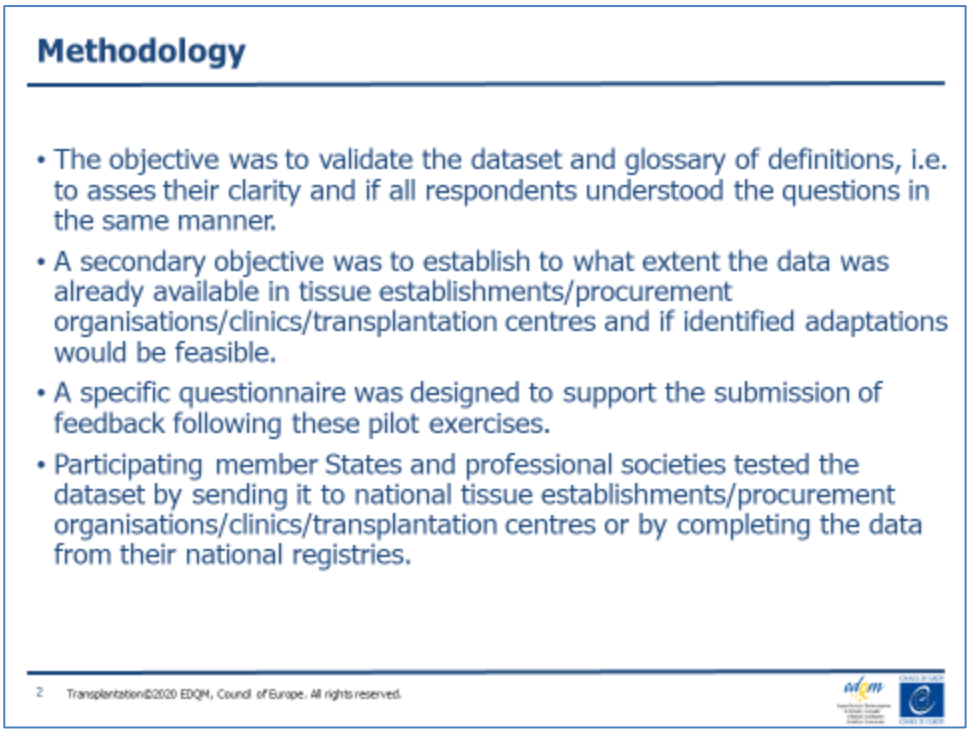
❖ **Results of the pilot tests for validation of the datasets and the glossary of definitions**
Jaime Marco (European Directorate for the Quality of Medicines and Healthcare)



Feedback received

- The survey was sent back by **14 participating CA/professional societies**. In total **54 responses** were received:
  - 15 of the responses were completed by CA/professional societies summarising the responses provided by the contacted tissue establishments/clinics or completed using existing databases/registries.
  - 39 responses were provided by tissue establishments/clinics.

RT (14 responses)	HPC (10 responses)	MAR (30 responses)
Croatia (2 TE)	Bulgaria	Belgium (Registry)
EEBA	Croatia	Bulgaria (1 MAR clinic)
France	Germany	Croatia (6 MAR clinics)
Ireland (2 TE)	Ireland (2 TE/clinics)	Estonia
Italy	Italy	Ireland (3 clinics)
Netherlands	Netherlands (2 TE/clinics)	Netherlands (3 MAR clinics)
Portugal	Portugal	Portugal (11 MAR clinics)
Spain	Spain	Spain
UK (4 TE)		UK (3 MAR clinics)

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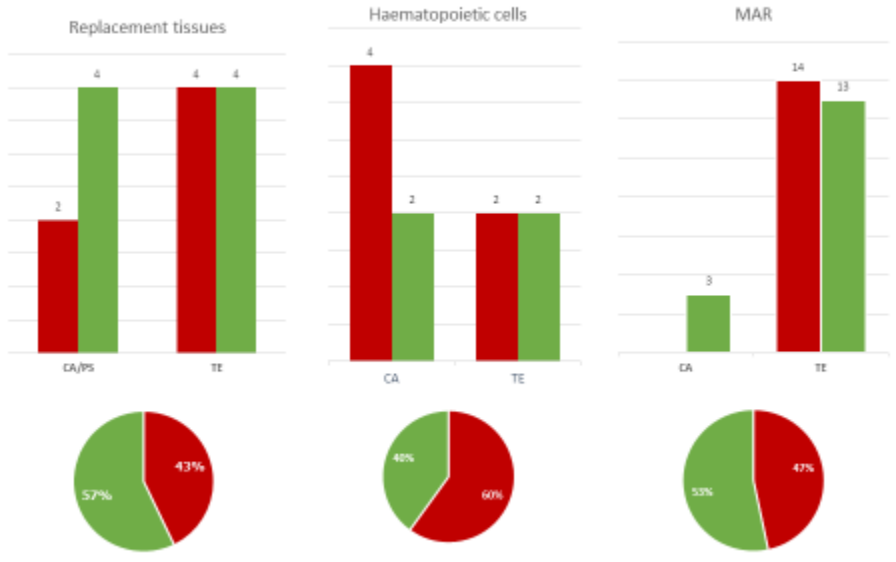
Have you experienced any difficulties understanding what data was requested for any item?



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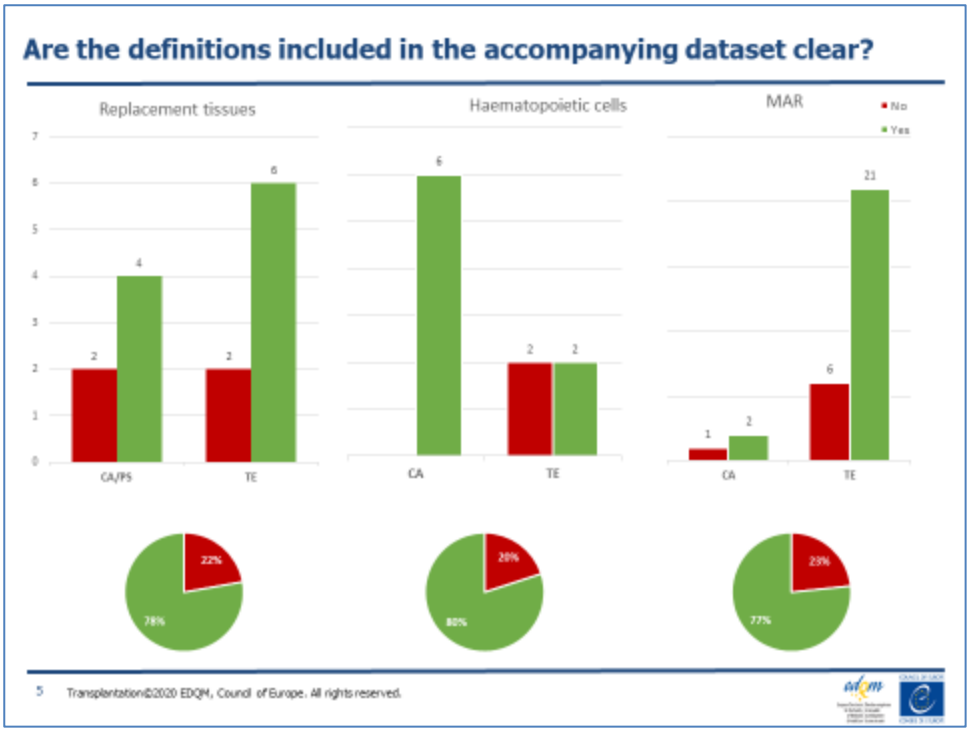
Are the definitions included in the accompanying dataset clear?
Replacement tissues
Haematopoietic cells
MAR
No
Yes
CA/PS
TE
CA
TE
CA
TE
22%
78%
20%
80%
23%
77%
5
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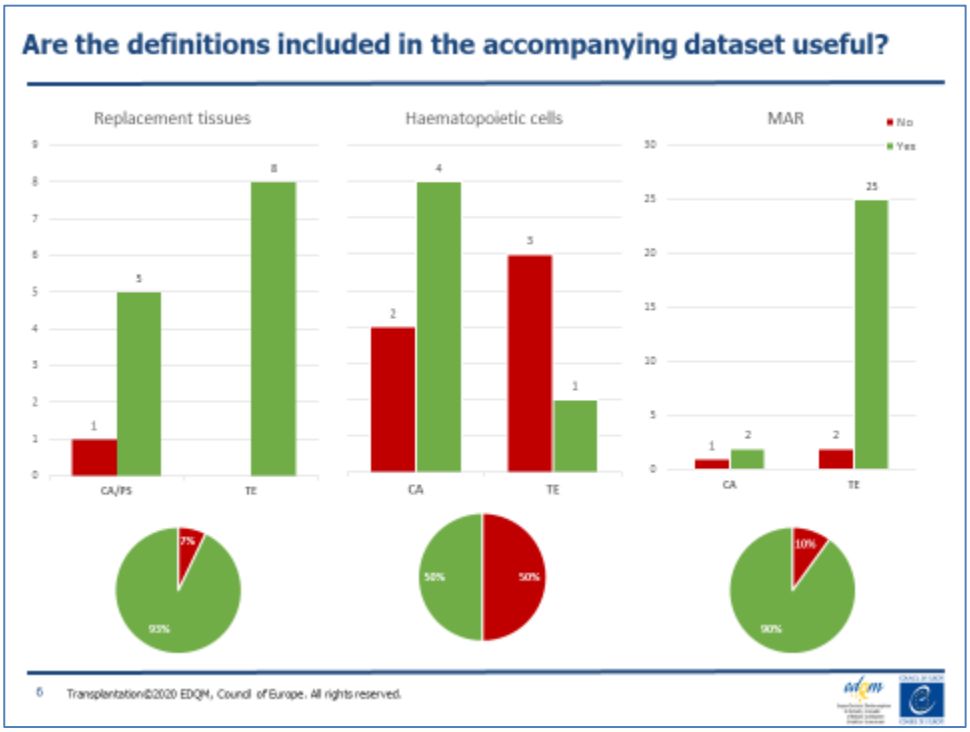
Are the definitions included in the accompanying dataset useful?
Replacement tissues
Haematopoietic cells
MAR
No
Yes
CA/PS
TE
CA
TE
CA
TE
7%
93%
50%
50%
10%
90%
6
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Issues identified and subsequent reaction

Replacement tissues

- Donor, donations, application procedures, containers ➔ Definitions and examples have been added to the glossary.
- Living donors and deceased donors were included for all tissue types, even if they did not apply ➔ Dataset has been revised to ask for this data only when it applies.

HPC

- Donation ➔ Definition added to the glossary.

MAR

- Fertility preservation ➔ Definition added to the glossary.
- Number of straws/vials collected varies for each sperm collection➔ Explanation in the dataset modified to make this clearer when asking for number of sperm collections.
- Number of treatment cycles with or without ovarian stimulation ➔ Explanation reworded in dataset to make it more clear and definition added to glossary.
- Number of embryos cryopreserved after donation ➔ Has been deleted. Data on embryos cryopreserved is collected in other parts of the dataset and was a duplication.

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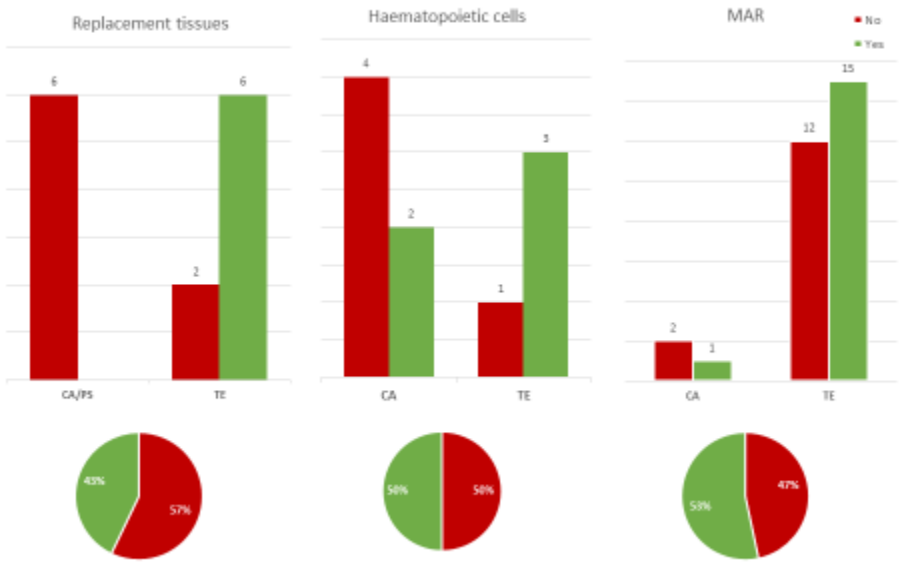
Would you currently be able to provide all the data contained in the dataset?



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Examples of data not available

Replacement tissues

- Some TE do not differentiate between high density and low density cornea.
- Figures on transport and distribution are not available at some TE.
- Some TE do not have data on clinical application.

HPC

- Paediatric data (some do not collect it, paediatric age assessed differently) .
- Distribution and exchange figures not available for some cell types.

MAR

- Number of couples treated not recorded in some clinics.
- Number of donors not available.
- Distribution and exchange data not available for partner procedures.
- Some clinics did not have data on deliveries and live born children as it is not reported back to them.
- Discrepancies in cycle data reporting (2 yr retrospective) vs. 1 year retrospective data reporting difficult outcome data collection.

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Would you need to make any changes in your current data collection practices to be able to provide all the requested data?

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Details

Replacement tissues

- Some respondents would need to adapt their IT systems and add specific questions in their currently used questionnaires.
- Most respondents do not expect major problems to adapt to the proposed dataset.

HPC

- Some respondents would need to make changes, but do not expect major problems to adapt to the proposed dataset.

MAR

- Most respondents would need to introduce changes in order to collect information on deliveries.
- Most respondents do not expect major problems to adapt to the proposed dataset.

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Main findings and conclusions

- Explanations in the dataset are useful and complemented by the glossary of definitions, which has been expanded to address gaps detected during the pilot tests.
- A number of tissue establishments and clinics already collect the data identified in the dataset. However, in many cases this information is not transmitted to the relevant national Competent Authorities.
- Competent Authorities and tissue establishments would need to make adjustments in their current data collection practices in order to be able to provide all the requested information but the necessary changes would be feasible.
- Legislative changes (as detailed in the conclusions and recommendations) would be necessary to ensure the collection of the identified minimum dataset.
- The identified dataset would streamline and harmonise data collection exercises in the EU and, overall, lead to the collection of better, more coherent and accurate data in the level of detail necessary for transparency and biovigilance purposes and for all relevant users.

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ACRONYMS

ATMP	Advanced therapy medicinal product
ID	Identification
CA	Competent Authority
CAR-T	Chimeric antigen receptor T-cell
CD-P-TO	European Committee on Organ Transplantation (EDQM, Council of Europe)
EATCB	European Association of Tissue and Cell Banks
EBMT	European Society for Blood and Marrow Transplantation
EC	European Commission
ECCTR	European Cornea and Cell Transplantation Registry
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEBA	European Eye Banking Association
ESHRE	European Society for Human Reproduction and Embryology
ESCRS	European Society of Cataract and Refractive Surgeons
EU	European Union
EUROCET	European Registry for Organs, Cells and Tissues
FET	Frozen embryo transfer
HPC	Haematopoietic progenitor cells
ICSI	Intracytoplasmic sperm injection
IUI	Intrauterine insemination
IVF	*In vitro* fertilisation
MAR	Medically assisted reproduction
MESA	Micro epididymal sperm aspiration
NK	Natural killer
PESA	Percutaneous epididymal sperm aspiration
SAR	Serious Adverse Reactions
SARE	Serious Adverse Events and Reactions
SLA	Service level agreement
TESE	Testicular sperm extraction
VES	EU Vigilance Expert Subgroup
WMDA	World Marrow Donor Association