



MINISTERS' DEPUTIES

Recommendations

CM/Rec(2022)19

14 September 2022

Recommendation CM/Rec(2022)19

of the Committee of Ministers to member States

on establishing measures for the harmonised collection of activity data related to the availability and use of tissues and cells of human origin with a view to supporting self-sufficiency and facilitating international data sharing

(Adopted by the Committee of Ministers on 14 September 2022. at the 1442nd meeting of the Ministers' Deputies)

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe (ETS No. 1),

Considering that the aim of the Council of Europe is to achieve greater unity between its member States and that this aim may be pursued, *inter alia*, by the adoption of common action in the health field;

Taking into account the right to protection of health, enshrined in the European Social Charter (ETS No. 035);

Having regard to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164), in particular to Articles 10 and 19, and the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186);

Having regard to Resolution Res(78)29, adopted by the Committee of Ministers, on the harmonisation of legislation of member States relating to removal, grafting and transplantation of human substances and the final text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987);

Recalling Recommendation CM/Rec(2020)5 of the Committee of Ministers to member States on the quality and safety of tissues and cells for human application;

Recalling Recommendation CM/Rec(2019)2 of the Committee of Ministers to member States on the protection of health-related data which replaces Recommendation Rec(97)5 of the Committee of Ministers to member States on the protection of medical data;

Recalling Resolution CM/Res(2015)11, adopted by the Committee of Ministers, on establishing harmonised national living donor registries with a view to facilitating international data sharing;

Recalling Parliamentary Assembly Recommendation 2173 (2020) on "Combating trafficking in human tissues and cells";

Taking into account the latest available edition of the Council of Europe Guide to the quality and safety of tissues and cells for human application;

Taking into account the World Health Organization (WHO) Guiding Principles on Human Cell, Tissue and Organ Transplantation as endorsed by the 63rd World Health Assembly in May 2010, in Resolution WHA63.22 on Human Organ and Tissue Transplantation, and in particular Guiding Principles 10 and 11, which call for health authorities to oversee that transplant programmes ensure traceability and vigilance and to monitor outcomes of both living donation and transplantation;

Taking into account the Madrid Resolution on Organ Donation and Transplantation, adopted in 2010, calling WHO member States to strive towards self-sufficiency in transplantation;

Considering Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, and Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells;

Considering Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells, and in particular Article 5(1)(a) and Article 7;

Considering Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), and in particular Article 9, paragraph 2, points (a), (h) and (i), which contain provisions permitting the processing of health data;

Taking into account the Barcelona Principles on the use of human donated tissue for ocular transplantation, research and future technologies;

Considering that human tissues and cells can restore essential functions or, in some cases, save lives;

Considering that achieving self-sufficiency based on voluntary unremunerated donation and security of supply, as well as timely and equitable access to safe transplantation, are important national (and European) goals to prevent shortages and meet the transplantation requirements of the patient population;

Considering that to ensure rational, fair, timely and equitable access to safe tissues and cells for human application, governments and donation and transplantation services need to know how many tissues and cells are available and how many are required for their populations so their needs can be met consistently and an appropriate level of funding to support donation programmes is maintained;

Considering that complete and accurate activity data related to the availability and use of tissues and cells of human origin would provide transparency for citizens and healthcare professionals;

Considering that complete activity data would be essential in order to avoid overreliance on countries outside of Europe or on a few European countries, as well as to prepare for risk scenarios that might impact supply;

Considering that this information would also be necessary to put into context the figures related to serious adverse events and reactions associated with the use of tissues and cells of human origin, which would allow the identification of trends and benchmarking of the performance of donation and transplantation programmes and tissue establishments with a view to maximising the quality and safety of tissues and cells for human application;

Aware that the increased transportation of tissues and cells between tissue establishments or even across national borders gives rise to difficulties in ensuring traceability, but that it is essential to maximise the safety and quality of donated tissues and cells and for ethical reasons;

Considering that the current picture of tissue and cell activity, whether for tissues and cells procured and distributed in individual member States or those exchanged at international level, is fragmented and incomplete;

Considering that, paradoxically, many stakeholders, including some member States and professional associations, are trying to collect activity data in this field, posing a significant burden on reporting bodies such as tissue establishments and clinical users, and that their efforts have been undermined by the lack of consensus and clarity on the data needed for different purposes and the heterogeneous terminology and units used to describe and quantify tissues and cells;

Considering that a common terminology would be required to ensure clarity on the data needed and the units used to describe and quantify tissue and cell availability and supply;

Recognising, therefore, the need to provide health authorities, transplant organisations, tissue establishments and organisations responsible for human application of tissues and cells, including clinical users, with a harmonised and common dataset to record activity data related to the availability and use of tissues and cells of human origin;

Considering that significant developments in IT solutions will help to ensure timely and regular data input and that technical developments will support data exchange between countries/regions,

Recommends that the governments of member States:

- having due regard to their national laws, rules and administrative provisions, take all necessary measures and steps to regularly collect activity data related to the availability and use of tissues and cells of human origin, taking into consideration the list of parameters and definitions shown in the appendix to this recommendation;
- translate, publish and disseminate widely this recommendation and its appendix among relevant national, regional, and local authorities, professionals, and other key stakeholders.

Authorises the Council of Europe European Committee on Organ Transplantation or, if necessary, a subordinate body, to revise the appendix to this recommendation in the future in keeping with developments in the field.

Appendix to Recommendation CM/Rec(2022)19

This appendix to Recommendation CM/Rec(2022)19 provides a list of the parameters member States should consider collecting and specifies how units should be counted. A supporting glossary of terms provides, where necessary, additional information clarifying how to measure or collect each parameter in a manner that will ensure accuracy and consistency and facilitate harmonised international data sharing. It should be noted that the glossary of terms should be used exclusively for the purpose of this data collection, as the definitions included might not be suitable for other purposes (e.g. during clinical practice). If a definition is not found among the terms included in this glossary, the Council of Europe Guide to the quality and safety of tissues and cells for human application should be used as a reference.

The set of variables and the glossary of terms are those developed within the framework of a co-operation Grant Agreement (GA 2018 53 01) between the European Commission and the EDQM/Council of Europe. Therefore, the terms and definitions used align with those of the relevant EU legislation. However, the data set may also prove valuable for non-EU Council of Europe member States with a view to supporting self-sufficiency and facilitating international data sharing.

The parameters detailed in the data set and the glossary of terms may be revised in the future in keeping with developments in the field.

REPLACEMENT TISSUES ACTIVITY DATA

COUNTRY

Year

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

		DCULAR TI\$\$UE		NUMBERS	UNITS/EXPLANATIONS
	001	Depart	Living donors		# of living ocular tissue/cell donors at national level
E	002	Donore	Deceased donors		# of deceased ocular tissue/cell donors at national level
Г	003	Donations	Ocular tissue donations		# of donation events from one donor, may include 1 or 2 eyes/comeas
Г	004		Comea, full thickness (high endothelial cell density)		# of comeas with endothelial cell density ≥ 2000 cells per mm2
Г	005		Comea, full thickness (low endothelial cell density)		# of comeas with endothelial cell density < 2000 cells per mm2
	006	Releases for olinical application, whether distributed or not	Comea for Endothelial Keratoplasty (precutipeeled in the Tissue Establishment)		# of comeas
	007		Sciera		# of containers
Г	800		Other ocular		# of containers
Г	009		Comea, full thickness (high endothelial cell density)		# of comeas with endothelial cell density ≥ 2000 cells per mm2
	OC 10		Comea, full thickness (low endothelial cell density)		# of comeas with endothelial cell density < 2000 cells per mm2
	OC 11	Distributed to end user in the	Comea for Endothelial Keratoplasty (precutipeeled in the Tissue Establishment)		# of comeas
	OC 12	ocentry	Sciera		# of containers
	OC 13		Other ocular		# of containers
	OC 14		Comea, full thickness (high endothelial cell density)		# of comeas with endothelial cell density ≥ 2000 cells per mm2
	OC 15		Comea, full thickness (low endothelial cell density)		# of comeas with endothelial cell density < 2000 cells per mm2
	OC 16	Ell country	Comea for Endothelial Keratoplasty (precutipeeled in the Tissue Establishment)		# of comeas
	OC 17	7 8	Sciera		# of containers
	OC 18		Other ocular		# of containers
	OC 19	19 20 21 Sent to a ticsue establishment (transport) in another EU country 22	Comea, full thickness (high endothelial cell density)		# of comeas with endothelial cell density ≥ 2000 cells per mm2
AR I	OC 28		Comea, full thickness (low endothelial cell density)		# of comeas with endothelial cell density < 2000 cells per mm2
30	OC 21		Comea for Endothelial Keratoplasty (precutipeeled in the Tissue Establishment)		# of comeas
<u></u>	OC 22		Sciera		# of containers
ں	OC 23		Other ocular		# of containers
	OC 24		Comea, full thickness (high endothelial cell density)		# of comeas with endothelial cell density ≥ 2000 cells per mm2
	OC 25	Received from a tissue	Comea, full thickness (low endothelial cell density)		# of comeas with endothelial cell density < 2000 cells per mm2
Ŀ	OC 26	establishment (transport) in	Comea for Endothelial Keratoplasty (precutipeeled in the Tissue Establishment)		# of comeas
	OC 27	another EU country	Sciera		# of containers
	OC 28		Other ocular		# of containers
	OC 29		Comea, full thickness (high endothelial cell density)		# of comeas with endothelial cell density ≥ 2000 cells per mm2
	OC 30		Comea, full thickness (low endothelial cell density)		# of comeas with endothelial cell density < 2000 cells per mm2
Ŀ	OC 31	(non EU)	Comea for Endothelial Keratoplasty (precutipeeled in the Tissue Establishment)		# of comeas
	OC 32		Sciera		# of containers
	OC 33		Other ocular		# of containers
	OC 34		Comea, full thickness (high endothelial cell density)		# of comeas with endothelial cell density ≥ 2000 cells per mm2
	OC 35		Comea, full thickness (low endothelial cell density)		# of comeas with endothelial cell density < 2000 cells per mm2
	OC 36	(non EU)	Comea for Endothelial Keratoplasty (precutipeeled in the Tissue Establishment)		# of comeas
	OC 37		Sciera		# of containers
- F	OC 38	C 38	Other ocular		# of containers

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OC 39		Applications for Penetrating Keratoplasty	# of applications (one surgical procedure, regardless of the # of grafts used)
OC 40		Applications for Anterior Lameliar Keratoplasty	# of applications (one surgical procedure, regardless of the # of grants used)
OC 41	Application procedures	Applications for Endothelial Keratoplasty	# of applications (one surgical procedure, regardless of the # of grafts used)
OC 42	42 43	Applications for scieral 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
PL 1	Depart	Living donors		# of living placental tissue donors at national level
PL 2	Donors	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
PL4		Amniotic membrane		# of containers
PL 5	whether distributed or not	Amniotic membrane eyedrops		# of batches prepared for a single patient
PL 6		Other placental		# of containers
PL 7		Amniotic membrane		# of containers
PL 8	country	Amniotic membrane eyedrops		# of batches prepared for a single patient
PL 9		Other placental		# of containers
PL 10		Amniotic membrane		# of containers
PL 11	Ell country	Amniotic membrane eyedrops		# of batches prepared for a single patient
PL 12	20 0021107	Other placental		# of containers
PL 13		Amniotic membrane		# of containers
PL 14	Sent to a tissue establishment (transport) in another EU country	Amniotic membrane eyedrops		# of batches prepared for a single patient
PL 15	(Other placental		# of containers
PL 16	Received from a tissue	Amniotic membrane		# of containers
PL 17	establishment (transport) in	Amniotic membrane eyedrops		# of batches prepared for a single patient
PL 18	another EU country	Other placental		# of containers
PL 19		Amniotic membrane		# of containers
PL 20	(non EL)	Amniotic membrane eyedrops		# of batches prepared for a single patient
PL 21		Other placental		# of containers
PL 22	Immedia	Amniotic membrane		# of containers
PL 23	(non EU)	Amniotic membrane eyedrops		# of batches prepared for a single patient
PL 24		Other placental		# of containers
PL 25		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	Application procedures	Amniotic membrane applications for non-ocular bum/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 TISSUE		NUMBERS	UNITS/EXPLANATIONS
CU 1	Depart	Living donors		# of living cutaneous tissue donors at national level
CU 2	Donore	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		Skin		cm2
CU 5	Releases for olinical application,	Acellular dermal matrix		cm2
CU 6	whether distributed or not	Keraönocytes/melanocytes		# of containers
CU7		Other cutaneous tissues		# of containers
CU 8		Skin		cm2
CU 9	Distributed to end user in the oountry	Acellular dermal matrix		cm2
CU 10		Keraŭnocytes/melanocytes		# of containers
CU 11		Other cutaneous tissues		# of containers

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•	U 12	2 3 4 5 2 3 5 2 5 2 3 1 1 2 1 2 3 1 3 1 1 2 1 1 1 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1	Skin	cm2
0	U 13		Acellular dermal matrix	cm2
<u> </u>	U 14		Keraŭnocytes/melanocytes	# of containers
ž 🛛	U 15		Other cutaneous tissues	# of containers
1	U 16		Skin	cm2
20	SU 17	Sent to a tissue establishment	Acellular dermal matrix	cm2
5	U 18	(transport) In another EU country	Keratinocytes/melanocytes	# of containers
5 0	U 19		Other cutaneous tissues	# of containers
0	U 20		Skin	cm2
0	SU 21	Received from a tissue establishment (transport) in	Aceilular dermal matrix	cm2
•	:U 22	another EU country	Keratinocytes/melanocytes	# of containers
0	U 23		Other cutaneous tissues	# of containers
0	U 24		Skin	cm2
0	U 25	Exports	Aceilular dermal matrix	cm2
	U 26	(non EU)	Keraŭnocytes/melanocytes	# of containers
0	U 27		Other cutaneous tissues	# of containers
0	U 28		Skin	cm2
0	U 29	Imports	Acellular dermal matrix	cm2
0	:U 30	(non EU)	Keraŭnocytes/melanocytes	# of containers
0	SU 31		Other cutaneous tissues	# of containers
0	U 32		Applications for burns/wound healing	# of applications (one surgical procedure, regardless of the # of grafts used)
0	U 33	Application procedures	Applications for reconstructive surgery	# of applications (one surgical procedure, regardless of the # of grafts used)
0	U 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 grants used)

	CARDIAC TISSUE		NUMBERS	UNITS/EXPLANATIONS
CA1	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
CA4		HV, aortic		# of HV
CAS		HV, pulmonary		# of HV
CA6		HV, aortic decellularised		# of HV
CA7	Releases for olinical application, whether distributed or not	HV, pulmonary decellularised		# of HV
CAS		Non-valved patches and conduits		# of containers
CAS		Pericardium		# of containers
CA 10		Other heart tissues		# of containers
CA 11		HV, aortic		# of HV
CA 12		HV, pulmonary		# of HV
CA 13		HV, aortic decellularised		# of HV
CA 14	Distributed to end user in the	HV, pulmonary decellularised		# of HV
CA 15	(Colling)	Non-valved patches and conduits		# of containers
CA 16		Pericardium		# of containers
CA 17		Other heart tissues		# of containers
CA 18		HV, aortic		# of HV
CA 19		HV, pulmonary		# of HV
CA 20		HV, aortic decellularised		# of HV
CA 21	EU country	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		HV, aortic	# of HV
CA 26]	HV, pulmonary	# of HV
CA 27		HV, aortic decellularised	# of HV
CA 28	Sent to a tissue establishment (transport) in another EU country	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		HV, aortic	# of HV
CA 33]	HV, pulmonary	# of HV
CA 34	Received from a ticsue	HV, aortic decelularised	# of HV
CA 35	establishment (transport) in	HV, pulmonary decellularised	# of HV
CA 36	another EU country	Non-valved patches and conduits	# of containers
CA 37]	Pericardium	# of containers
CA 38		Other heart tissues	# of containers
CA 39		HV, aortic	# of HV
CA 40]	HV, pulmonary	# of HV
CA 41	E	HV, aortic decellularised	# of HV
CA 42	(non EU)	HV, pulmonary decellularised	# of HV
CA 43		Non-valved patches and conduits	# of containers
CA 44]	Pericardium	# of containers
CA 45	1	Other heart tissues	# of containers
CA 46		HV, aortic	#HV
CA 47]	HV, pulmonary	#HV
CA 48		HV, aortic decelularised	# HV
CA 49	EU)	HV, pulmonary decellularised	# HV
CA 50		Non-valved patches and conduits	# of containers
GA 51]	Pericardium	# of containers
CA 52		Other heart tissues	# of containers
CA 53		Applications for HV replacement	# of applications (one surgical procedure, regardless of the # of grants used)
CA 54	Application procedures	Applications for cardiac reconstruction	# of applications (one surgical procedure, regardless of the # of grafts used)
CA 55	1	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
VE 1	Depart	Living donors		# of living vessel donors at national level
VE 2	Donore	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 olinical application,	Vessels, arteries		# of containers
VE 5	whether distributed or not	Vessels, veins		# of containers
VE 6	Distributed to end user in the	Vessels, arteries		# of containers
VE 7	country	Vessels, veins		# of containers
VE 8	Distributed to end user in another	Vessels, arteries		# of containers
VE 9	EU country	Vessels, veins		# of containers
VE 10	Sent to a tissue establishment	Vessels, arteries		# of containers
VE 11	(transport) In another EU country	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	Vessels, arteries		# of containers
VE 15	(non EU)	Vessels, veins		# of containers

VESSELS

VE 16	Imports	Vessels, arteries		# of containers
VE 17	(non EU)	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	Doport	Living donors		# of living musculoskeletal tissue donors at national level (including for autologous use of cranial bone and cartilage)
	MU 2	Denter	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		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	Releases for olinical application,	Bone filing material (excluding femoral heads)		# of containers
	MU 8	whether distributed or not	Femoral heads		# of containers
	MU 9		Demineralised bone matrix (including combined with a carrier)		# of containers
- 1	/U 10		Meniscus		# of pieces
1	/U 11		Other musculoskeletal (e.g. ear ossicles, cranial bone, cartilage)		# of containers
- 1	/U 12		Whole or part of structural/supporting bone		# of pieces
	/U 13		Tendons (including with bony attachments/ligaments/fascia		# of pieces
	/U 14		Osteochondral grafts		# of pieces
1	/U 15	Distributed to end user in the	Bone filing material (excluding femoral heads)		# of containers
- 1	/U 16	oountry	Femoral heads		# of containers
	/U 17		Demineralised bone matrix (including combined with a carrier)		# of containers
	/U 18		Meniscus		# of pieces
- 1	/U 19	1	Other musculoskeletal (e.g. ear ossicles, cranial bone, cartilage)		# of containers
	AU 20		Whole or part of structural/supporting bone		# of pieces
	/U 21		Tendons (including with bony attachments/ligaments/fascia		# of pieces
	/U 22		Osteochondral grafts		# of pieces
	/U 23	Distributed to end user in another	Bone filing material (excluding femoral heads)		# of containers
- 1	/U 24	EU country	Femoral heads		# of containers
- 1	AU 25		Demineralised bone matrix (including combined with a carrier)		# of containers
-1	AU 26		Meniscus		# of pieces
≰ lī	AU 27		Other musculoskeletal (e.g. ear ossicies, cranial bone, cartilage)		# of containers
5	/U 28		Whole or part of structural/supporting bone		# of pieces
삪	AU 29		Tendons (including with bony attachments/ligaments/fascia		# of pieces
8	AU 30		Osteochondral grafts		# of pieces
Ξh	/U 31	Sent to a tissue establishment	Bone filing material (excluding femoral heads)		# of containers
렸는	/U 32	(transport) In another EU country	Femoral heads		# of containers
š lī	/U 33		Demineralised bone matrix (including combined with a carrier)		# of containers
≤	/U 34		Meniscus		# of pieces
	AU 35		Other musculoskeletal (e.g. ear ossicies, cranial bone, cartilage)		# of containers
	AU 36		Whole or part of structural/supporting bone		# of pieces
	AU 37		Tendons (including with bony attachments/ligaments/fascia		# of pieces
1	/U 38		Osteochondral grafts		# of pieces
	AU 39	Received from a tissue	Bone filing material (excluding femoral heads)		# of containers
	/U 40	establichment (transport) in	Femoral heads		# of containers
H	/U 41	another EU country	Demineralised bone matrix (including combined with a carrier)		# of containers
H	/U 42		Meniscus		# of pieces
	/U 43		Other musculoskeletal (e.g. ear ossicles, cranial bone, cartilage)		# of containers
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MU 44		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	Exports	Bone filling material (excluding femoral heads)	# of containers
MU 48	(non EU)	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		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	Imports	Bone filing material (excluding femoral heads)	# of containers
MU 56	(non EU)	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 for orthopaedic/maxiliofacial surgery	# of applications (one surgical procedure, regardless of the # of grafts used)
MU 61	Application procedures	Application for dental procedures	# of applications (one surgical procedure, regardless of the # of grafts used)
MU 62	52	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
E	NE 1	Depart	Living donors		# of living neuronal tissue donors at national level
	NE 2	Donore	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 olinical application, whether distributed or not	Nerves		# of containers
F	NE 5	Distributed to end user in the country	Nerves		# of containers
IRONA	NE 6	Distributed to end user in another EU country	Nerves		# of containers
NE	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
Γ	NE 11	Application procedures	Applications		# of applications (one surgical procedure, regardless of the # of grants used)

	ADIPOSE TISSUE		NUMBERS	UNITS/EXPLANATIONS
AD 1	Depart	Living donors		# of living adipose tissue donors at national level
AD 2	Denore	Deceased donors		# of deceased adipose tissue donors at national level
AD 3	Donations	Donations Adjose tissue donations		# of donation events from one donor, regardless of the number of tissues obtained

	AD 4	Releases for olinical application, whether distributed or not	Adipose tissue	# of containers
	AD 5	Distributed to end user in the country	Adipose tissue	# of containers
SE	AD 6	Distributed to end user in another EU country	Adipose tissue	# of containers
ADIPO	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		Applications for reconstructive surgery	# of applications (one surgical procedure, regardless of the # of grafts used)
	AD 12	Application procedures	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 TISSUE		NUMBERS	UNITS/EXPLANATIONS
	PA1	Depart	Living donors		# of living pancreatic tissue donors at national level
	PA 2	Denore	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
	PA4	Releases for olinical application, whether distributed or not	Pancreatic islets		# of containers
2	PA 5	Distributed to end user in the country	Pancreatic isiets		# of containers
CREAT	PA 6	Distributed to end user in another EU country	Pancreatic isiets		# of containers
PAN	PA7	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 isiets		# of containers
	PA 9	Exports (non EU)	Pancreatic isiets		# of containers
	PA 10	Imports (non EU)	Pancreatic isiets		# 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	Depart	Living donors		# of living hepatic tissue donors at national level
HE 2	Donore	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

НЕРАПС	HE 4	Releases for olinical application, whether distributed or not	Hepatocytes	# of containers
	HE 5	Distributed to end user in the country	Hepatocytes	# of containers
	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
ľ	HE 10	Imports (non EU)	Hepatocytes	# of containers
Г	HE 11	Application procedures	Applications	# of applications (one procedure, regardless of the # of grafts used)

	PARATHYROID TISSUE		NUMBERS	UNITS/EXPLANATIONS
PR 1	Danag	Living donors		# of living parathyroid tissue donors at national level
PR 2	Donore	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 olinical 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)	Parathyrold 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		
_		POTENTIAL FOR ALLOGENEIC DONATION		Registered at 01/01 00:00				
[SS a 1	# of registered and typed HPC donors						
5 [SS a 2	# of registered and typed cord blood units available for transplantation of unrela	ated patients					
ž.								
FICIE		DISTRIBUTION AND EXCHANGE			DISTRIBUTED		IMPORT	EXPORT
Ins-		# of unrelated (unit: Cell product from one donor, regardless of the number	er of donations/containers)	Nationally	From EU countries	To EU countries	From non-EU countries	To non-EU countries
3	SS b 1	HPC from bone marrow for transplantation						
s	SS b 2	HPC from peripheral blood for transplantation						
	SS b 3	Peripheral blood mononuclear cells for transplant support (e.g. donor lymphocy	tes for infusion)					
	SS b 4	Peripheral blood mononuclear cells for other purposes, excluding ATMP (e.g. p	roduction of CAR-T cells, NK cells)					
	SS b 5	HPC from cord blood for transplantation						

		DONATION/COLLECTION		ALLOGENEIC			
R			AUTOLOGOUS	Related donor		Unrelated	
5		# of donations (unit: Cell product collected from one donor in one donation procedure - may encompass more		Paedlatric	Adult	registry donor	
Ξ.		than one apheresis session)		(<18 yr.)			
20	Ca1	HPC from bone marrow for transplantation					
δD	Ca2	HPC from peripheral blood for transplantation					
AT D	Ca3	Peripheral blood mononuclear cells for transplant support (e.g. donor lymphocytes for infusion)					
S D	Ca4	Peripheral blood mononuclear cells for other purposes, excluding ATMP (e.g. production of CAR-T cells, NK cells)					
۵D	Ca5	HPC from cord blood					
D	Ca6	Other cells (e.g. bone marrow for other purposes), excluding ATMP					

I		RELEASED FOR CLINICAL APPLICATION	AUTOLOGOUS	ALLOG	ENEIC
Ĩ		# 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)		Related donor	Unrelated registry donor
ï	TE a 1	HPC from bone marrow for transplantation			
9	TE a 2	HPC from peripheral blood for transplantation			
5	TE a 3	Peripheral blood mononuclear cells for transplant support (e.g. donor lymphocytes for infusion)			
ï	TE a 4	Peripheral blood mononuclear cells for other purposes, excluding ATMP (e.g. production of CAR-T cells, NK cells)			
SSUE	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, mesenchymais)			
F	TE a 7	Other cells (e.g. bone marrow for other purposes), excluding ATMP			

		TRANSPLANT PROCEDURES ASSOCIATED WITH CLINICAL APPLICATION		ALLOG	ENEIC
				Related donor	Unrelated registry donor
[TC a 1	# of transplants (unit: One transplant procedure with cells obtained from one or more donors)			
2	TC a 2	# of recipients (unit: One patient who had at least one transplant procedure during the year concerned)			
2	TC a 3	HPC from bone marrow for transplantation			
R I	TC a 4	HPC from peripheral blood for transplantation			
3	TC a 5	HPC from cord blood for transplantation			
z					
ş			AUTOLOGOUS	ALLOG	ENEIC
SN SN		OTHER PROCEDURES ASSOCIATED WITH CLINICAL APPLICATION		Related donor	Unrelated registry donor
2	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)			
1	TC b 4	Peripheral blood mononuclear cells for other purposes (e.g. NK cells, Tregs, virus-specific cells), excluding ATMP			

TC	b 4	Peripheral blood mononuclear cells for other purposes	(e.g. NK cells, Tre	gs, virus-specific cells),	excluding ATMP
TC	b 5	Other cells for other purposes, excluding ATMP			

MEDICALLY ASSISTED REPRODUCTION ACTIVITY DATA

COUNTRY YEAR

			Treatment ty pe		
	MAR PARTNER ACTIVITIES	IUI	IVF/ICSI	Frozen/cryo embryo transfers (FET)	UNTS/EXPLANATIONS
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 a3	# 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)	UNIT S/E XPLANATION \$
PA b1	# of oocyte retrievals		# of retrieval procedures where at least one oocyte was retrieved
PA b2	# of oocytes retrieved		# of oocytes retrieved in total
PA b 3	# of a acytes crya preserved		# oo cytes cryopreserved in total
PA b4	# of sperm collections (including MESA, PESA and TESE)		# of collections, regardless of number of straws and method of collection used
PA b 5	# of spermunits cryapreserved		# of straws/vials
PA b6	# of embryos cryopreserved		# of embryos
PA b7	# of embryo transfers (fresh or cryo)		# of procedures, regardless of the number of embryos transferred
PA b8	# of embryos transferred (fresh or cryo)		# of embryos
PA b 9	# of embryos transferred (fresh or cryo) from donated sperm and partner occytes		# of embryos
PA b 10	# of embryos transferred (fresh or cryo) from donated oocytes and partner sperm		# of embryos

	DISTRIBUTION AND EXCHANGE OF PARTNER	TRAN SPORT/	DISTRIBUTION	IMPORT	EXPORT	UNIT REVEALAND TION R
	GAMETES/TISSUES/EMBRYOS (ACCESS TO CARE)	From other EU countries	To other EU countries	From non-EU countries	To non-EU countries	UNIT BEAPEARA HONG
PAc1	# of a acytes					#ofoocytes
PAc2	# of sperm units					#ofstraws/vials
PAc3	# of embryos					# of embryas
PAc4	# of ovarian tissues					# of vials/containers
PAc 5	# of testicular tissues (including MESA, PESA and TESE)					# of vials/containers

	DELIVERIES AND LIVE BORN CHILDREN (born during the reporting	Treatment type		
	year regardless of when conceived)	UI	IV FIIC SI (free h or cry o)	ORTSEAFEARATIONS
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, spilt 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	TRANSPORT/	DISTRIBUTION	IMPORT	EXPORT	UNIT REVEALANATIONS
	GAMETES/EMBRYOS (COMMERCIALISATION)	From other EU countries	To other EU countries	From non-EU countries	To non-EU countries	UNIT S/EXPLANATIONS
NP b 1	# of sperm units					# of straws/viais
NP b 2	# of donated embryos					# of embryos

	MAR with non-periner CREPH densition	Treatment type			
	MAR with non parties apermition	IUI	IVF/ICSI	UNIT STEAP LANA HONS	
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 retrievais			# 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	

NON-PARTNER PROCEDURES

	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 <u>AND</u> SPERM donation (double donation)	IVF/ICSI	UNITS/EXPLANATIONS
N	NP e 1	# of recipients		# women who underwent at least one embryo transfer involving donated oocytes and sperm (in the reporting country)
N	IP e 2	# of treatment cycles with donated oocytes and sperm		# of cycles, stimulated or non-stimulated, where donated oocytes and sperm were used
N	IP 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

women who underwent at least one embryo transfer involving donated supernumerary embryos (in the reporting country)
of cycles, stimulated or non-stimulated, where donated supernumerary embryos were used
of procedures involving donated supernumerary embryos regardless of the number of embryos transferred
of embryos (transferred) from donated supernumerary embryos
-

	DELIVERIES AND LIVE BORN CHILDREN (during the reporting year regardless of when conceived)	Treatment type		
		IUI	IVF/ICSI (fresh or cryo)	own arear canalition a
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	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 terms

Application procedure: clinical use of tissues/cells in a recipient, regardless of the number of grafts applied.

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 supplied for clinical use.

Examples:	
Musculoskeletal tissue	One individually packaged or supplied 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 supplied graft (e.g. one cornea, one piece of sclera).
Cardiac tissues	One individually packaged or supplied graft (e.g. one valve).
Vessels	One individually packaged or supplied 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 are in an intimate physical relationship.

Cycle: the process (potentially including medication) that leads to a single collection of gametes (for donation or own use), to the single (one-off) use of gametes or to the transfer of one or more embryos in a single procedure.

Dedicated oocyte donation: an 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 gestation, including both live and stillbirths. A single delivery may result in the birth of one or multiple offspring. If more than one foetus is delivered, it is often recognised as a single 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, from whom tissue, cells or embryos for human application and/or for other purposes including research, 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): a medically assisted reproduction 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 gestation which then breathes or shows some other evidence of life, such as a heartbeat, 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 achieved 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 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: an 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: an 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.