COMMITTEE OF MINISTERS
COMITÉ DES MINISTRES
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

MINISTERS' DEPUTIES Recommendations **CM/Rec(2023)7** 6 September 2023

Recommendation CM/Rec(2023)7 of the Committee of Ministers to member States on establishing national harmonised organ transplant registries with a view to facilitating international data sharing

(Adopted by the Committee of Ministers on 6 September 2023 at the 1473rd 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;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms (ETS No. 5)

Bearing in mind the European Social Charter (ETS No. 35) and its revised version (ETS No. 163), with specific attention to Article 11, which enshrines the right to protection of health, as interpreted by the European Committee of Social Charter;

Having regard to the Council of Europe 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 the provisions of the Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108) and its Protocols, in particular the amending Protocol CETS No. 223, and convinced of the application of those principles to the processing of health-related data, as special categories of data;

Taking into account Resolution Res(78)29 of the Committee of Ministers to the governments of member States on harmonisation of legislation of member States relating to removal, grafting and transplantation of human substances and the final declaration of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987);

Recalling Recommendation Rec(2004)7 of the Committee of Ministers to member States on organ trafficking;

Recalling Recommendation Rec(2006)15 of the Committee of Ministers to member States on the background, functions and responsibilities of a National Transplant Organisation (NTO);

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

Recalling Recommendation CM/Rec(2020)4 of the Committee of Ministers to member States on the quality and safety of organs for transplantation;

Recalling Recommendation CM/Rec(2022)3 of the Committee of Ministers to member States on the development and optimisation of programmes for the donation of organs after the circulatory determination of death;

Recalling Resolution CM/Res(2013)55 on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system;

Recalling Resolution CM/Res(2015)11 on establishing harmonised national living donor registries with a view to facilitating international data sharing and its Explanatory Memorandum;

Recalling Resolution CM/Res(2017)2 on establishing procedures for the management of patients having received an organ transplant abroad upon return to their home country to receive follow-up care;

Considering the latest available edition of the Council of Europe Guide to the quality and safety of organs for transplantation;

Considering the World Health Organization Guiding Principles on Human Cell, Tissue and Organ Transplantation, as endorsed by the 63rd World Health Assembly in May 2010 in Resolution WHA63.22, and in particular Guiding Principle number 10, stating the need to assess the long-term outcomes of cell, tissue and organ donation and transplantation for both living donors and recipients in order to document benefit and harm, and encouraging transplant programmes to participate in national and/or international transplant registries;

Considering Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation;

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;

Considering Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC;

Considering Resolution 77/236, adopted by the United Nations General Assembly on 15 December 2022, on strengthening and promoting effective measures and international co-operation on organ donation and transplantation to prevent and combat trafficking in persons for the purpose of organ removal and trafficking in human organs, that urges member States to consider "*Establishing and developing registries that include information regarding each organ recovery and transplantation procedure and outcomes for living donors and recipients of organs, as well as identification systems that facilitate tracing each organ from donor to recipient and vice versa, with the purpose of ensuring the transparency of practices and the quality and safety of human organs, with due regard to professional confidentiality and personal data protection*";

Considering the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, adopted in 2008, and updated in 2018;

Considering that, while data on organ donation and transplant activities in member States are readily available and published annually by the Council of Europe, data on specific recipient and donor variables and transplant outcomes are lacking in many countries;

Aware that transplant registries, which should systematically collect short-, medium- and long-term outcomes of transplant recipients and include donor and recipient confounding factors, are important in order to gain knowledge about transplantation practices;

Considering that gaining this knowledge is required to: i) ensure the highest possible protection of transplant recipients and the timely identification of associated risk factors, so that adverse occurrences can be addressed adequately and prevented in the future; ii) support evidence-based decision-making regarding treatment choices; iii) enable recommendations regarding tailored treatments for patients with specific comorbidities and risk factors; and iv) facilitate evidence-based research related to transplantation practices, outcomes and quality assurance;

Considering also that in-depth knowledge about transplantation, its applications, impact and outcomes is an essential prerequisite for balanced decision-making and informed consent by patients on the waiting list and transplant recipients;

Taking into account that transplant registries are valuable at a national level to: i) evaluate the quality and safety of healthcare related to organ donation and transplantation; ii) develop allocation schemes as well as preventive strategies and health policies; iii) help optimise the use of scarce organs as well as the overall benefits of organ transplantation, primarily reflected in patient survival rates and quality of life and; iv) provide good quality and cost-effective healthcare;

Considering that donation and transplantation registries should meet privacy requirements, as regulated by each country's data protection legislation and Council of Europe standards;

Considering that combining data from various national registries would allow knowledge and experience regarding different treatment options and outcomes to be shared at international level, enable a faster accumulation of data to identify the absolute risk and the risk factors, facilitate further improvement of donation and transplantation across Europe, promote research into donation and transplantation that is based on high-quality data and support the alignment of healthcare throughout Council of Europe member States and beyond,

1. Recommends that the governments of member States promote the development and maintenance of national transplant registries, according to the general principles presented in Appendix 1 to this Recommendation and taking into consideration the list of parameters shown in Appendix 2 to this Recommendation, with a view to facilitating harmonisation of the said registries and international data sharing;

2. Authorises the Council of Europe European Committee on Organ Transplantation or, if necessary, its subordinate body, to revise the appendices of this Recommendation in the future in keeping with developments in the field.

Appendix 1 to Recommendation CM/Rec(2023)7

General principles on establishing national harmonised organ transplant registries with a view to facilitating international data sharing

With the aim of facilitating and harmonising the collection of baseline and follow-up data on transplant recipients, this appendix provides the characteristics and general guidelines for the construction of a national registry. These are:

1. Health authorities should be in charge of developing and maintaining transplant registries at a national level, in close co-operation with the relevant scientific societies. This should not preclude the possibility of officially delegating this task to other organisations.

2. The procedures and infrastructure of transplant registries within Europe should be designed in such a way that international data sharing is feasible, taking into account the following:

   i. there should be separate sections for kidney, liver, pancreas, heart and lung transplant recipients. The registry needs to have the flexibility to accommodate new sections related to specific areas of interest;

   ii. variables should be defined and standardised.

3. Transplant registries should contain the following donor and recipient information:

   i. donor and recipient demographic information;

   ii. pre-donation donor data;

   iii. peri- and post-operative recipient data;

   iv. follow-up recipient data.

4. Follow-up duration/intervals:

   i. long-term follow-up (preferably lifelong) is essential to obtain comprehensive data and for the security of transplant recipients;

   ii. transplantation centres should provide and guarantee proper donor and recipient follow-up as part of the authorisation requirements;

   iii. owing to restrictive capacity or national regulations, mandatory follow-up data collection may have to be limited to a specified timeframe.

5. Data security/legislation:

   i. national and international data protection rules must be adhered to. Overall data security has to be attained and assured in the country hosting the registry;

   ii. owing to more restrictive data security legislation in recent years, additional measures are required in most countries, e.g. informed consent for storage of personal donor data and separate, national permission for this kind of storage (according to national legislation).

6. Access/publication of data:

   i. each transplant centre should have full access to all data pertaining to its own donors and recipients;

   ii. simple, unidentifiable, summary reports on all recipients in the transplant registries should be made publicly available and presented in annual reports;

   iii. more extensive analyses, intended for publication, should be regulated by predefined protocols.

Appendix 2 to Recommendation CM/Rec(2023)7

Establishing national harmonised organ transplant registries with a view to facilitating international data sharing

This appendix, containing the three datasets detailed below, provides a detailed list of parameters that can be taken into consideration for inclusion in any national transplant registry:

1. European Kidney Recipient Registry (EKRR) Variables, as developed during the EDITH (Pilot Project [PP-1-2016] on chronic kidney disease), which received funding from the European Union.

2. European Liver Transplant Registry (ELTR) Variables, as developed by the European Liver and Intestine Transplant Association (ELITA), a section of the European Society of Organ Transplantation (ESOT).

3. European Pancreas and Islet Transplant Registry (EPITR) Variables, as developed by the European Pancreas and Islet Transplant Association (EPITA), a section of the European Society of Organ Transplantation (ESOT).

The parameters detailed in the datasets may be revised by the Council of Europe European Committee on Organ Transplantation or, if necessary, its subordinate body in the future in keeping with developments in the field.

- # EKRR Dataset (D6.3/.4/.5)

Responsible partner: ET
Document. EKRR dataset from 29.01.2020

X.1. Donor variables

NR referring to EFRETOS or New field	short_name	Variable name	Definition	Unit or coding	Allowed values
D1.1:ER	d_id	Donor ER ID	ER ID code, could be the same as used in the National or Regional registry in combination with a country code (ISO code) of the country that delivers the data or determined by Organization	String	example NL-000001
D1.2	d_gender_birth	Donor Gender at birth	Donor's gender at birth	Coded list	- Male - Female - Unknown
D1.3	d_blood_group	Donor Blood Group	Donor's blood group	ET_ABO	- A - B - AB - O
	d_rhesus Donor	Donor Rhesus	Donor Rhesus	terminology ET_RHESUS	- Positive - Negative
D1.4	d_height	Donor Height	Donor's body height	decimal (3.2)	
	d_height_unit	Donor Height unit		unit	- Cm - in_i (inch)
D1.5	d_weight	Donor Weight	Donor's body weight	weight decimal (3.2)	
	d_weight_unit	Donor Weight unit		unit	- kg - lb_av (pound)

NR referring to EFRETOS or New field	short_name	Variable name	Definition	Unit or coding	Allowed values
D1.6	d_age	Donor Age in Years at Organ Donation	Donor age in years at time of organ donation. For children under the age of two, the value will be recorded with an exact first decimal. For all other ages, it will be recorded with “0” as the first decimal.	Duration ISO 8601	- Years and months
		Donor Cause of Death - coded system		not implemented as pilot is for KI	
D1.7		Donor Cause of Death	Two separate fields: one for coding system used and one for the respective death code	not implemented as pilot is for KI	
D1.8	d_cause_of_death_unified	Unified Cause of Death	For kidney and pancreas: ICD- 10.	terminology ICD-10	
D1.10	d_type	Donor Type	Type of donor	coded list	- DCD - DBD - Living
D1.11	d_malignant_tomour	Malignant tumours in the	Evidence for malignant tumours	coded list	Evidence for malignant
D1.11	d_malignant_tomour_absence		No information available about malignant tumours	coded list	No information available about malignant tumours
D1.11	d_malignant_tomour_exclusion		No evidence for malignant tumours	coded list	No evidence for malignant
D1.12 (D3.24)	d_hla_code	Donor HLA - typing A-B-DR (1-2)	One string only A1, A2, B1, B2, DR1, DR2 either or split is possible	Terminology HLA_nomenclature_2010	
	d_hla_locus	Donor HLA Locus	Locus e.g. HLA-A, HLA-B	Terminology HLA_nomenclature_2010	

NR referring to EFRETOS or New field	short_name	Variable name	Definition	Unit or coding	Allowed values
New	d_medication_name, d_medication_ever_used	Donor past history of hypertension	Was the donor treated with anti-hypertension drugs?	Medication name (string): Medication_ever_used (boolean):	Anti-hypertension drugs - True - False
New	d_creat_mass_volume d_creat_moles_volume	Donor Creatinine at time of	Donor creatinine at time of offer/retrieval	decimal (3.2)	
	d_creat_mass_volume_unit d_creat_moles_volume_unit	Donor creatinine unit		unit	- Umol/l - mmol/dl - mg/dl
D.2.2	d_cmv_igg	Anti-CMV	IgG	Positive if there is a CMV IgG titre higher than 2, Non-Reactive, Unknown	Reactive, Non-Reactive, Unknown
D2.4	d_hiv_ab	HIV (I/II)	Antibodies against Human Immunodeficiency virus, subtype 1 or 2	Reactive (= if IgG>2), Non- Reactive, Unknown	Reactive, Non-Reactive, Unknown
D2.8	d_hcv_ab	HCV Ab*	Antibodies against hepatitis C virus	Reactive (= if IgG>2), Non- Reactive,	Reactive, Non-Reactive, Unknown
D3.33	d_diabetes_type	Diabetes	Was the donor diabetic? And what type?	Terminology ICD_10_diabetes	
D3.33	d_diabetes_absence		No information available about diabetes	coded list	- No information available about diabetes
D3.33	d_diabetes_exclusion		Patient is not diabetic	coded list	- Patient is not diabetic

X.2. Recipient variables

NR referring to EFRETOS or New field	short_name	Variable name	Definition	Unit or coding	Allowed values
NEW: ER	r_id	Recipient ER ID	ER ID code, could be the same as used in the National or Regional registry in combination with a country code (ISO code) of the country that delivers the data	String	example NL-000001
R1.1	r_gender (from demographics)	Recipient Gender at birth	Patient's gender at birth	Male, Female, Unknown	- Male - Female - Unknown
R1.2	r_blood_group	Recipient ABO Blood Group	Patient's blood group type	Terminology ET_ABO	- A - B - AB - O
	r_rhesus	Donor Rhesus	Donor Rhesus	terminology ET_RHESUS	- Positive - Negative
R1.3	r_prim_diag_local	Primary Diagnosis	All codings from national registries are stored: one variable describing which coding system (see derived variables) is used and one with the national coding.	string	
R1.4: ER	r_age_at_listing	Recipient age at listing in	Number of years between date of listing and date of	Duration ISO 8601	Years and months
R1.5	r_prim_diag_unified	Unified Primary Diagnosis	For kidney and pancreas: ICD-10	terminology ICD-10	ICD-10

R1.9:ER	r_dial_age_at_first r_dial_age_at_first_unit	Age in years at start of first dialysis	The age the recipient had reached being put on dialysis for the first time, before his first transplantation. For second and third transplantation, this variable is [illegible]	decimal (3.1)	unit: yr

NR referring to EFRETOS or New field	**short_name**	**Variable name**	**Definition**	**Unit or coding**	**Allowed values**
NEW	r_dial_time_from_first	Time from first dialysis to waiting list	Number of days between date first dialysis and date of waiting list	Duration ISO 8601	days
T1.19 (T3.22)	r_hla_code	Recipient's HLA - typing A-B-DR (1-2) antigen	One string only A1, A2, B1, B2, DR1, DR2 either or split is possible	Terminology HLA_nomenclature_2010	
	r_hla_locus	Donor HLA Locus	Locus e.g. HLA-A, HLA-B	Terminology HLA_nomenclature_2010	
R2.1	r_hiv_ab	HIV (I/II) Ab*	Reactive (= if IgG>2), Non- Reactive, Unknown	coded list	- Reactive - Non-reactive - Unknown
R2.5	r_hcv_ab	HCV Ab	Reactive (= if IgG>2), Non- Reactive, Unknown	coded list	- Reactive - Non-reactive - Unknown
New	r_hbv	HBV	Reactive (= if IgG>2), Non- Reactive, Unknown	coded list	- Reactive - Non-reactive - Unknown
New	r_cmv_igg	CMV	Reactive (= if IgG>2), Non- Reactive, Unknown	coded list	- Reactive - Non-reactive - Unknown
New	r_dial_tech	Dialysis type	The type of last dialysis used - Haemodialysis (HD) - Peritoneal (PD)	coded list	- HD - PD
New	r_sensitised	Sensitisation before first transplantation		Boolean	- True - False

	r_current_pra_technique	Technique for determining antibodies on which PRA is based			- Luminex - ELISA - DTT - CDC - Other

NR referring to EFRETOS or New field	short_name	Variable name	Definition	Unit or coding	Allowed values
	r_current_pra r_current_pra_unit	Current PRA (=last value known before transplantation)		Integer / unit	0-100%
	r_highest_pra_technique	Technique for determining antibodies on which PRA is			- Luminex - ELISA - DTT - CDC - Other
	r_highest_pra r_highest_pra_unit	highest PRA(=last value known before transplantation)		Integer / unit	0-100%

X.3. Transplantation variables

NR referring to EFRETOS or New field	short_name	Variable name	Definition	Unit or coding	Allowed values
T1.1:ER	tx_id	Transplant ER Number ID	ER ID code, could be the same as used in the National or Regional registry in combination with a country code (ISO code) of the country that delivers the data or	string	example NL-000001
NEW	d_gender_birth	Donor Gender at birth	Donor's gender at birth	Coded list	- Male - Female - Unknown

NR referring to EFRETOS or New field	short_name	Variable name	Definition	Unit or coding	Allowed values
NEW	d_id	Donor ID	ER ID code, could be the same as used in the National or Regional registry in combination with a country code (ISO code) that delivers the data or determined by	string	example NL-000001
T1.2:ER	r_age_at_transplant	Age in years at transplant	the number of years and months between date of transplant and date of birth	Duration ISO 8601	years and months
NEW	tx_time_dialysis_and_transplant	Time from first dialysis to transplant	the number of days between date of first dialysis and date of transplant	Duration ISO 8601	days
New	tx_date	Year of transplant		Partial date (Year)	

T1.3	country (from demographics)	Country	Country where recipient is registered as recipient at time of transplant.	ISO code 3166	
New	tx_centre_id	Centre code	National ISO code combined with National	string	example NL-001
New	tx_pre_emptive_transplant	Preemptive transplantation	Was the patient preemptively transplanted?	coded list	- Yes - No
New	tx_number_previous_kidney	Number of previous kidney transplants	How many kidney transplant did the patient have before this transplantation	integer	
T1.7	tx_cold_ischemia_time	Total Ischaemic Time HOURS	Time elapsed between the time of clamping of the aorta and the time of declamping. For DCD: time elapsed between circulatory arrest and the time of declamping.	Duration ISO 8601	hours and minutes

NR referring to EFRETOS or New field	**short_name**	**Variable name**	**Definition**	**Unit or coding**	**Allowed values**
T2.11	tx_graft	Type of transplant	Multiple grafts can be added. two rows for LKI plus RKI transplant or two or more for a multi-organ transplant. Alternatively enter only kidney here and use the multi_organ_transplant checkbox to indicate multiple organs were used. LKi, Left Kidney RKi, Right Kidney BKi, Kidney en Bloc WLiv, Whole Liver LLSLiv, Left Lateral Segment ERLLiv, Extended Right Lobe RLLiv, Right Lobe LLLiv, Left Lobe	Terminology graft_v1	- LKi - RKi - BKi - WLiv - LLSLiv - ERLLiv - RLLiv - LLLiv - LLiv - RLiv - He - BLu - LLu - RLu - Pa - In - Ut - Eso
			LLiv, Left Split Liver		- Sm

			RLiv, Right Split Liver He, Heart BLu, Both Lungs LLu, Left Lung RLu, Right Lung Pa, Pancreas In, Intestine Ut, Uterus Eso, Oesophagus Sm, Stomach Col, Large intestine (Colon) VCA, Vascularised composite allograft		- Col - VCA

NR referring to EFRETOS or New field	**short_name**	**Variable name**	**Definition**	**Unit or coding**	**Allowed values**
New and Tier 2 or 3 data fields that would be advisable	tx_graft_id	Graft ID	National ISO code combined with National graft ID. Only applicable if grafts get their own IDs.		
New	tx_multi_organ_transplant	Was the kidney transplanted part of a multi-organ	Multi-organ, kidney(s) plus any other organ as defined in graft	Boolean	- True - False
	tx_sequence	Sequence of this transplant within the year of transplant	Starting with 1 for first transplant within the transplant year. Can be left empty if transplant_id is a sequential	Integer	

T1.4	htx_id	Historic: Transplant ID	Specification of previous transplant(s). For each of the previous transplants the specification will be required. Multiple historic transplants can be stored. Historic transplants are transplants not registered within the EDITH database. ER ID code, could be the same as used in the National or Regional registry in combination with a country code (ISO code) of the country that delivers the data	string	example NL-000001
	htx_multi_organ_transplant	Historic: Was the kidney transplanted part of a multi-organ	Multi-organ, kidney(s) plus any other organ as defined in graft	Boolean	- True - False
	htx_centre_id	Historic: Centre code	National ISO code combined with National	string	example NL-001

NR referring to EFRETOS or New field	short_name	Variable name	Definition	Unit or coding	Allowed values
	htx_graft	Historic: Type of transplant	Multiple grafts can be added. two rows for LKI plus RKI transplant or two or more for a multi-organ transplant. Alternatively enter only kidney here and use the multi_organ_transplant checkbox to indicate multiple organs were used. LKi, Left Kidney RKi, Right Kidney BKi, Kidney en Bloc WLiv, Whole Liver LLSLiv, Left Lateral Segment	Terminology graft_v1	- LKi - RKi - BKi - WLiv - LLSLiv - ERLLiv - RLLiv - LLLiv - LLiv - RLiv - He - BLu - LLu - RLu - Pa

			ERLLiv, Extended Right Lobe RLLiv, Right Lobe LLLiv, Left Lobe LLiv, Left Split Liver RLiv, Right Split Liver He, Heart BLu, Both Lungs LLu, Left Lung RLu, Right Lung Pa, Pancreas In, Intestine Ut, Uterus Eso, Oesophagus Sm, Stomach Col, Large intestine (Colon) VCA, Vascularised composite allograft		- In - Ut - Eso - Sm - Col - VCA

NR referring to EFRETOS or New field	short_name	Variable name	Definition	Unit or coding	Allowed values
	htx_graft_id	Historic: Graft ID	National ISO code combined with National graft ID. Only applicable if grafts get their own IDs.		
	htx_sequence	Sequence of this transplant within the year of transplant	Starting with 1 for first transplant within the transplant year. Can be left empty if transplant_id is a sequential	integer	

X.4. Follow-up variables

NR referring to EFRETOS or New field	short_name	Variable name	Definition	Unit or coding	Allowed values
F1.1: ER	r_id	Recipient ER ID	ER ID code, could be the same as used in the National or Regional registry in combination with a country code (ISO code) of the country that delivers the data	Alphanumerical code	example NL-000001
	tx_id	Transplant ER Number ID	ER ID code, could be the same as used in the National or Regional registry in combination with a country code (ISO code) of the country that delivers the data	string	example NL-000001

NR referring to EFRETOS or New field	short_name	Variable name	Definition	Unit or coding	Allowed values
T2.11	fup_graft	Type of transplant	Multiple grafts can be added. two rows for LKI plus RKI transplant or two or more for a multi-organ transplant. Alternatively enter only kidney here and use the multi_organ_transplant checkbox to indicate multiple organs were used. LKi, Left Kidney RKi, Right Kidney BKi, Kidney en Bloc WLiv, Whole Liver LLSLiv, Left Lateral Segment	Terminology graft_v1	- LKi - RKi - BKi - WLiv - LLSLiv - ERLLiv - RLLiv - LLLiv - LLiv - RLiv - He - BLu - LLu - RLu - Pa
			ERLLiv, Extended Right Lobe		- In

			RLLiv, Right Lobe LLLiv, Left Lobe LLiv, Left Split Liver RLiv, Right Split Liver He, Heart BLu, Both Lungs LLu, Left Lung RLu, Right Lung Pa, Pancreas In, Intestine Ut, Uterus Eso, Oesophagus Sm, Stomach Col, Large intestine (Colon) VCA, Vascularised composite allograft		- Ut - Eso - Sm - Col - VCA
NR referring to EFRETOS or New field	**short_name**	**Variable name**	**Definition**	**Unit or coding**	**Allowed values**
New and Tier 2 or 3 data fields that would be advisable	fup_graft_id	Graft ID	National ISO code combined with National graft ID. Only applicable if grafts get their own IDs.	string	example NL-000001
	fup_status	Follow-up event for which the follow-up is	- Patient deceased - In follow-up (normal follow-up) - Lost to follow-up - Graft failed	coded list	- Patient deceased - In follow-up - Lost to follow-up - Graft failed
F1.3, F1.6 and NEW	fup_days_since_transplant	Time (Number of days) between transplantation and follow-up	Time (number of days) between transplantation and the date that the recipient was last seen alive	Duration ISO 8601	days
F1.4	fup_cause_of_graft_failure_local	Primary Cause of Graft failure		string	
	fup_cause_of_graft_failure_local	Unified Primary Cause of Graft failure	ICD-10	Terminology ICD-10	ICD-10
F1.7	fup_cause_of_death_local	Cause of Death	All coding systems are allowed	Death cause code	
F1.8	fup_cause_of_death_unified	Unified Cause of Death	For kidney and pancreas: ICD-10	Terminology ICD-10	ICD-10

F1.9	fup_creat_mass_volume fup_creat_moles_volume	Serum creatinine at		decimal (3.2)	
	fup_creat_mass_volume_unit fup_creat_moles_volume_unit	Unit of Creatinine at data last seen		unit	- Umol/l - mmol/dl - mg/dl

European Liver Transplant Registry Variables - ELTR	
Centre identification	**Code** number
Patient identification	
Patient code in centre	alphanumeric
OSO patient Nº	alphanumeric
Family name	3 first letters
Given name	3 first letters
Recipient date of birth	dd/mm/yyyy
Recipient gender	F/M
Recipient blood group	A/B/AB/O
Inscription/LT indication/Pre-LT check-up	
OSO LT Nº	alphanumeric
Transplantation in another centre	YES/NO
If yes, other centre name	text
Date of inscription in WL	dd/mm/yyyy
Recipient weight	kg
Recipient height	cm
Dialysis twice in the week prior creatinine test	YES/NO
Creatinine	micromol/l or mg/dl
Bilirubin	micromol/l or mg/dl
INR	IU
MELD declared	number
Serum sodium	mmol/l
Serum albumin	g/l
Clinical ascites	0=none, 1=controlled with medication, 2=refractory (poorly controlled)
Encephalopathy	0=none, 1=grade I-II (controlled with medication), 2=grade III-IV (refractory)
Recipient HBsAg	NEG/POS
Recipient HBV DNA	NEG/POS
Recipient B Delta	NEG/POS
Recipient Anti HCV	NEG/POS
Recipient HCV RNA	NEG/POS
Recipient HIV	NEG/POS
Indication	1=acute liver disease, 2=chronic liver disease, 3=tumours, 4=metabolic disease
Primary disease (list disease) or	list disease
cause of graft loss (list cause of death or reLT)	list cause of death or reLT
Secondary disease (list disease) or	list disease
cause of graft loss (list cause of death or reLT)	list cause of death or reLT
Other disease, specify	text
UNOS status	1=intensive care unit-bound, 2=continuous hospitalisation, 3=continuous medical care, 4=at home with normal function
Hepatocellular carcinoma (pathology data)	
Time of diagnosis	1=Before LT, 2=After LT (at pathology)
Non-tumoral liver status	1=Cirrhosis (Metavir F4), 2=Fibrosis (Metavir F1-F3), 3=Normal (Metavir F0)
Cumulative pre-LT treatment	list HCC treatments
Number of nodules	number
Main size of nodules	mm
Vascular invasion	0=No, 1=Macro, 2=Micro
Portal tumoral thrombosis	YES/NO

LT technical aspects	
Date of LT	dd/mm/yyyy
Urgency	YES/NO
Type1 of graft	1=full size, 2=reduced, 3=split, 4=split “in situ”, 5=split “ex situ”, 6=living
Type2 of graft	1=left lobe (segment 2+3), 2=left liver (segment 2+3+4), 3=right liver (segment 5+6+7+8), 4=other
Site of LT	1=orthotopic, 2=heterotopic
Type of LT	1=auxiliary, 2=non-auxiliary
Bypass	1=extracorporeal bypass, 2=lateral clamping of the vena cava, 3=neither EC nor VCP
Total ischaemia time	minutes
Preservation liquid	1=Collins, 2=UW, 3=Belzer, 4=Marshall, 5=HRK, 6=Celsior, 7=Custodiol, 8=IGL, 9=Perfadex, 10=Ringer, 11=SCOT, 12=other
Associated transplantation	1=kidney, 2=lung, 3=small bowel, 4=bone marrow, 5=heart, 6=pancreas, 7=Langerhans islets, 8=clusters, 9=other
Post reperfusion biopsy	YES/NO
Donor / Graft	
Donor date of birth	dd/mm/yyyy
Donor gender	F/M
Donor blood group	A/B/AB/O
Country of liver procurement	1=same country, 2=other country
Group matching	1=isogroup, 2=incompatible, 3=compatible
Donor weight	kg
Donor height	cm
Type of donor	1=DBD, 2=DCD, 3=domino, 4=living
Cadaveric donor cause of death	list CD cause of death
Graft weight	g
Macrovesicular steatosis	1=none, 2=mild (<30%), 3=moderate (30%-60%), 4=severe (>60%)
Microvesicular steatosis	1=none, 2=mild (<30%), 3=moderate (30%-60%), 4=severe (>60%)
Overall steatosis rate, if type non-specified	1=none, 2=mild (<30%), 3=moderate (30%-60%), 4=severe (>60%)
Living donor	
Donor relation	list LD relations
Early complications	list LD early complications
Treatment of complication	1=medical, 2=interventional (percutaneous drainage…), 3=reoperation, 4=other
Min PT within 15 days following LT	%
Max INR within 15 days following LT	IU
Max bilirubin within 15 days following LT	micromol/l or mg/dl
Last donor outcome	1=alive without reoperation, 2=alive with reoperation, 3=alive with transplantation, 4=dead
Last donor outcome date	dd/mm/yyyy
Cause of death of living donor	text
Post-LT induction immunosuppression	
	list immunosuppression
Patient outcome	
Recipient outcome	1=alive, 0=dead
Recipient outcome date	dd/mm/yyyy
Status of graft if patient dead	1=died with functioning graft, 2=died with chronic dysfunctioning graft
Main cause of death	list cause of death or reLT
Second cause of death	list cause of death or reLT
Third cause of death	list cause of death or reLT
If other cause, specify	text

FU-immunosuppression	
Date of update	dd/mm/yyyy
Any change since last update?	YES/NO
If yes, date of change	dd/mm/yyyy
Reason of change	list reason change immunosuppression
If other reason, specify	text
Current immunosuppression	list immunosuppression

DISEASE
A1: Acute hepatic failure-Fulminant or Subfulm hepatitis-Virus A
A2 : Acute hepatic failure-Fulminant or Subfulm hepatitis-Virus B
A3 : Acute hepatic failure-Fulminant or Subfulm hepatitis-Virus C
A4: Acute hepatic failure-Fulminant or Subfulm hepatitis-Virus D
A5: Acute hepatic failure-Fulminant or Subfulm hepatitis-Other known
A6: Acute hepatic failure-Fulminant or Subfulm hepatitis-Other unknown
A7: Acute hepatic failure-Fulminant or Subfulm hepatitis-Paracetamol
A8: Acute hepatic failure-Fulm or Subfulm hep-Other drug related, specify
A9: Acute hepatic failure-Fulminant or Subfulm hepatitis-Toxic (non-drug)
A91: Acute hepatic failure-Fulminant or Subfulm hepatitis-Heat shock
A10: Acute hepatic failure-Post-operative
A11: Acute hepatic failure-Post-traumatic
A12: Acute hepatic failure-Others, specify
A13: Subacute hepatitis-Virus A
A14: Subacute hepatitis-Virus B
A15: Subacute hepatitis-Virus C
A16: Subacute hepatitis-Virus D
A17: Subacute hepatitis-Other known
A18: Subacute hepatitis-Other unknown
A19: Subacute hepatitis-Paracetamol
A20: Subacute hepatitis-Other drug-related, specify
A21: Subacute hepatitis-Toxic (non-drug)
B1: Cholestatic disease-Secondary biliary cirrhosis
B2: Cholestatic disease-Primary biliary cirrhosis
B3: Cholestatic disease-Primary sclerosing cholangitis
B4: Cholestatic disease-Others, specify
C1 : Congenital biliary disease-Caroli disease
C2: Congenital biliary disease-Extrahepatic biliary atresia
C4 : Congenital biliary disease-Congenital biliary fibrosis
C5 : Congenital biliary disease-Choledocal cyst
C6: Congenital biliary disease-Alagille syndrome
C7: Congenital biliary disease-Others, specify
D1: Cirrhosis-Alcoholic cirrhosis
D2: Cirrhosis-Autoimmune Cirrhosis
D3 : Cirrhosis-Virus B-related cirrhosis
D4 : Cirrhosis-Virus C-related cirrhosis
D5 : Cirrhosis-Virus BD-related cirrhosis
D6: Cirrhosis-Virus BC-related cirrhosis
D7: Cirrhosis-Virus BCD-related cirrhosis
D71: Cirrhosis-Combined virus C and alcoholic cirrhosis
D72: Cirrhosis-Combined virus B and alcoholic cirrhosis
D73: Cirrhosis-Virus E-related cirrhosis
D8: Cirrhosis-Virus-related cirrhosis-Other viruses, specify
D9: Cirrhosis-Post-hepatitic cirrhosis-Drug-related
D10: Cirrhosis-Other cirrhosis, specify
D11: Cirrhosis-Cryptogenic (unknown) cirrhosis
E1 : Cancers-Hepatocellular carcinoma and cirrhosis

E2: Cancers-Hepatocellular carcinoma and non-cirrhotic liver
E3 : Cancers-Hepatocellular carcinoma-Fibrolamellar
E4: Cancers-Biliary tract carcinoma (Klatskin)
E5 : Cancers-Hepatic cholangiocellular carcinoma
E6 : Cancers-Hepatoblastoma
E7 : Cancers-Epithelioid hemangioendothelioma
E8 : Cancers-Angiosarcoma
E9 : Cancers-Secondary liver tumours-Carcinoid
E10 : Cancers-Secondary liver tumours-Other neuroendocrine
E11 : Cancers-Secondary liver tumours-Colorectal
E12 : Cancers-Secondary liver tumours-GI non colorectal
E13 : Cancers-Secondary liver tumours-Non-gastrointestinal
E14: Cancers-Other liver malignancies, specify
F1 : Metabolic diseases-Wilson disease
F2: Metabolic diseases-Haemochromatosis
F3 : Metabolic dis-Alpha-1-antitrypsin deficiency
F4 : Metabolic diseases-Glycogen storage disease
F5 : Metabolic dis-Homozygous Hypercholesterolaemia
F6 : Metabolic diseases-Tyrosinaemia
F7 : Metabolic diseases-Familial amyloid polyneuropathy
F8 : Metabolic diseases-Primary hyperoxaluria
F9 : Metabolic diseases-Protoporphyria
F91: Metabolic diseases-NASH
F10 : Metabolic diseases-Other porphyria
F11 : Metabolic diseases-Crigler-Najjar
F12 : Metabolic diseases-Cystic fibrosis
F13 : Metabolic diseases-Byler disease
F14 : Metabolic diseases-Others
G: Budd-Chiari
H1: Benign liver tumours or polycystic dis-Hepatic adenoma
H2: Benign liver tumours or polycystic dis-Adenomatosis
H3: Benign liver tumours or polycystic dis-Haemangioma
H4: Benign liver tumours or polycystic dis-Focal nodular hyperplasia
H5: Benign liver tumours or polycystic dis-Polycystic disease
H6: Benign liver tumours or polycystic dis-Nodular regenerative hyperplasia
H7: Benign liver tumours or polycystic dis-Other benign tumors, specify
I1: Parasitic disease-Schistosomiasis (Bilharzia)
I2: Parasitic disease-Alveolar echinococcosis
I3: Parasitic disease-Cystic hydatidosis
I4: Parasitic disease-Others, specify
J: Other liver diseases
J1 : Human immunodeficiency virus (HIV)
K: Not available
L: Total Parenteral Nutrition (TPN)-induced cholestasis
M : Hepatopulmonary syndrome
N : Microangiopathy
O: Small-for-size syndrome

CAUSE OF DEATH OR reLT
A1: Intraoperative death (death on the table)
-
B1: Infection-Bacterial infection
B2: Infection-Viral infection
B3: Infection-HIV
B4: Infection-Fungal infection
B5: Infection-Parasitic infection
B6: Infection-Other known infect, specify
-
C1 : Liver complications-Acute rejection
C2: Liver complications-Chronic rejection
C3: Liver complications-Arterial thrombosis
C4: Liver complic-Hepatic vein thrombosis
C41: Liver complic-Early portal vein thrombosis
C42: Liver complic-Outflow impairment
C5: Liver complic-Primary N-function (Retx or death ≤ 7 d)
C6: Liv complic-Primary dysfunction (Retx or death > 7d)
C61 : Liv complic-Small-for-size syndrome
C7 : Liver complic-Anastomotic biliary complic
C8 : Liver complic-Non-anastomotic biliary complic
C9: Liver complic-Recurrence of initial dis-Virus B
C10 : Liv complic-Recurrence of initial dis-Virus C
C11 : Liv complic-Recurrence of initial dis-Virus D
C12 : Liv complic-Recurrence of initial dis-Alcoholic
C13 : Liv complic-Recurrence of initial dis-PBC
C14 : Liv complic-Recurrence of initial dis-PSC
C15 : Liv complic-Recurrence of initial dis-Autoimmune
C16 : Liv complic-Recurrence of initial dis–Budd-Chiari
C17 : Liv complic-Recur of init dis-Other non-tumoral, specify
C18 : Liver complic-De novo hepatitis B virus
C19 : Liver complications-De novo hepatitis C virus
C20 : Liver complications-De novo hepatitis D virus
C21: Liver complic-Massive haemorrhagic necrosis
C22: Liver complications-Other viral hepatitis
C23: Liver complications-Infection
C24: Liver complications-Others, specify
-
D1: Gastrointestinal complications-GI haemorrhage
D2: Gastrointestinal complications-Pancreatitis
D3 : Gastrointestinal complic-Visceral perforation
D4: Gastrointestinal complications-Others, specify
-
E1: Cardiovascular complications-Myocardial infarction
E2: Cardiovascular complications-Others, specify
-
F1 : Cerebrovascular complications-Intracranial haemorrhage
F2: Cerebrovascular complications-Ischaemic stroke

F3 : Cerebrovascular complications-Cerebral oedema
F4 : Cerebrovascular complications-Cerebral infection
-
G1: Tumour-Recurrence of initial tumour
G2: Tumour-Recurrence of previously unrelated tumour
G3: Tumour-De novo solid organ tumour, specify
G4: Tumour-Donor transmitted tumour
G5: Tumour- Lymphoproliferative disease
-
H1: Kidney failure
H2: Urinary tract infection
-
I1: Pulmonary complications-Embolism
I2: Pulmonary complications-Infection
-
J1 : Social complic-Non-compliance with immunosup therapy
J2 : Social complications-Suicide
J3 : Social complications-Trauma (motor, vehicle,..)
-
K1 : Bone marrow depression
-
L1: Other cause, specify
-
M1: Not available
-
N1: Neurological complication, specify
-
list HCC treatment
NO: None
CE : Chemoembolisation (TACE)
RE: Resection
RF: Radiofrequency
AL: Alcohol
CR: Cryotherapy
RT: Radiotherapy
SO: Sorafenib
RS: Radioembolisation
OT: Other
list CD cause death
DR: Drowning
DI: Drug intoxication
AS: Asphyxiation
CA: Cardiovascular
EL: Electrical
GU: Gunshot wound
ST: Stab
BI: Blunt injury
SD: Sudden infant death
IC: Intracranial Haemorrhage / Stroke

OT: Others
list LD relation
MF: Mother/Father
SD: Son/Daughter
GP: Grandparent
HS: Husband/Spouse
BS: Brother/Sister
OT: Others
list LD early complication
NO: No major complication
PE: Pulmonary embolism
BF: Biliary fistula
BS: Biliary stenosis
AT: Arterial thrombosis
PT: Portal thrombosis
PH: Phlebitis
BL: Bleeding
LI: Liver insufficiency
SS: Small-for-size syndrome
WI: Wound infection
IF: Infection (not wound)
IC: Infected collection
NC: Non-infected collection
PE: Pleural effusion
OT: Others
list immunosuppression
1 Tacrolimus, non Advagraf
2 Advagraf
3 Tacrolimus, unprecised
4 Neoral
5 Steroids oral
6 Steroids IV
7 Azathioprine
8 Certican
9 Sirolimus
10 Ciclosporin (Sandimum) oral
11 Ciclosporin (Sandimum) IV
12 Simulect
13 Rapamune
14 Zenapax
15 Mofetil (Mycophenolate)
16 Campath-1
17 FTY
18 OKT3
19 ALS ATG
20 MNA (FK778)
21 Treg
98 Others

Reasons of imm change
1 Acute rejection
2 Chronic rejection
3 Intolerance
4 Chronic renal failure
5 Treated diabetes
6 Treated AHT
7 Treated hyperlipidaemia
8 Neurological complication
9 Infection
10 Recurrence of initial disease
11 Viral hepatitis
12 De novo cancer
13 Recurrent cancer
14 Autoimmune hepatitis
15 Others

Recipient at transplant			
Question title	**Question type**	**Question status**	**Option text**
Recipient personal information			
Recipient age	Integer	**Mandatory**	
Recipient gender	SingleChoice	**Mandatory**	Male Female
Recipient height	Integer	**Mandatory**	
Recipient weight	FloatingPoint	**Mandatory**	
Recipient BMI	Auto-calculated		
Recipient blood group	SingleChoice	**Optional**	A B AB O
Recipient health status			
Time on the waiting list	Integer	**Optional**	
On chronic dialysis	Yes/No	**Mandatory**	
Type of dialysis	SingleChoice	**Optional**	Haemodialysis Peritoneal Haemodialysis AND peritoneal
Time on dialysis – years	Integer	**Optional**	
Total dose of insulin per day	Integer	**Optional**	
Type 1 diabetes	Yes/No	**Mandatory**	
Duration of diabetes – years	Integer	**Mandatory**	
No. of diabetic organ complications	SingleChoice	**Desirable**	One Two Three Four Five Six
Organs with complications	Multiple Choice	**Optional**	Cardiovascular Neurological Renal Ocular Diabetic foot Other organs
Details of other organs affected	SingleLineString	**Optional**	
Anticoagulation/anti-aggregation	Yes/No	**Optional**	
Recipient biochemistry			
Pre-Tx serum C-peptide value	Integer	**Mandatory**	
Pre-Tx A1C glycated Hb	Integer	**Mandatory**	
Recipient HLA-A#1	SingleLineString	**Mandatory**	Two letters = 00 => not done
Recipient HLA-A#2	SingleLineString	**Mandatory**	
Recipient HLA-B#1	SingleLineString	**Mandatory**	
Recipient HLA-B#2	SingleLineString	**Mandatory**	
Recipient HLA-C#1	SingleLineString	**Mandatory**	
Recipient HLA-C#2	SingleLineString	**Mandatory**	
Recipient HLA-DR#1	SingleLineString	**Mandatory**	
Recipient HLA-DR#2	SingleLineString	**Mandatory**	
Recipient HLA-DQ#1	SingleLineString	**Mandatory**	
Recipient HLA-DQ#2	SingleLineString	**Mandatory**	
Recipient HLA-DP#1	SingleLineString	**Mandatory**	
Recipient HLA-DP#2	SingleLineString	**Mandatory**	

Donor specific antibody class 1	SingleChoice	**Mandatory**	Negative Positive
Donor specific antibody class 2	SingleChoice	**Mandatory**	Negative Positive
Non-donor-specific antibody	SingleChoice	**Mandatory**	Negative Positive
Diabetic autoantibodies	SingleChoice	**Mandatory**	negative anti-ICA anti-IA2 anti-GAD anti-insulin Not tested
Recipient COVID-19 Ac	SingleChoice	**Optional**	Negative Positive Not tested
COVID-19 vaccination	SingleChoice	**Optional**	No One dose Two doses Three doses
COVID-19: First dose given	SingleChoice	**Optional**	Pfizer BioNtech Moderna AstraZeneca Johnson & Johnson Sinovac Spoutnik V Other
COVID-19: Second dose given	SingleChoice	**Optional**	Pfizer BioNtech Moderna AstraZeneca Johnson & Johnson Sinovac Spoutnik V Other
COVID-19: Third dose given	SingleChoice	**Optional**	Pfizer BioNtech Moderna AstraZeneca Johnson & Johnson Sinovac Spoutnik V Other
COVID-19: Seroconvertion after vaccination	Yes/No	**Optional**	
COVID-19: Value of Anti-spike IgG one month after last injection	Integer	**Optional**	
Recipient infections			
Recipient CMV infection (serology)	SingleChoice	**Desirable**	Negative Positive Not tested
Recipient EBV infection (serology)	SingleChoice	**Desirable**	Negative Positive Not tested
Recipient HCV at the time of transplantation (serology)	SingleChoice	**Desirable**	Negative Positive Not tested
Recipient HIV at the time of transplantation (serology)	SingleChoice	**Desirable**	Negative Positive Not tested
Recipient COVID-19 at the time of transplantation (PCR)	SingleChoice	**Desirable**	Negative Positive Not tested
Recipient HBsAG at the time of transplantation	SingleChoice	**Desirable**	Negative Positive Not tested

Recipient HBcAB at the time of transplantation	Single Choice	**Desirable**	Negative Positive Not tested
Recipient historic transplants			
Any historic transplants	Yes/No	**Mandatory**	
LOOP for each historic transplant			
Organ transplanted	SingleChoice	**Mandatory**	Pancreas Islets Kidney Lung Heart Liver Other organs
Details of other organs	SingleLineString	**Optional**	
Date of historic transplant	Year/Month/Day	**Desirable**	
Current status of **this** organ	SingleChoice	**Desirable**	Optimal Good Marginal Failure

Donor			
Question title	**Question type**	**Question status**	**Option text**
Donor personal data			
Age of donor	Integer	**Mandatory**	
Donor gender	SingleChoice	**Mandatory**	Male Female
Donor height	Integer	**Desirable**	
Donor weight	FloatingPoint	**Desirable**	
Donor BMI	**Auto-calculated**		
Donor vital status	SingleChoice	**Mandatory**	Living Brainstem DCB Cardiac DCD
Donation after cardiac death status	SingleChoice	**Mandatory**	Controlled Uncontrolled
Donor cause of death	SingleChoice	**Mandatory**	Vascular Trauma Anoxia Other
Organs donated	Multiple Choice	**Mandatory**	Pancreas Islets Kidney Other organs
Details of other organs donated	SingleLineString	**Optional**	
DCD (donation after cardiac death) status	SingleChoice	**Desirable**	Controlled Uncontrolled
Normothermic regional perfusion	Yes/No	**Desirable**	
Pre-mortem cannulation	Yes/No	**Desirable**	
Post-mortem cannulation	Yes/No	**Desirable**	
Super-rapid recover	Yes/No	**Desirable**	
Total warm ischaemia	Integer	**Desirable**	
Functional warm ischaemia	Integer	**Desirable**	
Post-mortem NRP running time	Integer	**Desirable**	
Stay on ICU	Yes/No	**Desirable**	
Days on ICU	Integer	**Desirable**	
Stay in hospital	Yes/No	**Desirable**	
Days in hospital	Integer	**Desirable**	
Donor brainstem: cardiac arrest	Yes/No	**Desirable**	
Time of cardiac arrest with resuscitation manoeuvres	Integer	**Desirable**	
Time of cardiac arrest without resuscitation manoeuvres	Integer	**Desirable**	
Donor health status			
Donor ongoing hypertension	Yes/No	**Mandatory**	
Donor history of hypertension	Yes/No	**Mandatory**	
Donor currently smoking	Yes/No	**Desirable**	
Donor history of smoking	Yes/No	**Desirable**	
Donor ongoing alcoholism	Yes/No	**Desirable**	
Donor history of alcoholism	Yes/No	**Desirable**	
Donor drugs (any)	Yes/No	**Desirable**	
Donor biochemistry			
Donor highest sodium value	Integer	**Desirable**	
Donor highest creatinine value	Integer	**Desirable**	

Donor A1C glycated haemoglobin	Integer	**Desirable**	
Donor ASAT/ALAT	SingleChoice	**Desirable**	Normal Abnormal
Donor lipase	SingleChoice	**Desirable**	Normal Abnormal
Donor amylase	SingleChoice	**Desirable**	Normal Abnormal
Donor HLA-A#1	SingleLineString	**Mandatory**	See recipient
Donor HLA-A#2	SingleLineString	**Mandatory**	
Donor HLA-B#1	SingleLineString	**Mandatory**	
Donor HLA-B#2	SingleLineString	**Mandatory**	
Donor HLA-C#1	SingleLineString	**Mandatory**	
Donor HLA-C#2	SingleLineString	**Mandatory**	
Donor HLA-DR#1	SingleLineString	**Mandatory**	
Donor HLA-DR#2	SingleLineString	**Mandatory**	
Donor HLA-DQ#1	SingleLineString	**Mandatory**	
Donor HLA-DQ#2	SingleLineString	**Mandatory**	
Donor HLA-DP#1	SingleLineString	**Mandatory**	
Donor HLA-DP#2	SingleLineString	**Mandatory**	
Donor blood group	SingleChoice	**Optional**	A / B / AB / O
Donor infection screening			
Donor CMV at the time of donation (serology)	SingleChoice	**Desirable**	Negative Positive
Donor EBV at the time of donation	SingleChoice	**Desirable**	Negative Positive
Donor HCV at the time of donation	Single Choice	**Desirable**	Negative Positive
Donor HIV at the time of donation	SingleChoice	**Desirable**	Negative Positive Not tested
Donor HBsAg at the time of donation	SingleChoice	**Desirable**	Negative Positive Not tested
Donor HBcAb at the time of donation	SingleChoice	**Desirable**	Negative Positive Not tested
Donor COVID test at the time of donation	Yes/No	**Desirable**	
Donor donated organs			
Donor organ preservation solution	SingleChoice	**Mandatory**	UW (University of Wisconsin) HTK (Histidine Tryptophan Ketoglutarade) IGL (Institut Georges Lopez) Other
Details of other preservation solution	SingleLineString	**Optional**	
Donor organs retrieved	Multiple Choice	**Desirable**	Pancreas Kidney Liver Heart Lung Bowel
Donor perfusion machine pancreas	Yes/No	**Desirable**	
Perfusion machine (pancreas)	Table Single Choice	**Desirable**	hyperlink
Donor perfusion machine kidney	Yes/No	**Desirable**	
Perfusion machine (kidney)	Table Single Choice	**Desirable**	hyperlink

Operation			
Question title	**Question type**	**Question status**	**Option text**
Operation overview			
Date of procedure	Date	**Mandatory**	
Which transplantation type	SingleChoice	**Mandatory**	Pancreas Islets
Any other organs transplanted at the same time	Yes/No	**Mandatory**	
Which other organs implanted simultaneously	Multiple Choice	**Mandatory**	Kidney Heart Lung Liver
Clavien-Dindo Classification for pancreas complications	SingleChoice	**Desirable**	Grade 1 Grade 2 Grade 3a Grade 3b Grade 4a Grade 4b Grade 5
Graft – all procedures			
Pancreas macroscopic aspect	SingleChoice	**Mandatory**	Not damaged Damaged
Pancreas procurement team	SingleChoice	**Mandatory**	Local External
Elapsed time from donor arterial clamp (cross-clamp) to cold storage preservation	Integer	**Desirable**	
Type of cold storage preservation solution	SingleChoice	**Desirable**	UW (University of Wisconsin) Celsior HTK (Histidine Tryptophan Ketoglutarade) IGL-1 (Institut Georges Lopez 1) Other
Crossmatch: virtual	SingleChoice	**Mandatory**	Negative Positive Not tested
Crossmatch: non-virtual	SingleChoice	**Mandatory**	Negative Positive Not tested
Pancreas cold ischaemic time	Integer	**Mandatory**	
Graft – pancreas procedure only			
Back table arterial vascular reconstruction	Yes/No	**Desirable**	
Venous extension graft	Yes/No	**Desirable**	
Operative technique	Yes/No	**Desirable**	
Pancreatic graft position	SingleChoice	**Desirable**	Right side, intraperitoneal Right side, retroperitoneal Left side, intraperitoneal Left side, retroperitoneal
Duct management	SingleChoice	**Desirable**	Duodeno-jejuno side to side Duodeno-jejuno Roux-en-Y Duodeno-ileum Duodeno-duodeno Duodeno-bladder

Graft – islet procedure only			
Islet yield at transplant	Integer	**Mandatory**	
Islet transplant purity at transplant	Integer	**Desirable**	
Islet surgical procedure	SingleChoice	**Mandatory**	
Procedures involving simultaneous kidney			
Kidney cold ischaemic time	Integer	**Mandatory**	
Recipient post-procedure data			
Question title	**Question type**	**Question status**	**Option text**
Immunosuppression: induction	Multiple Choice	**Mandatory**	None ATG anti-CD25 Campath 1H Belatacept anti-TNFα anti-CD20 Other
Details of other immunosuppression: induction	SingleLineString	**Optional**	
Intended post-operative maintenance	Multiple Choice	**Mandatory**	Tacrolimus CsA m-TOR Steroid Azathioprine MMF / MPA Other
Anticoagulation / anti-aggregation	Yes/No	**Mandatory**	
Need for dialysis during the first week after transplantation	Yes/No	**Mandatory**	
Follow-up			
Question title	**Question type**	**Question status**	**Option text**
Date of recorded events	Date	**Mandatory**	
Kind of follow-up entry	Multiple Choice	**Mandatory**	Patient vital status only Organ status only Rejection Infection Cancer Function Quality of life
Recipient health status			
Time since transplant	**Auto-calculated**		
Current patient status	Single Choice	Mandatory	Alive Deceased
Main cause of patient death (independent from graft function)	SingleChoice	Mandatory	Cardiac Vascular Infection Cancer Accidental Unknown Other (free text)
Details of the main cause of death	SingleLineString	**Optional**	
Insulin independence	Yes/No	**Mandatory**	
Insulin	Integer	**Mandatory**	
Oral / subcutaneous antidiabetics independence	Yes/No	**Mandatory**	

Type of oral / subcutaneous antidiabetics	SingleLineString	**Mandatory**	
Pregnancy	SingleChoice	**Desirable**	No Yes, successful Yes, unsuccessful
Date of delivery	Date	**Desirable**	
Date of loss of child	Date	**Desirable**	
PTLD after transplantation	Yes/No	**Mandatory**	(cancer)
Other malignancy after transplant	Yes/No	**Mandatory**	
Organ function			
Graft function (Igls definition)	SingleChoice	**Mandatory**	Optimal Good Marginal Failure
Gold score	SingleChoice	**Desirable**	<4 ≥4
Clarke score	SingleChoice	**Desirable**	<4 ≥4
Main cause of pancreas or islet failure	SingleChoice	**Mandatory**	Thrombosis Rejection Bleeding Diabetes recurrence Immunosuppression toxicity Pancreatitis Non-immune cause Unknown
Details of other main reason for pancreas or islets failure	SingleLineString	**Optional**	
Kidney function (Igls definition)	SingleChoice	**Mandatory**	Optimal Good Marginal Failure
Main cause of kidney failure	SingleChoice	**Mandatory**	Thrombosis Acute rejection Chronic rejection Urological Recurrence of initial kidney disease Immunosuppression toxicity BKV nephropathy Cancer Unknown Other (free text)
Details of other main reason for kidney failure	SingleLineString	**Optional**	
Clavien-Dindo Classification for kidney complications	SingleChoice	**Desirable**	Grade 1 Grade 2 Grade 3a Grade 3b Grade 4a Grade 4b Grade 5
Was pancreas / islet graft rejected	Yes/No	**Mandatory**	No Temporarily Irreversibly
Was pancreas / islet graft rejection treated	Yes/No	**Mandatory**	
Was kidney irreversibly rejected	Yes/No	**Mandatory**	
Was kidney rejection treated	Yes/No	**Mandatory**	
New kidney transplant	Yes/No	**Mandatory**	

Recipient biochemistry			
Hb A1C value	Integer	**Mandatory**	
Fasting glycaemia	Integer	**Mandatory**	
C-peptide	Integer	**Desirable**	
Levels of amylase	Integer	**Optional**	
Diabetic autoantibodies	Multiple Choice	**Mandatory**	Negative anti-ZnT8 anti-ICA anti-IA2 anti-GAD anti-Insulin
Does histology of pancreas biopsy confirm recurrence?			Yes No Not done
Serum creatinine	Single Choice	**Mandatory**	<100 100-200 200-300 300-400 400-500 500-600 >600
GFR	Single Choice	**Mandatory**	<15 15-30 30-40 40-50 50-60 60-70 >70
Proteinuria	Single Choice	**Mandatory**	<1 g g-1 ≥1 g g-1
De novo DSA	Single Choice	**Mandatory**	No Class 1 Class 2
Recipient treatment			
Immunosuppression	Multiple Choice	**Mandatory**	Tac CsA m-TOR Steroid MMF/MPA Belatacept Aza Other
Recipient infections			
Severity of infection: was hospitalisation needed?			Yes No
Type of infection			Viral Bacterial Fungal
Post-transplant COVID-19 infection	Yes/No	**Optional**	
Date of post-transplant COVID-19 infection	Date	**Optional**	
Hospitalisation for COVID-19 infection	Yes/No	**Optional**	
Date of hospitalisation for COVID-19 infection	Date	**Optional**	
In-hospital therapy for COVID-19	Multiple Choice	**Optional**	None Steroids Tocilizumab Tofacitinib Monoclonal Antibodies Other

Recipient COVID-19 infection after transplantation (PCR)	SingleChoice	**Optional**	Negative Positive Not tested
CMV infection/disease after transplantation	Yes/No	**Desirable**	
BKV infection after transplantation	Yes/No	**Desirable**	
Documented BKV nephropathy after transplantation	Yes/No	**Desirable**	
Immunosuppression at the time of infection	SingleLineString	**Optional**	
Withdrawal of maintenance immunosuppression	Yes/No	**Optional**	
Treatment	**Not specified**	**Optional**	Anti-proliferative mTOR inhibitors Steroids Belatacept
Allograft pancreatic failure following COVID-19	Yes/No	**Optional**	
Allograft kidney failure following COVID-19	Yes/No	**Optional**	
Cause of allograft failure(s)	SingleLineString	**Optional**	
Recipient quality of life			
Did the patient resume professional activity after transplant?	Yes/No	**Desirable**	
Is the patient happy with the transplant?	Yes/No	**Desirable**	
Would the patient recommend transplantation?	Yes/No	**Desirable**	

Matrix for follow-up questions

	Sections							
	Routine check (annual)	Death	Rejection	Graft failure	Infections	Cancer	Recurrence of diabetes	Pregnancy
DATE OF EVENTS RECORDED	■	■	■	■	■	■	■	■
Recipient health status								
Time since transplant	■	■	■	■	■	■	■	■
Current patient status	■							
Main cause of patient death (independent from graft function)		■						
Details of other main cause of death		■						
Insulin independence	■							
Insulin	■							
Oral / subcutaneous antidiabetics independence	■							
Type of oral / subcutaneous antidiabetics	■							
Pregnancy								■
Date of delivery								■
Date of loss of child								■
PTLD after transplantation						■		
Other malignancy after transplant						■		
Organ function								
Organ function	■							
Graft function (Igls definition)	■							
Gold score	■							
Clarke score	■							
Main cause of pancreas or islet failure				■				
Details of other main reason for pancreas or islets failure				■				
Kidney function (Igls definition)	■							
Main cause of kidney failure				■				
Details of other main reason for kidney failure				■				
Clavien-Dindo Classification for kidney complications	■							
Was pancreas / islet graft rejected			■					
Was pancreas / islet graft rejection treated			■					
Was kidney irreversibly rejected			■					
Was kidney rejection treated			■					
New kidney transplant			■					

Recipient biochemistry								
Hb A1C value	■							
Fasting glycaemia	■							
C-peptide	■							
Levels of amylase	■							
Diabetic autoantibodies	■						■	
Does histology of pancreas biopsy confirm recurrence?							■	
Serum creatinine	■							
GFR	■							
Proteinuria	■							
De novo DSA	■		■					
Recipient treatment								
Immunosuppression	■							
Recipient infections								
Severity of infection: was hospitalisation needed?					■			
Type of infection					■			
Post-transplant COVID-19 infection					If type = viral			
Date of post-transplant COVID-19 infection								
Hospitalisation for COVID-19 infection								
Date of hospitalisation for COVID-19 infection								
In-hospital therapy for COVID-19								
Recipient COVID-19 infection after transplantation (PCR)								
CMV infection/disease after transplantation								
BKV infection after transplantation								
Documented BKV nephropathy after transplantation								
Immunosuppression at the time of infection								
Withdrawal of maintenance immunosuppression								
Treatment								
Allograft pancreatic failure following COVID-19								
Allograft kidney failure following COVID-19								
Cause of allograft failure(s)								
Recipient quality of life								
Did the patient resume professional activity after transplant?	■							
Is the patient happy with the transplant?	■							
Would the patient recommend transplantation?	■							