CRYOSTEM - Cryoconservation during allogeneic hematopoietic Stem cell transplantation

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General	
Identification	
Detailed name	Cryoconservation during allogeneic hematopoietic Stem cell transplantation
Sign or acronym	CRYOSTEM
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CPP Sud-Méditerranée (17/02/2012) : AC-2011-1420, CCTIRS (09/02/2012) : 11-710bis, CNIL
General Aspects	
Medical area	Cancer research Hematology Immunology Infectious diseases Pediatrics
Health determinants	latrogenic
Keywords	Graft-versus-host-disease, GvHD, Allogeneic Hematopoietic Stem Cell Transplantation, HSCT, Biobanking network, Complications

Scientific investigator(s) (Contact)	
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Collaborations

Participation in projects, networks and consortia

Yes

Funding

Funding status	Mixed
Details	ANR "Investissements d'avenir - Grand emprunt"
Governance of the database	
Sponsor(s) or organisation(s) responsible	CRYOSTEM
Organisation status	Private
Presence of scientific or steering committees	Yes
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is is made on the basis of:	Another treatment or procedure
Database recruitment is carried out as part of an interventional study	No
Database objective	
Main objective	The goal of CryoStem is to create a national, multicenter, prospectie, longitudinal, standardized HSCT human-sample collection (derived from adult and pediatric patients) with the purpose of enabling better characterization and prediction of HSCT complications occurence and outcome, including GvHD. CryoStem has generated a French network involving all the French transplant units, adult and pediatric and 28 Biological Resources Centres. Only in a network such as this may the full potential be realized of having concrete and effective interactions between scientists with top knowledge in specific areas and physicians. CryoStem fosters interactions among internationally recognized experts in advanced biotechnology

	(genomics,transcriptomics, proteomics, and flow cytometry). Altogether, CryoStem provides a structured approach for a range of different research activities, bringing together leading-edge researchers who can access documented biological (CryoStem) and clinical (ProMISe) samples from transplanted patients in order to better characterize and predict HSCT complications.
Inclusion criteria	Any patient suffering from a severe blood disease or blood cancer (leukemia, lymphoma, aplastic anemia) justifying a first HSCT in one of the transplant units of CRYOSTEM network.

	transplant units of CRYOSTEM network.
Population type	
Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years) Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Pathology	III - Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
Gender	Male Woman
Geography area	National
Detail of the geography area	Metropolitan France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2012
Date of last collection (YYYY or MM/YYYY)	2019

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	5 756 patients and 2 375 donors as of August, 31 2019
Data	
Database activity	Current data collection
Type of data collected	Clinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	transplant type and date / relapse / graft failure / second transplant / stages and corticoresistance for the acute GvHD / type, classification and evolution of the chronic GvHD
Biological data (detail)	Blood samples
Presence of a biobank	Yes
Contents of biobank	Plasma Blood cells isolated Others
Details of biobank content	Viable mononuclear cells, plasma, and dried cell pellets
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Data collection method	Data are collected via a unique document filled in as the time of blood samples by the transplant units staff in charge of the patient medical follow-up.
Quality procedure(s) used	Sampling and sending / blood samples reception and processing
Participant monitoring	Yes
Details on monitoring of participants	Duration of CryoStem: 7 years (inclusion: 6 years)
Links to administrative sources	No
Promotion and access	

Promotion	
Description	The first publications have been submitted during the summer 2019.
Other information	The embargo on the CRYOSTEM samples has ended on 2015/04/15. Since 2015, and as of August, 31 2019, almost 7 000 samples have been provided to 10 research projects on GvHD and HSCT complications.
Access	
Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	Any investigator selected by CRYOSTEM Scientific Committee commits himself to respect the general terms of the current call of projects to access the collection biological resources. The investigator could access to demographical and clinical information, extracted from the European register of the EBMT (European Society for Blood and Marrow Transplantation), provided via an Excel file made anonymous. Once selected, CRYOSTEM project managers schedule interviews with the investigators in order to identify and select the samples of interest. The delay of provision depend on the number of the samples waited for.
Access to aggregated data	Access on specific project only

Access on specific project only

Access to individual data