Canadian Blood Services
Société canadienne du sang

Heart Data Working Group Report

September 29, 2015

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Letter of Introduction

One of the strategic objectives of Canadian Blood Services is to leverage the organization's services, tools, expertise and knowledge in, support of the national effort to improve patient outcomes. In alignment with this objective is the effort undertaken by the Organ Donation and Transplantation (ODT) Data Working Groups to build on a vision, defined by the Canadian Council for Donation and Transplantation (CCDT) in collaboration with the ODT community, for an integrated information system where, *"Every Canadian who needs a transplant has equitable and timely access to safe tissues and organs, and every Canadian who wishes to donate is optimally supported so donation is compassionate, safe and efficient."* (Information Management Blueprint, CCDT April 25, 2007).

Accurate, relevant and timely data is a critical enabler of a better information management system and Canadian Blood Services is proud to work with its national and provincial partners to continue evolving the CCDT vision, a vision that was further articulated at the June 2013 ODT Data, Analytics and Reporting System Workshop. Through the contributions made by the (ODT) Data Working Groups, we are steps closer to achieving the strategic imperative for improved, fair and transparent information management. The data identified will provide clarity for listing and allocation, organ-specific criteria which will in turn inform the evolving shared programs in the Canadian Transplant Registry (CTR).

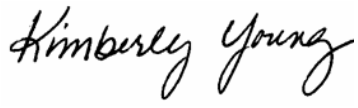
On behalf of Canadian Blood Services, we would like to thank the Heart Data Working Group (HDWG) members for their participation. This effort represents an important step in building a national data system that will serve the needs of clinicians and researchers by facilitating clinical practice decision-making, developing standards, and informing outcomes reporting for Heart transplantation in Canada. It builds on work done previously by the CCDT, which included forums to consult with health professionals and other stakeholders on best practices in listing and allocation of organs.

The report begins with a description of the objectives of the HDWG, including the scope, guiding principles, key considerations and the process followed by the group to arrive at a minimum data set. Chapter Seven of the report provides a summary of the recommendations and emerging issues that will be forwarded to the Heart Transplant Advisory Committee (HTAC). Subsequent chapters, still in development, will be released in the coming months and will outline how the data identified in the minimum data set will be collected, validated, measured, accessed, and audited.

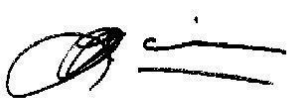
Future work involves laying the fundamental building blocks of the new data system. Using this report, and the final reports of all ODT Data Working Groups, the following initiatives will be undertaken:

- communication of the report contents with ODT Operational groups and committees
- consolidation of the minimum data sets from all data working groups
- enhancement of the CTR to include the new data
- modification of existing data feeds, the development of new feeds or the implementation of CTR links with other data repositories
- implementation of data collection projects
- creation/revision of inter-provincial organ-sharing policies
- development of a process for accessing the CTR data system for research purposes
- implementation of standard data reviews
- establishment of regular performance and audit measures

Our work has just begun. We look forward to the opportunity to continue working together in key stakeholder groups to further advance this important initiative.



Kimberly Young, Director,
Donation and Transplantation



Kathryn Tinckam, Medical Advisor,
Transplantation

September 29, 2015

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1. Acronyms

CCTN	Canadian Cardiac Transplant Network
CORR	Canadian Organ Replacement Register
CTR	Canadian Transplant Registry
DAAC	Data & Analytics Advisory Committee
DDAC	Deceased Donation Advisory Committee
DDDWG	Deceased Donor Data Working Group
DTAAC	Donation and Transplantation Administrators Advisory Committee
HDWG	Heart Data Working Group
IMACS	Mechanically Assisted Circulatory Support Registry
INTERMACS	Interagency Registry for Mechanically Assisted Circulatory Support
ISAC	Information Strategy Advisory Committee
ISHLT	International Society for Heart & Lung Transplantation
NHSBT	National Health Services Blood and Transplant
NORPAC	National Organ Registry Privacy Advisory Committee
ODT	Organ Donation Transplantation
ODTEAC	Organ Donation & Transplantation Expert Advisory Committee
UNOS	United Network of Organ Sharing

2. Background

The Heart Data Working Group (HDWG) was convened by Canadian Blood Services in collaboration with the Canadian Cardiac Transplant Network (CCTN) in October 2013. Canadian Blood Services is responding to the vision articulated in 2007, and revisited at the June 2013 ODT Data, Analytics and Reporting System Workshop, to build a world-leading data system that provides timely access to high quality ODT information for patient care, system management, transplant measurement, outcome reporting and accountability.

The provincial and territorial governments have funded Canadian Blood Services to continue to lead the development and operation of the Canadian Transplant Registry (CTR). The national registry system includes a data warehouse with business intelligence tools that provide accurate, timely and comprehensive data to support research, measurement, and the modeling and analytical needs of the Canadian organ donation and transplantation community.

The objective of the HDWG is to develop a national heart transplant data set that will support and facilitate:

1. A comprehensive data warehouse inclusive of both adult and pediatric patients
2. Interprovincial policies, standards of practice and evidence-based research with respect to heart listing and allocation
3. Clinical practice decision-making and research
4. Outcomes reporting for heart transplantation in Canada

The report recommends a national heart data set to be incorporated in a pan-Canadian organ donation and transplantation system; and advises on the development of data, analytics and reporting for heart transplantation in Canada. In addition, it summarizes key considerations and activities of the HDWG. The report will be presented and discussed at the CCTN annual business meeting and Information Strategy Advisory Committee (ISAC). This will be followed by further discussions with key stakeholder groups.

3. Scope of the Data Working Group

The HDWG's scope encompasses matters related to inter-provincial heart transplant practices, including documentation of listing and allocation practices, donor and recipient information, and heart transplant outcomes in support of the CTR. To contribute to the data needs that will inform clinical decisions and support clinical research with respect to heart transplantation and outcomes reporting, the HDWG will:

1. Develop a minimum data set for heart transplantation to support clinical decisions and research, with regards to heart waitlist outcomes, heart transplant activity, heart transplant outcomes, and mechanical circulatory support use and outcomes;

2. Identify data points along the heart donation, allocation and transplant critical path;

3. Develop a quality control strategy to assess the quality and completeness of data submissions to the registry; and

4. Identify the availability, gaps, and comparability of current data systems amongst heart transplant programs.

4. Principles

Building on the vision developed by CCDT in collaboration with the ODT community for better information management across Canada's OTDT System, Canadian Blood Services, in support of its role to lead the development and operation of the CTR and its shared programs, is committed to re-affirming the direction set for this vision and to continue to evolve a national information management network. This vision was further articulated at the June 2013 ODT Data, Analytics and Reporting System Workshop, at which a set of guiding principles for data was proposed that will promote accurate, timely and valid data which will move us closer to greater transparency in information management. The HDWG focused on these principles to guide it through the development of a national data set and assist it with the recommendations presented in this report. The principles are as follows:

1. Primarily, adopt the eight guiding principles for national organ transplant and donation data management as recommended by the participants of the June 2013 Data Analytics and Reporting System Workshop. The guiding principles focus on:
    a. Governance
    b. Data Scope
    c. Data Compliance
    d. Data Standardization
    e. Data Quality
    f. Data Stewardship
    g. Data Accessibility
    h. System Efficiency

In addition to the guiding principles listed above, the HDWG expanded its list of guiding principles to encompass elements specific to its scope of developing a national minimum data set for heart transplantation:

2. Data collection will be instrumental in advancing scientific evidence-based healthcare.

3. Data chosen for the national data set is meaningful, comparable, measurable and unambiguous, making data collection easy for data collectors.

4. The minimum data set will support data sharing and satisfy international data contributions.

5. The national data set will provide guidance on data definitions and interpretations where national data standardization is required. It will serve as a national minimal data platform, while provincial data sets can include additional data.

6. The HDWG will ensure that the national data set lends itself to national and international benchmarking by Transplant Programs.

5. Key Considerations

During the development of the national minimum data set, the HDWG made note of the following considerations:

1. The changes required as a result of the recommended national data set will impact Transplant Program data collection and reporting processes.

2. There is a definite financial impact to stakeholders due to the need for increased resources, infrastructure and development of requirements necessary to support the recommended data collection and data linkages between systems.

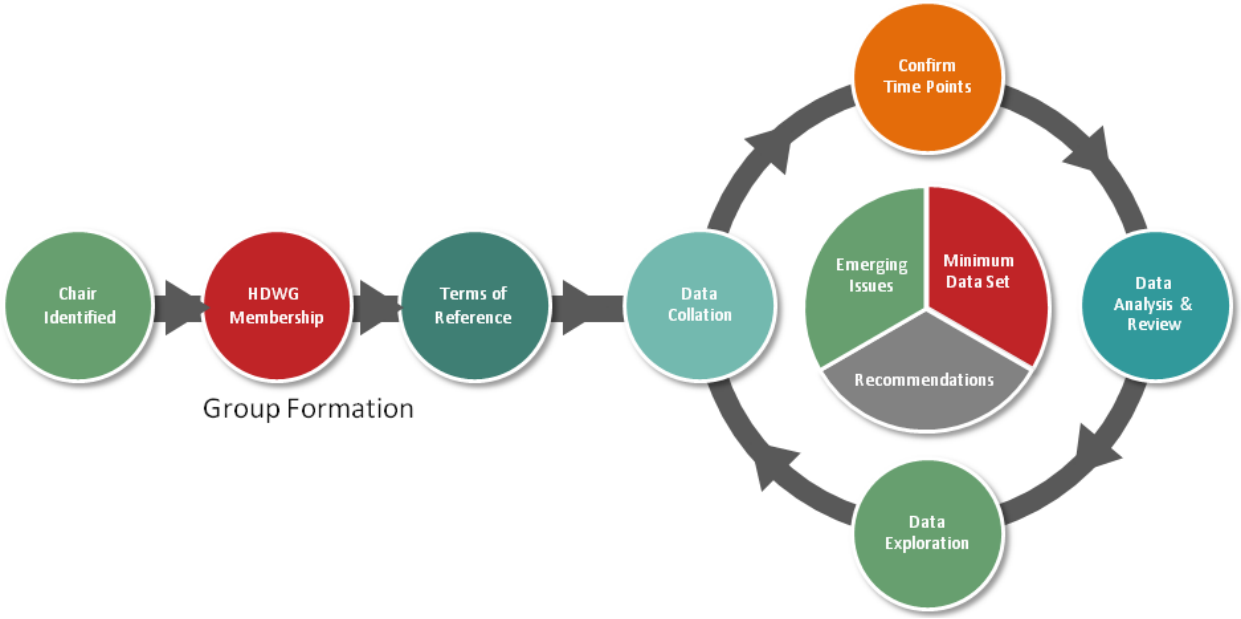
3. There is an opportunity to satisfy international data commitments through a consolidated approach to the minimum data set that would reduce workload and data burden on registry support.

4. The data set considers national practices and the data needs of all health care professionals involved on the patient critical pathway.

5. The transplant and donation community is working towards a national data, analytics and reporting system that will benefit Heart Transplantation, Mechanical Circulatory Support and Heart Failure care in Canada.

6. Process

The diagram below outlines the basic process methodolgy adopted by the group.



6.1 Group Formation

The Chair of the Data Working Group was appointed by Canadian Blood Services and CCTN. Canadian Blood Services met with the Chair to discuss the objectives and scope of the HDWG. As part of group formation, members selected had different medical professional backgrounds (i.e. surgical, nursing, and pediatric). Once members of the HDWG were identified, an initial face-to-face meeting was convened to agree on the terms of reference and approach which the working group would take to achieve its scope. The HDWG informed Canadian Blood Services regarding the data sources it would analyze and review. Monthly teleconference meetings were set up in collaboration with Canadian Blood Services to discuss emerging issues, recommendations and gain expertise from other knowledge areas such as HLA.

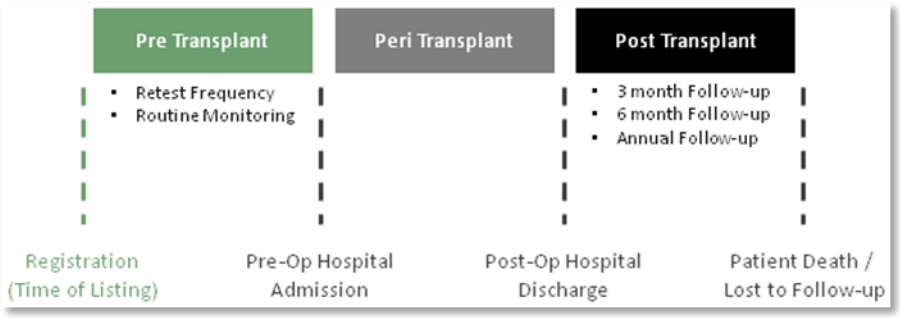
6.2 Data Collation

In order to best inform cardiac transplant reporting practices, Canadian Blood Services developed an assessment of other transplant registries from the international community. The outcome of this assessment was an Environmental Scan, containing data elements captured in the CTR and other transplant registries. This provided the group with perspective on what mature registries are collecting and helped inform what elements might be missing from the CTR. Secondly, there are some organ-specific organizations that perform detailed data collection that might be facilitated by the CTR in the future, and this review process presented an excellent opportunity to capture these data needs as well. The following sources were utilized as comparators by the HDWG:

1. Canadian Organ Replacement Register (CORR) - Canada
2. National Health Services Blood and Transplant (NHSBT) – United Kingdom
3. United Network of Organ Sharing (UNOS)- United States of America
4. International Society for Heart & Lung Transplantation (ISHLT)
5. ISHLT Mechanically Assisted Circulatory Support Registry (IMACS)
6. Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)

6.3 Time Point Definition

In the interest of consistency and thoroughness, a detailed timeline was necessary in order to ensure that all major events and data were captured at the appropriate point along the patient's critical path. The HDWG agreed on four specific time reference points to inform clinical practices and improve patient care through the transplant process. The major time points / periods are as follows:



Defining these different points is necessary in order to gain a clear understanding of the impact on both users and data systems.

Time Point	Definition	Rationale for Collection
Registration / Listing	Time when patient is activated on the transplant waiting list	Provides a snapshot of the patient information at time of listing.
Pre-Transplant	From time of registration/listing up to pre-op hospital admission	Time range which results from routine monitoring and testing that may occur while the patient is waiting for a transplant.
Peri- Transplant	From pre-op admission date to post-op hospital discharge	Time range which includes all surgical detail and complications as well as graft function and treatment details.
Post-Transplant	From post-op hospital discharge to patient graft failure, patient lost to follow-up or patient death	Time range includes regular follow-up schedule, recommended at 3 months, 6 months and annually barring graft or immunosuppressive complications.

6.4 Data Analysis and Review

The HDWG was responsible for highlighting potential data gaps and determining what elements are required to reconcile these disparities. To accommodate the identification of data gaps, the Environmental Scan was organized along two axes: data category and time point (chronology). This set up provided the HDWG with a detailed understanding of what elements are currently collected in the CTR for different data categories (see Appendix B for details) at each major time point from registration through to follow-up. This framework, coupled with indicators of what other major international registries and other pertinent cardiac community organizations are collecting, provided the HDWG with the means to perform a detailed scan of the various data areas and bolster the element list where needed.

The identification of data gaps, while not formally documented, is indicated in the environmental scan, where new data fields were added, modified or expanded.

The HDWG employed an iterative review approach, in order to refine the data set and ensure that all aspects of the recipient's critical path were captured with the appropriate level of detail.

As part of the analysis process, specific sub-areas of interest were often assigned to individual members for further independent exploration. The results were presented to the larger group for discussion, modification, approval and inclusion into the final data set.

7. Recommendations

7.1 Minimum Data Set

Appendix C contains a detailed description of the data set. It presents the data element name, description and data value(s) grouped by registration, medical history, laboratory/diagnostics, matching, surgical and outcome. For each data element, the group identified whether it was mandatory to collect the data and specified the time point(s) along the patient's critical pathway when collection is required.

7.2 Ventricular Assist Device Data

The HDWG recommends the inclusion of the VAD data set in addition to the heart data set for transplant. The HDWG recommends that VAD data fields align with the current IMACS data set to facilitate data-sharing. The VAD data set is presented in Appendix D – VAD Data.

7.3 Post-Transplant Antibody Data

Currently, there are international recommendations regarding the frequency of which post-transplant antibody data should be captured. As there are some program specific differences, the HDWG recommends that international societal standards (ISHLT) are followed.

7.4 Deceased Donor Data

The HDWG reviewed deceased donor data captured in the Canadian Transplant Registry to make recommendations on data that should be mandatory from the perspective of the heart community. In particular, the group identified data required at the time of offer acceptance. The recommended data is presented in Appendix E – Deceased Donor Data for Heart Community. This recommendation will be taken to the Deceased Donor Data Working Group (DDDWG), and will be considered as part of the development of the deceased donor minimum data set.

7.5 Time Points

The HDWG identified several key time points along that patient's critical path, and recommended that certain elements be collected at predetermined points along this timeline (See Appendix C for details). It is the recommendation of the HDWG that these time points and related data gathering practices be adopted nationally for cardiac transplant patient data.

7.6 Quality Control Strategy

Part of the HDWG's scope was to develop a data control strategy by which the quality, completeness, and accuracy of data submissions would be assessed and measured. To help inform the group's strategy recommendations, the HDWG reviewed the outcomes of the Data, Analytics and Reporting Systems Workshop where the Information Strategy Advisory Committee (ISAC) outlined a national guiding principle for data quality:

- *High data quality (accurate, reliable, complete, and timely) is paramount to achieving a trusted system from informed decision making.*
- *Data should be validated at multiple levels to ensure quality (e.g., audits, cross-validation through existing data-sets, checks when entering data, essential data quality recognized at data entry).*

Furthermore the HDWG was presented with the Data Quality Framework, as developed by the Canadian Organ Replacement Register (CORR):

> *CIHI's Data Quality Framework (2009) sets out an approach to systematically assess, document and improve data quality for all of our data holdings. This framework is based on the five dimensions of quality and helps us identify both strengths and limitations in our data. After the assessment, we identify how to improve the data, and we provide documentation to help users determine whether the data meets their needs and, if so, how to use it appropriately.*
>
> *Dimensions of data quality*
>
> - *CIHI uses five dimensions to define data and information quality:*
> - *Accuracy—How well information from a data holding reflects the reality it was designed to measure*
> - *Timeliness—How current the data is at the time of release*
> - *Comparability—The extent to which a data holding is consistent over time and collects data in a way similar to other data holdings*
> - *Usability—The ease with which data can be accessed and understood*
> - *Relevance—The degree to which a data holding meets users' current and potential future needs*

It is the recommendation of the HDWG that the Canadian Cardiac Transplantation Network (CCTN) and the ISAC endorse the CORR Data Quality Framework as a starting philosophy for data quality management.

Source: Canadian Organ Replacement Register 2014, http://www.cihi.ca/CIHI-ext-portal/internet/en/tabbedcontent/standards+and+data+submission/data+quality/cihi021513#_Data_Quality_Framework

7.7 Emerging Issues

The HDWG identified several issues that they felt were important and should be brought to the attention of the ISAC as items that will require ongoing discussions and development within the CTR. These emerging issues are as follows:

Emerging Issues	Comment	Recommendation
Data Linkages	1. Enabling data links with Vital Statistics to track death. 2. Supporting existing provincial data infrastructure 3. Creation of data-linkages with international existing databases (i.e. ISHLT and IMACS).	Work with IMACS, ISHLT, CIHI, Vital Statistics
Quality of Life Measure	Recognized as an important data to capture and track in the CTR. Requires development or agreement on currently utilized validated QoL measure. This requires consulting experts in the area and consensus on a standard measure (possible opportunity to develop a standard measure).	Take to ISAC
Re-admission Data	Linkage with provincial data systems to auto-capture these events are ideal rather than creation of individual organ specific CTR data fields. This will be an ongoing development.	Work with CIHI
Data Capture Logistics	Personnel required for data entry.	Take to ISAC

Appendix A – Heart Data Working Group Membership

Brian Clarke, MD (Chair)	Assistant Professor, Division of Cardiology – Heart Failure and Cardiac Transplantation Dalhousie University, Queen Elizabeth II Health Science Centre Halifax
Jennifer Conway, MD	Pediatric Cardiologist University of Alberta, Stollery Children's Hospital Edmonton
Annemarie Kaan, RN MCN	Clinical Nurse Specialist – Heart Failure / Transplant St Paul's Hospital Vancouver
Shelley Zieroth, MD FRCPC	Associate Professor, Section of Cardiology St. Boniface Hospital WRHA Cardiac Sciences Program Winnipeg
Dave Nagpal, MD	Assistant Professor, Divisions of Cardiac Surgery and Critical Care Medicine Surgical Director, Advanced Heart Failure Program Adult Cardiac Surgeon and Critical Care Physician University of Western Ontario London
Sean Delaney	Associate Director, Listing and Allocation Canadian Blood Services
JoAnne Lussier-True	Sr. Program Manager, Listing and Allocation Canadian Blood Services
Machi Danha	Program Manager, Listing and Allocation Canadian Blood Services
Nick Lahaie	Data Analyst, CODTN Data, Analytics & System Reporting Canadian Blood Services

Appendix B – Heart National Data Set

The HDWG is recommending a national data set of 179 mandatory fields (101 new), 83 optional fields (54 new) and 52 calculated fields (3 new) for a total of 315 distinct data elements.

Heart Data Working Group Data Set Recommendation Summary

	Total	● New Fields	● Modified	● No Change
All Fields	**314**	**158**	**26**	**130**
Mandatory	**179**	101	22	56
Calculated	**52**	3	2	47
Optional	**83**	54	2	27

Appendix B lists the recommended data elements being proposed by the HDWG, grouped for the critical path time points outlined in the Process section of this document:

1. Referral (R)
2. Registration / Listing (L)
3. Pre-Transplant (PR)
4. Peri-transplant (PE)
5. Post-transplant (PO)

Beside each element is a letter (M, O or C). These letters indicate whether HDWG is proposing the element as Mandatory (M), Optional (O) or Calculated (C). Where necessary a brief description of the element is included below the element name in italics. Each element is listed with a colour indicator. These indicators help demonstrate potential resource impact, both from system design and maintenance perspective as well as a data collection requirement.

● indicates existing mandatory, optional or calculated data elements that will require no change to system function or data collection requirements.

● indicates existing mandatory, optional or calculated data elements that will require some change to system function or data collection requirements. Typically these indicate fields that have shifted from optional collection to mandatory collection. Though they will have minor impact on system design, the majority of the impact will be on the data collection resources required to collect this data.

● indicates new mandatory, optional or calculated elements that will have both system design impact as well as data collection implications.

P These are data elements used to record data elements that only pertain to pediatric patient records

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Registration							
	Identifying Information							
●	Date of Birth	Date of birth of patient.	Date	≤ current date	M			
●	First Name	First name of patient.	Name	≤ 50 characters	M			
●	Middle Name	Middle name of patient.	Name	≤ 50 characters	O			
●	Last Name	Last name of patient.	Name	≤ 50 characters	M			
●	Former Last Name	Former last name of patient.	Name	≤ 50 characters	O			
●	Local Recipient ID	Unique local identifier provided by local Transplant Program.	Identifier	≤ 50 characters	O			
●	National Recipient ID	Unique national identifier created by the Registry.	Identifier	n/a	C			
●	PHN	Provincial health number of patient.	Identifier	≤ 50 characters. If patient has a PHN then PHN and PHN Province are required.	M			
●	PHN/Home/Listing Province	Province associated to PHN or Home or Listing province of patient.	Alberta British Columbia Manitoba New Brunswick, Newfoundland & Labrador Northwest Territories Nova Scotia Nunavut Ontario Prince Edward Island Quebec, Saskatchewan Yukon	If patient has a PHN then PHN and PHN province are required. If patient does not have a PHN then another government health identifier and Home province are required. If patient's home is out of country then Listing province is required.	M			

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Contact Information							
●	Address	Address where patient can be contacted by Transplant Program. This could be a temporary address.	Address line 1 and 2	≤ 70 characters	M	M		
●	City	City associated to patient's address where they can be contacted.	City	≤ 70 characters	O	O		
●	Postal Code	Postal code associated to patient's address where they can be contacted.	Postal code	Format must be X9X 9X9	M	M		
●	Province	Province associated to patient's address where they can be contacted.	Alberta British Columbia Manitoba New Brunswick Newfoundland and Labrador Northwest Territories Nova Scotia Nunavut Ontario Prince Edward Island Quebec Saskatchewan Yukon Not Applicable	Single selection list	M	M		
	Demographics							
	Body Metrics							
●	Age	Age of patient.	Age in years, months, weeks	Calculated by the system based on Date of Birth.	C			
●	Gender	Gender of patient.	Male Female Other Unknown	Single selection list	M			
●	Height	Height of patient.	cm	If in-utero=no then this data must be 0.0 to 300.0. Else if in-utero=yes then this data is not required to be entered.	M			

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Weight	Weight of patient.	kg	If in-utero=no then this data must be 0.0 to 700.0. Else if in-utero=yes then this data is not required to be entered.	M			
●	BMI	Body mass index of patient.	Numeric	BMI = weight(kg)/ (height(m) * height(m))	C			
●	BSA	Body surface area of patient.	Numeric	BSA = square root of (height * weight / 3600)	C			
●	ABO	Blood group of patient.	A B AB O unknown	Initially ABO may be unknown.	M			
●	Confirm ABO	Confirm blood group of patient.	Free text entry	≤ 4 characters	M			
●	RH	RH of patient.	+ -	Single selection list	O			
●	Confirm RH	Confirm RH of patient.	Free text entry	≤ 4 characters	O			
●	In-utero	Flag indicating if patient is not yet born.	Yes No	n/a	M			
	Social Details							
●	Citizenship	Citizenship of patient.	List of countries	Multiple selection list		M		
●	Country of Residence	Country where patient is currently living.	List of countries	Single selection list		M		

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Ethnicity	Ethnicity of patient.	Aboriginal Black Caucasian Indian subcontinent Latin American Middle Eastern/Arabian Pacific Islander Other/Multicultural Unknown	Single selection list	O			
	Highest Educational Level	Highest educational level of primary care giver and patient.	None Grade 1-6 Grade 7-12 High School Diploma University Undergraduate Degree University Graduate Degree Community College or Vocational Program	Single selection list		O		O
P	Academic Activity Level	Pediatric patient's academic activity level.	Full Academic Load Reduced Academic Load Unable to Participate in Academic due to Disease / Condition Not Applicable < 5 Years Old / High School Graduate / GED Status Unknown	Single selection list. Pediatric patients only.		O		O
P	Academic Progress	Pediatric patient's academic progress.	Within One Grade Level of Peers Delayed Grade Level Special Education Not Applicable < 5 Years Old / High School Graduate / GED Status Unknown	Single selection list. Pediatric patients only.		O		O
	Working for Income	Working for income of primary care giver and patient.	<20,000/year 20-50,000/year 50-100,000/year >100,000/year Not Working, Unknown	Single selection list	O	O	O	O

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Reason Not Working For Income	Reason not working for income for patient.	Disability Inability to Find Work Patient Choice, Unknown	If patient not working for income then reason is required.	O	O	O	O
●	Alcohol Abuse	Flag indicating if patient has a history of alcohol abuse.	Yes No Unknown	n/a	M	M	M	M
●	Smoker	Flag indicating if a patient has a history of smoking.	Yes (Current) Yes (Ex-Smoker) No Unknown	Single selection list	M	M	M	M
●	Cigarette Per Day	Number of cigarettes per day.	Number of days	If smoker = yes then cigarette per day required.	O			
●	Ex-Smoker-Duration of Abstinence		0-2 month 3-12 months 13-24 months 25-36 months 37-48 months 49-60 months >60 months Unknown	Single selection list. If smoker = Yes (Ex-Smoker) then duration of abstinence required.	O			
●	Drug Abuse	Flag indicating if patient has a history of drug abuse.	Yes No Unknown	n/a	M	M	M	M
● P	Cognitive Development	Patient's cognitive development.	Definite cognitive delay/impairment Probable cognitive delay/impairment Questionable cognitive delay/impairment No cognitive delay/impairment, Not assessed	Single selection list. Pediatric patients only.	O	O	O	O
● P	Motor Development	Patient's motor development.	Definite motor delay/impairment Probable motor delay/impairment Questionable motor delay/impairment, No motor delay/impairment Not Assessed	Single selection list. Pediatric patient only.	O	O	O	O

Name	Description	Values	Data Rules	R	PR	PE	PO
Physical Capacity	Patient's physical capacity.	No Limitations Limited Mobility Wheelchair Bound or More Limited Not Applicable (<1 year old or Hospitalized) Unknown	n/a	O	O	O	O
Marital Status	Patient's marital status.	Single Married Domestic Partners Divorced/Separated Widowed Unknown	n/a	O	O	O	O
Treating Facilities							
Transplant Centre	Centre responsible for providing transplant surgery.	List of Transplant Centres	Single selection list	M		M	
Referral Centre	Centre that assesses/monitors patients before transplant, but does not perform the transplant for the specific organ request (e.g. St John's, Regina). A Transplant Centre may be a Referral Centre for patients of organs for which it does not perform transplants.	List of Transplant Centres and Referral Centres	Single selection list	M			
Follow Up Centre	Centre where primary post - transplant follow up takes place. These are centres which are responsible for pre-transplant and post-transplant care but actual transplant is carried out by a Transplant Centre.	List of Transplant and Referral Centres	Single selection list	M		M	M
HLA Lab	HLA Lab responsible for providing HLA Typing and Antibody Screening results on patient.	List of HLA Labs	Single selection list. Derived by system based on associated Transplant Centre.	M			M
ODO	Organ Donation Organization associated to patient's Transplant Centre	List of ODOs	Single selection list. Derived by system based on associated Transplant Centre.	M			

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Consent							
●	Consent to be in Registry	Date consent to be in CBS registry obtained. If this date is not entered then identifiable patient information must not be shared.	Date	≤ current date Entered by Canadian Blood Services Customer Solutions only. Conditional mandatory – patients can be listed before written consent received by Canadian Blood Services.	M			
●	Consent Received by CBS	Consent Form has been received by CBS.	Yes No	Entered by Canadian Blood Services Customer Solutions only. Conditional mandatory – patients can be listed before written consent received by Canadian Blood Services.	M			
●	Registry Entry Date/Time	Date and time patient record created in registry.	Date and time	n/a	C			
●	Withdrew Consent	Date and time patient has withdrawn consent to be in the registry.	Date and time	If consent is withdrawn then patient record is locked.	O			
	Organ Request							
●	Organ Requested	Organ requested for transplant (single or multiple) at time of registration. A patient can have multiple organ requests over time .i.e. one in 1970 and another in 1990.	Heart Lung Liver Pancreas Kidney Small Bowel Stomach	Multiple selection list	M			
●	Organ Request State	State of patient's readiness to accept an organ offer.	New File Active On Hold Off List	For each organ requested one state is required.	M			

Name	Description	Values	Data Rules	R	PR	PE	PO
Organ Request State Reason	Reason for recipient organ request state change i.e. reason changed from Active to On Hold.	On Hold Reasons: Improving, Medical Issue (s) Not Available (away) Pending Investigations Potential LDPE Transplant Psychosocial Issue (s) Too Sick Other Off List Reasons: Improved Patient Choice Too Sick for Transplant Unsuitable for Transplant – medical reasons Unsuitable for Transplant – psychosocial Deceased Withdrew Consent Duplicate Cancelled Unlocked Created in Error Other	For each organ requested, one reason is required if state = On Hold or Off List.	O			
Organ Request State Change Date/Time	Date and Time Organ Request State is updated in registry.	Date and time	n/a	C			
List Date/Time	Date and time patient is listed.	Date and time	≤ current date/time. ≥ (date of birth - 1 year).	M			
Wait Time	Time patient on waitlist (in days) Starting from first date with a status of “1” or higher.	Days	n/a	C			
Organ Medical Status	Medical status of patient with respect to organ requested.	Heart Medical Status : 4 4S 3.5 3 2 1 0	n/a	M		M	

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Medical Status Change Date/Time	Date and time medical status is updated in the registry.	Date and time	n/a	C			
	Status 4 CCTN Review	Flag to indicate that every status 4 patient has been reviewed, at CCTN annual business meeting.	Yes No	Associated to each status 4 heart patient.		O		
	Urgent/Not Urgent Status	Urgency of medical status.	Urgent Non Urgent	The following are urgent statuses: Heart Medical Status: 4, 4S Liver Medical Status: 4F, 3F	C			
	Transplant Type	The type of transplant requested i.e. Heart, combined Heart-Other.	Single Multiple Same Donor Multiple	Single selection list	O			
	Medical History							
	Past Medical History							
	Patient on Dialysis	Flag indicating if patient is on dialysis.	Yes No	n/a	M		M	M
	Most Recent Dialysis Start Date	Patient's most recent dialysis start date.	Date	≤ current date. If patient on dialysis = yes then date is required.	M		M	M
	Time on Dialysis (days)	Duration of time patient has been on dialysis.	Days	Calculated into days based on Most Recent Dialysis Start Date.	C		C	C
	Diabetes	Flag indicating if patient has diabetes.	Yes No Unknown	n/a	M		M	M
	Insulin Dependent	Flag indicating if patient is insulin dependent.	Yes No Unknown	If diabetes = yes then insulin dependency is required.	M		M	M
	Previous Cardiac Surgery	Flag indicating if patient has previous cardiac surgery.	Yes No Unknown	If yes then specify type of previous cardiac surgery.	M			
	Type of Previous Cardiac Surgery		CABG Valve Replacement / Repair Congenital Left Ventricular Remodeling Other	Single selection list. If 'other' selected then the surgery must be specified.	M			

Name	Description	Values	Data Rules	R	PR	PE	PO
Previous Congenital Cardiac Surgery	Flag indicating if patient has previous congenital cardiac surgery.	Yes No Unknown	If yes then specify details.	M			
Prior CRT-D, CRT or ICD		Yes No Unknown	n/a	M			
Renal Dysfunction	Flag indicating if patient had renal dysfunction.	Yes No Unknown	n/a	M		M	M
Previous Malignancy	Flag indicating if patient had previous malignancy.	Yes No Unknown	If yes then specify all that apply: Skin Melanoma Skin Non-Melanoma CNS Tumour Genitourinary Breast Thyroid Tongue/Throat/Larynx Lung Leukemia/Lymphoma Liver Hepatocellular Carcinoma, Other-please specify	M			
Previous Pregnancies	Number of previous pregnancies.	Number	≤ 20	M			
Cerebrovascular Disease	Flag indicating if patient has cerebrovascular disease.	Yes No Unknown	n/a		M		M
Congenital Disease	Flag indicating if patient has congenital disease.	Yes No Unknown	n/a		M		
Hyperlipidemia	Flag indicating if patient has hyperlipidemia.	Yes No Unknown	n/a		M		M
Hypertension	Flag indicating if patient has hypertension.	Yes No Unknown	n/a		M		M

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	COPD	Flag indicating if patient has COPD.	Yes No Unknown	n/a		M		M
●	Renal Dysfunction, Serum Creatinine >200 mmol/L	Flag indicating if patient has renal dysfunction, Serum Creatinine >200 mmol/L.	Yes No Unknown	n/a		M	M	M
●	Ischemic Heart Disease	Flag indicating if patient has ischemic heart disease.	Yes No Unknown	n/a		M	M	M
●	Malignancy	Flag indicating if patient has an existing malignancy and type of malignancy.	Yes No Unknown	If yes then specify all that apply: Skin Melanoma Skin Non-Melanoma CNS Tumour Genitourinary Breast Thyroid Tongue/Throat/Larynx Lung Leukemia/Lymphoma Liver Hepatocellular Carcinoma Other - please specify				M
●	Malignancy Diagnosis Date	Date of each malignancy diagnosis specified.	Date	≤ current date. For each malignancy that is specified a date is required.				M
●	Malignancy De Novo Tumour	Flag indicating patient has Malignancy De Novo Tumour.	Yes No Unknown	n/a				M
●	Malignancy Donor Related	Flag indicating patient has Malignancy Donor Related.	Yes No Unknown	n/a				M
●	Malignancy, Recurrence of Pre-Transplant Tumour	Flag indicating patient has Malignancy, Recurrence of Pre-Transplant Tumour.	Yes No Unknown	n/a				M

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Malignancy De Novo Lymphoproliferative Disease and Lymphoma	Flag indicating Malignancy De Novo Lymphoprofilerative Disease and Lymphoma.	Yes No Unknown	n/a				M
	Diagnoses							
	Organ Primary Diagnosis	The diagnosis that is chiefly responsible for cause of organ failure.	Dilated Myopathy: Idiopathic Dilated Myopathy: Adriamycin Dilated Myopathy: Post-Partum Dilated Myopathy: Familial Dilated Myopathy: Myocarditis Dilated Myopathy: Alcoholic Dilated Myopathy: Viral Dilated Myopathy: Ischemic Dilated Myopathy: Other Specify Restrictive Myopathy: Idiopathic Restrictive Myopathy: Amyloidosis Restrictive Myopathy: Endocardial Fibros Restrictive Myopathy: Sarcoidosis Restrictive Myopathy: Sec To Radiat/Chem Restrictive Myopathy: Other Specify Heart Re-Tx/Gf: Hyperacute Rejection Heart Re-Tx/Gf: Acute Rejection Heart Re-Tx/Gf: Coronary Artery Disease Heart Re-Tx/Gf: Non-Specific Heart Re-Tx/Gf: Restrictive/Constrictive Heart Re-Tx/Gf: Chronic Rejection Heart Re-Tx/Gf: Primary Failure Heart Re-Tx/Gf: Other Specify Coronary Artery Disease Hypertrophic Cardiomyopathy Valvular Heart Disease Congenital Heart Defect - Prior Surgery Unknown Cancer Congenital Heart Defect - Hypoplastic Left Heart Syndrome - Unoperated Congenital Heart Defect - Without Surgery	Single selection list	M			

Name	Description	Values	Data Rules	R	PR	PE	PO
		Congenital Heart Defect - With Surgery Eisenmenger's Syn: Atrial Septal Defec Eisenmenger's Syn: VSD Eisenmenger's Syn: PDA Eisenmenger's Syn: Multi Congenital Anom Eisenmenger's Syn: Other Specify Sarcoidosis					
Organ Secondary Diagnosis	The diagnosis that coexists with the primary diagnosis.	Dilated Myopathy: Idiopathic Dilated Myopathy: Adriamycin Dilated Myopathy: Post-Partum Dilated Myopathy: Familial Dilated Myopathy: Myocarditis Dilated Myopathy: Alcoholic Dilated Myopathy: Viral Dilated Myopathy: Ischemic Dilated Myopathy: Other Specify Restrictive Myopathy: Idiopathic Restrictive Myopathy: Amyloidosis Restrictive Myopathy: Endocardial Fibros Restrictive Myopathy: Sarcoidosis Restrictive Myopathy: Sec To Radiat/Chem Restrictive Myopathy: Other Specify Heart Re-Tx/Gf: Hyperacute Rejection Heart Re-Tx/Gf: Acute Rejection Heart Re-Tx/Gf: Coronary Artery Disease Heart Re-Tx/Gf: Non-Specific Heart Re-Tx/Gf: Restrictive/Constrictive Heart Re-Tx/Gf: Chronic Rejection Heart Re-Tx/Gf: Primary Failure Heart Re-Tx/Gf: Other Specify Coronary Artery Disease Hypertrophic Cardiomyopathy Valvular Heart Disease Congenital Heart Defect - Prior Surgery Unknown Cancer Congenital Heart Defect - Hypoplastic Left	Single selection list	O			

Name	Description	Values	Data Rules	R	PR	PE	PO
		Heart Syndrome - Unoperated Congenital Heart Defect - Without Surgery Congenital Heart Defect - With Surgery Eisenmenger's Syn: Atrial Septal Defec Eisenmenger's Syn: VSD Eisenmenger's Syn: PDA Eisenmenger's Syn: Multi Congenital Anom Eisenmenger's Syn: Other Specify Sarcoidosis					
Organ Tertiary Diagnosis	The diagnosis that coexists with the primary diagnosis.	Dilated Myopathy: Idiopathic Dilated Myopathy: Adriamycin Dilated Myopathy: Post-Partum Dilated Myopathy: Familial Dilated Myopathy: Myocarditis Dilated Myopathy: Alcoholic Dilated Myopathy: Viral Dilated Myopathy: Ischemic Dilated Myopathy: Other Specify Restrictive Myopathy: Idiopathic Restrictive Myopathy: Amyloidosis Restrictive Myopathy: Endocardial Fibros Restrictive Myopathy: Sarcoidosis Restrictive Myopathy: Sec To Radiat/Chem Restrictive Myopathy: Other Specify Heart Re-Tx/Gf: Hyperacute Rejection Heart Re-Tx/Gf: Acute Rejection Heart Re-Tx/Gf: Coronary Artery Disease Heart Re-Tx/Gf: Non-Specific Heart Re-Tx/Gf: Restrictive/Constrictive Heart Re-Tx/Gf: Chronic Rejection Heart Re-Tx/Gf: Primary Failure Heart Re-Tx/Gf: Other Specify Coronary Artery Disease Hypertrophic Cardiomyopathy Valvular Heart Disease Congenital Heart Defect - Prior Surgery Unknown	Single selection list	O			

Name	Description	Values	Data Rules	R	PR	PE	PO
		Cancer Congenital Heart Defect - Hypoplastic Left Heart Syndrome - Unoperated Congenital Heart Defect - Without Surgery Congenital Heart Defect - With Surgery Eisenmenger's Syn: Atrial Septal Defec Eisenmenger's Syn: VSD Eisenmenger's Syn: PDA Eisenmenger's Syn: Multi Congenital Anom Eisenmenger's Syn: Other Specify Sarcoidosis					
Previous Transplant							
Date of previous transplant		Date	≤ current date. When transplant recorded in registry then this is derived by registry. Each patient requires the ability to record multiple dates.	M			
Organ Previously Transplanted		Heart Lung Liver Pancreas Kidney Small Bowel Stomach	Single selection list	M			

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Organ Type of Previous Transplant		Right Lung Left Lung Double Lung Whole Liver Left Lobe Liver Right Lobe Liver Whole Pancreas Islets Segment 1 Segment 2 Right Kidney Left Kidney En Bloc Kidney Double Kidney	Single selection list	O			
	Infections							
●	Date of infection	Date infection identified.	Date	≤ current date. For every infection date recorded specify whether patient has an infection. If infection exists then specify type, location, whether it was treated and the treatment.		O		M
●	Infection	Flag indicating if patient has an infection.	Yes No	Provide yearly		O		M
●	Infection Type	Selected infection type.	Bacterial Viral Fungal Unknown	Single selection list. For each infection type, specify the pathogen if available i.e. E.Coli.		O		M
●	Infection Location	All locations of infection.	Pulmonary Gastro-intestinal Urine Soft tissue Line-related Ophthalmologic	Multiple selection list. Provide yearly.		O		M

	Name	Description	Values	Data Rules	R	PR	PE	PO
			Other – please specify					
●	Infection Treated	Flag indicating if infection treated.	Yes No	If infection = yes then provide flag if patient treated.		O		M
●	Infection Treatment	List of treatments.	Free-text entry	If treated = yes then provide treatment.		O		M
	Laboratory / Diagnostics							
	Serology – For each serology - multiple time points can be captured - a test type must be recorded for each serology result - sample drawn date/time recorded for each result							
●	CMV	CMV result based on IgG test.	Positive Negative Indeterminate Not Tested	n/a	M			O
● P	EBV	EBV result based on any of the following tests: IgG (VCA) or IgG (EBNA), IgM.	Positive Negative Indeterminate Not Tested	Required for pediatric patient only.	M			
●	Varicella	Varicella test result based on IgG test.	Positive Negative Indeterminate Not Tested	n/a	O			
●	Hepatitis B Core Antibody	HBV result based on Anti-HBc (HBcAb) test.	Positive Negative Indeterminate Not Tested	n/a	M			
●	Hepatitis B Surface Antibody	HBV result based on Anti-HBs (HBsAb) test.	Positive Negative Indeterminate Not Tested	n/a	M			
●	Hepatitis B Surface Antigen	HBV result based on the following test: HBsAG test, NAT.	Positive Negative Indeterminate Not Tested	n/a	M			

Name	Description	Values	Data Rules	R	PR	PE	PO
Hepatitis C	HCV result based on the following tests: IgG, HCV RNA NAT, Double NAT (HIV, HCV), Triple NAT (HIV, HCV, and HBV).	Positive Negative Indeterminate Not Tested	Double NAT and Triple NAT cannot be Indeterminate. If HCV RNA NAT positive then provide viral load.	M			
HIV I and II	HIV I and II result based on any of the following tests: IgG, Antibody/p24antigen.	Positive Negative Indeterminate Not Tested	Required to have HIV I and II antibody test result and optional to provide HIV NAT.	M			
HSV	HSV test result based on IgG.	Positive Negative Indeterminate Not Tested	n/a	O			
HTLV I and II	HTLV I and II result based on IgG test.	Positive Negative Indeterminate Not Tested	n/a	O			
Syphilis	Syphilis result based on the following tests: EIA, RPR, VDRL, FTA-ABS.	Positive Negative Indeterminate Not Tested	n/a	O			
Hematology – For each hematology - multiple time points can be captured - collection date/time recorded for each result							
Hgb	Hemoglobin.	g/L	≥ 0.0 and ≤ 500.0	M			O
WBC	White Blood Cell count.	4.1-10.9*103/µL	≥ 0.0 and ≤ 99.9	M		O	O
Platelets	Platelet count.	150-400*109/L	≥ 0.0 and ≤ 999.9	O			O
INR	International normalized ratio.	Ratio	≥ 0.0 and ≤ 99.9	M			

	Name	Description	Values	Data Rules	R	PR	PE	PO
● P	Isohemagluttin;Anti A level		1 1:4 1:8 1:16 1:32 1:64 1:128 1:256 >1:256	Single selection list	M			
● P	Isohemagluttin; Anti B level		1 1:4 1:8 1:16 1:32 1:64 1:128 1:256 >1:256	Single selection list	M			
	Hemodynamics – For each hemodynamic - multiple time points can be captured - collection date/time recorded for each result							
●	PA Systolic	Pulmonary Artery Pressure Systolic.	mmHg	≥ 0 and ≤ 99	O	O	O	O
●	PA Diastolic	Pulmonary Artery Pressure Diastolic.	mmHg	≥ 0 and ≤ 99	O	O	O	O
●	PA Mean	Mean Pulmonary Artery Pressure.	mmHg	≥ 0 and ≤ 99	O	O	O	O
●	PCWP/LAP	Pulmonary Capillary Wedge Pressure.	mmHg	≥ 0.0 and ≤ 40.0	O	O	O	O
●	Cardiac Index		L/min/m2	≥ 0.0 and ≤ 20.0	O	O	O	O
●	Cardiac Output		L/min	≥ 0 and ≤ 40	O	O	O	O

Name	Description	Values	Data Rules	R	PR	PE	PO
Right ventricular pressure		mmHg	≥ 0 and ≤ 99	O	O	O	O
Right atrial pressure		mmHg	≥ 0 and ≤ 99	O	O	O	O
Chemistry – For each chemistry - multiple time points can be captured - collection date/time recorded for each result							
Alk Phos	Alkaline Phosphate.	U/L	≥ 0 and ≤ 99999		O	O	O
AST	aka SGOT.	U/L	≥ 0 and ≤ 99999	M		O	O
ALT	aka SGPT.	U/L	≥ 0 and ≤ 99999	M		O	O
GGT		U/L	≥ 0 and ≤ 9999			O	O
Total Bilirubin		µmol/L	≥ 0 and ≤ 999	M		O	O
Direct Bilirubin		µmol/L	≥ 0.0 and ≤ 50.0			O	O
Total Cholesterol		mmol/L	n/a	O			O
LDL	Low Density Lipoprotein.	mmol/L	n/a	O			O
HDL	High Density Lipoprotein.	mmol/L	n/a	O			O
Triglycerides		mg/dL	n/a	O		O	O
Albumin	Serum Albumin.	g/L	≥ 0 and ≤ 99	M		O	O
Electrolytes – For each electrolyte - multiple time points can be captured - collection date/time recorded for each result							

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	K	Serum Potassium.	mmol/L	≥ 0.0 and ≤ 20.0	M		O	O
●	Na	Serum Sodium.	mmol/L	≥ 0 and ≤ 9999	M		O	O
●	Urea	Serum Urea.	mmol/L	≥ 0.0 and ≤ 99.9	M		O	O
●	Cr	Serum Creatinine.	mmol/L	≥ 0 and ≤ 9999	M		O	M
●	Lactate	Serum Lactate.	mmol/L	≥ 0.0 and ≤ 40.0	O		O	O
	Cardiothoracic Profile							
●	LVED Dimension		mm	n/a	O	O		
●	Ejection Fraction		%	n/a	M			M
●	Cardio Pulmonary Stress Test	aka Exercise Oxygen Consumption.	ml/kg/min	n/a	O			
●	FVC_1 (L)/FVC (L)		%	n/a	O			
●	FVC		L	n/a	O			
	Renal Profile							
●	eGFR-MDRD	Estimated Glomerular Filtration Rate based on MDRD methodology.	ml/min/1.73m2	MDRD = 32788 * Serum Creatinine$^{-1.154}$ * Age at Collection Date$^{-0.203}$ * (1.212 if Black) * (0.741 if female) Note: Creatinine levels in µmol/L can be converted to mg/dL by dividing them by 88.4. The 32788 number above is equal to 186 * 88.4-1.154.	C			
●	eGFR-Schwartz	Estimated Glomerular Filtration Rate based on Schwartz	ml/min/1.73m2	Schwartz = (constant * height)/ serum creatinine	C			

Name	Description	Values	Data Rules	R	PR	PE	PO
	methodology.		Constant is 36.5 = (0.413 * 88.4).				
HLA Typing – Conditional mandatory rules - Required for 4S heart listing - Optional for all other heart listings but required for virtual cross match							
A_1	HLA typing of patient.	Molecular allele	≤ 20 characters Required for 4S heart listing. Optional for all other heart listings but required for virtual cross match.	M			
A_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
B_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
B_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
C_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
C_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DRB1_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DRB1_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DRB3_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele. Of the six text-entry fields which are available for the locus DRB3, DRB4, and DRB5, a maximum of two values may be entered, and a minimum of one value must be entered.	M			
DRB3_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			

Name	Description	Values	Data Rules	R	PR	PE	PO
DRB4_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DRB4_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DRB5_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DRB5_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DRB 3/4/5 Tested, but not present	Flag indicating if DRB3, DRB4 and DRB5 tested but not present.	Yes No	When no values are entered for DRB3, DRB4, and DRB5, and the HLA typing is to be considered complete, then indicate that DRB3, DRB4, and DRB5 were “Tested, but not present”.	M			
DPA1_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DPA1_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DPB1_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DPB1_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DQA1_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DQA1_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DQB1_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			
DQB1_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	M			

Name	Description	Values	Data Rules	R	PR	PE	PO
HLA Typing Confirmed	User confirms HLA Typing.	Yes No	Default = blank	M			
HLA Typing Confirmed By	User who confirmed HLA Typing along with date/time of confirmation.	Date/Time and User Name	n/a	C			
HLA Typing Complete Class I	System verifies HLA Typing complete for class I based on organ specific rules.	Yes No	n/a	C			
HLA Typing Complete Class II	System verifies HLA Typing complete for Class II based on organ specific rules.	Yes No	n/a	C			
HLA Typing Last Updated By	User who last updated HLA Typing along with date/time of update.	Date/Time of Update and User Name	n/a	C			
HLA Comments	General HLA comments.	Free text comments	≤ 1024 characters	O			
A_1	HLA typing of patient.	Serological equivalent	Calculated serological equivalent derived from National Canadian HLA Dictionary	C			
A_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
B_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
B_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
Bw4	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
Bw6	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
Cw_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
Cw_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
DR_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			

Name	Description	Values	Data Rules	R	PR	PE	PO
DR_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
DR52	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
DR53	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
DR51	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
DPA_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
DPA_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
DPB_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
DPB_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
DQA_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
DQA_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
DQB_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
DQB_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.	C			
Antibody Testing – Conditional mandatory rules - Required for calculated PRA and virtual cross matching							
Serum Collection Date	Date serum collected for antibody screening.	Date	≤ current date	M	M		M
Acceptable Antibody Results	HLA serum results of patient.	Acceptable antigens	Cumulative and current are captured.	M	M		M
Unacceptable Antibody Results	HLA serum results of patient.	Unacceptable antigens	Cumulative and current are captured.	M	M		M

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Indeterminate Antibody Results	HLA serum results of patient.	Indeterminate antigens	Cumulative and current are captured.	M	M		M
	Not Tested Antibody Results	HLA serum results of patient.	Not tested antigens	Cumulative and current are captured.	M	M		M
	Allele-Specific Antibody Results	HLA serum results of patient.	Allele specific antigens	Cumulative and current are captured.	M	M		M
	Antibodies Confirmed	User confirms antibody test results.	Yes No	Default = blank	M	M		M
	Antibodies Confirmed By	User who confirmed HLA Typing along with date/time of confirmation.	Date/Time and User Name	n/a	C	C		C
	PRA Results Calculation Date	Date of PRA calculation by Registry.	Date	n/a	C	C		C
	Cumulative PRA	Cumulative Class I and II calculated PRA.	Whole number percentage	n/a	C	C		C
	Cumulative PRA Class I	Cumulative Class I calculated PRA.	Whole number percentage	n/a	C	C		C
	Cumulative PRA Class II	Cumulative Class II calculated PRA.	Whole number percentage	n/a	C	C		C
	Current PRA	Current Class I and II calculated PRA.	Whole number percentage	n/a	C	C		C
	Current PRA Class I	Current Class I calculated PRA.	Whole number percentage	n/a	C	C		C
	Current PRA Class II	Current Class II calculated PRA.	Whole number percentage	n/a	C	C		C
	Treatment							
	Medications							
	Antiarrhythmics	Flag indicating use of Antiarrhythmics.	Yes No	n/a	O	O	O	O
	Anticoagulants	Flag indicating use of Anticoagulants.	Yes No	n/a	O	O	O	O
	Aspirin	Flag indicating use of Aspirin.	Yes No	n/a	O	O	O	O

Name	Description	Values	Data Rules	R	PR	PE	PO
Antihypertensives	Flag indicating use of Antihypertensives.	Yes No	n/a	O	O	O	O
Beta Blockers	Flag indicating use of Beta Blockers.	Yes No	n/a	O	O	O	O
Ace Inhibitors	Flag indicating use of Ace Inhibitors.	Yes No	n/a	O	O	O	O
Diuretics	Flag indicating use of Diuretics.	Yes No	n/a	O	O	O	O
Inhaled Nitric Oxide	Flag indicating use of Inhaled Nitric Oxide.	Yes No	n/a	M	M	M	
Inotropic Support	Flag indicating use of Inotropic Support.	Yes No	n/a	M	M	M	
Vasoconstrictor Support	Flag indicating use of Vasoconstrictor Support.	Yes No	n/a	M	M	M	
Immunosuppressive Medication - Induction	List of induction immunosuppressive medications used.	ATG Basiliximab (Simulect) Dacluzimab Other – please specify	Multiple selection list			M	
CMV Prophylaxis	Flag indicating use of CMV Prophylaxis.	Yes No Other – please specify	n/a				M
EBV Prophylaxis	Flag indicating use of EBV Prophylaxis.	Yes No Other – please specify	n/a				M
Statin	Flag indicating use of Statin.	Yes No Other – please specify	n/a				M
Septra	Flag indicating use of Septra.	Yes No Other – please specify	n/a				M
Bisphosphonate	Flag indicating use of Bisphosphonate.	Yes No Other – please specify	n/a				O

Name	Description	Values	Data Rules	R	PR	PE	PO
Matching							
Donor Acceptance Criteria							
Accept Incompatible ABO	Flag indicating transplant team is willing to accept an incompatible ABO donor.	Yes No	Default = No		O		
Accept VXM ABC Positive	Flag indicating transplant team is willing to accept positive VXM ABC.	Yes No	Default = No		O		
Accept VXM DRDQb	Flag indicating transplant team is willing to accept positive VXM DRDQb.	Yes No	Default = No		O		
Cross Match Required	Flag indicating transplant team requires actual cross match.	Yes No	Default = No		O		
Accept DCD	Flag indicating transplant team is willing to accept DCD donor.	Yes No	Default = Yes		O		
Height Max	The maximum height that transplant team is willing to accept of a donor.	cm	0.0 to 700.0		O		
Height Min	The minimum height that transplant team is willing to accept of a donor.	cm	0.0 to 700.0		O		
Min Age	The minimum age that transplant team is willing to accept of a donor.	Years	0.0 to 150.0		O		
Max Age	The maximum age that transplant team is willing to accept of a donor.	Years	0.0 to 150.0		O		
Weight Min	The minimum weight that transplant team is willing to accept of a donor.	kg	0.0 to 700.0		O		
Weight Max	The maximum weight that transplant team is willing to accept of a donor.	kg	0.0 to 700.0		O		
Accept Hepatitis B Core Antibody Positive	Flag indicating transplant team is willing to accept a Hepatitis B Core Antibody Positive donor.	Yes No	Default = No		O		

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Accept Hepatitis C Antibody Positive	Flag indicating transplant team is willing to accept a Hepatitis C Antibody Positive donor.	Yes No	Default = No		O		
●	Local Donor Only	Flag indicating transplant team is willing to accept local donor only.	Yes No	Default = No		O		
	Virtual Cross Match							
●	ABO Match Result	Blood group compatibility test between a donor and list of recipients.	Yes No	If virtual cross match run and patient's blood group exists then ABO match result provided based on the following rules: – O donor can match to an O, A, B, or AB recipient – A donor can match to an A or AB recipient – B donor can match to a B or AB recipient – AB donor can match to an AB recipient		C		
●	VXM Result	HLA compatibility test between a donor and list of recipients.	Positive Negative	If virtual cross match run and patient's antibody results exist then VXM result provided based on the following rules: Donor-recipient matches are positive when the donor has HLA antigens that have been listed in the recipient's record as being unacceptable.		C		
	Surgical							
●	Date/Time of Admission to Hospital	Date and time of admission to hospital for transplant.	Date	≤ Current Date			M	

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Admission Status	Recipient in hospital or outpatient.	Hospital Outpatient	Single selection list		O		O
●	Procedure Type	Type of surgical procedure use for transplant.	Bi-Cayal Bi-atrial	Single selection list			O	
●	Cardiac Re-operation	Flag indicating if patent had cardiac re-operation.	Yes No Unknown	n/a			M	
●	Transplant Date/Time	Clamp Off Time or Time off cardiopulmonary bypass.	Date	≤ current date ≥ Donor Cross Clamp Date/Time			M	
●	Organ Transplanted	Transplant state of donor's organ after organ recovery.	Transplanted Not Transplanted	When transplant date/time recorded then data derived by Registry.			C	
●	Reason organ not transplanted	Reason organ not transplanted.	Recipient died Recipient medically unsuitable Storage and preservation problems Transportation logistics	If not transplanted is selected then reason required.			M	
●	Recipient Intended	Flag indicating if recipient was the intended.	Yes No	n/a			M	
●	Recipient Not Intended Reason	Reason not intended recipient received organ.	Recipient medically unsuitable Recipient died Positive actual cross match result Recipient unable to travel Recipient refused Organ not as described Organ test results unacceptable	If not intended recipient then reason required.			M	
●	Transplant Centre at Time of Transplant	Transplant Centre where transplant took place.	List of Transplant Centres	When transplant date/time recorded then data derived by Registry.			C	
●	IABP	Flag indicating if Intra-aortic Balloon Pump used.	Yes No	n/a				M
●	Mechanical Circulatory Support	Flag indicating if mechanical circulatory support device used.	Yes No	n/a				M
●	Mechanical Circulatory Support Implantation Date		Date	≤ Current Date		M		M

Name	Description	Values	Data Rules	R	PR	PE	PO
ECMO	Flag indicating if ECMO used.	Yes No	n/a		M		
Days ventilated	Number of days patient is ventilated, after surgery.	days	< 366			M	
Ventilated	Flag indicating if patient was ventilated.	Yes No	n/a			M	
Blood Products Given – Intraoperatively-Blood	Quantity of blood given intraoperatively.	units	n/a			O	
Blood Products Given – Intraoperatively – Cryoprecipitate	Quantity of cryoprecipitate given intraoperatively.	units	n/a			O	
Blood Products Given – Intraoperatively – Fresh Frozen Plasma	Quantity of fresh frozen plasma given intraoperatively.	units	n/a			O	
Blood Products Given – Intraoperatively – Platelets /OCTAPLEX/FVII	Quantity of platelets or OCTAPLEX/FVII given intraoperatively.	units	n/a			O	
Operative Reperfusion Time		Time	≤ Current Time			M	
Out of Ice Date/Time		Date	≤ Current Date			M	
Donor Cross Clamp Date/Time	Date and time organs were recovered and flushed with a specially prepared, ice-cold solution.	Date	≤ Current Date			M	
Cold Ischemia Time	Length of time of cold preservation.	Duration	Transplant Date/Time - Donor Cross Clamp Date/Time			C	
Total Ischemic Time		Duration	n/a			M	
Perfusion	Flag indicating if perfusion fluid used.	Yes No	If yes then specify perfusion fluid.			M	
Perfusion Method		Free-text entry	≤70 characters			M	

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Perfusion Volume		Free-text entry	≤70 characters			O	
	Surgical Complications							
●	Hemorrhage Requiring Reoperation	Flag indicating if patient had hemorrhage requiring reoperation.	Yes No	n/a			M	
●	Intraoperative Death	Flag indicating if patient had intraoperative death.	Yes No	n/a			M	
●	Other Mechanical Assistance Post-Op	Flag indicating if patient had other mechanical assistance post-op.	IABP IMPELLA	Single selection list			M	
●	Reintubated	Flag indicating if patient was reintubated.	Yes No	n/a			O	
●	Return to Theatre	Flag indicating patient returned to theatre.	Yes No	If yes then specify a date and reason why.			M	
●	Date Returned to Theatre		Date	≤ current date. ≥ transplant date. Required, if return to theatre = yes.			M	
●	Return to Theatre Reason		Free-text entry	≤100 characters. Required, if return to theatre = yes.			M	
	Outcome							
	Post-Transplant Complications							
●	Atrial Arrhythmias		Atrial fibrillation Atrial flutter Atrial Tachycardia	Provide yearly			M	M
●	Non-Specific Graft Dysfunction		Yes No	Provide yearly			M	M
●	CAV Date		Date	Provide yearly			M	M
●	CAV Grade		ISHLT CAV 0 (not significant) ISHLT CAV 1 (mild) ISHLT CAV 2 (moderate) ISHLT CAV 3 (severe)	Provide yearly. Refer to ISHLT CAV GRADING REPORT FORM			M	M
	Graft Rejection							

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Acute Rejection Post Transplant	Flag indicating if patient was hospitalized for rejection.	Yes No Unknown	Provide each biopsy with a date. AMR episode required on a yearly basis. Cellular required at multiple time points but not pre-specified.			M	M
●	Acute Rejection Date		Date	Required if Acute Rejection Post Transplant = yes.			M	M
●	Acute Rejection ≥ 2r Cellular Rejection	Flag indicating if patient has acute rejection ≥ 2r Cellular Rejection.	Yes No Unknown	Provide number (i.e. 2 episodes) _ done YEARLY.				M
●	Number of acute rejection episodes			Calculated by system.				C
●	Biopsy Proven Rejection Type		Cellular Antibody Mediated	Required for each biopsy.			M	M
●	New DSA	Flag indicating patient has new DSA.	Yes No	If yes then specify DSA.			M	M
	Cellular Rejection							
●	Rejection Grade		1R 2R 3R 0	If biopsy proven rejection is cellular then provide rejection grade.			M	M
●	Treated	Flag indicating if biopsy proven rejection was treated.	Yes No	If biopsy proven rejection is cellular then provide treatment.			M	M
●	Treatment	Treatments for biopsy proven rejection – cellular.	Steroid pulse ATG Basiliximab Dacluzimab Augmentation of baseline immunosuppression Immunosuppression substitution TLI (total lymphoid irradiation) Addition of new immunosuppressant (specify)	Multiple selection list. If treated = yes then provide treatment.			M	M

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Graft Dysfunction	Flag indicating graft dysfunction with rejection episode – defined as decline in LVEF or new diastolic dysfunction.	Yes No	If biopsy proven rejection is cellular then provide graft dysfunction.			M	M
	Antibody Mediated Rejection							
●	pAMR	Flag indicating if patient has pAMR.	Yes No	If biopsy proven rejection is antibody mediated then provide pAMR.			M	M
●	pAMR Grade		1 (H+/H-) 2 3	If pAMR = Yes then provide the grade.			M	M
●	Treated	Flag indicating if biopsy proven rejection was treated.	Yes No	If biopsy proven rejection is antibody mediated then provide treatment.			M	M
●	Treatment	Treatments for biopsy proven rejection – cellular.	Steroids Plasmapheresis IVIG Rituximab Bortezomib Eculizumab Immunoadsorption TLI (total lymphoid irradiation)	If treated = yes then provide treatment and pick all that apply.			M	M
●	Graft Dysfunction	Flag indicating graft dysfunction.	Yes No	If biopsy proven rejection is antibody mediated then provide graft dysfunction.			M	M
	Graft Failure							
●	Graft Failure Cause	Cause of graft failure.	Primary Non-Function Acute Rejection Chronic Rejection/Arherosclerosis Other - specify	Single selection list			M	M
●	Graft Failure Date	Date of graft failure.	Date	≤ current date			M	M
	Immunological Regimen							
●	Did the Patient Participate in any Clinical Research		Yes No	n/a			M	M

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Protocol for Immunosuppressive Medications							
●	Immunosuppressive Medication - Induction	List of induction immunosuppression's used.	Steroids (Prednisone, Methylprdnisolone, Solumedrol, Medrol, Decadron) Atgam (ATG) OKT3 (Orthoclone, Muromonab) Thymoglubulin Simulect - Basiliximab Zenapax - Daclizumab Azathioprine (AZA, Imuran) EON (Generic, Cyclosporine) Gengraf (Abbott Cyclosporine) Other generic Cyclosporine, specify brand: Neoral (CyA-NOF) Sandimmune (Cyclosporine A) CellCept (Mycophenolate Mofetil; MMF) Generic MMF (Generic CellCept) Prograf (Tacrolimus, FK506) Generic Tacrolimus (Generic Prograf) Advagraf (Tacrolimus Extended or Modified Release) Nulojix (Belatacept) Sirolimus (RAPA, Rapamycin, Rapamune) Myfortic (Mycophenolate Sodium) Campath - Alemtuzumab (anti-CD52) Cyclophosphamide (Cytoxan) Leflunomide (LFL, Arava) Methotrexate (Folex, PFS, Mexate-AQ, Rheumatrex) Rituximab Other Immunosuppressive Medication, Specify	Multiple selection list. Provide number of days for each medication selected.			M	
●	Immunosuppressive Medication - Maintenance	List of maintenance immunosuppression's used.	Steroids (Prednisone, Methylprdnisolone, Solumedrol, Medrol, Decadron) Atgam (ATG) OKT3 (Orthoclone, Muromonab)	Multiple selection list. Done Yearly. Provide number of days for each medication selected.			M	M

	Name	Description	Values	Data Rules	R	PR	PE	PO
			Thymoglubulin Simulect - Basiliximab Zenapax - Daclizumab Azathioprine (AZA, Imuran) EON (Generic, Cyclosporine) Gengraf (Abbott Cyclosporine) Other generic Cyclosporine, specify brand: Neoral (CyA-NOF) Sandimmune (Cyclosporine A) CellCept (Mycophenolate Mofetil; MMF) Generic MMF (Generic CellCept) Prograf (Tacrolimus, FK506) Generic Tacrolimus (Generic Prograf) Advagraf (Tacrolimus Extended or Modified Release) Nulojix (Belatacept) Sirolimus (RAPA, Rapamycin, Rapamune) Myfortic (Mycophenolate Sodium) Campath - Alemtuzumab (anti-CD52) Cyclophosphamide (Cytoxan) Leflunomide (LFL, Arava) Methotrexate (Folex, PFS, Mexate-AQ, Rheumatrex) Rituximab					
●	Noncompliance with Immunosuppressive	Flag indicating noncompliance with immunosuppressive medications.	Yes No	n/a				M
	Discharge							
●	Date of Discharge from Hospital	Date of discharge.	Date	≤ current date. ≥ Transplant Date/Time.			M	
●	Days in Hospital	Number of days a patient in the hospital for transplant (from time of admission to discharge).	Numeric	≤ 999			O	
●	Patient Status		Living Dead Lost to Follow-up	Calculated by system based on Lost to Follow-up Date and Date of Death.		C	C	C

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Patient Status Date		Date	≤ current date		M	M	M
●	Primary Reason for Readmission		Infection Rejection Unknown Other - specify	Multiple selection list				O
●	Lost to Follow-up Date		Date	≤ current date. ≥ Transplant Date.		M	M	M
	Death							
●	Date of Death		Date	≤ current date. ≥ Date of Birth.		M	M	M
●	Cause of Death	Primary cause of death	Unknown Other Specify Graft Failure: Primary Failure Graft Failure: Rejection- Hyperacute Graft Failure: Rejection- Acute Graft Failure: Rejection- Chronic Graft Failure: Technical Graft Failure: Graft Infection Graft Failure: Recurrent Disease Graft Failure: Non-Specific Infection: Bacterial Septicemia Infection: Bacterial Pneumonia Infection: Bacterial- Other Specify Infection: Viral- Cytomegalovirus (CMV) Infection: Viral- Hepatitis Infection: Viral-Septicemia Infection: Viral- Other Specify Infection: Fungal- Aspergillus Infection: Fungal- Other Specify Infection: Protozoal Infection: Mixed Other Specify Infection: Other Specify Cardiovascular: Myocardial Infarction Cardiovascular: Cardiac Arrest Cardiovascular: Arterial Embolism	n/a		M	M	M

Name	Description	Values	Data Rules	R	PR	PE	PO
		Cardiovascular: Ventricular Failure Cardiovascular: Coronary Artery Disease Cardiovascular: Atherosclerosis Cardiovascular: Rhythm Disorder Cardiovascular: Carditis Cardiovascular: Aortic Aneurysm Cardiovascular: Cardiogenic Shock Cardiovascular: Other Specify Pulm: Dehiscencepulm: Bronchiolitis Pulm: Primary Pulmonary Hypertension Pulm: Pulmonary Embolismpulm: Respiratory Failure Pulm: Acute Respiratory Distress Disease Pulm: Other Specify Cerebrovascular: Stroke Cerebrovascular: Hemorrhage (Non-Stroke) Cerebrovascular: Brain Anoxia Cerebrovascular: Degenerative Brain Disease Cerebrovascular: Other Specify Hemorrhage: Gastrointestinal Hemorrhage: Intraoperative Hemorrhage: Disseminated Intravas Coagulation Hemorrhage: Post-Operative Hemorrhage: Respiratory Hemorrhage: Other Specify Malig: Metastatic Other Specify Malig: Primary Other Specify Malig: Post-Tx Lymphoproliferative Disorder Malig: Lymphoma Malig: Skinmalig: Other Specify Diabetes Mellitus Intraop: Not Hemorrhage - Other Specify Pancreatitis Renal Failure Liver Failure Multiple Organ Failure Fluid/Electrolyte Disorder Acid/Base Disorder				

	Name	Description	Values	Data Rules	R	PR	PE	PO
			Amyloidosis Hematologic Other Specify Immunosuppressive Drug Related - Hematologic Immunosuppressive Drug Related - Non-Hematologic Non-Immuno Drug Related - Hematologic Non-Immuno - Non-Hematologic, Specify Drug Motor Vehicle Accident Suicide Non-Compliance Trauma Other Specify					
●	Death in hospital		Yes No	n/a				M
●	Sudden death		Yes No	n/a				M
●	Province of Death	Province where patient died.	Alberta British Columbia Manitoba New Brunswick Newfoundland and Labrador Northwest Territories Nova Scotia Nunavut Ontario Prince Edward Island Quebec Saskatchewan Yukon Not Applicable	Single selection list				M

Appendix C – IMACS Data Set

Name	Description	Values	Data Rules
Screening Log	*Each patient who receives a durable MCSD at your institution must be screened for eligibility into The International Society of Heart and Lung Transplant Registry for Mechanically Assisted Circulatory Support (IMACS). The screening log records the results of the inclusion/exclusion criteria which includes obtaining informed consent.*		
Device Type	List of device types.	LVAD RVAD Both (in same OR visit) Total Artificial Heart (TAH)	drop down

Device Brand		HeartMate II LVAS HeartMate IP HeartMate VE HeartMate XVE Micromed DeBakey Child VAD Novacor PC Novacor PCq Thoratec IVAD Thoratec PVAD Abiocor TAH Syncardia Cardiowest Micromed HeartAssist 5 Berlin Heart EXCOR Pediatric Berlin Heart EXCOR Adult Berlin Heart EXCOR HeartWare HVAD Jarvik 2000 Terumo DuraHeart EvaHeart LVAS Circilite Synergy Medos VAD Levacor LVAD Abiomed AB5000 Abiomed BVS 5000 Levitronix Centrimag TandemHeart Rotaflow Impella Biomedicus	List is dependent upon the selection made under Device Type. If single device (LVAD or RVAD)
Implant Date	VAD implant date.	Date	≤ current date

International IMACS Consent	Each participating institution will provide IMACS with documentation of Institutional Review Board (IRB) approval and follow their site's guidelines for obtaining informed consent. The institution will provide IMACS with documentation if the IRB waives the informed consent process.	
Demographics	*The patient Demographics Form is to be completed prior to implant and as close to implant as possible and consent has been obtained. All entries on the screen with red asterisk * are required pieces of information. These entries must be completed.*	
First Name	Enter the implant patient's first name.	Free-text
MI (Middle Initial)	Enter the implant patient's middle initial.	Free-text
Last Name	Enter the implant patient's last name.	Free-text
Date of Birth	Enter the implant patient's date of birth.	MMDDYYYY
Gender	Click in the appropriate circle to indicate the implant patient's gender.	Male Female Unknown
Marital Status	Enter patient's current marital status from the list below.	Single Married Domestic Partners Divorced/Separated Widowed Unknown
Highest Education Level	Enter patient's current highest education level from the list below.	None Unknown N/A (< 5 yrs. old) 0-6 years 7-12 years > 12 years

Working for Income	Answer this question if patient is over 18 years of age. Select Yes if the patient was currently working for income or attending school within 3 months prior to implant. If not, select No. If Unknown, select Unknown.	**If Yes, select one of the following**: Working Full Time Working Part Time due to Demands of Treatment Working Part Time due to Disability Working Part Time due to Insurance Conflict Working Part Time due to Inability to Find Full Time Work Working Part Time due to Patient Choice Working Part Time Reason Unknown Working, Part Time vs. Full Time Unknown **If No, select reason patient was not working from one of the following:** Disability Demands of Treatment Insurance Conflict Inability to Find Work Patient Choice - Homemaker Patient Choice - Student Full Time/Part Time Patient Choice - Retired Patient Choice - Other Not Applicable - Hospitalized Unknown	
Pre-Implant	*The Pre-implant Form should be collected at time of implant or closest to implant date within 30 days pre-implant but not in the OR.*		
Demographics			
Height	Enter the height of the patient at the time of implantation in inches or centimeters.	Numeric	The height must fall between 10 and 80 inches or 25 and 203 centimeters. ST (status) = Unknown or Not Done
Weight	Enter the weight of the patient at the time of implantation in the appropriate space, in pounds or kilograms.	Numeric	The weight must fall between 5 and 450 pounds or 2 and 205 kilograms. ST (status) = Unknown or Not Done

Blood Type	Select the patient's blood type.	O, A, B, AB, Unknown
Medical Support Status		
Current Device Strategy at Time of Implant	This should be determined in conjunction with the heart failure cardiologist and surgeon at the time of the implant. This determination will be re-visited and recorded at 3 months, 6 months, and every 6 months thereafter.	Bridge to Recovery Rescue Therapy Bridge to Transplant Possible bridge to transplant - Likely to be eligible Possible bridge to transplant - Moderate likelihood of becoming eligible Possible bridge to transplant - Unlikely to become eligible Destination therapy - (patient definitely not eligible for transplant). All factors that weigh in to the decision of non–transplant candidacy should be indicated below.
Comorbidities/Concerns	*Treatment or contraindication for transplant.* *Checking any of these contraindications/comorbidities/concern does not necessarily mean that a condition is a contraindication or concern for the patient. No specific thresholds are provided for these concerns or contraindications. They should represent the results of formal discussion with the medical and surgical transplant team prior to the decision for device implantation.*	
Overall Status		
Advance Age	Overall status.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Frailty	Overall status.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Patient Doesn't Want a Transplant	Overall status.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Musculoskeletal Limitation to Ambulation	Overall status.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Contraindication to Immunosuppression	Overall status.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Allosensitization	Overall status.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Chronic Renal Disease		Is Condition Present: Yes/No Limitation to Transplant: Yes/No

Cardiothoracic Issues		
Frequent ICD Shocks	Cardiothoracic issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Pulmonary Disease	Cardiothoracic issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Pulmonary Hypertension	Cardiothoracic issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Recent Pulmonary Embolus	Cardiothoracic issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
History of Atrial Arrhythmia	Cardiothoracic issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Unfavorable Mediastinal Anatomy	Cardiothoracic issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Thoracic Aortic Disease	Cardiothoracic issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Nutritional/GI		
Large BMI	Nutritional/GI.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Severe Diabetes	Nutritional/GI.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Malnutrition/Cachexia	Nutritional/GI.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
History of GI Ulcers	Nutritional/GI.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
History of Hepatitis	Nutritional/GI.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Liver Dysfunction	Nutritional/GI.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Vascular Issues		
Heparin-Induced thrombocytopenia	Vascular issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No

Chronic Coagulopathy	Vascular issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Major Stroke	Vascular issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Other Cerebrovascular Disease	Vascular issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Peripheral Vascular Disease	Vascular issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Major Stroke	Vascular issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Oncology/infection issues		
History of Solid Organ Cancer	Oncology/infection issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
History of Lymphoma Leukemia	Oncology/infection issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
History of Bone Marrow Transplant (BMT)	Oncology/infection issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
History of HIV	Oncology/infection issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Chronic infectious concerns	Oncology/infection issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Chronic coagulopathy	Oncology/infection issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Psychosocial issues		
Limited cognition/understanding	Psychosocial issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Limited social support	Vascular issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Repeated non-compliance	Vascular issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No

History of illicit drug use	Vascular issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
History of alcohol abuse	Psychosocial issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Narcotic dependence	Psychosocial issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
History of smoking	Psychosocial issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Currently smoking	Psychosocial issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Severe depression	Psychosocial issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Other major psychiatric diagnosis	Psychosocial issues.	Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Other co-morbidity		Is Condition Present: Yes/No Limitation to Transplant: Yes/No
Time since first cardiac diagnosis	The length of time that the patient had any known cardiac diagnosis. For example, the time since the patient had a myocardial infarction, congenital heart disease was noted or the patient was noted to have heart failure.	< 1 month 1 month – 1 year 1-2 years > 2years unknown
# of cardiac hospitalizations in the last 12 months		0-1 2-3 4 or more unknown

Cardiac diagnosis/primary	Primary reason for cardiac dysfunction.	Cancer Congenital Heart Disease Coronary Artery Disease Dilated Myopathy: Adriamycin Dilated Myopathy: Alcoholic Dilated Myopathy: Familial Dilated Myopathy: Idiopathic Dilated Myopathy: Ischemic Dilated Myopathy: Myocarditis Dilated Myopathy: Other Specify Dilated Myopathy: Post Partum Dilated Myopathy: Viral Hypertrophic Cardiomyopathy Restrictive Myopathy: Amyloidosis Restrictive Myopathy: Endocardial Fibrosis Restrictive Myopathy: Idiopathic Restrictive Myopathy: Other specify Restrictive Myopathy: Sarciodosis Restrictive Myopathy: Sec to Radiation/Chemotherapy Valvular Heart Disease Unknown	
Congenital Heart Disease		Complete AV Septal Defect Congenitally Corrected Transposition VSD/ASD Other, specify Ebstein's Anomaly Kawasaki Disease Hypoplastic Left Heart Other, specify Left Heart Valvar/Structural Hypoplasia Unknown Pulmonary Atresia with IVS Single Ventricle TF/TOF variant Transposition of the Great Arteries Truncus Arteriosus VSD/ASD	This field is dependent on a Cardiac Diagnosis/ Primary selection of Congenital Heart Disease

Previous cardiac operation	None CABG Aneuryomectomy (DOR) Aortic Valve replacement / repair Mitral valve replacement / repair Triscuspid replacement /repair Congenital card surg LVAD RVAD TAH Other, specify à (INCLUDE ONLY OPERATIONS ACTUALLY PERFORMED ON HEART OR GREAT VESSELS)	Check all cardiac operations that the patient has had prior to MCSD implantation
Congenital cardiac surgery	Norwood Stage I Congenitally Corrected Transposition Repair PA Banding Damus Kaye Stansel (DKS) TOF/DORV/RVOTO Repair Ebstein's Anomaly Repair VSD Repair Fontan Transposition of the Great Vessels Repair Glenn, Bi-directional Truncus Arteriosus Repair Glenn, Classical Valve Replacement of Repair for Outflow Obstruction Previous heart transplant AP Shunt ECMO ASD Repair Previous mechanical support, specify Complete AV Septal Defect Repair Other, specify	This field is dependent on Previous Cardiac Operation of Congenital card surg being selected

Clinical Events and Interventions this hospitalization (Pre-implant):	Pertaining to the implant hospitalization, select all other events that apply.	IABP Dialysis Ultrafiltration Ventilator/ Intubation Feeding tube ECMO CABG Aortic Valve replacement / repair Mitral valve replacement / repair Congenital cardiac surg LVAD RVAD TAH Aneursyomectomy (DOR) Cardiac surgery, other Cardiac arrest Major MI Other surgical procedures Major infections Unknown None	
Infection Location	No. of each infection 1 Month prior to Surgery The infection must be culture proven. Check all that apply.	Catheter -related bloodstream infection - IABP Catheter -related bloodstream infection - PICC Line Catheter -related bloodstream infection - CVL Endocarditis, native Mediastinitis Pneumonia Urinary Tract Infection of Unknown Source Other, Specify	If Major Infection selected from Clinical Events and Interventions this hospitalization (Pre-implant, then for each of the following, chose Yes or No: If Yes, please choose Number of Infections and Genus Species:

Genus Species	Predominant organism for each event of infection 1 month prior to surgery. Choose causative organism from the drop down list or add other list organism genus and species if not on the list.	ACINETOBACTER spp ASPERGILLUS Aspergillus fumigatus Aspergillus spp BACTEROIDES Bacteroides spp Bacteroides fragilis BACILLUS spp CANDIDA Candida spp Candida albicans Candida glabrata CLOSTRIDIUM Clostridium spp Clostridium perfringens CORYNEBACTERIUM spp ENTEROBACTER Enterobacter spp Enterobacter cloacae Enterobacter aerogenes ENTEROCOCCUS Enterococcus spp Enterococcus faecalis Enterococcus faecalis VRE Enterococcus faecium Enterococcus faecium VRE ESCHERICHIA COLI KLEBSIELLA Klebsiella spp Klebsiella pneumoniae Klebsiella pneumoniae KPC Klebsiella oxytoca PROTEUS Proteus spp Proteus mirabilis Proteus vulgaris PSEUDOMONAS Pseudomonas spp Pseudomonas aeruginosa	If Major Infection selected from Clinical Events and Interventions this hospitalization (Pre-implant, then for each of the following, chose Yes or No: If Yes, please choose Number of Infections and Genus Species:

		SERRATIA Serratia spp Serratia liquefaciens Serratia marcescens STAPHYLOCCUS Staphlococcus aureus (MSSA) Staphylococcus aureus (MRSA) Staphylococcus Lugdunensis Staphylococcus Warneri Staphylococcus epidermidis Staphylococcus coag-neg, not epidermidis STENOTROPHOMONAS Stenotrophomonas spp Stenotrophomonas maltophilia STREPTOCOCCUS Streptococcus spp Streptococcus constellatus group Streptococcus Group B/ agalactiae Streptococcus Group C/G Streptococcus Group A/Strep pyogenes Streptococcus pneumonia Other,Specify:_____
IV inotrope therapy within 48 hours of implant:	If the patient has gone to the operating room for the purpose of the implant and is on intravenous inotropes of any sort, the answer should be Yes. If an agent is known to have been used but discontinued within 48 hours prior to arriving in the operating room, Yes should also be checked.	Yes No

If Yes, IV inotrope therapy agents	All intravenous inotropes used at the time of the MCSD implant that apply.	Dobutamine Dopamine Milrinone Levosimendan Epinephrine Norepinephrine Isoproterenol Other, specify Unknown	If Yes selected from IV inotrope therapy within 48 hours of implant:
INTERMACS Patient Profile at time of implant:	Select one. These profiles will provide a general clinical description of the patients receiving primary LVAD or TAH implants. If there is significant clinical change between the initial decision to implant and the actual implant procedure, then the profile closest to the time of implant should be recorded. Patients admitted electively for implant should be described by the profile just prior to admission.	INTERMACS 1: Critical cardiogenic shock INTERMACS 2: Progressive decline INTERMACS 3: Stable but inotrope dependent INTERMACS 4: Resting symptoms INTERMACS 5: Exertion Intolerant INTERMACS 6: Exertion Limited INTERMACS 7: Advanced NYHA Class 3	Include profile descriptions as outlined in the IMACS User Guide
MODIFIERS of the INTERMACS Patient Profiles:	Modifiers can be added to INTERMACS Patient Profile.	A - Arrhythmia TCS –Temporary Circulatory Support FF – Frequent Flyer	Must be able to append modifiers to INTERMACS Patient Profile Include profile descriptions as outlined in the IMACS User Guide
Evidence for Right Heart Failure	*Prior to implant – closest to implant but not in OR*		
Peripheral edema	Does patient have moderate or worse peripheral edema?	Yes No Unknown	
Ascites	This is in the clinicians' best judgment, as it is sometimes difficult to tell whether abdominal protuberance is fluid or adipose tissue.	Yes No Unknown	
Echo Findings	*closest to implant but not in OR*		

Mitral regurgitation	Mitral regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".	0 (none) 1 (mild) 2 (moderate) 3 (severe) Not Recorded or Not Documented	
Tricuspid regurgitation	Tricuspid regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".	0 (none) 1 (mild) 2 (moderate) 3 (severe) Not Recorded or Not Documented	
Aortic regurgitation	Aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".	0 (none) 1 (mild) 2 (moderate) 3 (severe) Not Recorded or Not Documented	
LVEF% Left ventricular ejection fraction	If a number or range is available, check the number range that best applies. E.g. 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as "left ventricular function" or "systolic function" in words. "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild".	> 50 (normal) 40-49 (mild) 30-39 (moderate) 20-29 (moderate/severe) < 20 (severe) Not Recorded or Not Documented	
LVEDD	Left ventricular end-diastolic dimension.	cm	ST= Not Recorded or Not Documented
RV Function	Is generally NOT measured in numbers, as it is difficult to quantify. It may be described as "right ventricular function" or "right ventricular contractility". "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild". Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as "severe".	Free-text	
Swan Hemodynamics	*closest to implant but not in OR*		
Pulmonary artery systolic pressure:	This may be abbreviated PAS or pulmonary pressures.	mmHg	ST= Unknown or Not Done.

Pulmonary artery diastolic pressure	This may be abbreviated PAD or pulmonary pressures.	mmHg	ST= Unknown or Not Done.
Mean RA Pressure:	May be listed also as RAP or CVP.		ST= Unknown or Not Done.
CVP	Central venous pressure.	mmHg	ST= Unknown or Not Done.
Mean Pulmonary artery wedge pressure	May be listed also as PCW or pulmonary capillary wedge pressure. It is not always provided in the hemodynamic data.	mmHg	ST= Unknown or Not Done.
Cardiac output	Will be expressed as Liters/min or L/min. Enter this number. The cardiac index is NOT what we want; it is a smaller number expressed as Liters/min/m2.	L/min/m	ST= Unknown or Not Done.
Medications	*Collected at time nearest to implant but not in OR. Mark whether the medications listed fall into one of the following categories*		
Currently using	At the time of VAD placement		
Known previous use within the past year-	**Known previous use within the past year-** Is intended to capture the adequacy of medical therapy prior to determining heart failure to be refractory. For instance, ACEI, beta blockers, and diuretics are considered standard necessary therapy for heart failure but may be stopped due to hypotension or renal failure during a hospitalization for severely decompensated heart failure. If patients are known to have received these agents within the past year, please check known previous use. **No (not being used)** - If there is no reason to believe that they have taken those agents, and reasonable certainty that information is accurate, check No. **Unknown** - If it is not known whether the patient has taken those agents within the previous year, check Unknown.	Allopurinol Angiotension receptor blocker drug Amiodarone ACE inhibitors Beta-blockers Aldosterone antagonist Warfarin (coumadin) Antiplatelet therapy drug Nesiritide Check Yes for Nesiritide only if currently being administered. Note that there is no option for previously taken. Nitric oxide Check Yes for Nitric oxide only if currently being administered. Note that there is no option for previously taken. Loop diuretics – Check Yes or No	

Outpatient (prior to admission) inotrope infusion		Yes No Unknown
Current ICD device in place	If the patient currently has an implantable defibrillator, then Yes should be checked. If the patient has already had it explanted at the time of the MCSD implant, then "no" should be checked. Note that patients with bi-ventricular pacing and ICD should have Yes checked for ICD also.	Yes No Unknown
CRT	Chronic Resynchronization Therapy.	Yes No Unknown
Is patient on Metalozone/Thiazide?		Yes -Regular Yes - Intermittent No Unknown
Is patient on Phosphodiesterase inhibitors?		Yes No Unknown
Laboratory Values	*Collected nearest to time of implant but not in OR* *The laboratory values are the LAST values available prior to implant. It is anticipated that the blood urea nitrogen, creatinine, total bilirubin, sodium, INR, white blood cell count, platelet count, and SGOT and SGPT will usually be measured within 48 hours of the implant surgery. Other lab values may be less recent*	

Laboratory Values	Blood urea nitrogen, creatinine, total bilirubin, sodium, INR, white blood cell count, platelet count, and SGOT and SGPT.	Sodium Potassium Blood urea nitrogen Creatinine SGPT/ALT (alanine aminotransferase/ALT) SGOT/AST (aspartate aminotransferase/AST) Total Bilirubin Albumin Pre- Albumin White blood cell count Hemoglobin Platelets INR Sensitivity (C Reactive Protein) Uric Acid Lymphocyte Count LDH	Values obtained more than a month prior to the implant date should NOT be included. For all of the tests listed below, give the appropriate measurement.
Medical Condition			
NYHA Class	New York Heart Association Class for heart failure.	Class I: No limitation of physical activity; physical activity does not cause fatigue, palpitation or shortness of breath. Class II: Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue, palpitations or shortness of breath. Class III: Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue, palpitation or shortness of breath. Class IV: Unable to carry on minimal physical activity without discomfort; symptoms may be present at rest. Unknown	
Exercise Function	*All patients should attempt to complete these functional capacity measurements especially for those patients classified as IMACS patient profile level 4-7.*		

6 minute walk	This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk behind the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here.	min	All efforts should be made to perform the 6 minute walk test for any patient able to walk more than a few steps. A distance as short as 3 feet may be recorded. If the test is not done, the reason must be indicated as “not done: too sick” or “not done: other”, for which an example might be a patient needing to remain supine after a groin puncture for routine catheterization. Any musculoskeletal limitation to walking should be recorded as “not done: too sick”.
Gait speed (1st 15 foot walk)	Record the time (seconds) required for the patient to walk the first 15 feet of the 6 minute walk. The “starting” line and the 15 foot line should be clearly marked. Record the time to the first footfall at 0 feet and end with the first footfall at 15 feet in the nearest 0.1 sec with a stopwatch. NOTE: You may use the time from the first 15 feet of the 6 minute walk for the Gait speed test.	seconds	
Peak VO2 Max	Maximum volume of oxygen the body can consume during exercise.	(mL/min	
R Value at peak	Is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort.	numeric	

Implant Form	*The Implant Form is to be completed within 1 week post implant.*		
Additional Indication for VAD		Failure to wean from CPB Post cardiac surgery None	Select one of the following as indication for VAD.
Cardiac Operation	Type the cardiac operation performed in the block provided.	text	For Additional Indication for VAD, If post cardiac surgery
Device Type	List of device types.	LVAD RVAD Both (in same OR visit) Total Artificial Heart (TAH)	drop down

Device Brand		HeartMate II LVAS HeartMate IP HeartMate VE HeartMate XVE Micromed DeBakey Child VAD Novacor PC Novacor PCq Thoratec IVAD Thoratec PVAD Abiocor TAH Syncardia Cardiowest Micromed HeartAssist 5 Berlin Heart EXCOR Pediatric Berlin Heart EXCOR Adult Berlin Heart EXCOR HeartWare HVAD Jarvik 2000 Terumo DuraHeart EvaHeart LVAS Circilite Synergy Medos VAD Levacor LVAD Abiomed AB5000 Abiomed BVS 5000 Levitronix Centrimag TandemHeart Rotaflow Impella Biomedicus	List is dependent upon the selection made under Device Type. If single device (LVAD or RVAD)
Implant Date	VAD implant date.	Date	≤ current date

Associated Findings	Surgical Observations or Intraoperative TEE.	PFO/ASD Aortic Insufficiency - Select: Mild, Moderate, Severe Tricuspid Insufficiency - Select: Mild, Moderate, Severe None	
Concomitant Surgery		None ASD closure PFO closure ECMO decannulation CABG VSD closure Congenital cardiac surgery Valve Surgery: Aortic Repair Valve Surgery: Mitral Repair Valve Surgery: Tricuspid Repair Valve Surgery: Pulmonary Repair Valve Surgery: Aortic Replacement - Mechanical Valve Surgery: Aortic Replacement - Biological Valve Surgery: Mitral Replacement - Mechanical Valve Surgery: Mitral Replacement - Biological Valve Surgery: Tricuspid Replacement - Mechanical Valve Surgery: Tricuspid Replacement - Biological Valve Surgery: Pulmonary Replacement - Mechanical Valve Surgery: Pulmonary Replacement - Biological Other, specify	Check all concomitant surgeries that apply. If Other, specify is selected, type in the specification in the block provided.
1 Month Follow-up	*The data on this form is collected at following time periods post implant:* *1 month (+/- 7 days i.e., POD 23 day – 37 day) post implant*		

Patient Availability		o Inpatient (complete follow-up form) o Outpatient (complete follow-up form) o Other Facility: Yes No (complete follow-up form) o Nursing Home/Assisted Care o Hospice o Another hospital o Rehabilitation Facility o Unknown o Unable to obtain follow-up information - this will result in an incomplete follow-up (cannot complete follow-up form) State reason why you are unable to obtain follow-up information (check one): o patient didn't come to clinic o Not able to contact patient o Not addressed by site	Check one of the following If Inpatient, outpatient or other facility is checked then – Enter follow-up date: MM/DD/YYYY please enter the actual follow-up date post implant.
Evidence for Right Heart Failure	*during report interval*		
Peripheral edema	Does patient have moderate or worse peripheral edema?	Yes No Unknown	
Ascites	This is in the clinicians' best judgment, as it is sometimes difficult to tell whether abdominal protuberance is fluid or adipose tissue.	Yes No Unknown	
Echo Findings	*during report interval*		
Mitral regurgitation	Mitral regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".	0 (none) 1 (mild) 2 (moderate) 3 (severe) Not Recorded or Not Documented	
Tricuspid regurgitation	Tricuspid regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".	0 (none) 1 (mild) 2 (moderate) 3 (severe) Not Recorded or Not Documented	

Aortic regurgitation	Aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".	0 (none) 1 (mild) 2 (moderate) 3 (severe) Not Recorded or Not Documented	
LVEF% Left ventricular ejection fraction	If a number or range is available, check the number range that best applies. E.g. 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as "left ventricular function" or "systolic function" in words. "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild".	> 50 (normal) 40-49 (mild) 30-39 (moderate) 20-29 (moderate/severe) < 20 (severe) Not Recorded or Not Documented	
LVEDD	Left ventricular end-diastolic dimension.	cm	ST= Not Recorded or Not Documented
RV Function	Is generally NOT measured in numbers, as it is difficult to quantify. It may be described as "right ventricular function" or "right ventricular contractility". "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild". Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as "severe".		
Swan Hemodynamics	*during report interval*		
Pulmonary artery systolic pressure:	This may be abbreviated PAS or pulmonary pressures.	mmHg	ST= Unknown or Not Done.
Pulmonary artery diastolic pressure	This may be abbreviated PAD or pulmonary pressures.	mmHg	ST= Unknown or Not Done.
Mean RA Pressure:	May be listed also as RAP or CVP		ST= Unknown or Not Done.
CVP	Central venous pressure.	mmHg	ST= Unknown or Not Done.
Mean Pulmonary artery wedge pressure	May be listed also as PCW or pulmonary capillary wedge pressure. It is not always provided in the hemodynamic data.	mmHg	ST= Unknown or Not Done.

Cardiac output	Will be expressed as Liters/min or L/min. Enter this number. The cardiac index is NOT what we want; it is a smaller number expressed as Liters/min/m2.	L/min/m	ST= Unknown or Not Done.
Was patient intubated		Yes No Unknown	
Was patient on dialysis		Yes No Unknown	
Medications			
IV inotrope therapy	Currently on IV inotrope therapy at follow-up time period.	Yes No Unknown	
IV inotrope therapy agents	Check all intravenous inotropes used at the follow-up time period.	Dopamine Dobutamine Milrinone Isoproterenol Epinephrine Norepinephrine Levosimendan Unknown	If Yes, IV inotrope Therapy

Medications During Follow-up	Mark whether the medications listed are used at the follow-up time period: Yes, No or Other.	Hydralazine (at 1 month only) Calcium channel blockers (at 1 month only) Nesiritide Angiotensin receptor blocker drug Amiodarone ACE inhibitors Beta-blockers Aldosterone antagonist Lovenox Warfarin (coumadin) Antiplatelet therapy drug – additionally, check all that apply. If Other, specify is selected, type in the specification in the block provided. Nitric oxide Phospodiesterase Inhibitor Digoxin Loop diuretics
Medical Condition		
NYHA Class	New York Heart Association Class for heart failure.	Class I: No limitation of physical activity; physical activity does not cause fatigue, palpitation or shortness of breath. Class II: Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue, palpitations or shortness of breath. Class III: Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue, palpitation or shortness of breath. Class IV: Unable to carry on minimal physical activity without discomfort; symptoms may be present at rest. Unknown

Intervention Since Implant	Select the type of intervention since VAD implant date from the list.	Transplant Surgical Procedure Invasive Cardiac Procedures (Other than Heart Cath) Other Unknown None	
Transplant Date	Date of transplant procedure.	date	If Intervention since implant = Transplant
Surgical Procedure		Device related operation Other Cardiac Surgical Procedure Non Cardiac Surgical Procedure Other Procedure Unknown	If Device related operation, please remember to go to the Device Malfunction Adverse Event form and complete.)
Other Cardiac Surgical Procedure		Reoperation for Bleeding within 48 hours of implant Reoperation for Bleeding and/or tamponade > 48 hours Surgical Drainage of pericardial effusion Valve Surgery: Aortic Repair Valve Surgery: Mitral Repair Valve Surgery: Tricuspid Repair Valve Surgery: Pulmonary Repair Valve Surgery: Aortic Replacement - Mechanical Valve Surgery: Aortic Replacement - Biological Valve Surgery: Mitral Replacement - Mechanical Valve Surgery: Mitral Replacement - Biological Valve Surgery: Tricuspid Replacement - Mechanical Valve Surgery: Tricuspid Replacement - Biological Valve Surgery: Pulmonary Replacement - Mechanical Valve Surgery: Pulmonary Replacement - Biological Other, specify _____ Unknown	If Surgical Procedure = Other Procedure
Transferred Care to Another Hospital	Patient followed exclusively at another hospital.	Yes No	
Transferred Care Date		date	If Transferred Care to Another Hospital = Yes

Adverse Events	Did the patient have one or more of the following adverse events occur during this follow-up time period? Please make sure you have entered all events that have occurred during this follow-up period.	Major Bleeding Major Infection Neurological Dysfunction Device Malfunction (if suspected device thrombosis, then enter as Device Malfunction) Death Transplant Explant due to Transplant Explant due to Recovery Explant due to Exchange Respiratory Failure Arterial Non-CNS Thromboembolism	
3 Month & 6 Month Follow-up	*The data on this form is collected at the following time periods:* *3 months post-implant (+/- 30 days i.e., POD 60 days - 120 days)* *6 months post-implant (perpetual - +/- 60 days)*		
Patient Availability		o Inpatient (complete follow-up form) o Outpatient (complete follow-up form) o Other Facility: Yes No (complete follow-up form) o Nursing Home/Assisted Care o Hospice o Another hospital o Rehabilitation Facility o Unknown o Unable to obtain follow-up information - this will result in an incomplete follow-up (cannot complete follow-up form) State reason why you are unable to obtain follow-up information (check one): o patient didn't come to clinic o Not able to contact patient o Not addressed by site	Check one of the following If Inpatient, outpatient or other facility is checked then – Enter follow-up date: MM/DD/YYYY please enter the actual follow-up date post implant.
Evidence for Right Heart Failure	*during report interval*		

Peripheral edema	Does patient have moderate or worse peripheral edema?	Yes No Unknown	
Ascites	This is in the clinicians' best judgment, as it is sometimes difficult to tell whether abdominal protuberance is fluid or adipose tissue.	Yes No Unknown	
Echo Findings	*during report interval*		
Evidence of Elevated CVP Pressure	Dilated IVC, IVS with collapse, or physical exam (signs of increased jugular venous pressure.	Yes No Unknown	
Mitral regurgitation	Mitral regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".	0 (none) 1 (mild) 2 (moderate) 3 (severe) Not Recorded or Not Documented	
Tricuspid regurgitation	Tricuspid regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".	0 (none) 1 (mild) 2 (moderate) 3 (severe) Not Recorded or Not Documented	
Aortic regurgitation	Aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".	0 (none) 1 (mild) 2 (moderate) 3 (severe) Not Recorded or Not Documented	
LVEF% Left ventricular ejection fraction	If a number or range is available, check the number range that best applies. E.g. 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as "left ventricular function" or "systolic function" in words. "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild".	> 50 (normal) 40-49 (mild) 30-39 (moderate) 20-29 (moderate/severe) < 20 (severe) Not Recorded or Not Documented	
LVEDD	Left ventricular end-diastolic dimension.	cm	ST= Not Recorded or Not Documented

RV Function	Is generally NOT measured in numbers, as it is difficult to quantify. It may be described as "right ventricular function" or "right ventricular contractility". "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild". Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as "severe".		
Swan Hemodynamics	*During report interval (NOTE: You may be able to get the following information from a right heart catheterization test if it was performed.)*		
Pulmonary artery systolic pressure:	This may be abbreviated PAS or pulmonary pressures.	mmHg	ST= Unknown or Not Done.
Pulmonary artery diastolic pressure	This may be abbreviated PAD or pulmonary pressures.	mmHg	ST= Unknown or Not Done.
Mean RA Pressure:	May be listed also as RAP or CVP.	mmHg	ST= Unknown or Not Done.
CVP	Central venous pressure.	mmHg	ST= Unknown or Not Done.
Mean Pulmonary artery wedge pressure	May be listed also as PCW or pulmonary capillary wedge pressure. It is not always provided in the hemodynamic data.		ST= Unknown or Not Done.
Cardiac output	Will be expressed as Liters/min or L/min. Enter this number. The cardiac index is NOT what we want; it is a smaller number expressed as Liters/min/m2.	L/min/m	ST= Unknown or Not Done.
Was patient intubated		Yes No Unknown	
Was patient on dialysis		Yes No Unknown	
Medications			

IV inotrope therapy	Currently on IV inotrope therapy at follow-up time period.	Yes No Unknown	
IV inotrope therapy agents	Check all intravenous inotropes used at the follow-up time period.	Dopamine Dobutamine Milrinone Isoproterenol Epinephrine Norepinephrine Levosimendan Unknown	If Yes, IV inotrope Therapy
Medications During Follow-up	Mark whether the medications listed are used at the follow-up time period: Yes, No or Other.	Hydralazine (at 1 month only) Calcium channel blockers (at 1 month only) Nesiritide Angiotensin receptor blocker drug Amiodarone ACE inhibitors Beta-blockers Aldosterone antagonist Lovenox Warfarin (coumadin) Antiplatelet therapy drug – additionally, check all that apply. If Other, specify is selected, type in the specification in the block provided. Nitric oxide Phospodiesterase Inhibitor Digoxin Loop diuretics	
Medical Condition			

NYHA Class	New York Heart Association Class for heart failure.	Class I: No limitation of physical activity; physical activity does not cause fatigue, palpitation or shortness of breath. Class II: Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue, palpitations or shortness of breath. Class III: Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue, palpitation or shortness of breath. Class IV: Unable to carry on minimal physical activity without discomfort; symptoms may be present at rest. Unknown	
Has patient been rehospitalized since last follow-up		Yes 0-1 Yes 2-3 Yes 4 or More No Unknown	
Intervention Since Implant	Select the type of intervention since VAD implant date from the list.	Transplant Surgical Procedure Invasive Cardiac Procedures (Other than Heart Cath) Other Unknown None	
Transplant Date	Date of transplant procedure.	Date	If Intervention since implant = Transplant
Surgical Procedure		Device related operation Other Cardiac Surgical Procedure Non Cardiac Surgical Procedure Other Procedure Unknown	If Device related operation, please remember to go to the Device Malfunction Adverse Event form and complete.)

Other Cardiac Surgical Procedure		Reoperation for Bleeding within 48 hours of implant Reoperation for Bleeding and/or tamponade > 48 hours Surgical Drainage of pericardial effusion Valve Surgery: Aortic Repair Valve Surgery: Mitral Repair Valve Surgery: Tricuspid Repair Valve Surgery: Pulmonary Repair Valve Surgery: Aortic Replacement - Mechanical Valve Surgery: Aortic Replacement - Biological Valve Surgery: Mitral Replacement - Mechanical Valve Surgery: Mitral Replacement - Biological Valve Surgery: Tricuspid Replacement - Mechanical Valve Surgery: Tricuspid Replacement - Biological Valve Surgery: Pulmonary Replacement - Mechanical Valve Surgery: Pulmonary Replacement - Biological Other, specify _____ Unknown	If Surgical Procedure = Other Procedure
Transferred Care to Another Hospital	Patient followed exclusively at another hospital.	Yes No	
Transferred Care Date		date	If Transferred Care to Another Hospital = Yes
Withdrawal Date	Patient withdraws consent and therefore no more clinical data is to be collected.	Date	
Adverse Events	Did the patient have one or more of the following adverse events occur during this follow-up time period? Please make sure you have entered all events that have occurred during this follow-up period.	Major Bleeding Major Infection Neurological Dysfunction Device Malfunction (if suspected device thrombosis, then enter as Device Malfunction) Death Transplant Explant due to Transplant Explant due to Recovery Explant due to Exchange Respiratory Failure Arterial Non-CNS Thromboembolism	

Implant Discharge	*The Implant Discharge Form is intended to collect information about a patient from the device implant to one of the following occurrences during the implant hospitalization:* *o Patient is discharged from the hospital with a device in place.* *o Patient receives a transplant during the implant hospitalization. The date of transplant will be considered the date of discharge.* *o Patient dies during the implant hospitalization. The date of death is considered to be the date of discharge.* *o Patient has the device(s) explanted due to recovery. The date of device(s) explant is considered to be the date of discharge.*		
Chronology of Hospital Time Course			
During the implant hospitalization was the patient?		Discharged alive with a device in place Died during the implant hospitalization Transplanted during the implant hospitalization Explanted due to recovery during the implant hospitalization	check one
Implant Discharge Date	Please select the appropriate discharge date from the list below: o Patient is discharged from the hospital with a device in place. The date of discharge is considered to be the implant discharge date. o Patient receives a transplant during the implant hospitalization. The date of transplant will be considered the date of discharge. o Patient dies during the implant hospitalization. The date of death is considered to be the date of discharge. o Patient has the device(s) explanted due to recovery. The date of device(s) explant is considered to be the date of discharge.	date	
Patient Discharged To	Select one of the following facility types. If patient alive with device in place at time of implant discharge.	Home - residential setting Nursing Home/Assisted Care Hospice Another hospital Rehabilitation Facility Unknown	

Acute care (ICU / CCU) - duration of stay	Type the number of days patient in Acute care (i.e. ICU/CCU).	numeric	Days should not exceed number of days from implant date to implant discharge date. Note: ICU/CCU duration + Intermediate/step-down duration cannot exceed the total days from implant date to implant discharge date (remember if the patient was transplanted, explanted or died during the implant hospitalization, then the discharge date is the transplant date, explant date or death date respectively).

Intermediate/step-down care - duration of stay	Type the number of days patient in Intermediate care (i.e. Step Down care).	numeric	Days should not exceed number of days from implant date to implant discharge date. Note: ICU/CCU duration + Intermediate/step-down duration cannot exceed the total days from implant date to implant discharge date (remember if the patient was transplanted, explanted or died during the implant hospitalization, then the discharge date is the transplant date, explant date or death date respectively).
Date of approximate discontinuation of inotropes	Select the approximate time when patient stopped taking inotrope therapy from the list below.	< 1 week 1-2 weeks 2-4 weeks > 4 weeks Ongoing Unknown	
Intervention Since Implant	Select the type of intervention since VAD implant date from the list.	Transplant Surgical Procedure Invasive Cardiac Procedures (Other than Heart Cath) Other Unknown None	
Transplant Date	Date of transplant procedure.	date	If Intervention since implant = Transplant

Surgical Procedure		Device related operation Other Cardiac Surgical Procedure Non Cardiac Surgical Procedure Other Procedure Unknown	If Device related operation, please remember to go to the Device Malfunction Adverse Event form and complete.)
Other Cardiac Surgical Procedure		Reoperation for Bleeding within 48 hours of implant Reoperation for Bleeding and/or tamponade > 48 hours Surgical Drainage of pericardial effusion Valve Surgery: Aortic Repair Valve Surgery: Mitral Repair Valve Surgery: Tricuspid Repair Valve Surgery: Pulmonary Repair Valve Surgery: Aortic Replacement - Mechanical Valve Surgery: Aortic Replacement - Biological Valve Surgery: Mitral Replacement - Mechanical Valve Surgery: Mitral Replacement - Biological Valve Surgery: Tricuspid Replacement - Mechanical Valve Surgery: Tricuspid Replacement - Biological Valve Surgery: Pulmonary Replacement - Mechanical Valve Surgery: Pulmonary Replacement - Biological Other, specify _____ Unknown	If Surgical Procedure = Other Procedure
Other Procedure	Intervention: select one of the following from the list	Reintubation due to Respiratory Failure Dialysis Bronchoscopy Other, specify	If Intervention since implant = Other then specify details
Explant: For Device Exchange, Recovery or Transplant	*Note: Complete this section for devices that are removed or devices that are "turned off" AND left in place. The Explant Form is to be collected at time of explant or transplant or both.*		
Device explanted		LVAD RVAD Both (in the same OR visit)	Select appropriate device type for this explant event

Explant Date		date	MMDDYYYY

Explant Reason		Transplant
		Device Malfunction
		  Emergent
		  Elective
		Infection
		  Emergent
		  Elective
		Device Thrombosis
		  Emergent
		  Elective
		Ventricular Recovery
		  Device removed
		  Device not removed but turned off
		Other, Specify
			Select one of the following as the reason for explant. If Other, specify is selected, type in the specification in the block provided.

Transplant Date		date	If Explant Reason = Transplant
Waitlist ID	UNOS Waitlist ID	text	If Explant Reason = Transplant
Death	*The Death Form is to be collected at time of death.*		
Death Date		date	
Device Functioning Normally	If the device was functioning normally at time of death, select Yes. If the device was not functioning normally at time of death, select No. If it is not known whether the device was functioning normally at time of death, select Unknown.	Yes No Unknown	If No, fill out the Device Malfunction Adverse Event Form.
Location of Death	Select whether patient was in or out of hospital at time of death. If location was not known, select Unknown	In Hospital Out of Hospital Unknown	

Timing of Death	Select one of the timings of death	Expected Unexpected Unknown
Primary Cause of Death	Many of the causes of death also represent an adverse event. Please complete the associated adverse event form.	<u>Respiratory</u> Venous Thromboembolism Event Respiratory Failure Pulmonary Other, specify <u>Circulatory</u> Arterial Non-CNS Thromboembolism Myocardial Infarction Myocardial Rupture Ruptured aortic aneurysm Right Heart Failure Major Bleeding Cardiac Arryhthmia Hemolysis Hypertension Cardiovascular, Other Sudden unexplained death CHF Heart Disease End Stage Cardiomyopathy Ischemic Cardiomyopathy Pericardial Fluid Collection <u>Digestive</u> Hepatic Dysfunction Renal Dysfunction GI Disorder Fluid/Electrolyte Disorder Pancreatits <u>Nervous System</u> Neurological Dysfunction <u>Psychiatric Episode/Suicide</u> Major Infection

		Device Malfunction MSOF Withdrawal of Support <u>Other</u> Wound Dehiscence Trauma/Accident, specify Cancer (if you select Cancer as a Primary cause of death, please select the following type of cancer) CNS, GI, Lymph, ENT, Pulmonary, Renal, Breast, Reproductive, Skin, Other, Unknown Endocrine Hematological
Adverse Events	*There are 4 major adverse events which have a form associated with the adverse event: Device Malfunction, Infection, Bleeding and Neurological Dysfunction.*	
AE Device Malfunction	*Device malfunction denotes a failure of one or more of the components of the MCSD system which either directly causes or could potentially induce a state of inadequate circulatory support (low cardiac output state) or death. A failure that was iatrogenic or recipient-induced will be classified as an Iatrogenic/Recipient-Induced Failure.* *Device failure should be classified according to which components fails as follows:* *1) Pump failure (blood contacting components of pump and any motor or other pump actuating mechanism that is housed with the blood contacting components). In the special situation of pump thrombosis, thrombus is documented to be present within the device or its conduits that result in or could potentially induce circulatory failure.* *2) Non-pump failure (e.g., external pneumatic drive unit, electric power supply unit, batteries, controller, interconnect cable, compliance chamber)*	
Device Type	Select appropriate device side (if BiVAD) for this device malfunction event.	LVAD RVAD Both

Date of Event	Date of adverse event.	Date	MMDDYYYY
Location of Patient	Select whether patient was in or out of hospital at time of adverse event.	In Hospital Out of Hospital Unknown	
Major Pump Unit Involved	Check all pump units that apply with this adverse event.	Blood Pump Drive Unit Failure External Control System Failure	
Suspected Device Thrombosis		Yes No Unknown	If Major Pump Unit Involved = Blood Pump
Anticoagulant Therapy		Warfarin Bivalirudin Heparin Fondaparinux Lovenox Dextran Aspirin Ticlopidine Dipyridamole Hirudin Clopidogrel (plavix) Lepirudin Argatroban Ximelagatran None Other, specify, enter other therapy in box provided	If Suspected Device Thrombosis = Yes
Surgical Procedure Required	Surgical procedure was required in this device malfunction adverse event.	Yes No Unknown	If yes fill out surgical intervention on the Rehospitalization
Device Explanted	Was device explanted at this event?	Yes No Unknown	If Yes fill out explant form
Device malfunction adverse event cause patient's death	Did this device malfunction adverse event cause the patient’s death?	Yes No Unknown	

Causative or contributing factors to the device malfunction.	Select all causes or contributing factors that apply to this device malfunction.	Patient/Device Interaction Medical Management (interaction between health system and patient) Primary Device Malfunction Patient/Disease Related End of Pump Life No specific contributing cause identified	
Specific Component Affected	Select all components affected that apply to this adverse event.	External Battery Malfunction Internal Battery Malfunction External Controller Malfunction Internal Controller Malfunction Driveline Malfunction Inflow Graft Malfunction/Malposition Outflow Graft Malfunction/Malposition Pump Drive Unit Malfunction Inflow Valve Outflow Valve Volume Compensator Malfunction Other Component Malfunction, specify	For each specific component affected that is selected a text box will appear at the bottom of the list where you may enter details concerning this adverse event relating to the particular component affected.
Device malfunction intervention	Select all device interventions that apply to this adverse event.	Replacement of External Battery Replacement of Internal Battery Replacement of External Controller Replacement of Internal Controller Replacement of Driveline Replacement of Inflow Graft Replacement of Outflow Graft Replacement of Pump Repair of Driveline Replacement of Pump Valve Replacement of Volume Compensator Replacement of Other Component, specify Switch from Vented Electric to Pneumatic-mode Other Interventions, specify None Unknown	If Replacement of Other Component, specify is selected, type in the specification in the block provided. If Other Interventions, specify is selected, type in the specification in the block provided.

AE Infection	*A clinical infection accompanied by pain, fever, drainage and/or leukocytosis that is treated by anti-microbial agents (non-prophylactic). A positive culture from the infected site or organ should be present unless strong clinical evidence indicates the need for treatment despite negative cultures. The general categories of infection are listed below:* *Localized Non-Device Infection* *Infection localized to any organ system or region (e.g. mediastinitis) without evidence of systemic involvement (See sepsis definition), ascertained by standard clinical methods and either associated with evidence of bacterial, viral, fungal or protozoal infection, and/or requiring empirical treatment.* *Percutaneous Site and/or Pocket Infection* *A positive culture from the skin and/or tissue surrounding the drive line or from the tissue surrounding the external housing of a pump implanted within the body, coupled with the need to treat with antimicrobial therapy when there is clinical evidence of infection such as pain, fever, drainage, or leukocytosis.* *Internal Pump Component, Inflow or Outflow Tract Infection* *Infection of blood-contacting surfaces of the LVAD documented by positive site culture. (There should be a separate data field for paracorporeal pump that describes infection at the percutaneous cannula site, e.g. Thoratec PVAD).* *Sepsis* *Evidence of systemic involvement by infection, manifested by positive blood cultures and/or hypotension.*		
Date of Event	Date of adverse event.	date	MMDDYYYY
Location of Patient	Select whether patient was in or out of hospital at time of adverse event.	In Hospital Out of Hospital Unknown	
Did this Infection Contribute to Death		Yes No Unknown	

Location of infection	Select all locations of infection that apply to this adverse event.	Pump / related - Drive Line Pump / related – Exit Cannula Pump / related - Pump Pocket Pump / related - Pump Interior Pulmonary Urinary Tract Mediastinum Peripheral Wound Positive Blood cultures GI Line Sepsis Unknown Other, specify	
Type of Infection	Select one of the following types of infection.	Bacterial Fungal Viral Potozoan Unknown	
Intervention Since Implant	Select drug therapy, surgery or both.	Drug Therapy Oral IV Unknown Surgery	
AE Neurological Dysfunction	*Any new, temporary or permanent, focal or global neurological deficit ascertained by a standard neurological examination (administered by a neurologist or other qualified physician and documented with appropriate diagnostic tests and consultation note). The examining physician will distinguish between a transient ischemic attack (TIA), which is fully reversible within 24 hours (and without evidence of infarction), and a stroke, which lasts longer than 24 hours (or less than 24 hours if there is evidence of infarction). Each neurological event must be subcategorized as:* *1) Transient Ischemic Attack (acute event that resolves completely within 24 hours with no evidence of infarction)* *2) Ischemic or Hemorrhagic Cardiovascular Accident/CVA (event that persists beyond 24 hours or less than 24 hours associated with infarction on an imaging study.)*		
Date of Event	Date of adverse event.	date	MMDDYYYY

Location of Patient	Select whether patient was in or out of hospital at time of adverse event.	In Hospital Out of Hospital Unknown
Neurological Dysfunction Categories	Select one of the neurological dysfunction categories.	TIA Confusion CVA Type of CVA Ischemic Hemorrhagic Other Stroke Severity Left sided weakness Right sided weakness Left sided paralysis Right sided paralysis Speech deficit Altered mental status Coma Other, specify Seizure Generalized Focal Encephalopathy Metabolic Anoxic Traumatic Other
Did this Neurological Dysfunction Adverse Event contribute to the patient's death		Yes No Unknown

Anticoagulant therapy at time of event	If anticoagulant therapy was used at the time of this event, check all therapies that apply.	Warfarin Fondaparinux Heparin Dextran Lovenox Ticlopidine Aspirin Hirudin Dipyridamole Lepirudin Clopidogrel (plavix) Ximelagatran Argatroban None Bivalirudin Other, specify	
AE Major Blood	*An episode of suspected internal or external bleeding that results in one or more of the following:* *1. Death,* *2. Re-operation,* *3. Hospitalization,* *4. Transfusion of red blood cells*		
Date of Bleeding Episode Onset	Enter date of bleeding episode onset	date	unknown (ST=)
Location of Patient		In Hospital Out of Hospital Unknown	
Did the major bleeding episode result in one or more of the following		Episode resulted in Death (fill out death form) Episode resulted in Re-operation Episode resulted in Hospitalization (Currently in the hospital or re-hospitalized) Episode resulted in transfusion(s) for bleeding episode	

Source/cause/location of Bleeding	Mediastinal: chest wall Mediastinal: outflow-aorta anastomosis Mediastinal: outflow conduit Mediastinal: inflow conduit Mediastinal: aortic- venous cannulation site Mediastinal: coagulopathy with no surgical site Mediastinal: other surgical site Pump Pocket Pleural space Intra-abdominal Retroperitoneal Pulmonary Device anastamosis Urinary tract GI: Upper gastrointestinal (esophagus, stomach, duodenum, small bowel) GI: Lower gastrointestinal (colon, rectum, and anus) GI: unknown, but guaiac positive stools Other, specify	Check all that apply
Did the bleeding episode occur during the 1st 7 days post implant	Yes No	
Did the patient receive more than 4 units during any 24 hour period of the bleeding episode	Yes No	If Did the bleeding episode occur during the 1st 7 days post implant = Yes
Did the bleeding episode occur 8 or more days post implant	Yes No	
Did the patient receive 1 or more units during any 24 hour period of the bleeding episode	Yes No	If Did the bleeding episode occur 8 or more days post implant = Yes
INR	Numeric	unknown (ST=)

Anticoagulant therapy at time of event		Warfarin Bivalirudin Heparin Fondaparinux Lovenox Dextran Aspirin Ticlopidine Dipyridamole Hirudin Clopidogrel (plavix) Lepirudin Argatroban Ximelagatran None Other, specify	Check all that apply
AE Respiratory Failure	*Impairment of respiratory function requiring reintubation, tracheostomy or (for patients older than age 5 years) the inability to discontinue ventilatory support within six days (144 hours) post-VAD implant. This excludes intubation for re-operation or temporary intubation for diagnostic or therapeutic procedures.*		
Date of Event	Date of adverse event	Date	MMDDYYYY
Enter Intubation Duration in Days		Numeric	
Was a Tracheotomy Performed		Yes No Unknown	
AE Arterial Non-CNS Thromboembolic Event	*An acute systemic arterial perfusion deficit in any non-cerebrovascular organ system due to thromboembolism confirmed by one or more of the following:* *1) standard clinical and laboratory testing* *2) operative findings* *3) autopsy findings*		
Enter Date		Date	MMDDYYYY

Location of Thromboembolic Event		Pulmonary Renal Splenic Hepatic Limb Other Unknown	If Other selected, enter in block provided
Enter Confirmation Source		Standard clinical and laboratory testing Operative findings Autopsy finding Other Unknown	If Other selected, enter in block provided
Anticoagulant therapy at time of event	check all that apply	Warfarin Bivalirudin Heparin Fondaparinux Lovenox Dextran Aspirin Ticlopidine Dipyridamole Hirudin Clopidogrel (plavix) Lepirudin Argatroban Ximelagatran None Other, specify	

Appendix D – Deceased Donor Data for Heart Community

	Name	Description	Values	Data Rules	Mandatory
	Registration				
	Identifiers				
●	Local Donor ID	Local donor identifier entered by OPO.	Identifier	≤ 50 characters	Required to create record
●	Date of Birth	Date of birth of donor.	Date	≤ current date	Required to create record
	Donor Case Status				
●	Donor Type	Flag indicating type of donor.	Deceased Living	Defaulted to Deceased	Required to create record
●	Donor Case	State of donor case e.g. open or closed.	Open Closed	Defaulted to Open	Required to create record
	Demographics				
●	Country of Residence	Donor country of residence.	List of countries	Single selection list	Optional
●	Gender	Gender of patient.	Male Female Other Unknown	n/a	Required to create record
●	Height (cm)	Height of patient.	cm	≥ 0.0 and ≤ 300.0	Required to create record
●	Weight (kg)	Weight of patient.	kg	≥ 0.0 and ≤ 700.0	Required to create record
●	ABO	Blood type of patient.	A B O AB unknown	n/a	Required to create record
●	Confirm ABO	Confirm blood group by re-entering blood group.	blood types e.g. A, B, O	≤ 4 characters	Required to create record

	Name	Description	Values	Data Rules	Mandatory
●	RH	RH of patient.	+ -	n/a	Optional
	Facility				
●	OPO	Organ Procurement Organization responsible for donor.	Abbreviated and full name of OPO	n/a	Required to create record
●	HLA lab	HLA lab responsible for providing HLA typing.	Abbreviated and full name of HLA	Derived by system based on associated Transplant Centre.	Required to create record
●	Referral Hospital	Hospital where potential deceased donor is identified.	Hospital name with city	n/a	Required to create record
●	Care Hospital	Hospital where deceased donor care takes place.	Hospital name with city	n/a	Required to close donor case
●	Retrieval Hospital	Hospital where the deceased donor organ procurement surgery takes place.	Hospital name with city	n/a	Required to close donor case
	Consent				
●	Heart Consent State	Consent state of heart.	Consented Not Consented Not Participating	n/a	Required for VXM and offer
	Declaration of Death				
	Death				
●	Type of Declaration of Death	Declaration of death could be neurological determination of death (NDD) or donor after cardio circulatory death (DCD).	NDD DCD	n/a	Required for VXM and offer
●	Cause of Death	Deceased donor cause of death.	Ancephalitis Encephalitis Ancephaly Anoxia/Hypoxia Arteriovenous malformation Cerebral abscess Cerebral oedema Cerebrovascular accident (stroke) – embolic Cerebrovascular accident (stroke) – hemorrhagic Cerebrovascular accident (stroke) - ischemic Diabetic ketoacidosis	Must be single selection	Required for VXM and offer

Name	Description	Values	Data Rules	Mandatory
		Drug Overdose-Barbiturate Drug Overdose-Benzodiazepine Drug Overdose-Carbon monoxide Drug Overdose-Opiate Drug Overdose-Other Fall Gunshot Hepatic failure Hydrocephalus Hyponatremia Inborn error of metabolism Meningitis Motor vehicle collision Primary CNS tumour Ruptured cerebral aneurysm Subarachnoid hemorrhage Non-Accidental Injury Trauma – specify Unknown Other-comment required		
Country of Death	Country where deceased donor was declared dead.	Canada United States Australia Austria Belgium Czechoslovakia Denmark France Germany Israel Italy Japan Mexico Spain Sweden United Kingdom	n/a	Required for VXM and offer

	Name	Description	Values	Data Rules	Mandatory
●	Province/State of Death	Province or state where donor was declared dead.	Canadian provinces and territories US states	n/a	Required for VXM and offer
	NDD				
●	First Brain Death Date/ Time	First brain death date/time for NDD.	YYYY-MM-DD HH:MM	≤ current date/time and ≥ date of birth of donor. ≤ cross clamp date/time. Required for NDD only.	Required for VXM and offer
●	Declaration of NDD	Method used for Declaration of NDD performed by physician e.g. Ancillary or Clinical Exam.	Ancillary - 4 Vessel Cerebral Angiogram CLINICAL EXAM Ancillary - Radionuclide Testing Ancillary - CT Angiogram Ancillary - MRI Angiography Other	Multiple selection list	Required for VXM and offer
	Assessment				
	Medical/Social History				
●	Alcohol Abuse	Flag indicating if patient has a history of alcohol abuse.	Yes No Unknown	n/a	Required for offer
●	Alcohol Abuse Details	Specific details on patient's alcohol abuse.	Details	≤ 2000 characters	Required if Alcohol History = Yes or Unknown
●	Smoking History	Flag indicating if patient has a history of smoking.	Yes No Unknown	n/a	Required for offer
●	Smoking History Details	Specific details on patient's smoking history.	Details	≤ 2000 characters	Required if Smoking History = Yes or Unknown
●	Cancer History	Flag indicating if patient has history of cancer.	Yes No Unknown	n/a	Required for offer
●	Cancer History Details	Specific details on patient's cancer history.	Details	≤ 2000 characters	Required if Cancer History = Yes or Unknown
●	Hypertension	Flag indicating if patient has hypertension.	Yes No Unknown	n/a	Required for offer

Name	Description	Values	Data Rules	Mandatory
Hypertension Details	Specific details on patient's hypertension.	Details	≤ 2000 characters	Required if Hypertension = Yes or Unknown
Heart Disease	Flag indicating if patient has heart disease.	Yes No Unknown	n/a	Required for offer
Heart Disease Details	Specific details on patient's heart disease.	Details	≤ 2000 characters	Required if Heart Disease = Yes or Unknown
Pulmonary Disease	Flag indicating if patient has pulmonary disease.	Yes No Unknown	n/a	Required for offer
Pulmonary Disease Details	Specific details on patient's pulmonary disease.	Details	≤ 2000 characters	Required if Pulmonary Disease = Yes or Unknown
Kidney Disease	Flag indicating if patient has kidney disease.	Yes No Unknown	n/a	Required for offer
Kidney Disease Details	Specific details on patient's kidney disease.	Details	≤ 2000 characters	Required if Kidney Disease = Yes or Unknown
Diabetes History	Flag indicating if patient has a history of diabetes.	Yes No Unknown	n/a	Required for offer
Diabetes History Details	Specific details on patient's diabetes history.	Details	≤ 2000 characters	Required if Diabetes = Yes or Unknown
Liver Disease	Flag indicating if patient has liver disease.	Yes No Unknown	n/a	Required for offer
Liver Disease Details	Specific details on patient's liver disease.	Details	≤ 2000 characters	Required if Liver Disease = Yes or Unknown
Cardio Respiratory Arrest	Flag indicating if patient had cardio respiratory arrest.	Yes No Unknown	n/a	Required for offer

	Name	Description	Values	Data Rules	Mandatory
●	Cardio Respiratory Arrest Details	Specific details on cardio respiratory arrest details.	Details	≤ 2000 characters	Required if Cardio Respiratory Arrest = Yes or Unknown
●	Cardio Respiratory Arrest Duration (min)	Duration of cardio respiratory arrest.	Minutes	≥ 0 minutes	Required if Cardio Respiratory Arrest = Yes
	Exceptional Distribution				
●	Exceptional Distribution	Flag indicating if donor is exceptional distribution.	Yes No	n/a	Required for offer
●	Exceptional Distribution flags	Selectable list of exceptional distribution reasons.	list of exceptional distribution reasons	n/a	Select reason if Exceptional Distribution = Yes
	HLA Typing – Conditional mandatory rules - Required for virtual cross match				
●	A_1	HLA typing of patient.	Molecular allele	≤ 20 characters. Optional for all other heart listings but required for virtual cross match.	Required for VXM and offer
●	A_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
●	B_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
●	B_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
●	C_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
●	C_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
●	DRB1_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
●	DRB1_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
●	DRB3_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele. Of the six text-entry fields	Required for VXM and offer

Name	Description	Values	Data Rules	Mandatory
			which are available for the locus DRB3, DRB4, and DRB5, a maximum of two values may be entered, and a minimum of one value must be entered.	
DRB3_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
DRB4_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
DRB4_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
DRB5_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
DRB5_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
DRB 3/4/5 Tested, but not present	Flag indicating if DRB3, DRB4 and DRB5 tested but not present.	Yes No	When no values are entered for DRB3, DRB4, and DRB5, and the HLA typing is to be considered complete, then indicate that DRB3, DRB4, and DRB5 were “Tested, but not present”.	Required for VXM and offer
DPA1_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
DPA1_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
DPB1_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
DPB1_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
DQA1_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer

	Name	Description	Values	Data Rules	Mandatory
●	DQA1_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
●	DQB1_1	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
●	DQB1_2	HLA typing of patient.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM and offer
●	HLA Typing Confirmed	User confirms HLA Typing.	Yes No	Default = blank	Required for VXM and offer
	Serology – For each serology - multiple time points can be captured - a test type must be recorded for each serology result - sample drawn date/time recorded for each result				
●	Sample Drawn Date/Time	Date/Time serology (blood) sample is drawn.	Date and Time	≤ current date/time and Must be greater than date of birth of donor. Required for any serology test result entered in registry.	Required for any serology test result entered in registry
●	CMV	CMV result based on IgG test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer
●	Hepatitis B Core Antibody	HBV result based on Anti-HBc (HBcAb) test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer
●	Hepatitis B Surface Antibody	HBV result based on Anti-HBs (HBsAb) test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer

Name	Description	Values	Data Rules	Mandatory
Hepatitis B Surface Antigen	HBV result based on HBsAG test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer
Hepatitis C	HCV result based on IgG test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required – not tested is permissible.	Required for VXM and offer
HIV I and II	HIV I and II result based on any of the following tests: IgG, Antibody/p24antigen, HIV NAT (HIV DNA, HIV Single NAT), Double NAT (HIV, HCV), and Triple NAT (HIV, HCV, and HBV).	Positive Negative Pending Not Tested Indeterminate	At least one result is required	Required for VXM and offer
Syphilis	Syphilis result based on the following tests: EIA, RPR, VDRL, FTA-ABS.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer
Toxoplasmosis	Toxoplasmosis result based on IgG.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer
West Nile	West Nile result based on IgG, IgM, NAT.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Optional
EBV	EBV result based on the following tests: IgG (VCA) or IgG (EBNA).	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer

	Name	Description	Values	Data Rules	Mandatory
●	HSV Antibody	HSV test result based on IgG.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer
	Medication – For each medication - multiple time points can be captured - infusion date/time recorded for each result - a unit must be recorded for each medication - maximum dosage must be recorded for each medication				
●	Infusion Date/Time	Date and time a group of medications were given to the patient.	Date and Time	≤ current date/time and Must be greater than date of birth of donor. For each medication recorded date required.	Required for any medication entered in the registry
●	Unit	Unit of measure for medication given to patient.	Grams Nanograms per kilo per minute Miliequivalent Micrograms per kilo per minute Microgram per minute Micrograms per hour Miligram per kilo per minute Miligram per hour Miligrams Units per minute Units per hour Microgram Micrograms per kilo per hour Miligram per kilo per hour Milliunit per kilo per minute Units per kilo per minute miligram per kilo micrograms per kilo	For each medication unit required.	Required for any medication entered in the registry
●	Maximum Dosage	Maximum dosage administered to donor.	Dosage	≥ 0.000 and ≤ 999.9999. For each medication maximum dosage is	Required for offer

Name	Description	Values	Data Rules	Mandatory
			required.	
Neosynephrine/Phenylephrine		Dosages	≥ 0.000 and ≤ 999.9999. Capture multiple time points. At least one dosage is required at time of declaration of death and one prior to organ retrieval.	Required for offer
Dopamine/Inatropin		Dosages	≥ 0.000 and ≤ 999.9999. Capture multiple time points. At least one dosage is required at time of declaration of death and one prior to organ retrieval.	Required for offer
Epinephrine		Dosages	≥ 0.000 and ≤ 999.9999. Capture multiple time points. At least one dosage is required at time of declaration of death and one prior to organ retrieval.	Required for offer
Esmolol/Brevibloc		Dosages	≥ 0.000 and ≤ 999.9999. Capture multiple time points. At least one dosage is required at time of declaration of death and one prior to organ retrieval.	Required for offer

Name	Description	Values	Data Rules	Mandatory
Nipride/Nitropusside		Dosages	≥ 0.000 and ≤ 999.9999. Capture multiple time points. At least one dosage is required at time of declaration of death and one prior to organ retrieval.	Required for offer
Levothyroxine/T4		Dosages	≥ 0.000 and ≤ 999.9999. Capture multiple time points. At least one dosage is required at time of declaration of death and one prior to organ retrieval.	Required for offer
Solumedrol		Dosages	≥ 0.000 and ≤ 999.9999 Capture multiple time points. At least one dosage is required at time of declaration of death and one prior to organ retrieval.	Required for offer
Vasopressin/Pitressin		Dosages	≥ 0.000 and ≤ 999.9999. Capture multiple time points. At least one dosage is required at time of declaration of death and one prior to organ retrieval.	Required for offer

Name	Description	Values	Data Rules	Mandatory
DDAVP		Dosages	≥ 0.000 and ≤ 999.9999. Capture multiple time points. At least one dosage is required at time of declaration of death and one prior to organ retrieval.	Required for offer
Insulin		Dosages	≥ 0.000 and ≤ 999.9999. Capture multiple time points. At least one dosage is required at time of declaration of death and one prior to organ retrieval.	Required for offer
Heparin		Dosages	≥ 0.000 and ≤ 999.9999. Capture multiple time points. At least one dosage is required at time of declaration of death and one prior to organ retrieval.	Required for offer
Vital Signs – For each vital signs - multiple time points can be captured - collection date/time recorded for each result				
Date/Time	Collection date and time.	Date and Time	≤ current date/time and must be greater than date of birth of donor.	Required for any Vital Sign entered in the registry

Name	Description	Values	Data Rules	Mandatory
BP Systolic (mmHg)		Fraction e.g. 120/70 Or select not recorded	≥ 0 and ≤ 400. Capture multiple time points. At least one value is required at time of declaration of death and one prior to organ retrieval.	Required for offer
BP Diastolic (mmHg)		Fraction e.g. 120/70 Or select not recorded	≥ 0 and ≤ 200. Capture multiple time points. At least one value is required at time of declaration of death and one prior to organ retrieval.	Required for offer
MAP (mmHg)		Numeric	≥ 0 and ≤ 200. Capture multiple time points. At least one value is required at time of declaration of death and one prior to organ retrieval.	Required for offer
Heart Rate (bpm)		Numeric	≥ 0 and ≤ 250. Capture multiple time points. At least one value is required at time of declaration of death and one prior to organ retrieval.	Required for offer

Name	Description	Values	Data Rules	Mandatory
CVP (mmHg)		Numeric	≥ 0 and ≤ 40. Capture multiple time points. At least one value is required at time of declaration of death and one prior to organ retrieval.	Required for offer (IF AVAILABLE)
Temp (Celsius)		Numeric	≥ 20.0 and ≤ 50.0. Capture multiple time points. At least one value is required at time of declaration of death and one prior to organ retrieval.	Required for offer
UO (mls/hr)		Numeric	≥ 0 and ≤ 9999. Capture multiple time points. At least one value is required at time of declaration of death and one prior to organ retrieval.	Required for offer
CO (L/min)		Numeric	≥ 0 and ≤ 40. Capture multiple time points. At least one value is required at time of declaration of death and one prior to organ retrieval.	Required for offer (IF AVAILABLE)

Name	Description	Values	Data Rules	Mandatory
CI (L/min/m2)		Numeric	≥ 0.0 and ≤ 20.0. Capture multiple time points. At least one value is required at time of declaration of death and one prior to organ retrieval.	Required for offer (IF AVAILABLE)
PCWP (mmHg)		Numeric	≥ 0.0 and ≤ 40.0. Capture multiple time points. At least one value is required at time of declaration of death and one prior to organ retrieval.	Required for offer (IF AVAILABLE)
PAP Systolic (mmHg)		Numeric	≥ 0 and ≤ 99. Capture multiple time points. At least one value is required at time of declaration of death and one prior to organ retrieval.	Required for offer (IF AVAILABLE)
PAP Diastolic (mmHg)		Numeric	≥ 0 and ≤ 99. Capture multiple time points. At least one value is required at time of declaration of death and one prior to organ retrieval.	Required for offer (IF AVAILABLE)

Name	Description	Values	Data Rules	Mandatory
Chemistry – For each chemistry - multiple time points can be captured - collection date/time recorded for each result				
Date/Time	Collection date and time.	Date and Time	≤ current date/time and must be greater than date of birth of donor.	Required for any Chemistry entered in the registry
T Bili (µmol/L)		Normal values 0-300	≥ 0 and ≤ 999. Capture multiple time points.	Optional for offer
D Bili (µmol/L)		Normal values <7	≥ 0.0 and ≤ 50.0. Capture multiple time points.	Optional for offer
ALT (U/L)		Normal values <50	≥ 0 and ≤ 99999. Capture multiple time points.	Optional for offer
AST (U/L)		Normal values <140	≥ 0 and ≤ 99999. Capture multiple time. points	Optional for offer
Alk Phos (U/L)		Normal values 30-500	≥ 0 and ≤ 99999. Capture multiple time points.	Optional for offer
GGT (U/L)		Normal values <70	≥ 0 and ≤ 9999. Capture multiple time points.	Optional for offer
Amylase (U/L)		Normal values 36-150	≥ 0 and ≤ 9999. Capture multiple time points.	Optional for offer
Lipase (U/L)		Normal values 23-300	≥ 0 and ≤ 9999. Capture multiple time points.	Optional for offer
Albumin (g/L)		Normal values 26-50	≥ 0 and ≤ 99. Capture multiple time points.	Optional for offer
LDH (U/L)		Normal values 100-430	≥ 0 and ≤ 9999. Capture multiple time points.	Optional for offer

Name	Description	Values	Data Rules	Mandatory
Total Protein (g/L)		Normal values 50-84	≥ 0 and ≤ 9999	Optional for offer
HgbA1C (%)		Normal values 4.3-6.1	≥ 0.0 and ≤ 99.9. Capture multiple time points.	Optional for offer
Troponin T (ug/L)		Normal values <0.15	≥ 0.000 and ≤ 999.999. Capture multiple time points.	Required for offer
Troponin I (ug/L)		Normal values <0.15	≥ 0.000 and ≤ 999.999. Capture multiple time points.	Required for offer
CK (U/L)		Normal values 40-250 (U/L)	≥ 0 and ≤ 99999. Capture multiple time points.	Required for offer
Cardiac Profile - For each data element - multiple time points can be captured - collection date/time recorded for each result				
Date/Time	Collection date and time.	Date and Time	≤ current date/time and must be greater than date of birth of donor.	Required for any Cardiac Profile entered in the registry
ECG	ECG Result.	Result	≤ 2000 characters. Capture multiple time points.	Required for offer
ECHO	ECHO Result.	Result	≤ 2000 characters. Capture multiple time points	Required for offer
Angiogram	Angiogram Result.	Result	≤ 2000 characters. Capture multiple time points	Required for offer
LVEF		Percentage	≥ 0 and ≤ 100. Capture multiple time points.	Required for offer

	Name	Description	Values	Data Rules	Mandatory
	Grades of MR	Grades of Mitral Regurgitation.	Trivial/trace Mild Moderate	Single selection list	Required for offer
	TR	Tricuspid Regurgitation.	Trivial/trace Mild Moderate	Single selection list	Required for offer
	AI	Aortic Insufficiency.	Trivial/trace Mild Moderate	Single selection list	Required for offer
	Recovery				
	Recovery				
	Cross Clamp Date/ Time	Date and time organs were recovered and flushed with a specially prepared, ice-cold solution.	Date and Time.	≤ current date/time and Must be greater than first brain death date/time for NDD Donor or DCD Declaration End Date/Time for DCD Donor. If organ recovered for transplant then cross clamp date/time required.	Required to close donor case
	Perfusion	Organ device used to perfuse organ.	Kidney Perfusion Pump Exvivo Pump None	n/a	Required to close donor case
	Heart Recovered State	Recovered state of organ.	Recovered or Not recovered	If organ consented then recovery details are required.	Required to close donor case
	Not Recovered Reason	Not recovered reason for each organ.	Coroner / medical examiner decline No suitable recipient (size/ABO) Storage and preservation problems No recipient located No recovery team available Medically unsuitable pre OR Medically unsuitable intra OR Unable to maintain donor pre OR Technical problem in OR Transportation logistics Problem with recipient	n/a	Required if not recovered selected

Name	Description	Values	Data Rules	Mandatory
		All offers declined DCD did not die within acceptable time High inotrope requirement Inadequate perfusion of organ (thrombosis) Infection/sepsis Organ damaged during recovery Unable to maintain donor intra OR		
Recovered For Reason	Recovered for a specific medical use, for each organ.	Transplant Research Medical Education Tissue Not Used Not Applicable Pathology	n/a	Required if recovered selected

Appendix E – Sample Data Scan

Data Element	HDWG ..	HDWG R	HDWG Pr	HDWG Pe	HDWG Po	CORR H	UNOS H	NHSBT H	ISHLT	IMACS
Registration	14	4	4	0	0	16	19	29	6	
Identifying Information	2	0	2	0	0	3	3	5	2	
Date of Birth						M	M	M	M	●
First Name						M	M	M	O	●
Middle Name									O	●
Last Name						M	M	M	O	●
Former Last Name										
LDPE ID										
Local Recipient ID									M	
National Recipient ID								M		
Provincial Health Number (PHN)	M		M			O	O	M		
PHN/Home Prov	M		M			O				
Registered On LDPE										
Contact Information	2	0	2	0	0	3	2	4	0	
Contact Relationship										
Order of contact										
Address								M		
City						M				
Email										
Postal Code	M		M			M	M	M		
Province	M		M			M	M	M		
Telephone-Home								M		
Telephone-Mobile										
Telephone-Work										
Patient Waiting in Permanent ZIP Code							O			
Demographics	5	4	0	0	0	5	8	9	3	
Body Metrics	3	4	0	0	0	4	3	6	3	
Age									M	
Advanced Age										●
Gender	M					M	M	M	M	●
Height (cm)	M					M	M	M	O	●
Weight (kg)	M					M	M	M	O	●
BMI							C			
Body Surface Area (Peds)		C						M		
ABO		M				M	O	M	M	●
Confirm ABO		M								
RH		M						M		
Confirm RH		M								
In-utero										

Appendix F – Terms of Reference

Organ Donation and Transplantation
Heart Data Working Group
Terms of Reference

Objectives

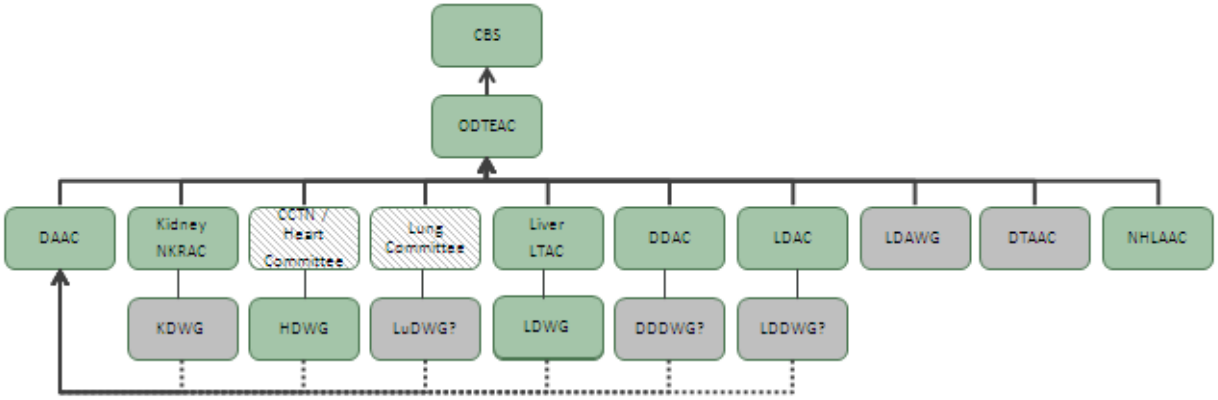
The provincial and territorial governments have funded Canadian Blood Services to develop and operate the Canadian Transplant Registry (CTR). The national registry system includes a data warehouse with business intelligence tools that provide accurate, timely and comprehensive data to support research, national and provincial measurement, and the modelling and analytical needs of the Canadian organ donation and transplantation community.

Building on the CTR data warehouse, Canadian Blood Services is responding to the vision articulated at the June 2013 ODT Data, Analytics and Reporting System Workshop, to build a world-leading data system that provides timely access to high quality ODT information for patient care, system management and accountability. One of the supporting activities to enhancing the ODT Data System is to convene organ and donation-specific data working groups to develop transplant measures and identify a transplant data set to facilitate clinical practice decision making, development of practice standards and inform outcomes reporting for transplantation in Canada.

The Heart Data Working Group will serve to:

- Develop heart transplant measures to form a heart transplant data set that will:
    - Facilitate clinical practice decision making
    - Aid in the development of practice standards
    - Inform outcomes reporting
    - Support clinical research
    - Provide data to support interprovincial operational and clinical policies, standards of practice and evidence-based practice with respect to heart listing and allocation.

Organ Donation & Transplantation Committees



CBS: Canadian Blood Services
ODTEAC: Organ Donation & Transplantation Expert Advisory Committee
DAAC: Data & Analytics Advisory Committee (In development)
NKRAC: National Kidney Registry Advisory Committee
KDWG: Kidney Data Working Group (In development)
CCTN: Canadian Cardiac Transplantation Network
HDWG: Heart Data Working Group
LuTAC: Lung Transplant Advisory Committee (TBD)
LuDWG: Lung Data Working Group (In development)
LTAC: Liver Transplant Advisory Committee
LDWG: Liver Data Working Group
DDAC: Deceased Donation Advisory Committee
DDDWG: Deceased Donation Data Working Group
LDAC: Living Donation Advisory Committee
LDDWG: Living Donation Data Working Group (In development)
LDAWG: Living Donation Administrators Working Group
DTAAC: Donation and Transplantation Administrators Advisory Committee (In development)
NHLAAC: National Human Leukocyte Antigen Advisory Committee
NORPAC: National Organ Registry Privacy Advisory Committee

Scope

The Working Group's scope encompasses matters related to inter-provincial heart transplant practices, including documentation of listing and allocation practices, donor and recipient information, and heart transplant outcomes in support of the CTR. To contribute to the data needs that will inform clinical decisions and support clinical research with respect to heart transplantation and outcomes reporting, the Working Group will:

- identify data points along the heart donation, allocation and transplant critical path
- identify the availability and gaps in current data and the comparability of data amongst heart transplant programs
- develop a minimum data set for heart transplantation with regards to heart waitlist outcomes, heart transplant activity and heart transplant outcomes to support clinical decisions and research
- develop a quality control strategy to assess the quality and completeness of data submissions to the registry

Authority

The Heart Data Working Group shall function under the current scope and authority of Canadian Blood Services until such time that a formal governance and accountability structure is approved by the FPT Deputy Ministers of Health. The Canadian Cardiac Transplantation Network (CCTN) is the heart representative for the Canadian Blood Services collaborative endeavour in the continued development of the CTR. The Chair of the Working Group committee shall be appointed by Canadian Blood Services and the CCTN.

Reporting

Heart Data Working Group will report to the Data and Analytics Advisory Committee (DAAC) and the Organ Donation and Transplantation Expert Advisory Committee (ODTEAC). Activities may also be reported to an interprovincial government committee, the Provincial and Territorial Blood Liaison Committee, as part of the performance reporting requirements for Canadian Blood Services as set out by governments.

Composition of the Heart Data Working Group

Membership in the Heart Data Working Group will include 5 – 8 individuals with relevant professional knowledge and experience in heart transplantation. Members will also have a deep appreciation and interest in the use of heart data to advance heart donation and transplantation in Canada.

Canadian Blood Services, with the concurrence of the Chair, has the ability to request the appointment of new members as the need is identified.

Membership will balance and encompass representation from heart transplantation programs across Canada. Subject matter experts may be invited to attend specific Working Group meetings as required. Membership participation is required at two out of every three meetings scheduled.

Chair

The Chair of the Committee shall be appointed by Canadian Blood Services and the CCTN, and shall serve a two year term. Upon completion of this term Canadian Blood Services may extend the appointment. The Chair of the Committee is responsible for ensuring that the Committee functions within these Terms of Reference and will provide regular updates to the DAAC and CCTN on the activities of the Heart Data Working Group.

Processes and Timeframes

- The day and time for teleconferences will be set based on agreed membership preference
- Materials will be circulated to members 5 business days in advance of the teleconference

Quorum

- A majority of the voting members of the Committee shall constitute a quorum.
- Ordinarily, decisions and recommendations of the Committee will be achieved by consensus

Meetings

- Canadian Blood Services will provide the Secretariat to the Committee meetings.
- Meetings will be held on the first Friday of each month, or at the call of the Chair.
- Attendance is expected at 2 of every 3 meetings.
- Members shall not send delegates to meetings, unless approved by the Chair.

Confidentiality

All materials used in support of committee business must be treated as confidential Heart Data Working Group business and should not be distributed without the approval of Canadian Blood Services.

Evaluation

Prior to the final teleconference of the Heart Data Working Group an evaluation of the performance of the working group will be undertaken and the results will be shared with members.