Background Information

11 June 2008

Overview

- Workload and current curation rate
- Factors driving the need to speed up curation
- Government regulations
- Initial UML model

Workload and Current Curation Rate

- Workload
  - 98 recipient forms
  - Approximately 8,000 CDEs
- Current Curation Rate
  - Experienced curator – 10 CDEs / day
  - New curator – 5 CDEs / day
- Estimated timeline
  - 18-24 months to complete

Factors Driving the Need to Speed up Curation

- Centers are currently doing double data entry
- Centers need time to map their data to CDEs
- Centers are required by law to submit some forms

Government Regulations

- C.W. Bill Young Cell Transplantation Program
- Stem Cell Therapeutic Outcomes Database (SCTOD)
- SCTOD mandates the submission of some forms

Initial UML Model

- Initially tried to replace form based model with a more abstract model
- Business constraints made adoption of abstract model difficult

NMDP Curation Process

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Overview of Workflow

- Prepare form for curation
- Curate CDEs
- Curators review CDEs
- Review Committee reviews CDEs
- Create Form Builder case report form
- Curators review case report form
- Review committee reviews case report form
- CDEs and case report form are released
- Translation database is populated

Prepare Form For Curation

- Make concept requests to EVS
- Determine cross-form reuse
- Determine cross-form curation consistency

Curate CDEs

- Curate in Excel
- Enter curation into the curation tool

Curate CDEs
Common EVS Terms Spreadsheet

Concept	Synonym	CUI	Note	Concatenation	Definition
Cytarabine	Ara-C	C408		C408 (Cytarabine)	An antimetabolite analogue of cytidine with a modified sugar moiety (arabinose instead of ribose). Cytarabine is converted to the triphosphate form within the cell and then competes with cytidine for incorporation into DNA. Because the arabinose sugar sterically hinders the rotation of the molecule within DNA, DNA replication ceases, specifically during the S phase of the cell cycle. This agent also inhibits DNA polymerase, resulting in a decrease in DNA replication and repair. (NCI04)
Cytogenetic Analysis	Cytogenetics, Cytogenetic Technique	C18280	Use alternate definition for cytogenetic analysis (MSH2001)	C18280 (Cytogenetic Analysis)	Examination of chromosomes to diagnose, classify, screen for, or manage genetic diseases and abnormalities. Following preparation of the sample, KARYOTYPING is performed and/or the specific chromosomes are analyzed.
del(9p)/9p-				C45577 (Deletion Abnormality), C13563 (9p)	Loss of a genomic DNA sequence. The extent of a deletion ranges from the loss of a single nucleotide to the loss of a substantial portion of an entire chromosome. Thus, deletions may alter the function of a single gene or multiple genes. _Proximal (short) arm of chromosome 9

Curate CDEs
Curation Spreadsheet

CDE	DEC	DEC Object Class Primary Concept	DEC Object Class Qualifier Concept	DEC Property Primary Concept	DEC Property Qualifier Concept	DEC Conceptual Domain	VD	VD Attribute Primary Concept	VD Attribute Qualifier Concepts	VD Conceptual Domain Public ID
2685090	2685088	C3171 (Acute Myeloid Leukemia)		C25688 (status)	C15342 (transplantation), C25207 (time)	2008550 (Disease Response)	2685085 (acute leukemia status)	C25688 (status)	C9300 (acute leukemia)	2008550 (Disease Response)
2674686	2674684	C3171 (Acute Myeloid Leukemia)		c4870 (complete remission)	C15342 (transplantation), C25207 (time), C16487 (cytogenetic)	2008556 (Assessment Results)	2182115 (Yes No Unknown Indicator)			
2676456	2676454	C3171 (Acute Myeloid Leukemia)		c4870 (complete remission)	C15342 (transplantation), C25207 (time), C25574 (molecular)	2008556 (Assessment Results)	2182115 (Yes No Unknown Indicator)			

Curate CDEs
Curation Spreadsheet – Additional Info

- FormsNet database field names
- Question number
- Permissible values and concepts
- Data type
- FormsNet max field length
- FormsNet multiple
- Notes

Curators review CDEs

CDE ID:	2750679						
Question Number:	26	**Normalized:**	Yes				
Long Name: ex vivo Manipulation Without Erythrocyte Remove Volume Reduced Graft Method Type							
Short Name: EX_MNP_GRFT_MD_TYP							
Definition: Outside the living body; referring to the use or positioning of an organ, tissue, or cell in an environment outside the living organism while the tissue or cells remain viable._Move, treat, or operate with the hands or by mechanical means, especially in a skillful manner._Used to indicate the absence or lack of something or someone._Cell specialized for oxygen transport, having a high concentration of hemoglobin in the cytoplasm and little else; biconcave, anucleate discs, 7nm diameter in mammals._Shift the position or location of; take out of._The amount of three dimensional space occupied by an object or the capacity of a space or container._Made less in size or amount or degree._Tissue or organ transplanted from a donor to a recipient._A means, manner of procedure, or systematic course of actions that have to be performed in order to accomplish a particular goal._Type; a subdivision of a particular kind of thing.							
Context: NHLBI	**Workflow Status:** DRAFT NEW		**Registration Status:** NULL				
Origin: NMDP:National Marrow Donor Program							
Reference Documents							
	Type: Preferred Question Text						
	Text: What was the method of ex vivo graft manipulation other than for RBC removal or voulme reduction?						
Alternate Names							
Classification							
	Scheme: NMDP: CDEs to be Reviewed						

Review Committee reviews CDEs

Question Number:	26-33
CDE ID:	2750687
Normalized:	Yes
Preferred Question Text:	Was a particular method of ex vivo graft manipulation other than for RBC removal or volume reduction performed?
Long Name:	Ex Vivo Manipulation Without Erythrocyte Remove Volume Reduced Graft Method Performed Yes No Character Indicator
Definition:	Outside the living body; referring to the use or positioning of an organ, tissue, or cell in an environment outside the living organism while the tissue or cells remain viable._Move, treat, or operate with the hands or by mechanical means, especially in a skillful manner._Used to indicate the absence or lack of something or someone._Cell specialized for oxygen transport, having a high concentration of hemoglobin in the cytoplasm and little else; biconcave, anucleate discs, 7nm diameter in mammals._Shift the position or location of; take out of._The amount of three dimensional space occupied by an object or the capacity of a space or container._Made less in size or amount or degree._Tissue or organ transplanted from a donor to a recipient._A means, manner of procedure, or systematic course of actions that have to be performed in order to accomplish a particular goal._Executed and carried through to completion._Indicator of Yes or No to a question.
Permissible Values:	
	Yes
	Description: The affirmative response to a question or activity.
	No
	Description: The non-affirmative response to a question.

Translation Database is Populated
Database Fields

FN Form Number	FN Form Major Version	FN Form Minor Version	AGNIS Form Public ID	AGNIS Form Version #	Normalized	FN Field Name	AGNIS Field Public ID	AGNIS Field Version #	AGNIS Value	Value Mapping Domain
2004	1.0	0.0	2630454	1.0		idm_anti_hiv1_hiv2_tst	2695078	1.0		REAC_NONREAC_NOTEST_NOREPORT
2004	1.0	0.0	2630454	1.0		idm_cmv_dte	2695094	1.0		NULL
2004	1.0	0.0	2630454	1.0		idm_cmv_tst	2695092	1.0		idm-cmv-rslts
2004	1.0	0.0	2630454	1.0		idm_hbsag_dte	2693572	1.0		NULL

Translation Database is Populated
Permissible Values

Value Mapping Domain	FN Value	AGNIS Value
idm-cmv-rslts	NONREACTIVE	Non-reactive
idm-cmv-rslts	NOTTEST	Not Done
idm-cmv-rslts	PREVREPORT	Previously reported reactive, not tested
idm-cmv-rslts	REACTIVE	Reactive

Workflow and Process Constraints

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Types of Constraints

- Business
- FormsNet application

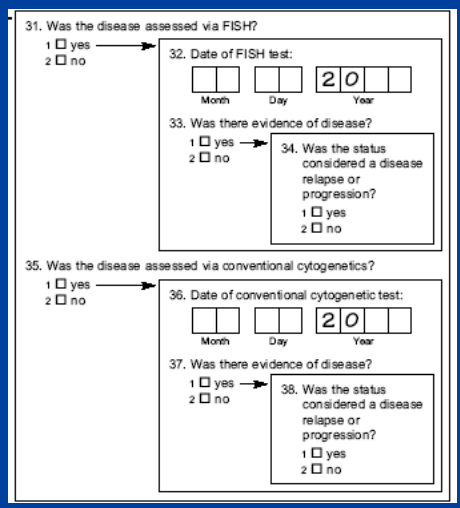
Business Constraints

- Staffing
  - Two full-time and 5 part-time curators
  - No additional funding for full-time curators
- Logistics
  - Coordinating Excel file access across sites

FormsNet Application Constraints

- Cannot use same CDE multiple times on one form
- Cannot normalize CDEs in FormsNet multiples
- Must curate so that FormsNet can capture the data

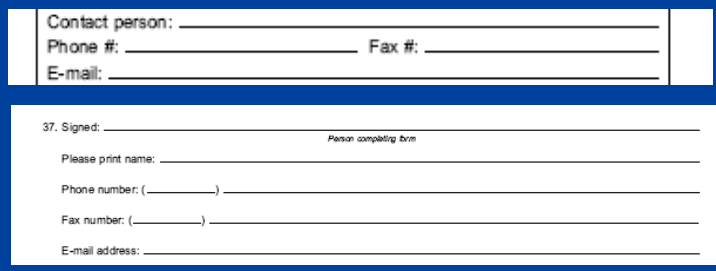
Cannot reuse a CDE on one form



Cannot normalize CDEs in FormsNet multiples

		Product Analysis at 1st Timepoint			Product Analysis at 2nd Timepoint		
In this section, report the total number of cells (not cells per kilogram).							
		Total Number	Exponent		Total Number	Exponent	
Nucleated cells:	144.	. x 10		☐ not tested	165.	. x 10	☐ not tested
Mononucleated cells:	145.	. x 10		☐ not tested	166.	. x 10	☐ not tested
Nucleated red blood cells:	146.	. x 10		☐ not tested	167.	. x 10	☐ not tested
CD34+ cells:	147.	. x 10		☐ not tested	168.	. x 10	☐ not tested
CD3+ cells:	148.	. x 10		☐ not tested	169.	. x 10	☐ not tested
CD4+ cells:	149.	. x 10		☐ not tested	170.	. x 10	☐ not tested
CD8+ cells:	150.	. x 10		☐ not tested	171.	. x 10	☐ not tested
Viability of cells:	151.	%		☐ not tested	172.	%	☐ not tested
Method of testing cell viability:	152.	1 ☐ 7-AAD 2 ☐ propidium iodide 3 ☐ trypan blue 4 ☐ other method			173.	1 ☐ 7-AAD 2 ☐ propidium iodide 3 ☐ trypan blue 4 ☐ other method	
Specify other method:	153.				174.		

Must Curate so that FormsNet can Capture the Data



Contact person: _____

Phone #: _____ Fax #: _____

E-mail: _____

37. Signed: _____
Person completing form

Please print name: _____

Phone number: (_____) _____

Fax number: (_____) _____

E-mail address: _____