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Centre Presentation on how new Med-A form has affected working practices in centres

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**City of Health and Science, Regina Margherita Children Hospital,
Turin, Italy**

Marseille, 27/March/2017

- Nothing to disclose about this topic

- Topics of this presentation
- My centre presentation and JACIE accreditation
- The data manager group within the CIC 305
- Promise Registration and updating
- The new Med-A



My centre presentation

- It was formed on 02/10/2010
- The Metropolitan Transplant centre of Torino (CIC 305) is a Functional Transplant Program, created by the partnership of three local programs, one pediatric and two adults, on the basis of clinical and pre-clinical collaborations that occurred in previous years on specific issues
- - CIC 305-1 (OIRM): Pediatric Program and coordinator role for CTMT (first alloHSCT 1989)
- - CIC 305-2 (FPO): Adult program (first alloHSCT 2001)
- CIC 305-3 (S.LUIGI): Adult program (first alloHSCT 2001)
- and from 4/2016 the Mauriziano-Umberto I Hospital ex CIC 455 is part of CTMT CIC 305 (autologous program only)

The step of this project.....

Our centre has been JACIE accredited since 2012

02/10/2010

CTMT constitution

- Quality Team meetings, clinical meetings, workgroups
- Training
- Drafting documents
- Share paths / procedures
- Internal audit

Dec 2010-March 2012

- application form sent to JACIE

January 2012

27/03/2012

- 1° Management review of the Program CTMT

01-02/10/2012

JACIE inspection and CNT/CNS (Centro Nazionale Trapianti/
Centro Nazionale Sangue, according to Italian law)

The step of this project.....

Our centre has been JACIE accredited since 2012



26/11/2012

Report JACIE

14/11/2013

Report CNT/CNS

April-June

Corrective plan to JACIE and CNT/CNS

11/07/2013

JACIE accreditation

Luglio 2013

Sending the second corrective plan to CNT/CNS

18/04/2014

CNT/CNS accreditation

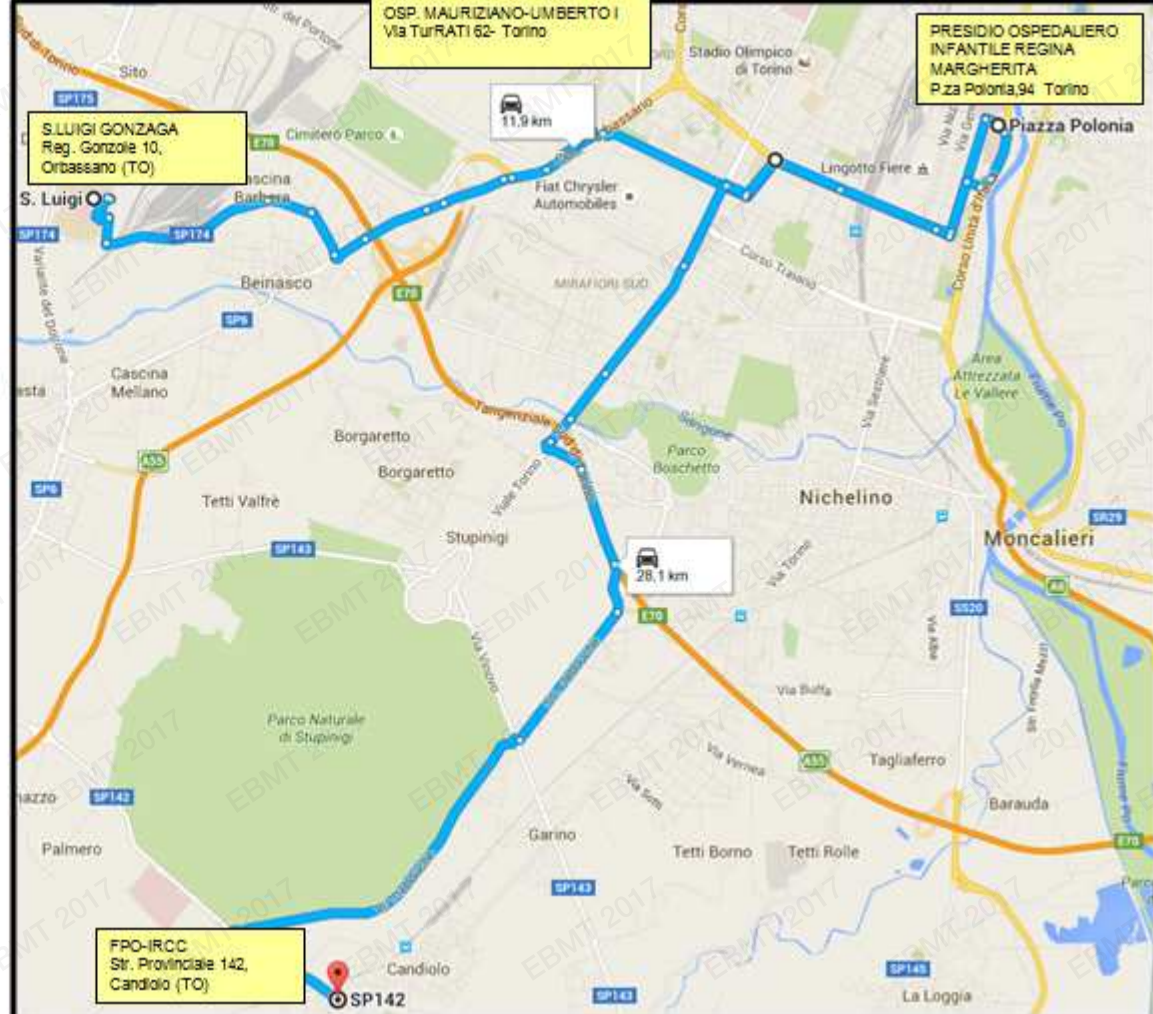
The Metropolitan HSCT of Turin (CTMT)

- CIC 305-1 (OIRM): Pediatric Program
- CIC 305-2 (FPO)
- CIC 305-3 (San Luigi Hospital)
- CIC 305-4: (Mauriziano Hospital)

Adult Programs



All centres are
within 20 minutes
by car



The Metropolitan HSCT of Turin (CTMT).....

.....Who take decisions in our centre?

- The Quality Team manages all activities of CTMT
- Monthly meetings for monitoring activities and critical processes
- Quarterly audit report
- Indicators analysis, NC / EA / AC / AP
- Validation / issue documents
- Targets for improvement planning
- It is formed by selected team with the aim of ensuring high standards of quality as required by the JACIE standards.
- The quality team is formed by various specific professionals for each sector involved in transplantation (section b, section c and section d)

Indicators analysis, NC / EA / AC / AP

PROSPETTO INDICATORI MOD. T.82.01 REV 03

CLASSE	N.	INDICATORE	CTMT	305-1	305-2	305-3	305-4	STANDARD	Rilevazione
		UNITÀ CLINICA							
ATTIVITÀ	1	Numero di trapianti autologhi						5+5+5	Trimestrale
	2	Numero di Trapianti allogenici						5+5+5	Trimestrale
	3	Distribuzione per patologia						NA	
	4	Tipo Donatore						NA	
	5	Sorgente di cellule staminali						NA	
CONTROLLO PROCESSO	6	Attività registro						>50%	
	7	Degenza media AUTO						18	
	8	Degenza media ALLO						28	
	9	Numero di MED-0 conformi						<10%	Trimestrale
	10	Aggiornamento follow-up su MED-A e schede AIEOP						>90%	Trimestrale
OUTCOME	11	TRM 100 giorni AUTO						<5%	
	12	TRM 100 giorni ALLO						<20%	
	13	TRM 12 mesi AUTO						<5%	
	14	TRM 12 mesi ALLO						<40%	
	15	Attecchimento PMN AUTO						>90%	Trimestrale
	16	Attecchimento PMN ALLO						>90%	Trimestrale
	17	GVHD acuta a 100 gg						NA	
	18	GVHD cronica a 1 anno						NA	
	19	Sopravvivenza a 1 anno da trapianto ALLO						NA	
	20	Sopravvivenza a 1 anno da trapianto AUTO						NA	
SICUREZZA	21	Numero di eventi avversi gravi						NA	Trimestrale
	22	Numero di infezioni da batteri alert ALLO						NA	
	23	Numero di infezioni fungine probabili ALLO						NA	
	24	Numero di infezioni da batteri alert AUTO						NA	
	25	Numero di infezioni fungine probabili AUTO						NA	
	26	N° infezioni da CVC							Trimestrale

Indicators analysis, NC / EA / AC / AP

SECTION C

	UNITÀ RACCOLTA								
ATTIVITÀ	27	Espianto di midollo osseo da paziente						NA	Trimestrale
	28	Raccolte aferetiche da paziente						NA	Trimestrale
	29	Espianto di midollo osseo da donatore						NA	Trimestrale
	30	Raccolte aferetiche da donatore						NA	Trimestrale
	31	Numero di altre raccolte/procedure (DLI, ECP)						NA	Trimestrale
CONTROLLO PROCESSO	32	Efficienza media raccolta CD34 da raccolta aferetica							Trimestrale
	33	Efficienza media raccolta TNC da midollo osseo							Trimestrale
OUTCOME	34	N° pazienti con mobilitazione adeguata							
	35	Conta PLT per valutazione attecchimento							Trimestrale
	36	Conta PMN per valutazione attecchimento							Trimestrale
SICUREZZA	37	Numero di eventi avversi gravi							

SECTION D

	UNITÀ PROCESSAZIONE								
ATTIVITÀ	38*	Numero di manipolazioni minime						NA	Trimestrale
	39	Numero di congelamenti						NA	Trimestrale
	40	Numero di scongelamenti unità CB						NA	
	41	Numero di separazioni su Clinimacs						NA	Trimestrale
CONTROLLO PROCESSO	42	Recupero TNC e CD34 dopo manipolazione minima						>80% TNC >90 %CD34	
	43	Vitalità dopo manipolazione minima						>85%	Trimestrale
	44	Recupero TNC e CD34 dopo scongelamento unità CB						TNC >50% CD34 >70%	
	45	vitalità CD34+ dopo scongelamento unità CB						>80%	
	46	Vitalità su provetta satellite congelata unità PBSC/BM						>50%	
	47	Recupero/deplezione cellule target dopo separazione Clinimacs						>70%	
	48	vitalità dopo separazione Clinimacs						>85%	
	49	Esiti controllo qualità esterni						<10%	
	50*	Tempo di refertazione						NA	
	51	Prodotti non conformi						<5%	Trimestrale
OUTCOME	52	Conta PLT per valutazione attecchimento							
	53	Conta PMN per valutazione attecchimento							
SICUREZZA	54	Prodotti non conformi per culturale positivo						<2%	Trimestrale
	55	Numero di eventi avversi gravi						NA	Trimestrale

- However, all HSCT indications, choice of donor or type of graft, etc are discussed every 2 weeks between clinicians. The final decision is taken by clinicians in charge of each patient

The Metropolitan HSCT of Turin (CTMT)

- The Pediatric Program OIRM is the reference centre for the search of volunteer donor (UD) of all Programs, it collaborates with the Italian Bone Marrow Donor registry (IBMDR) and manages the acceptance and the release of products for HSCT
 - donor search management UD (~ 40 searches/year);
 - share availability of donors with local programs;
 - choice of the donor on the basis of the declared policy in dedicated SOP;
 - centralization of information technology;
 - the path validation of the products and training professionals dedicated to transportation;
 - validation of quality control methods;
 - sharing procedures and documents;
 - sharing of engraftment data.





The data manager group within the CIC 305

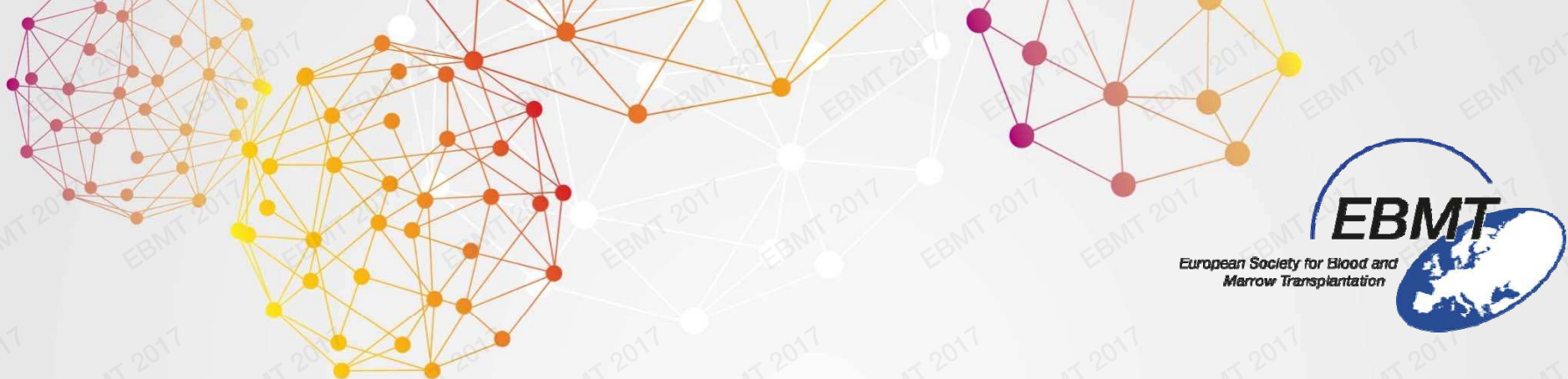
The data manager group within the CTMT Program

- It consists of 1-2 people / hospital who are responsible for: the completion of the MED-A day 0, day 100 and follow-up, sharing, storage and data updating on a private protected server
- According to the current policy of GITMO (Italian Group for Bone Marrow Transplantation), the registrations take place on:
 - the day of transplantation +5 days for MED-A day 0;
 - the MED-A day 100;
- On January 10, May 10 and September 10 the GITMO Data Managers transfer to regulatory authorities (National Transplant Centre) for each centre the number of AUTO/ALLO HSCT (Related, Unrelated, MM Related) and for each stem cell source the number of BM/PBSC/CB for AUTO and ALLO HSCT;
- By February 28th each data on timing of Med 0 registration (within 5 days), the conversion from MED 0 to MED 100 of each HSCT, the completeness of each required data and the follow-up of all HSCTs according to EBMT indications

The data manager group within the CTMT Program

- On January 10th , May 10th and September 10th a trimestral report of each centre (305-1, 305-2, 305-3) is discussed within the QT meetings:
- -Number of autologous and allogeneic HSCTs
- - MED 0 registrations
- -Engraftment
- -GvHD
- -Survival
- Adverse Event

The Italian registry (GITMO) was the first to indicate how compulsory timely the Day 0 registration, as a guarantee of transparency and monitoring of transplant national regulation compliance, while the Government Authority, represented by the National Transplant Centre (CNT), has the need to know the data of real-time activities in order to fulfil its institutional role. In recording on day 0, therefore converge scientific and regulatory interests



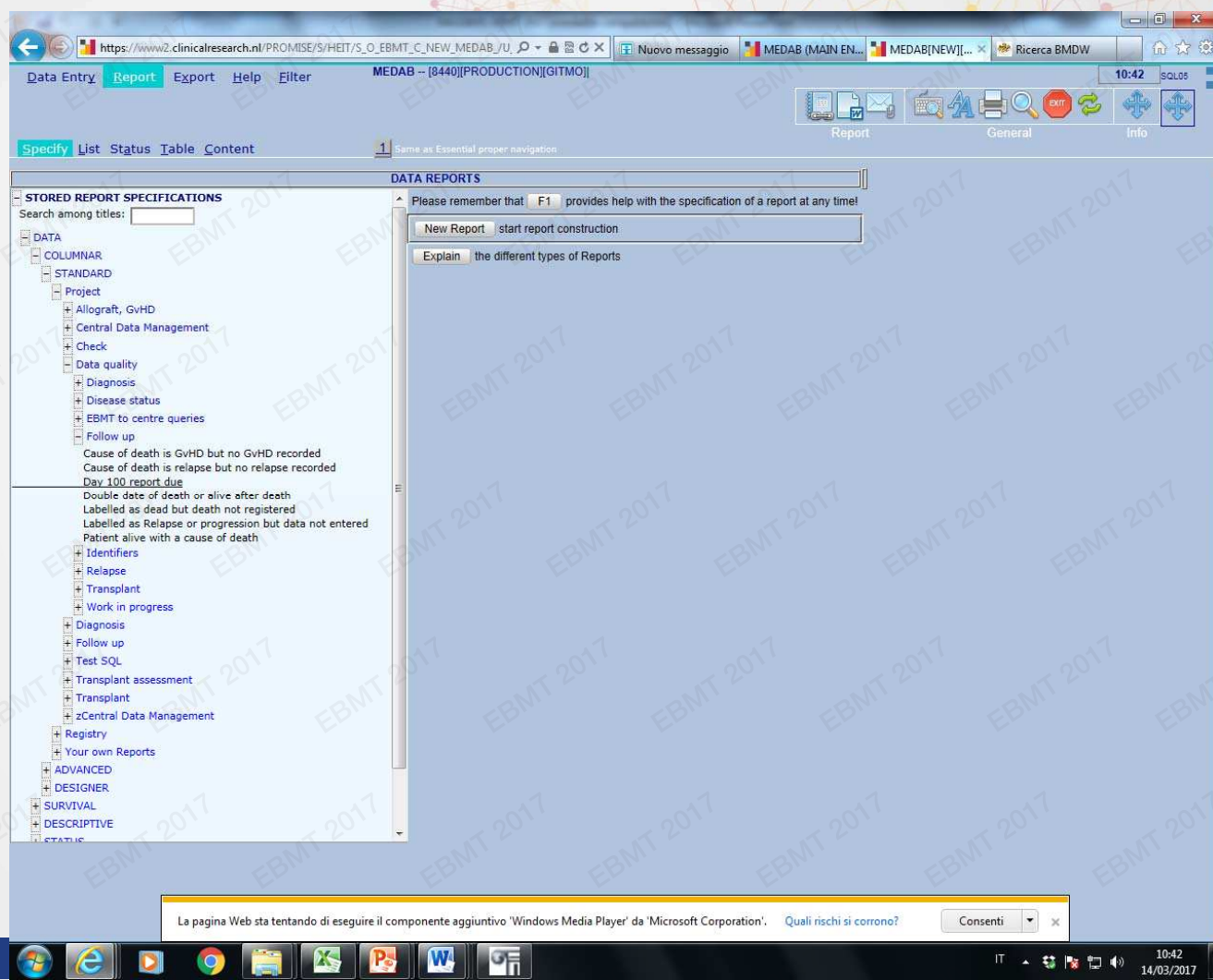
Promise Registration and updating

HOW WE TRY TO KEEP UPDATED AND NOT MISSING DEADLINES

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
	UPN NUOVI	COGNOME	NOME	DaNASC	DONOR	DATA Tx	REGISTRA ZIONE TRAPIANT O	GG+100 (DATA PREVISTA)	DATA REGIST RAZIONE	GG+365 (DATA PREVIST A)		scheda morte	MED 0	MED A+100
1														
2	829			15/07/2003	REL-PB	25/06/2015	OK	03/10/2015	ok	agg CTX alla proph GvHD			OK	ok
3	830			10/10/2014	REL-PB	01/07/2015	OK	09/10/2015	ok				OK	ok
4	831			23/12/2006	MUD-BM	03/07/2015	OK	11/10/2015	ok			31/08/2015	OK	ok
5	832			01/07/2014	MUD-BM	09/07/2015	ok	17/10/2015	ok	proph GvHD agg al 10/11/2015			ok	ok
6	833			14/07/2009	REL-BM	10/07/2015	ok	18/10/2015	ok	proph GvHD agg al 29/10/2015			ok	ok
7	834			10/09/2010	AUTO PB	29/07/2015	ok	06/11/2015	ok				ok	ok
8	835			22/06/1998	MUD-BM	14/08/2015	OK	22/11/2015	ok				OK	ok
9	836			22/09/2001	MUD-PB	26/08/2015	OK	04/12/2015	ok	proph e terapia GvHD agg al 04/12/2015			OK	ok
10	767			28/09/1999	sib-pb	31/08/2015	ok	09/12/2015	ok	proph GvHD agg al 15/12/2015			ok	ok
11	837			07/12/2013	REL-BM	04/09/2015	ok	13/12/2015	ok	proph GvHD agg al 21/12/2015			ok	ok
12	838			14/02/2001	MUD-BM	09/09/2015	ok	18/12/2015	ok	proph GvHD agg al 13/01/16			ok	ok
13	839			04/04/2005	SIB	29/09/2015	OK	07/01/2016	ok	proph gvhd agg al 21/01/2016			OK	ok
14	796			15/10/2005	REL-BM	02/10/2015	ok	10/01/2016	ok	proph GvHD agg al 13/01/16 agg CTX alla			ok	ok
15	840				MUD-BM	17/10/2015	ok	25/01/2016	ok				ok	ok
16	841			16/01/2008	REL-PB	10/11/2015	OK	18/02/2016	ok				OK	ok
17	842			22/11/2005	MUD-BM	22/11/2015	ok	01/03/2016	ok	proph GvHD agg al 17/03/2016			ok	ok
18	843			07/11/2014	MUD-PB	11/12/2015	ok	20/03/2016	ok	proph GvHD agg al 29/04/2016			ok	ok

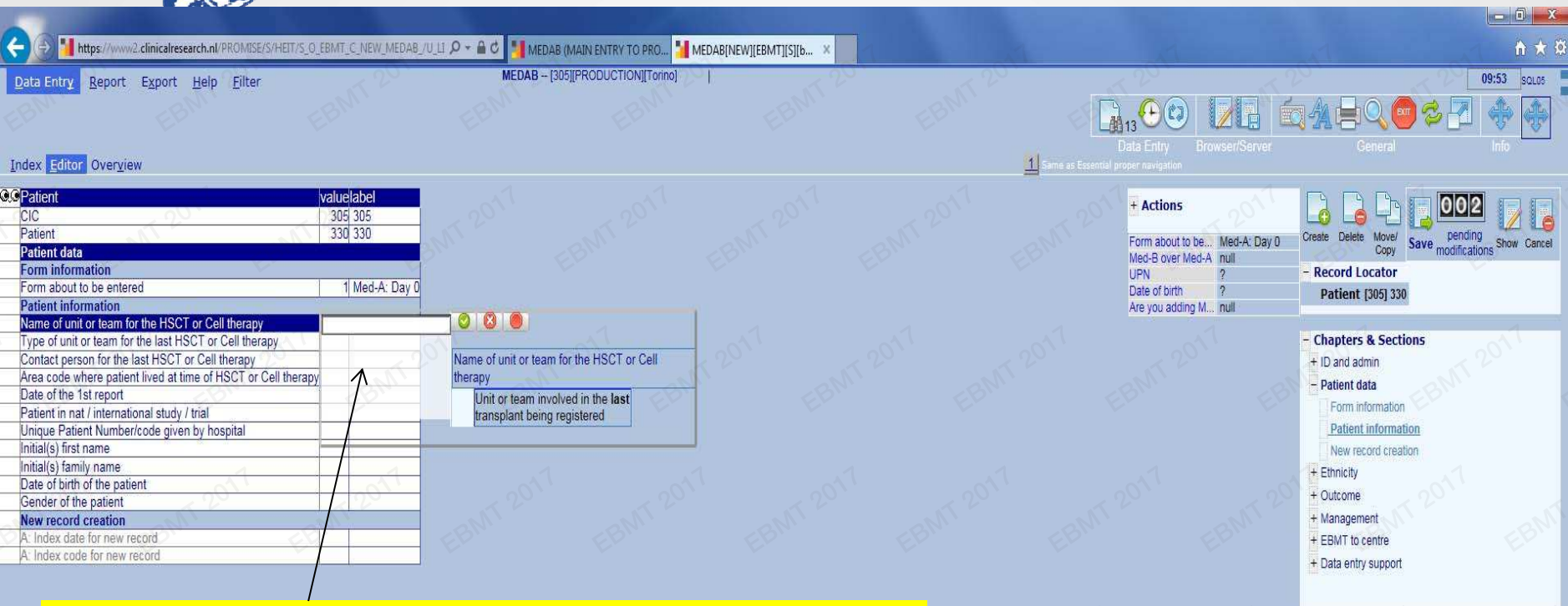
We use a database that records the main variables related to HSCT. It report the day 100 in order to have a constant reminder of deadlines. Obviously it is important to properly record MED-A day 0

Data extraction from ProMISE



The screenshot displays the ProMISE web application interface. The browser address bar shows the URL: https://www2.clinicalresearch.nl/PROMISE/S/HEIT/S_O_EBMT_C_NEW_MEDAB/_U_. The application has a top navigation bar with tabs: Data Entry, Report, Export, Help, and Filter. The current tab is 'Report'. Below the navigation bar, there's a sub-header 'MEDAB - [8440][PRODUCTION][GITMO]'. The main content area is divided into two panels. The left panel, titled 'STORED REPORT SPECIFICATIONS', contains a tree view of report categories: DATA, COLUMNAR, STANDARD, Project, Allograft, GvHD, Central Data Management, Check, Data quality, Diagnosis, Disease status, EBMT to centre queries, Follow up, Cause of death is GvHD but no GvHD recorded, Cause of death is relapse but no relapse recorded, Day 100 report due, Double date of death or alive after death, Labelled as dead but death not registered, Labelled as Relapse or progression but data not entered, Patient alive with a cause of death, Identifiers, Relapse, Transplant, Work in progress, Diagnosis, Follow up, Test SQL, Transplant assessment, Transplant, zCentral Data Management, Registry, Your own Reports, ADVANCED, DESIGNER, SURVIVAL, DESCRIPTIVE, and STATUS. The right panel, titled 'DATA REPORTS', contains a message: 'Please remember that F1 provides help with the specification of a report at any time'. Below this message are two buttons: 'New Report' (start report construction) and 'Explain' (the different types of Reports). At the bottom of the browser window, there's a Windows Media Player notification: 'La pagina Web sta tentando di eseguire il componente aggiuntivo 'Windows Media Player' da 'Microsoft Corporation'. Quali rischi si corrono?'. The bottom status bar shows the time 10:42 and date 14/03/2017.

HOW TO REGISTER A NEW TRANSPLANT AND MODIFICATIONS ACCORDING TO NEW-MED-A



The screenshot shows the MEDAB web application interface. The browser address bar displays the URL: https://www2.clinicalresearch.nl/PROMISE/S/HEIT/S_O_EBMT_C_NEW_MEDAB_U_L1. The page title is "MEDAB -- [305][PRODUCTION][Torino]". The navigation menu includes "Data Entry", "Report", "Export", "Help", and "Filter". The main content area is divided into three sections: "Patient", "Form information", and "Patient information". The "Patient" section shows a table with columns "value" and "label". The "Form information" section shows a table with columns "Form about to be entered" and "1 Med-A: Day 0". The "Patient information" section shows a table with columns "Name of unit or team for the HSCT or Cell therapy" and "Unit or team involved in the last transplant being registered". A dropdown menu is open for the "Name of unit or team for the HSCT or Cell therapy" field, showing options: "Name of unit or team for the last HSCT or Cell therapy", "Area code where patient lived at time of HSCT or Cell therapy", "Date of the 1st report", "Patient in nat / international study / trial", "Unique Patient Number/code given by hospital", "Initial(s) first name", "Initial(s) family name", "Date of birth of the patient", "Gender of the patient", and "New record creation". The "New record creation" section shows a table with columns "A: Index date for new record" and "A: Index code for new record". The right sidebar contains "Actions" (Form about to be entered, Med-A: Day 0, Med-B over Med-A, null, UPN, ?, Date of birth, ?, Are you adding M..., null), "Record Locator" (Patient [305] 330), and "Chapters & Sections" (ID and admin, Patient data, Form information, Patient information, New record creation, Ethnicity, Outcome, Management, EBMT to centre, Data entry support).

CENTRE AND PATIENT IDENTIFICATION

HOW TO REGISTER A NEW TRANSPLANT AND MODIFICATIONS ACCORDING TO NEW-MED-A

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index **Diagnosis** Overview

Diagnosis	value	label
CIC	305	305
Patient	330	330
Diagnosed date	1950/01/01 00:00	1950/01/01 exact
Diagnosis classification		
Diagnosis: main classification		
Diagnosis		
Age at this diagnosis		
Interval from last transplant to this diagnosis		

Diagnosis

- 1 Acute leukaemia
- 2 Chronic leukaemia
- 3 Lymphoma
- 4 Plasma cell disorders
- 5 Solid tumours
- 6 Myelodysplastic/myeloproliferative
- 7 Bone marrow failure
- 8 Inherited disorders
- 9 Hemocytic disorders
- 10 Auto-immune diseases
- 11 Hemoglobinopathies
- 88 Uncoded (other)
- 99 Unknown

IMPORTANT

You can obtain a file with a list of diagnoses by clicking on link [DISMCLFO.PDF](#) at the bottom of this notice.

If the diagnosis is not covered by any of the broad categories, that are shown, you may need to use code 88.

Before doing so, contact the registryhelpdesk@ebmt.org to confirm that the disease has not been categorised.

It is rare for a disease not to belong to one of the listed categories.

Additional help in [DISMCLFO.PDF](#)

Actions

Form about to be: Med-A; Day 0
Med-B over Med-A: null
UPN: 1970
Date of birth: 1900/01/01
Are you adding it: null

Record Locator

- Patient: [305] 330
Diagn: 1950/01/01
Asses: 1950/01/01

Chapters & Sections

- Diagnosis identification & administer
- Diagnosis record qualifier (manual)
- Data precision
- Event
- **Diagnosis classification**
 - + Leukaemias
 - + Lymphomas
 - + Plasma cell disorders
 - + Solid tumours
 - + Grade and staging
 - + Myelodysplastic & myeloproliferative
 - + Non malignancies
 - + Inheritance
 - + Other diagnosis & secondary disease
 - + Global subclassification
 - + New record creation

DIAGNOSIS CLASSIFICATION

HOW TO REGISTER A NEW TRANSPLANT AND MODIFICATIONS ACCORDING TO NEW-MED-A

https://www2.clinicalresearch.nl/PROMISE/S/HEIT/S_O_EBMT_C_NEW_MEDAB/_U_LI MEDAB (MAIN ENTRY TO PRO... MEDAB[NEW][EBMT][S][b... x

Data Entry Report Export Help Filter MEDAB - [305][PRODUCTION][Torno]

assume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index Editor Overview DynFil:20:Acute leukaemia

Diagnosis	value	label
CIC		305 305
Patient		330 330
Diagnosis date	1950/01/01 00:00	1950/01/01 (exact)
Other diagnosis & secondary disease		
Other diagnosis		
Indicate other diagnosis		
Secondary origin		
Disease of secondary origin or transformed		
Drugs or radiation related: Agents involved		
Predisposing condition prior to leukaemia diagnosis?		
Prior predisposition condition		
Is this leukaemia a Donor cell leukaemia?		

Disease of secondary origin or transformed

1	No
2	Yes
99	unknown

+ Actions

Form about to be... Med-A: Day 0
 Med-B over Med-A null
 UPN 1970
 Date of birth 1900/01/01
 Are you adding M... null

Record Locator

Patient [305] 330
Diagn 1950/01/01
 Asse1 1950/01/01

Chapters & Sections

- + Diagnosis identification & administr
- + Diagnosis record qualifier (manual)
- + Diagnosis classification
- + Leukaemias
- + Lymphomas
- + Plasma cell disorders
- + Solid tumours
- + Grade and staging
- + Myelodysplastic & myeloproliferative

SECONDARY OR PREDISPOSING CONDITIONS OR DONOR CELL LEUKEMIA

HOW TO REGISTER A NEW TRANSPLANT AND MODIFICATIONS ACCORDING TO NEW-MED-A

EBMT 2017

Data Entry Report Export Help

Resume with the first item in the current section

Index Editor Overview

DynFili20:Acute leukaemia

Assessment(1)	value	label
CIC	305	305
Patient	330	330
Assessment date	1950/01/01 00:00	1950/01/01 {exact}

Diagnostics

MDS / MPS / CLL / Hgbpthy class

Involvement & bone investigations

Immunophenotyping/histochemistry

Cytogenetics and molecular markers

Chromosome analysis

Complex karyotype: Are there 3 or more abnormalities

Monosomal karyotype

Molecular or other type of markers

Haematological values

Haematology, other

Biochemistry

Note: Cytogenetics at diagnosis

Chromosome analysis

- 1 Normal
- 2 Abnormal
- 3 Not done/Failed
- 99 unknown

Actions

- Form about to be... Med-A: Day 0
- Med-B over Med-A null
- UPN 1970
- Date of birth 1900/01/01
- Are you adding M... null

Record Locator

Patient [305] 330

Diagn 1950/01/01

Asse1 1950/01/01

Chapters & Sections

- + Investigations identificat & admin
- Assessment record qualifier (manual)
- Date precision
- Event
- Intervals
- + **Diagnostics**
- + Diagnostics (cont.)
- + Physical examination
- + History of disease and treatment
- + Patient viral & fungal history
- + Performance
- + Haematopoietic recovery & chimaerism
- + Complications & additional treatment
- at disease status
- at status
- Patient HLA: DNA results
- + Patient HLA: serology results
- + Prognostic scores
- + New record creation

CYTOGENETICS AT DIAGNOSIS

EBMT

[Data Entry](#) [Report](#) [Export](#) [Help](#) [Filter](#)

Resume with the **first** item in the **current** section by pres

HOW TO REGISTER A NEW TRANSPLANT AND MODIFICATIONS ACCORDING TO NEW-MED-A

SQL05

[Index](#) [Editor](#) [Overview](#)

DynFile:20:Acute leukaemia

Assessment(1)	value	label
CIC	305	305
Patient	330	330
Assessment date	1950/01/01 00:00	1950/01/01 (exact)
New record creation		
New record creation, Date		
E0: Index date for new record		
New record creation: Code		
E0: New record index: cytogenetics		
E2: New record index: infect & complications		
E3: New record index: involvement		
E4: New record index: markers		
Data entry help asses		

Note: Indicate abnormality studied

Record creation

E0: New record index: cytogenetics

6 Hypodiploid (<46 chromosomes)

7 Hyperdiploid (>46 chromosomes)

8 Monosomy

9 Trisomy

101 t(9;22)

102 t(4;11)

108 abn 11q23

112 del(11)(q22-23)

115 t(12;21)

116 t(1;19)

117 trisomy 8

153 t(5;14)(q31;q32)

701 Full Karyotype

777 Other abnormality 1

778 Other abnormality 2

779 Other abnormality 3

Actions

Form about to be... Med-A: Day 0

Med-B over Med-A null

UPN 1970

Date of birth 1900/01/01

Are you adding M... null

Create

Delete

Move/ Copy

Save

pending modifications

Show

Cancel

Record Locator

Patient [305] 330

Diagn 1950/01/01

Asse1 1950/01/01

Chapters & Sections

Investigations identificat & admin

Assessment record qualifier (manual)

Diagnostics

Diagnostics (cont.)

Physical examination

History of disease and treatment

Patient viral & fungal history

Performance

Haematopoietic recovery & chimaerism

Complications & additional treatment

Last disease status

Last status

Patient HLA: DNA results

Patient HLA: serology results

Prognostic scores

New record creation

New record creation, Date

New record creation: Code

Data entry help asses

CYTOGENETICS AT DIAGNOSIS

HOW TO REGISTER A NEW TRANSPLANT AND MODIFICATIONS ACCORDING TO NEW-MED-A

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index **Editor** Overview

DynFill:20:Acute leukaemia

Cytogenetics	value	label
CIC	305	305
Patient	330	330
Assessment date	1950/01/01 00:00	1950/01/01 (exact)
Cytogenetics	6	Hypodiploid (<46 chromosomes)
Cytogenetics		
Chromosomal aberrations		
Abnormality present or absent	<input type="checkbox"/>	
Describe the abnormalities		
Specify the number of chromosomes		
New record creation		
Index code for new abnormalities		

Abnormality present or absent

- 1 Absent
- 2 Present
- 3 Not evaluated

Actions

Form about to be... Med-A: Day 0
Med-B over Med-A null
UPN 1970
Date of birth 1900/01/01
Are you adding M... null



Record Locator

Patient [305] 330
Diagn 1950/01/01
Asse1 1950/01/01

Cytog 6

Chapters & Sections

+ Cytogenetics identification & admini
- Cytogenetics
Chromosomal aberrations
New record creation

CYTOGENETICS DATA AT DIAGNOSIS

HOW TO REGISTER A NEW TRANSPLANT AND MODIFICATIONS ACCORDING TO NEW-MED-A

[Data Entry](#) [Report](#) [Export](#) [Help](#) [Filter](#)

Resume with the **first** item in the **current** section by pressing the **first** icon in the **Record Locator** section.

[Index](#) [Editor](#) [Overview](#) DynFill/201:Acute leukaemia

Assessment(1)	value	label
CIC	305	305
Patient	330	330
Assessment date	1950/01/01 00:00	1950/01/01 (exact)

Diagnostics

MDS / MPS / CLL / Hgbphy class

Involvement & bone investigations

Immunophenotyping/histochemistry

Cytogenetics and molecular markers

Chromosome analysis	2	Abnormal
Complex karyotype: Are there 3 or more abnormalities	2	Yes
Monosomal karyotype		
Molecular or other type of markers		

Haematological values

Haematology, other

Biochemistry

Note: Molecular markers at diagnosis

Molecular or other type of markers

1	Absent
2	Present (at least one)
5	Not evaluated
99	unknown

Actions

Form about to be... Med-A: Day 0
Med-B over Med-A null
UPN 1970
Date of birth 1900/01/01
Are you adding M... null

Record Locator

[-] Patient [305] 330
Diagn 1950/01/01
[-] **Asse1** 1950/01/01
Cytog 6

Chapters & Sections

- + Investigations identifiat & admin
- + Assessment record qualifier (manual)
- + **Diagnostics**
- + Diagnostics (cont.)
- + Physical examination
- + History of disease and treatment
- + Patient viral & fungal history
- + Performance

Last status

- + Patient HLA: DNA results
- + Patient HLA: serology results
- + Prognostic scores
- + New record creation
 - [-] New record creation, Date
 - [-] New record creation: Code
 - [-] Data entry help asses

Resume with the **first** item in the **current** section by pressing the **first** button

Assessment(1)	value	label
CIC	305	305
Patient	330	330
Assessment date	1950/01/01 00:00	1950/01/01 (exact)
New record creation		
New record creation, Date		
E0: Index date for new record		
New record creation: Code		
E0: New record index: cytogenetics	6	Hypodiploid (<46 chromosomes)
E2: New record index: infect & complications		
E3: New record index: involvement		
E4: New record index: markers		
Data entry help asses		

☒ Note: Indicate the molecular marker tested

Record creation	
E4: New record index: markers	
3	BCR/ABL
22	MLLT3(AF9)-MLL
25	MLLT1(ENL)-MLL
26	MLLT4(AF6)-MLL
27	MLL, other
35	AFF1(AF4)-MLL
36	TEL(ETV6)-AML1(RUNX1)
37	IL3-IGH
38	TCF3-PBX1
39	IKZF1 (IKAROS)
40	NOTCH1 & FBXW7
777	Other

+ Actions	
Form about to be...	Med-A: Day 0
Med-B over Med-A	null
UPN	1970
Date of birth	1900/01/01
Are you adding M...	null

Create

Delete

Move/ Copy

Save

pending modifications

Show

Cancel

Record Locator

Patient

[305] 330

Diagn

1950/01/01

Asse1

1950/01/01

Cytog

6

- Chapters & Sections

Investigations identifiat & admin

Assessment record qualifier (manual)

Diagnostics

Diagnostics (cont.)

Physical examination

History of disease and treatment

Patient viral & fungal history

Performance

Haematopoietic recovery & chimaerism

Complications & additional treatment

Last disease status

Last status

Patient HLA: DNA results

Patient HLA: serology results

Prognostic scores

New record creation

New record creation, Date

New record creation: Code

Data entry help asses

MOLECULAR DATA AT DIAGNOSIS

Resume with the **first** item in the **current** section by pressing TIndex **Editor** Overview

Assessment(1)	value	label
CIC	305	305
Patient	330	330
Assessment date	1970/01/01 00:00	1970/01/01 00:00:00
Last disease status		
Last disease status before this date (1)		
Disease status		
Number of this status		
Cytogenetic remission		
Molecular remission		
Last disease status before this date (2)		
Last disease status before this date (3)		
Disease detected by clinical/haematological method		
Date of last clinical/haematological assessment		
Disease detected by cytogenetic/FISH method		
Cytogenetic detection of disease considered relapse/progression		
Date of last cytogenetic assessment		
Disease detected by molecular method		
Molecular detection of disease considered relapse/progression		
Date of last molecular assessment		

HOW TO REGISTER A NEW TRANSPLANT AND MODIFICATIONS ACCORDING TO NEW-MED-A

Disease status

10	Primary induction failure / Primary refractory
30	Complete remission (CR)
50	Relapse
77	Other
99	unknown

Acute leukaemia with hypoplasia

If there are less than 5% blasts in the bone marrow but insufficient cellularity to confirm normal myelopoiesis, use Other

Inherited Disorders

Use the following equivalence:

Cured - Complete remission
Improved - Partial remission
Unchanged - Stable
Worse - Progression

+ Actions

Form about to be... Med-A: Day 0
Med-B over Med-A
UPN 1970
Date of birth 1900/01/01
Are you adding M... null



Record Locator

- Patient [305] 330
Diagn 1950/01/01
- Asse1 1950/01/01
Cytog 6
Molec 3
Molec 22
Asse1 1970/01/01
Treat 1970/01/01

Chapters & Sections

- + Investigations identifiat & admin
- + Assessment record qualifier (manual)
- + Diagnostics
- + Diagnostics (cont.)
- + Physical examination
- + History of disease and treatment
- + Patient viral & fungal history
- + Performance
- + Haematopoietic recovery & chimaerism
- + Complications & additional treatment
- + **Last disease status**
- + Last status
- + Patient HLA: DNA results
- + Patient HLA: serology results
- + Prognostic scores
- New record creation
 - ☐ New record creation, Date
 - ☐ New record creation: Code

DISEASE STATUS AT HSCT

HOW TO REGISTER A NEW TRANSPLANT AND MODIFICATIONS ACCORDING TO NEW-MED-A

Assessment(1)	
CIC	305 305
Patient	330 330
Assessment date	1970/01/01 00:00 1970/01/01 00:00:00
Last disease status	
Last disease status before this date (1)	
Disease status	
Number of this status	
Cytogenetic remission	
Molecular remission	
Last disease status before this date (2)	
Last disease status before this date (3)	
Disease detected by clinical/haematological method	
Date of last clinical/haematological assessment	
Disease detected by cytogenetic/FISH method	
Cytogenetic detection of disease considered relapse/progression	
Date of last cytogenetic assessment	
Disease detected by molecular method	
Molecular detection of disease considered relapse/progression	
Date of last molecular assessment	

Disease status	
10	Primary induction failure / Primary refractory
30	Complete remission (CR)
50	Relapse
77	Other
99	unknown

Acute leukaemia with hypoplasia
If there are less than 5% blasts in the bone marrow but insufficient cellularity to confirm normal myelopoiesis, use **Other**

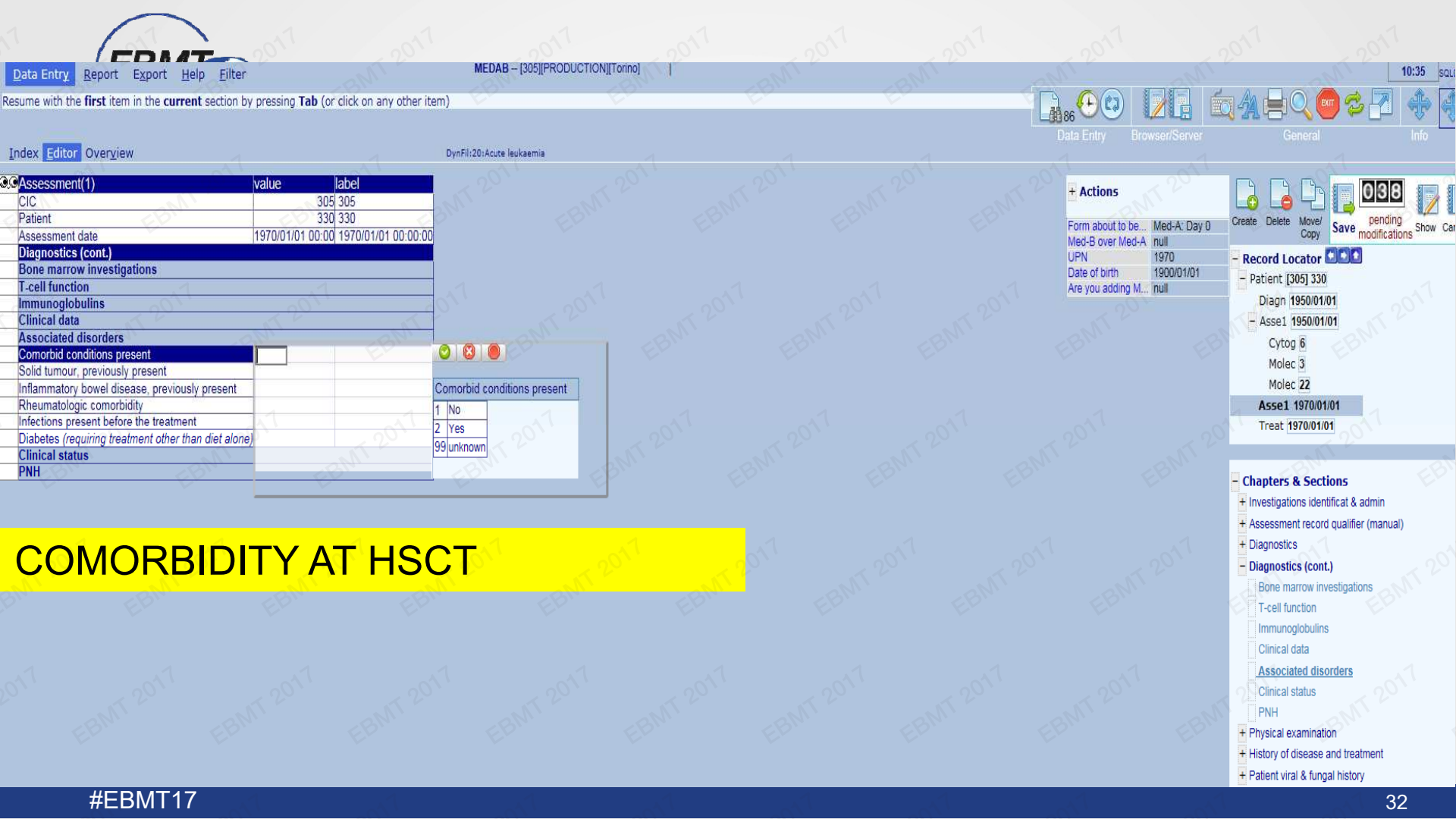
Inherited Disorders
Use the following equivalence:
Cured - Complete remission
Improved - Partial remission
Unchanged - Stable
Worse - Progression

+ Actions	
Form about to be...	Med-A: Day 0
Med-B over Med-A	null
UPN	1970
Date of birth	1900/01/01
Are you adding M...	null

Create	Delete	Move/ Copy	Save	pending modifications	Show C
- Record Locator					
- Patient [305] 330					
Diagn 1950/01/01					
- Asse1 1950/01/01					
Cytog 6					
Molec 3					
Molec 22					
Asse1 1970/01/01					
Treat 1970/01/01					

- Chapters & Sections	
+ Investigations identificat & admin	
+ Assessment record qualifier (manual)	
+ Diagnostics	
+ Diagnostics (cont.)	
+ Physical examination	
+ History of disease and treatment	
+ Patient viral & fungal history	
+ Performance	
+ Haematopoietic recovery & chimaerism	
+ Complications & additional treatment	
+ Last disease status	
+ Last status	
+ Patient HLA: DNA results	
+ Patient HLA: serology results	
+ Prognostic scores	
- New record creation	
New record creation: Date	
New record creation: Code	

CYTOGENETICS AND MOLECULAR STATUS AT HSCT



COMORBIDITY AT HSCT

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index Editor Overview

DynFill:20:Acute leukaemia

Assessment(1)	value	label
CIC	305	305
Patient	330	330
Assessment date	1970/01/01 00:00	1970/01/01 00:00:00
Physical examination		
Kidney		
Renal comorbidity (moderate to severe)		
Spleen and liver		
Hepatic comorbidity		
Heart and lung		
Arrhythmia / conduction blocks		
Cardiac comorbidity		
Cerebrovascular disease: Stroke/CNS haemorrhage		
Heart valve disease		
Pulmonary comorbidity		
Gastrointestinal and metabolism		
Obesity	1	No
Peptic ulcer requiring treatment		
Neuropathy		
Psychiatric disturbance		
Joints		
Other		
Other clinical abnormalities		

Renal comorbidity (moderate to severe)	
1	No
2	Yes
3	Not evaluated
99	unknown

Data Entry Browser/Server General Info

Actions

Form about to be... Med-A: Day 0
Med-B over Med-A null
UPN 1970
Date of birth 1900/01/01
Are you adding M... null

Create Delete Move/ Copy Save pending modifications Show Canc

Record Locator

Patient [305] 330
Diagn 1950/01/01
Asse1 1950/01/01
Cytog 6
Molec 3
Molec 22
Asse1 1970/01/01
Treat 1970/01/01

Chapters & Sections

- + Investigations identificat & admin
- + Assessment record qualifier (manual)
- + Diagnostics
- + Diagnostics (cont.)
- + Physical examination
 - Kidney
 - Spleen and liver
 - Heart and lung
 - Gastrointestinal and metabolism
 - Neuropathy
 - Joints
 - Other
- + History of disease and treatment
- + Patient viral & fungal history

COMORBIDITY AT HSCT: RENAL, KIDNEY, HEART, GI, BRAIN, JOINTS

Donor	11
Donor ID and order of infusion	
Identification of donor or CBU unit used by centre	
Number in the infusion order	
HLA relation and donor registry	
HLA match	8 Unrelated
Degree of mismatch in related donors	
ION code for the Donor Registry or Cord Blood Bank	
WMDA / BMDW code for the Donor Registry	
Name of the Donor registry	
Donor centre name	
Identification of donor or CBU given by donor registry	
Identification of patient given by donor registry	
Number of mismatches	
Number of antigenic mismatches: A	
Number of antigenic mismatches: B	
Number of antigenic mismatches: C	
Number of antigenic mismatches: DRB1	
Number of antigenic mismatches: DQB1	
Number of antigenic mismatches: DPB1	
Number of allelic mismatches: A	
Number of allelic mismatches: B	
Number of allelic mismatches: C	
Number of allelic mismatches: DRB1	
Number of allelic mismatches: DQB1	
Number of allelic mismatches: DPB1	
Donor details	
Donor birthdate	
Age of donor: years	
Age of donor: months	
Donor sex	
Age of the donor	
Serologic status	
CMV antibodies in donor	
Number of stem cell products	
Did this donor provide more than one stem cell product?	
Number of different stem cell products infused from this donor	

Note: Enter the ION (Issuing Organisation Number) < br > of the < b > Donor Registry < /b >

WARNING: Please, fax the HLA laboratory results to the EBMT Data Office < br > or National Registry Data Office. < br > Add the UIC of the patient to the results before faxing

ION code for the Donor Registry or Cord Blood Bank	
1005	Slovakia BMDR (SK)
1033	USA Gift of Life (USA4)
1102	Iran Royan CBB (T2CB)
1372	Romania BMT donors (RO)
1461	Greece-CBMDP (GR2)
1671	Mexico BMDR (MX)
1695	Hungarian SCDR (H)
1714	Taiwan Meribank (TICB)
1726	Wales BMDR (GB3)
1804	FGM France (F)
2015	Denmark Stem Cell Donors (DK)
2073	Lithuania BMDR (LT)
2107	Saudi Arabia-SSCDR (SA)
2197	CMDP China (CN)
2329	Spain DKMS (E2)
2614	Austria BMDR (A)
2731	UK-BBMR (GB4)
2824	India GeneBandhu (IN3)
3034	BMRN (NG)
3066	Canada Victoria Angel CORD (MHCB)
3099	Luxembourg LMDDP (LU)
3105	Hong Kong CBB
3146	Iran Taleghani (IR2)
3458	Taiwan Tzu Chi (TW)
3503	Turkok - Turkish SC Coordination Centre
3553	NMDP (USA1)
3785	Singapore BMDP (SG)
4076	UKMOR (UK)
4131	India MDR (IN4)
4201	MDPBR (B)

UPN	1970
Date of birth	1900/01/01
Are you adding M...	null
Record Locator	
Patient	[305] 330
Diagn	1950/01/01
Asse1	1950/01/01
Page	6
Molec	3
Molec	22
Asse1	1970/01/01
Treat	1970/01/01
Donor 1	

Chapters & Sections

Donor identification & administratio

Donor

- Donor ID and order of infusion
- HLA relation and donor registry**
- Number of mismatches
- Donor details
- Serologic status
- Number of stem cell products
- Legacy Donor harvest or collection
- Cell products
- Cord blood processing at Bank
- Cord blood cryopreservation at Bank
- Cord blood counts/viability at Bank
- HLA laboratory
- Donor HLA: DNA results
- Donor HLA: serology results
- Ex vivo manipulation of donor cells
- Donor cell infusion method
- Cells infused
- Donor milestones
- New record creation

ION CODE OF DONOR REGISTRY AND CORD BLOOD BANK



Donor		11
Cell products		
Product 1		
Stem cell source	1	BM
Stem cell source other, specify		
Ex-vivo manipulation of the donor cells		No
Graft manipulation product 1: Negative selection		
Negative selection of donor cells		
T-cell depletion by monoclonal antibodies		
T-cell receptor alpha-beta depletion		
B-cell depletion by monoclonal antibodies		
NK-cell depletion by monoclonal antibodies		
Negative selection: other		
Other negative selection: specify		
Graft manipulation product 1: Positive selection		
Positive selection of donor cells		
Positive selection by MoAB, CD 34+ enrichment		
Graft manipulation product 1: Other manipulations		
Gene manipulation of the donor cells		
Cells infused for product 1		
Units for nucleated cells		
Units for CD34 positive cells		
Units for CD3 positive cells		
Product 2		
Stem cell source		
Stem cell source other, specify		
Ex-vivo manipulation of the donor cells		
Graft manipulation product 2: Negative selection		
Negative selection of donor cells		
T-cell (CD3+) depletion by monoclonal antibodies		
T-cell receptor alpha-beta depletion by monoclonal antibodies		
B-cell (CD19+) depletion by monoclonal antibodies		
NK-cell depletion by monoclonal antibodies		
Negative selection: other		
Other negative selection: specify		
Graft manipulation product 2: Positive selection		
Positive selection of donor cells		
Positive selection by MoAB, CD 34+ enrichment		
Graft manipulation product 2: Other manipulations		
Gene manipulation of the donor cells		
Cells infused for product 2		
Units for nucleated cells		
Units for CD34 positive cells		
Units for CD3 positive cells		

Stem cell source
1 BM
2 PB
3 CB
99 Unknown

UPN	1970
Date of birth	1900/01/01
Are you adding M...	null

Record Locator

Patient	[305] 330
Diagn	1950/01/01
Asse1	1950/01/01
Cytog	6
Molec	3
Molec	22
Asse1	1970/01/01
Treat	1970/01/01

Donor 1**Chapters & Sections**

- + Donor identification & administration
- + Donor
- + Legacy Donor harvest or collection
- Cell products
 - Product 1
 - Graft manipulation product 1: Ne ...
 - Graft manipulation product 1: Po ...
 - Graft manipulation product 1: Ot ...
 - Cells infused for product 1
 - Product 2
 - Graft manipulation product 2: Ne ...
 - Graft manipulation product 2: Po ...
 - Graft manipulation product 2: Ot ...
 - Cells infused for product 2
- + Cord blood processing at Bank
- + Cord blood cryopreservation at Bank
- + Cord blood counts/viability at Bank
- + HLA laboratory
- + Donor HLA: DNA results
- + Donor HLA: serology results
- + Ex vivo manipulation of donor cells

STEM CELL SOURCE AND GRAFT MANIPULATION

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index Editor Overview

DynFill/20:Acute leukaemia



Assessment(1)	value	label
CIC	305	305
Patient	330	330
Assessment date	1970/01/01 00:00	1970/01/01 00:00:00
Patient HLA: DNA results		
DNA typing done		
HLA: DNA typing done		
Type A		
HLA A: DNA in allele 1 of the patient		
HLA A: MAC code for allele 1 in the patient		
HLA A: DNA in allele 2 of the patient		
HLA A: MAC code for allele 2 in the patient		
Type B		
HLA B: DNA in allele 1 of the patient		
HLA B: MAC code for allele 1 in the patient		
HLA B: DNA in allele 2 of the patient		
HLA B: MAC code for allele 2 in the patient		
Type C		
HLA C: DNA in allele 1 of the patient		
HLA C: MAC code for allele 1 in the patient		
HLA C: DNA in allele 2 of the patient		
HLA C: MAC code for allele 2 in the patient		
Type DRB1		
HLA DRB1: DNA in allele 1 of the patient		
HLA DRB1: MAC code for allele 1 in the patient		
HLA DRB1: DNA in allele 2 of the patient		
HLA DRB1: MAC code for allele 2 in the patient		
Type DQB1		
HLA DQB1: DNA in allele 1 of the patient		
HLA DQB: MAC code		
HLA DQB1: DNA in a		
HLA DQB: MAC code		
Type DPB1		
HLA DPB1: DNA in allele 1 of the patient		
HLA DPB1: MAC code for allele 1 in the patient		
HLA DPB1: DNA in allele 2 of the patient		
HLA DPB1: MAC code for allele 2 in the patient		

Note: Enter the HLA typing results for the < b >patient< /b >

HLA: DNA typing done

1 No
2 Yes
99 unknown

HLA DNA DONOR TYPING

+ Actions

Form about to be... Med-A: Day 0
Med-B over Med-A null
UPN 1970
Date of birth 1900/01/01
Are you adding M... null



Record Locator

Patient [305] 330
Diagn 1950/01/01
Asse1 1950/01/01
Cytog 6
Molec 3
Molec 22
Asse1 1970/01/01
Treat 1970/01/01
Donor 1

Chapters & Sections

- + Investigations identificat & admin
- + Assessment record qualifier (manua
- + Diagnostics
- + Diagnostics (cont.)
- + Physical examination
 - Kidney
 - Spleen and liver
 - Heart and lung
 - Gastrointestinal and metabolism
 - Neuropathy
 - Joints
 - Other
- + History of disease and treatment
- + Patient viral & fungal history

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index **Editor** Overview

DynFill:20:Acute leukaemia



Assessment(1)	value	label
CIC	305	305
Patient	330	330
Assessment date	1970/01/01 00:00	1970/01/01 00:00:00
Patient HLA: serology results		
HLA: serology typing done		
Serology HLA typing done	2	2 Yes
Type A		
HLA A: serology in the patient 1	A2	A2
HLA A: serology in the patient 2	A2	A2
Type B		
HLA B: serology in the patient 1	B14	B14
HLA B: serology in the patient 2	B15	B15
Type C		
HLA C: serology in the patient 1	Cw2	Cw2
HLA C: serology in the patient 2	Cw3	Cw3
Type DRB1		
HLA DRB1: serology in the patient 1	DR11(5)	DR11(5)
HLA DRB1: serology in the patient 2	DR12(5)	DR12(5)
Type DQB1		
HLA DQB1: serology in the patient 1	DQ4	DQ4
HLA DQB1: serology in the patient 2	DQ5(1)	DQ5(1)
Type DPB1		
HLA DPB1: serology in the patient 1	DPw3	DPw3
HLA DPB1: serology in the patient 2	DPw2	DPw2

Serology HLA typing done

1	No
2	Yes
99	unknown

Actions

Form about to be... Med-A: Day 0
Med-B over Med-A null
UPN 1970
Date of birth 1900/01/01
Are you adding M... null



Record Locator

Patient [305] 330
Diagn 1950/01/01
Asse1 1950/01/01
Cytog 6
Molec 3
Molec 22
Asse1 1970/01/01
Treat 1970/01/01
Donor 1

Chapters & Sections

- + Investigations identificat & admin
- + Assessment record qualifier (manual)
- + Diagnostics
- + Diagnostics (cont.)
- + Physical examination
- + History of disease and treatment
- + Patient viral & fungal history
- + Performance
- + Haematopoietic recovery & chimaerism
- + Complications & additional treatment
- + Last disease status
- + Last status
- + Patient HLA: DNA results
- Patient HLA: serology results
 - HLA: serology typing done

SEROLOGICAL HLA DONOR TYPING

Treatment	value	label
CIC	305	305
Patient	330	330
Treatment date	1970/01/01 00:00	1970/01/01 {exact}
Main treatment		
Collection		
Number of this mobilisation		
Number of courses from CR to collection		
Number of courses from collection to graft		
General		
Preparative (conditioning) treatment		
Regimen intended to be myeloablative (<i>full intensity</i>)		
Reason for non myeloablative (<i>reduced intensity</i>) regimen		
Other or additional reason for non myeloablative		
Remission induction or key therapy		
Sequential number of this treatment		
Reason for this treatment		
Other reason, specify		
Protocol		
Name of the treatment		
Did the 1st line treatment include HSCT?		
Drugs / chemo and TBI		
Drugs or chemotherapy		
Date conditioning chemo started		
Adjuvant chemotherapy		
Neoadjuvant chemotherapy		
TBI		
Total body irradiation, details		
Date conditioning TBI started		
CIC Radiophysics group		
Hospital of radiophysicist group		
Radiophysicist unit		
Radiophysicist phone/fax		
TBI total dose (Gy)		
Maximum superior (+) transverse deviation from TBI dose (%)		
Maximum inferior (-) transverse deviation from TBI dose (%)		
Maximum superior (+) longitudinal deviation from TBI dose (%)		
Maximum inferior (-) longitudinal deviation from TBI dose (%)		
Spleen dose (%)		
Rib cage dose (%)		
Estimated relative volume (%)		
Other important organ		
Dose organ above (%)		

Preparative (conditioning) treatment

1	No
2	Yes
99	unknown

Actions

Visibility

- Apply Item Filter ☐
- No DynFilters ☐
- Show Names ☐
- Hide Values ☐
- RecLoc at lvl=2 ☐
- Keep Chp&Sec closed ☐
- RecLoc 100% visible ☐
- History always visible ☐
- Trace always visible ☐

PREPARATIVE REGIMEN, ALSO IN THIS CASE, IF YOU FORGET THE REQUIRED FIELDS SUCH AS DRUGS OR DOSING, YOU CAN IN TREATMENT OR ASSESSMENT FIELDS ON THE RIGHT AND THEN BY CLICKING WITH RIGHT KEY

Treatment	value	label
CIC	305	305
Patient	330	330
Treatment date	1970/01/01 00:00	1970/01/01 (exact)
New record creation		
New record creation		
C0: Index date for new record		
C0: Index code for new donor	1	First
C2: Index code for new drug/agent		
C1: Index code for new cell count		
Data entry help Trt		
Navigation field		

✓ Note: Select the drug from the list. Drug can be any agent: < BR >chemo, growth factor (cytokine), MoAB, polyclonal AB, < br >hormone, etc.



Record creation

C2: Index code for new drug/agent

0 -SINGLE DRUG

1 Adriamycine

2 Amsacrine

3 ARA-C / Cytarabine

4 BCNU / Carmustine

5 Bleomycine

6 Busulfan / Busulphan

7 Carboplatin

8 CCNU

9 Cyclophosphamide / Endoxan

10 Chlorambucil

11 Cyclosporin / Cyclosporin / Neoral

12 Daunorubicin

13 Dexamethasone

14 Epirubicine

15 Etoposide / VP16

16 Fludarabine

17 Hydroxyurea

18 Idarubicine

19 Ifosfamide

20 Fluorouracil

21 Melphalan

22 Mercaptopur6

23 Methotrexate

24 Methyl prednisone/solone

25 Mitoxantrone

26 Prednisone/solone

27 Thioteoa

IMPORTANT

If you do not see the drug you are looking for, type "?" to see the whole list.

You can also start typing any part of the name of the drug; the list will shrink to only those items that share the text you have typed.

There is a help file with an alphabetical list of drugs and protocols.

To access it, click on the **MEDAB084.PDF** link below. You can save this file to your hard disk.

Additional help in **MEDAB084.PDF**

CHEMOTHERAPY FOR PREPARATIVE REGIMEN

Actions

Visibility

Apply Item Filter ☐

No DynFilters ☐

Show Names ☐

Hide Values ☐

RecLoc at lvl=2 ☐

Keep Chp&Sec closed ☐

RecLoc 100% visible ☐

History always visible ☐

Trace always visible ☐

+ Cancel,Change,Delete...

+ ClipBoard

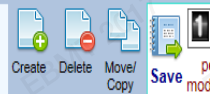
Form about to be... Med-A: Day 0

Med-B over Med-A null

UPN 1970

Date of birth 1900/01/01

Are you adding M... null



Record Locator

- Patient [305] 330

Diagn 1950/01/01

- Asse1 1950/01/01

Cytog 6

Molec 3

Molec 22

Asse1 1970/01/01

- Treat 1970/01/01

Donor 1

Chapters & Sections

+ Treatment identification & adm

+ Treatment record qualifier (ma

+ General

+ Transplant and cell source spe

+ Ex-vivo graft manipulation

+ Mivo treatment

+ Hospital admin (STABMT)

+ Supportive treatment in the pal

+ Cellular therapy (non HSCT)

+ Treatment related to complicat

+ Status after treatment

- New record creation

+ New record creation

+ Data entry help Trt

Drugs (Chemo_MoAB_etc)	value	label
CIC	305	305
Patient	330	330
Treatment date	1970/01/01 00:00	1970/01/01 00:00:00
Chemo	34	34
Drug treatment		
Indication		
Reason for this drug	10	GvHD Prophylaxis
Reason for drug if given during same period for another indication		
In-vivo treatment or ex-vivo culture	1	In vivo
Negative or positive selection		
Identification of donor or CBU unit used by centre		
Number in the infusion order		
Drug administration		
Drug or regimen given		
Other drug or chemo: specify if not coded		
Route of administration		
Animal origin	1	Rabbit
Other animal origin, specify		
Name of the brand		
Radiolabelled		
Dose of radioactive antibody		
Units of measurement of the radioactivity		
Dose of drug		
Units of measurement		
Number of cycles		
Type of delivery of the drug		
Period of treatment		
Treatment started on		
Treatment ended on		
Ongoing beyond date above		
Drug reaction		
Drug resistance		
New record creation		
CD: Index code for new drug		

✓ Note: If applicable, select an additional immunosuppressive therapy from the list, otherwise leave field empty



CD: Index code for new drug

9 Cyclophosphamide / Endoxan

11 Ciclosporin / Cyclosporin / Neoral

23 Methotrexate

24 Methyl prednisone/solone

26 Prednisone/solone

31 ATG or ALG (ATS or ALS)

34 ATG (anti-thymocyte globulin/serum)

35 ALG (anti-lymphocyte globulin/serum)

40 Corticosteroids

50 Mycophenolate mofetil

52 Tacrolimus

64 Sirolimus / Rapamune

94 Metronidazole

602 CD3

GVHD PROPHYLAXIS ALL DRUGS

If you do not see the drug you are looking for, type "?" to see the whole list.

You can also start typing any part of the name of the drug; the list will shrink to only those items that share the text you have typed.

There is a help file with an alphabetical list of drugs and protocols.

To access it, click on the **MEDAB084.PDF** link below.

You can save this file to your hard disk.

Index **Editor** Overview

Assessment(1) value label

CIC	305	305
Patient	330	330
Assessment date	1970/01/01 00:00	1970/01/01 00:00:00

Last status

Patient status

Conception after transplant?

Did pregnancy result in live birth?

Survival status on this date

Note: If patient died < b > before < /b > cell infusion was initiated, < br > enter code < b > 3 < /b > . < br > If patient died on the same day of the first cell infusion < br > but < b > after < /b > it was initiated, enter code < b > 1 < /b >

Survival status on this date

1	Dead
2	Alive
3	Died before HSCT but after conditioning was initiated

Form about to be... Med-A: Day 0
Med-B over Med-A null
UPN 1970
Date of birth 1900/01/01
Are you adding M... null

Actions

- Visibility
- Apply Item Filter ☐
- No DynFilters ☐
- Show Names ☐
- RecLoc at lvl=2 ☐
- Keep Chp&Sec closed ☐
- RecLoc 100% visible ☐
- History always visible ☐
- Trace always visible ☐
- + Cancel, Change, Delete...
- + ClipBoard

Record Locator

Drag 1970/01/01

Asse1 1970/01/01

Cytog 6

Molec 3

Molec 22

Asse1 1970/01/01

Treat 1970/01/01

Donor 1

Drug 9

Drug 14

Drug 11

Drug 23

Drug 34

Chapters & Sections

- + Investigations identificat & a
- + Assessment record qualifier
- + Diagnostics

PATIENT STATUS AT HSC INFUSION

- More info on cytogenetics and risk factors for certain diseases (eg lymphoproliferative disease)
- More info on pre HSCT disease therapy for certain diseases
- Co-morbidity index > SORROR SCORE
- Site specific GvHD

skin
liver
lower GI tract
upper GI tract
GvHD stage in gut

Impacts:

- Increase in data collected on disease
- Increased workload for data managers
- Need for data manager/physician collaboration
- Improved scientific output of EBMT



30 MINS ARE NEEDED
FOR A NEW HSCT
REGISTRATION
ESPECIALLY FOR
REFERRED PATIENTS-
SORROR CALCULATION
IF NOT DONE YET

HOW TO REGISTER A NEW TRANSPLANT AND MODIFICATIONS ACCORDING TO NEW-MED-A

- The SORROR SCORE

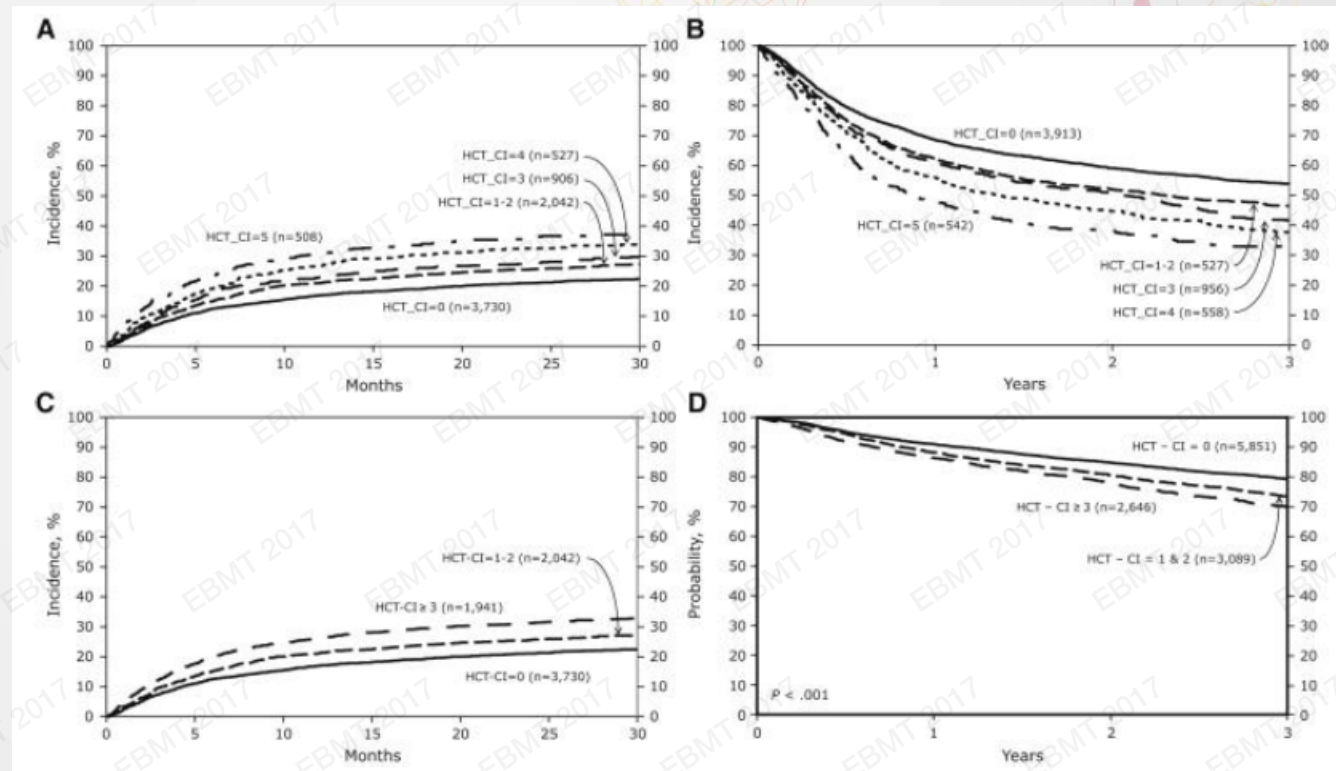
Table 1. HCT-CI

Comorbidities	HCT-CI score
Arrhythmia	1
Cardiovascular comorbidity	1
Inflammatory bowel disease	1
Diabetes or steroid-induced hyperglycemia	1
Cerebrovascular disease	1
Psychiatric disorder	1
Mild hepatic comorbidity	1
Obesity	1
Infection	1
Rheumatologic comorbidity	2
Peptic ulcer	2
Renal comorbidity	2
Moderate pulmonary comorbidity	2
Prior malignancy	3
Heart valve disease	3
Moderate/severe hepatic comorbidity	3
Severe pulmonary comorbidity	3
Total score = _____	

- A comorbidity tool suited for recipients of HCT
- Assesses pre-transplant organ impairment
 - Presence
 - Severity
- This information helps to understand the patient prognosis

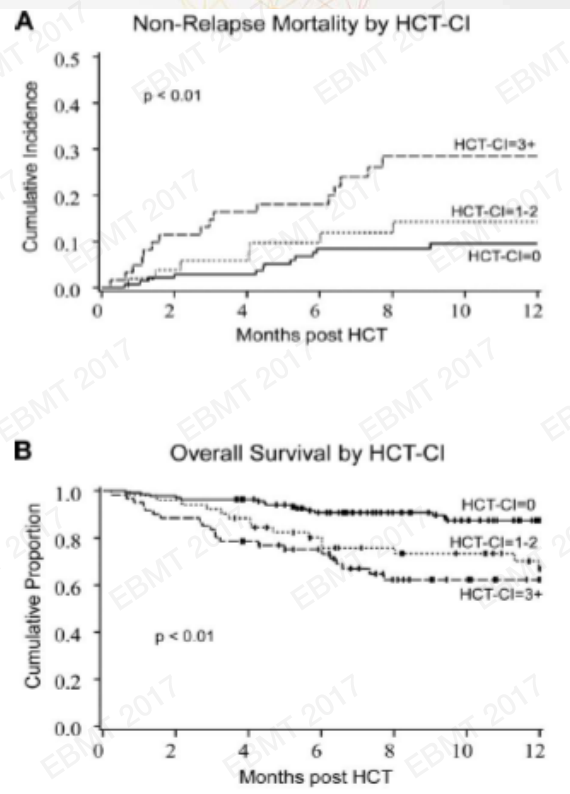
HOW TO REGISTER A NEW TRANSPLANT AND MODIFICATIONS ACCORDING TO NEW-MED-A

SORROR SCORE ADULTS



HOW TO REGISTER A NEW TRANSPLANT AND MODIFICATIONS ACCORDING TO NEW-MED-A

SORROR SCORE PEDIATRICS



Thank you!

Questions?