Project Manager Internet Server

a complete implementation of a tool to Design and Manage Structure and Data in multi-centre Registration Studies and Clinical Trials over Internet without additional software development

Ronald Brand
Senior Lecturer in Biostatistics
Department of Medical Statistics
Leiden University Medical Center

Henk Jan van der Wijk
Scientific Programmer
Department of Medical Statistics
Leiden University Medical Center

Implementation of trials and observational studies a biostatistician's perspective

- During the intellectual design of a study "I", the responsible researcher, have already established….
  * The methodology of the study
  * The required content of the Case Record Forms
  * The intended statistical (interim) analyses
  * The logistics and logic of the study
  * The data structure for data storage
- So the same knowledge is used …
  * to write down the protocol; to describe the logistics of the study; to create the coding forms; to write patient information…..
- Moreover …
  * I buy a text editor: I **do not create** my own one!
  * I use the **same** text editor for any project

Implementation of trials and observational studies a biostatistician's perspective

- If this is so logical, then why…
  * Do I have to write all definitions first in the protocol
  * Do I have to write down again all definitions as coding forms
  * Do I have to write down once more all definitions as SPSS syntax for analysis
  * Do I have to type in all definitions again to define a data base structure
  * Do I run into trouble if the data base structure turns out not to correspond with the intended analysis structure
  * Do clinicians and statisticians alike program their complete data entry and retrieval system again and again for each trial or registration study they undertake
  * Do researchers waste their time on technical issues while there are so many more interesting tasks to perform?

Implementation of long-term registration projects a biostatistician's perspective

- Data management should be an integral part of the methodology of clinical studies and hence belongs to the domain of biostatistics
- Design decisions should be made while seeking a compromise between the requirements from the domain of IT, clinical research, data management and statistics
- Keywords.....
  - "**Flexibility**" is a keyword for clinical reseachers designing and establishing long term (inter)national registries
  - "**Quality**" and "**Transparency**" are keywords for data managers and research nurses
  - "**Security**" and "**Portability**" are keywords for IT people
  - "**Ease-of-use**" and "**Accessibility**" are keywords for physicians using the data
  - "**Efficiency**" and "**Standardization**" are keywords for a biostatistician who is involved in many studies at the same time ...

Implementation of long-term registration projects a biostatistician's perspective

- Generic data management software must be …
  * **Flexible**
    - Study coordinator must be able to follow scientific developments and dynamically modify the system in any respect without technical support
    - The software must be able to follow relevant software developments
  * **Efficient**
    - Study coordinators, data managers and research nurses must be able to manage the system in an intuitive way
    - There should be no local copies of software and/or data bases
    - WWW access should be the normal way of data input/output
  * **Cost-effective**
    - The design of a particular project should take little time
    - The structure should automatically balance the requirements for ease-of-data input and ease-of-analysis, both faithful to the protocol
    - All projects must benefit from developments triggered by others

Implementation of trials and observational studies a biostatistician's perspective

This is what ProMISe is all about:

- one central core to contain the clinical definitions, the Dictionary of a study
- one central core to contain all data collected
- centralized generation of paper and electronic coding forms as a reflection of the current Dictionary
- structural design that pays attention to the way the data should be checked and analyzed
- one piece of software to run an infinite number of studies in the same way
- an open architecture which allows (and supports) export of Dictionary and Data to any other format or computer program and integration with local data management

Implementation of long-term registration projects

Example

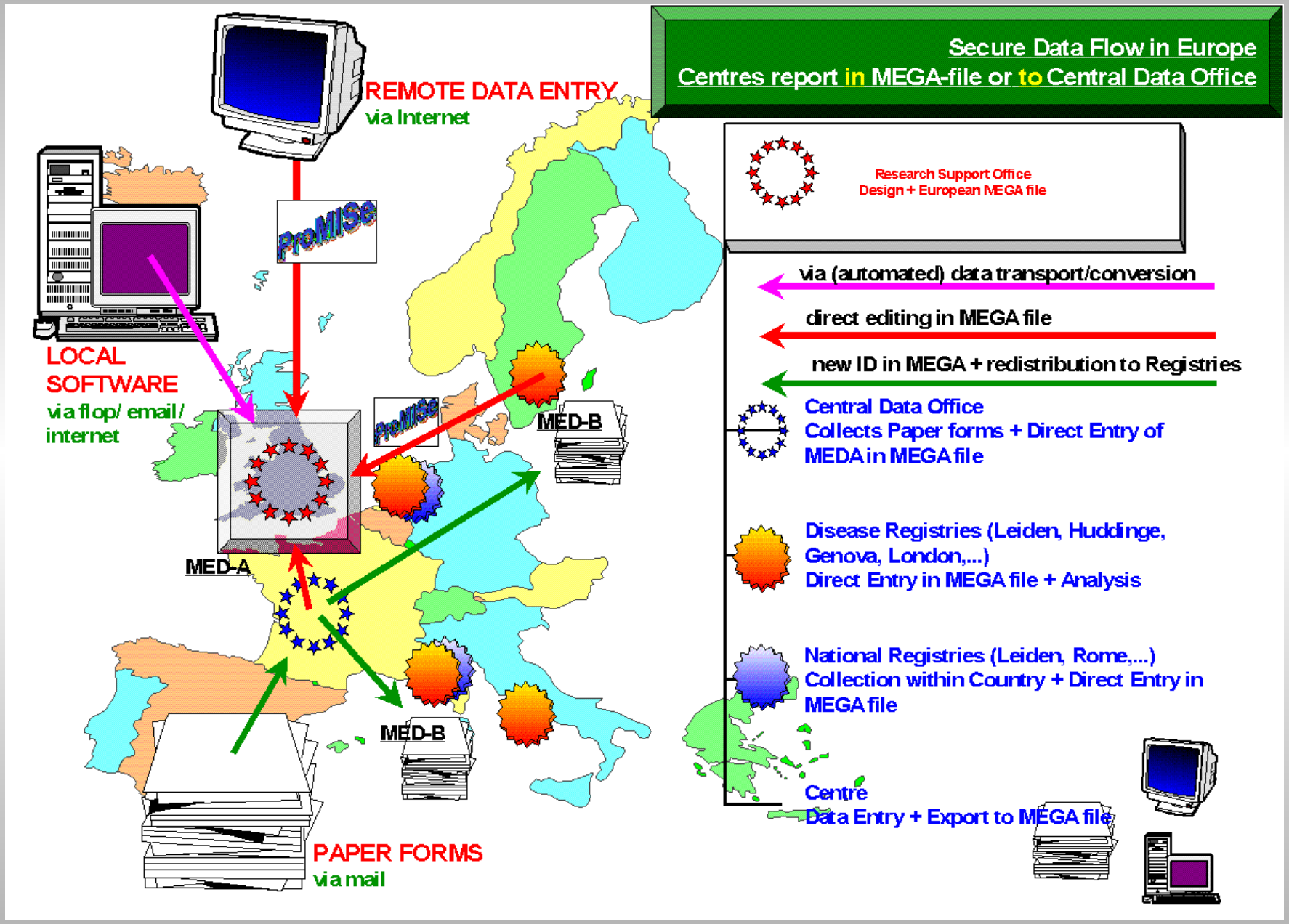
permanent registration of blood and marrow transplantations in Europe

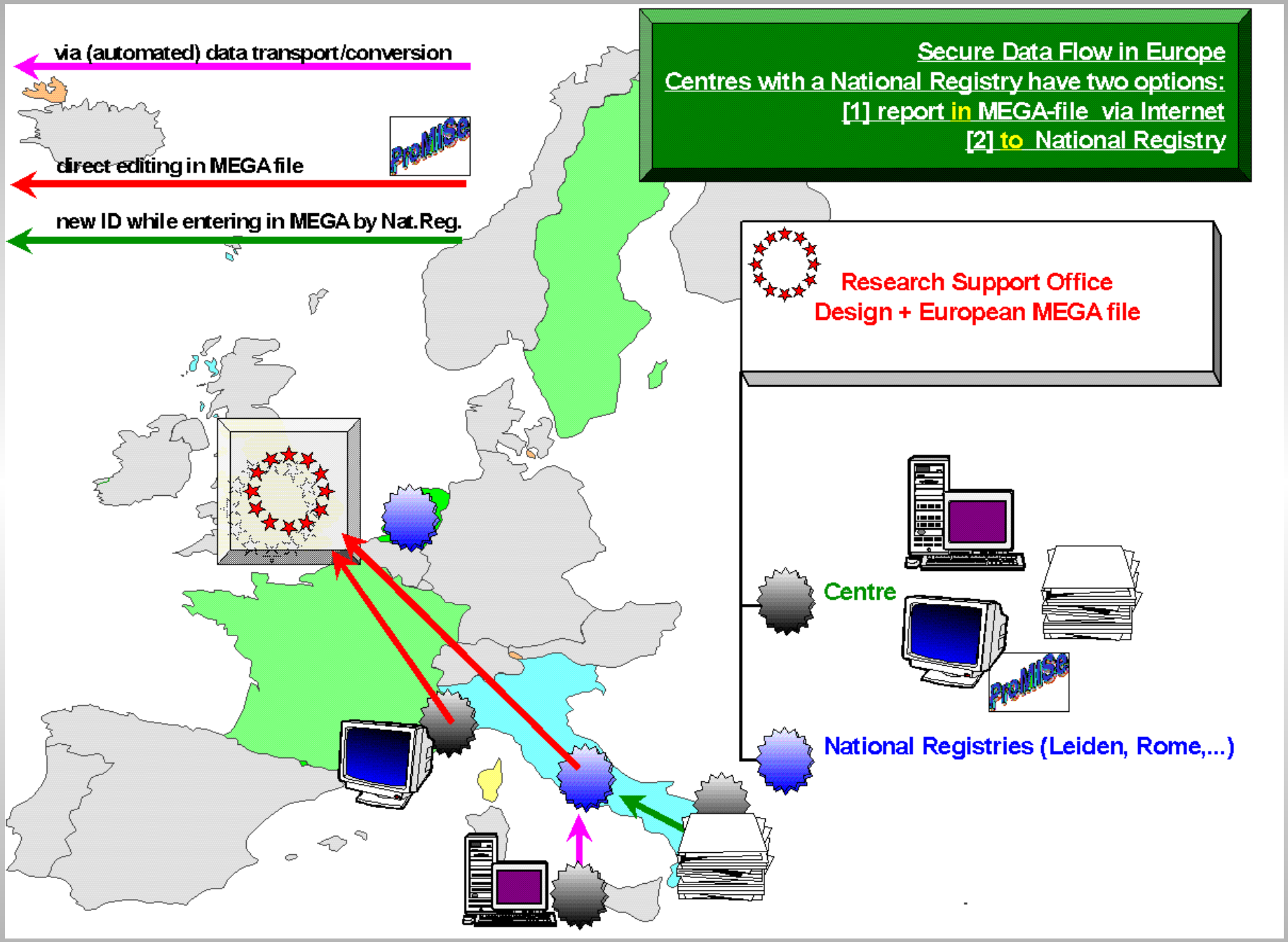
* central data base
  - Clinical design: Working Parties, coordinated
  - data base design: London Office/Leiden Office
  - data entry: paper; conversion; WWW pages
* size
  - 600 centers; 12 disease-registries; 6 national registries
  - >20 years; >230000 patients; >450000 treatments;>1000000 assessments; >1500 items;

Implementation of long-term registration projects

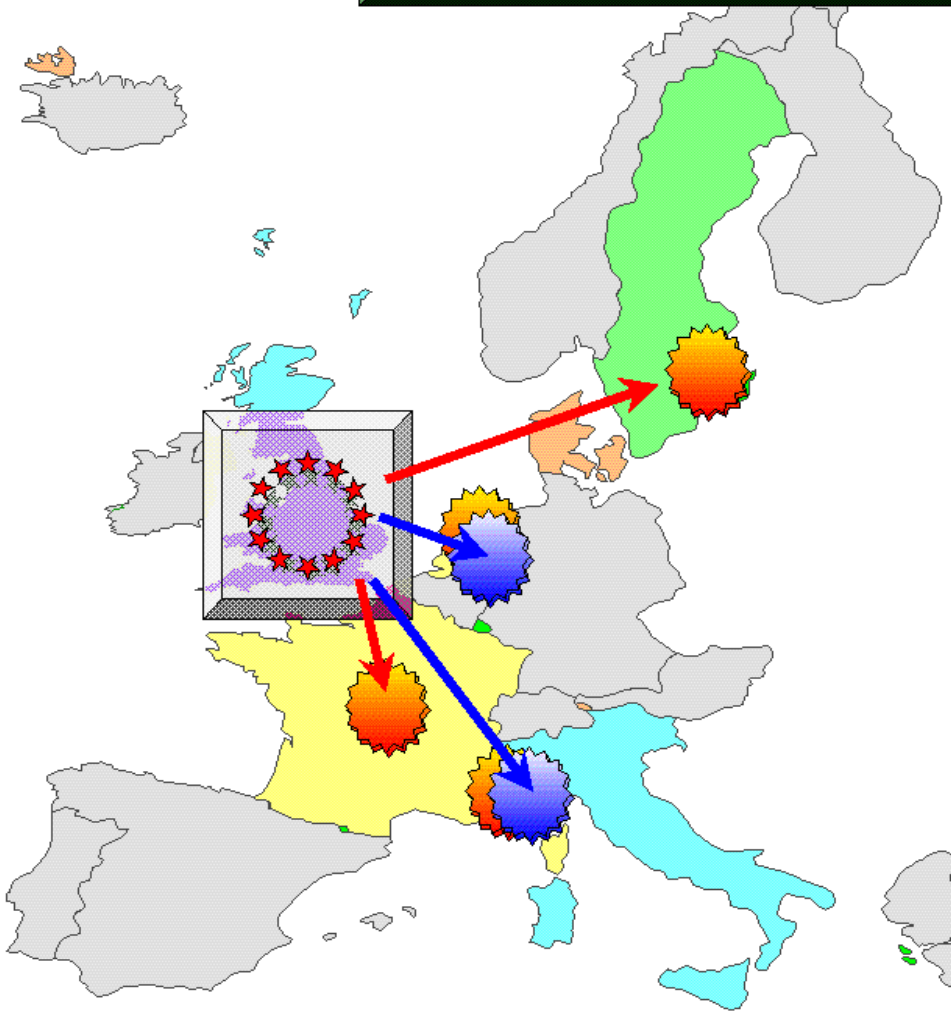
Example: EBMT

- logistics of data flow in Europe: support
  - Central Office (London)
    - coordination; helpdesk; conversions; trials
  - Disease Registries (Leiden,Paris,…)
    - data managers, statisticians
  - National Registries (Leiden,Genova,Roma,Basel,Innsbruck..)
    - data managers
  - Central data base (Leiden)
    - Information scientist, statistician


Secure Data Flow in Europe
Centres report in MEGA-file or to Central Data Office
REMOTE DATA ENTRY
via Internet
ProMISe
LOCAL
SOFTWARE
via flop/ email/
internet
ProMISe
MED-B
MED-A
MED-B
PAPER FORMS
via mail
Research Support Office
Design + European MEGA file
via (automated) data transport/conversion
direct editing in MEGA file
new ID in MEGA + redistribution to Registries
Central Data Office
Collects Paper forms + Direct Entry of
MEDA in MEGA file
Disease Registries (Leiden, Huddinge,
Genova, London,...)
Direct Entry in MEGA file + Analysis
National Registries (Leiden, Rome,...)
Collection within Country + Direct Entry in
MEGA file
Centre
Data Entry + Export to MEGA file


via (automated) data transport/conversion
direct editing in MEGA file
new ID while entering in MEGA by Nat.Reg.
PraNISe
Secure Data Flow in Europe
Centres with a National Registry have two options:
[1] report in MEGA-file via Internet
[2] to National Registry
Research Support Office
Design + European MEGA file
Centre
PraNISe
National Registries (Leiden, Rome,...)

Secure Data Flow in Europe
Registries always up-to-date extracting from European Mega File



Research Support Office
London: European MEGA file

combine patients on disease criteria

ProMISe

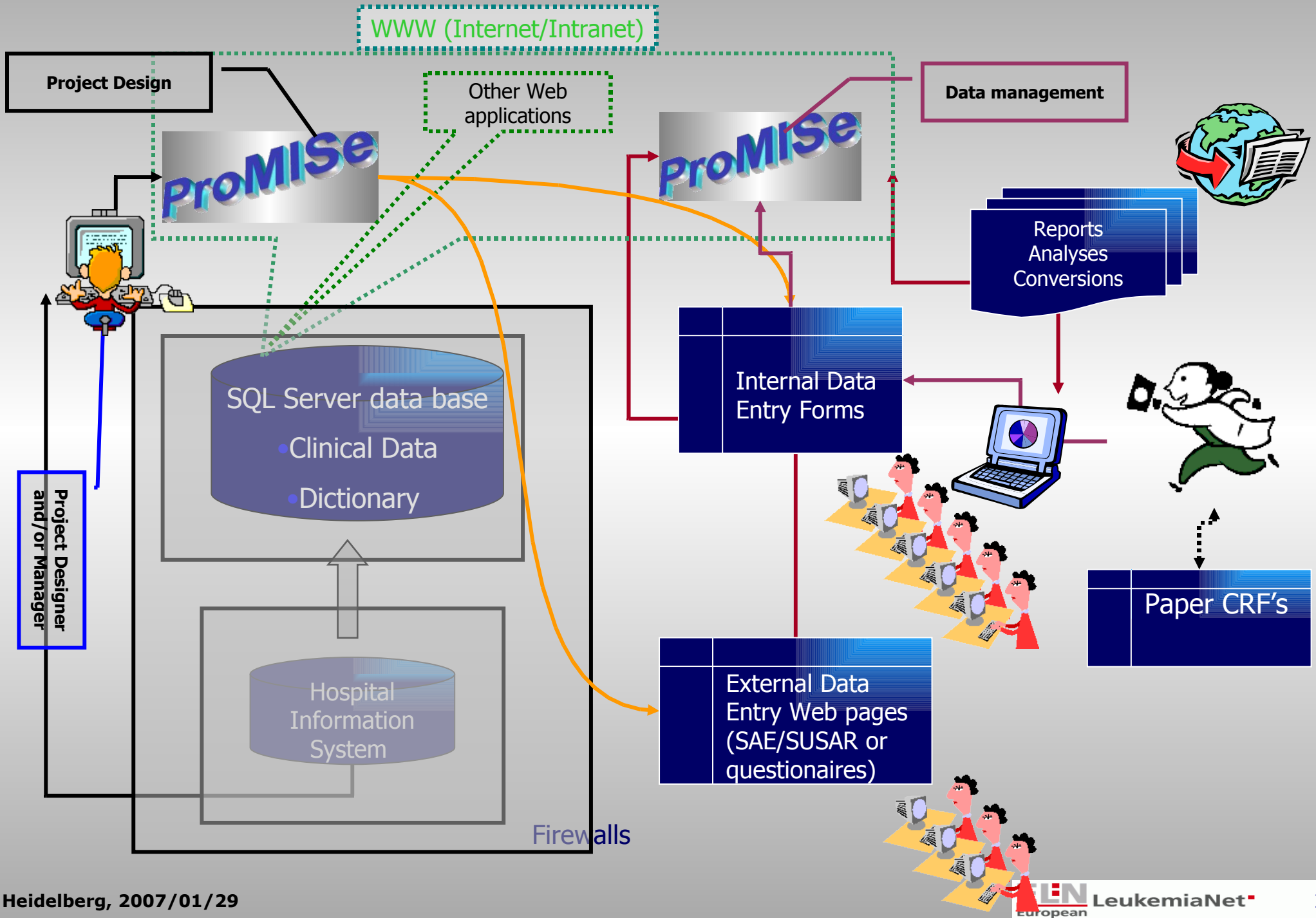
combine centres within a country

Disease Registries (Leiden, Huddinge, Genova, London,...)
Analysis

National Registries (Leiden, Rome,...)
Analysis and National Reporting

Overview

Implementation of long-term registration projects: general structure



Purpose

- ProMISe was conceived to ...
  * be a generic tool to Design and Manage single/multi center clinical research projects: both observational studies (registries) and experimental studies (prospective trials)
  * provide an information storage and retrieval system using the Internet Explorer (IE6.x;7.x) browser over a (secure) internet connection
  * to allow a single person (not being an information scientist) to manage an entire project (design as well as logistics)
  * to allow all projects to be dynamically modifiable and extendable during their life cycles, incorporating new scientific developments or the need for more in-depth information

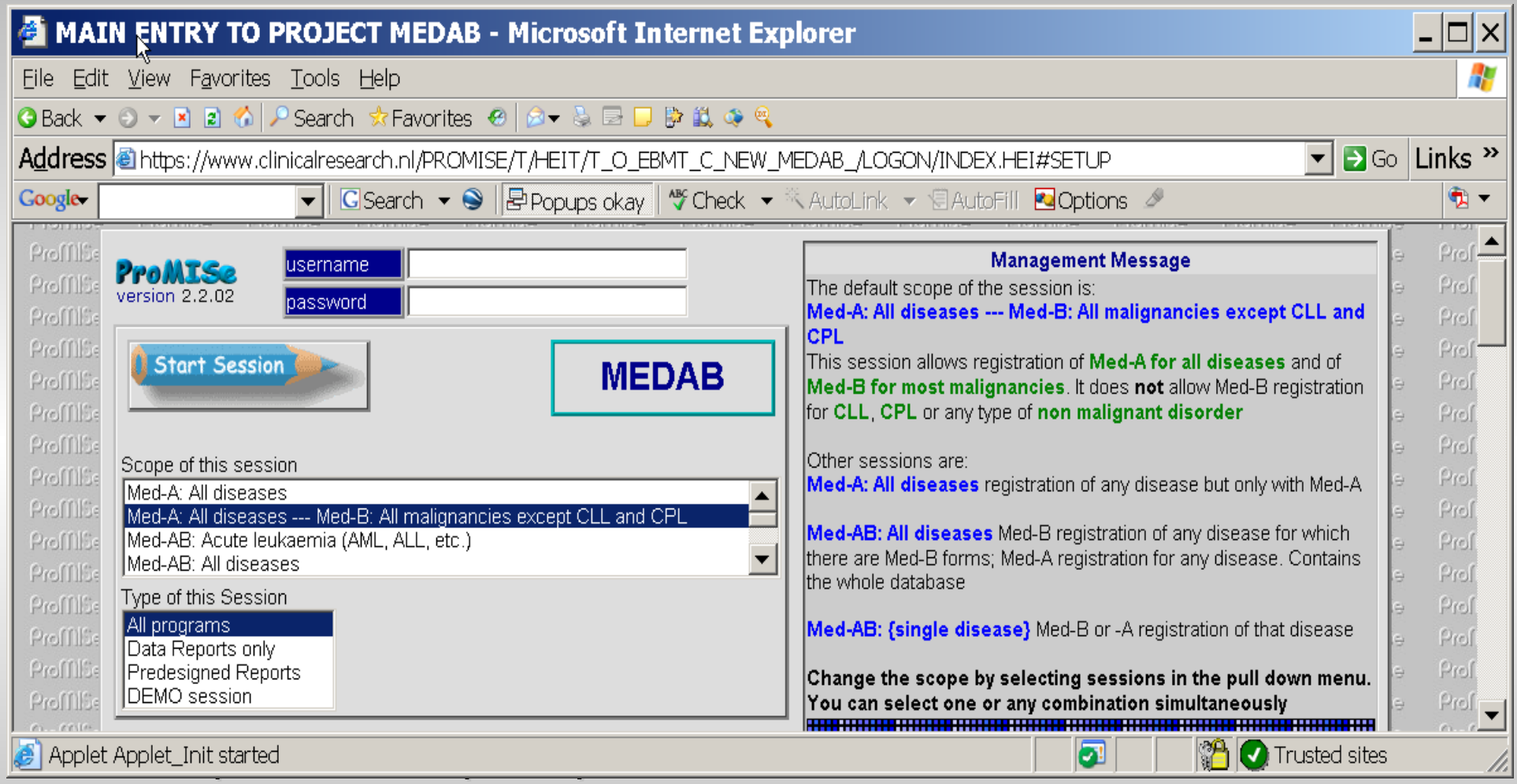
Design

- Studies are physically implemented at the Department of Medical Statistics of the Leiden University Medical Center in a highly secure environment
- The Design of a project is integrated into the web application, allowing the Designer to change any aspect of the project from any location on the Internet
- Tools are included to maintain the structure of the project, the data bases, log files and user access authorization tables
- The number of studies (projects) is unlimited
- Tools are included to "link" projects in a Publisher-Subscriber relationship enabling sharing of scientific data among independent organizations
- Projects can also contain membership information on centers, departments and persons involved as well as their roles in specific projects (mainly clinical trials)

Data base system: SQL-Server

- Data are stored in a relational data base system in SQL-Server
- Every project has its own data base
- The current Servers at the Department of Medical Statistics:
  * Win2000 advanced server, 8000 Mb memory, 8 CPU's, 14*32 Gigabyte RAID-controller
  * Win2005 advanced server, 4000 Mb memory, 4 dual core CPU's, 14*32 Gigabyte RAID-controller
  * HTML generating ISAPI DLL by Heitml, Germany
  * Interactive Graphics by R-Charts
  * Microsoft IIS with Thawte Security Signature
  * Microsoft SQL-Server 2000/2005

Privacy & Security



The logon screen is typically reached by a link on the website of the project organization

User interface

- ProMISe contains a set of dynamic HTML forms, computed in real time and automatically reflecting the underlying structure of the project and any user preferences
- Extensive dynamic help file support during data entry
- No local software or Active-X components involved *
  - * Active-X is however required for very special applications like
    - "save-to-local-disk"
    - "read from external application (HIS)"
    - "decryption/encryption to/from local applications"
- The design minimizes data traffic over Internet at the expense of heavy use of the local PC in terms of processor load and memory requirements

Efficiency

- Only *one* software copy exists on a server and any updates take effect immediately in **all** projects and **all** centers
- No programming is involved in the design and maintenance of a project: data bases with structural information are **continuously** queried to generate the user interface dynamically
- Support for "Publisher-Subscriber" sharing of data & definitions between scientific organizations is built into the design
- Support for separate projects containing members of organisations and their roles within studies / clinical trials
- Support for central storage of definitions of items or even entire scoring systems (QoL etc)

Cost-effectiveness

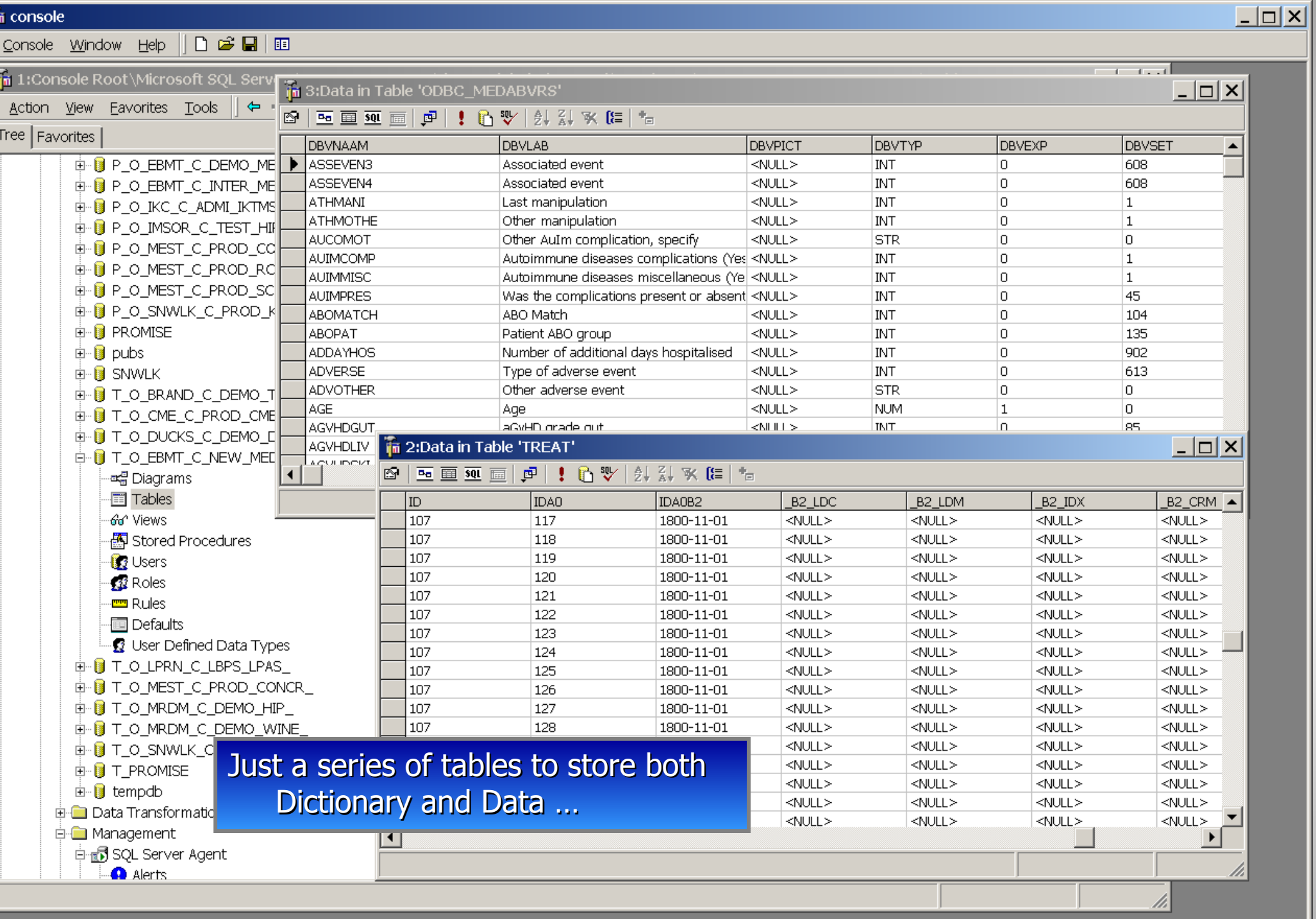
- Development of an entire Internet data management system is reduced to days or weeks of (clinical) specifications instead of many months of programming labor
- All aspects of the electronic CRF's can be modified during the study without jeopardizing the integrity of the data
- Software improvements/additions created for (or paid by) one project become available to all users of all projects instantaneously!
- Conversion from regular SPSS files to full-blown relational data base structure built into the system

Integration

- ProMISe can also be used as an information retrieval-only system for centers if the choice has been made to enter new data only in the central study center
- Organizations can independently build their own websites which can display data interactively requested from a protected ProMISe project (for example statistical data for patient information sites)
- Support for browser-independent standard web interface for patient questionaires, immediate SAE and SUSAR reporting
- Fully automatic e-mail and fax integration

Application

- Any clinical study that can be conducted using standard paper Case Report Forms (CRF's), can also be realized within the ProMISe framework
- Since only standard SQL-Server tables are used, already existing data can be converted to ProMISe easily after creating the appropriate structure
- If properly constructed, SPSS files can be integrally converted to a full-blown ProMISe project in an hour
- Users can download their own private MS-Access data bases or Excel files for local data analysis or connection to other local data base systems: open structure with well-defined conversion interfaces


console
Console Window Help
1:Console Root\Microsoft SQL Serv
Action View Favorites Tools
Tree Favorites
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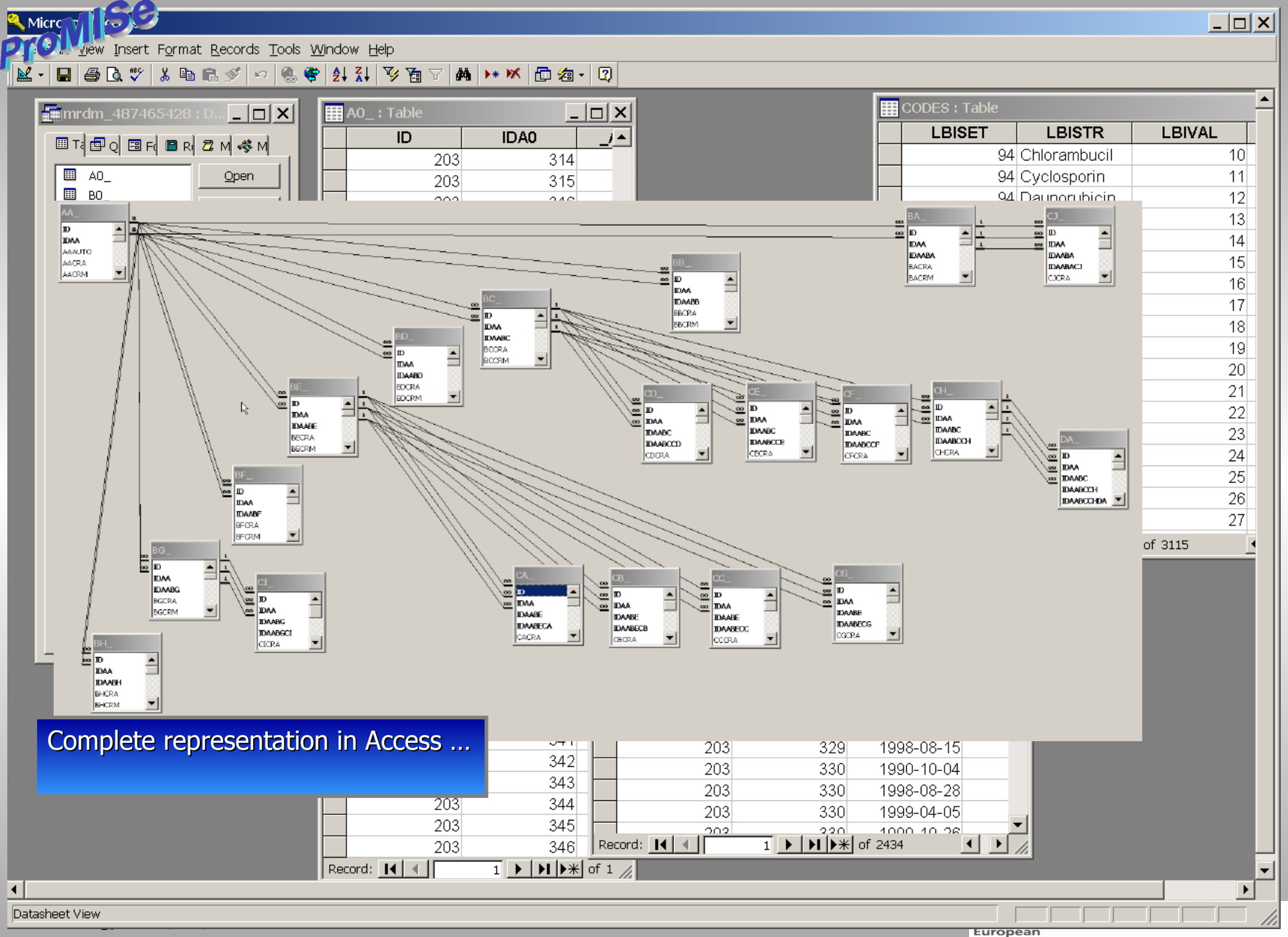
P_O_EBMT_C_INTER_ME
P_O_IKC_C_ADMI_IKTMS
P_O_IMSOR_C_TEST_HI
P_O_MEST_C_PROD_CC
P_O_MEST_C_PROD_RC
P_O_MEST_C_PROD_SC
P_O_SNWLK_C_PROD_K
PROMISE
pubs
SNWLK
T_O_BRAND_C_DEMO_T
T_O_CME_C_PROD_CME
T_O_DUCKS_C_DEMO_D
T_O_EBMT_C_NEW_MED
Diagrams
Tables
Views
Stored Procedures
Users
Roles
Rules
Defaults
User Defined Data Types
T_O_LPRN_C_LBPS_LPAS_
T_O_MEST_C_PROD_CONCR_
T_O_MRDM_C_DEMO_HIP_
T_O_MRDM_C_DEMO_WINE_
T_O_SNWLK_C
T_PROMISE
tempdb
Data Transformatio
Management
SQL Server Agent
Alerts
3:Data in Table 'ODBC_MEDABVRS'
DBVNAAM | DBVLAB | DBVPICT | DBVTYP | DBVEXP | DBVSET
ASSEVEN3 | Associated event | <NULL> | INT | 0 | 608
ASSEVEN4 | Associated event | <NULL> | INT | 0 | 608
ATHMANI | Last manipulation | <NULL> | INT | 0 | 1
ATHMOTHE | Other manipulation | <NULL> | INT | 0 | 1
AUCOMOT | Other AuIm complication, specify | <NULL> | STR | 0 | 0
AUIMCOMP | Autoimmune diseases complications (Yes | <NULL> | INT | 0 | 1
AUIMMISC | Autoimmune diseases miscellaneous (Ye | <NULL> | INT | 0 | 1
AUIMPRES | Was the complications present or absent | <NULL> | INT | 0 | 45
ABOMATCH | ABO Match | <NULL> | INT | 0 | 104
ABOPAT | Patient ABO group | <NULL> | INT | 0 | 135
ADDAYHOS | Number of additional days hospitalised | <NULL> | INT | 0 | 902
ADVERSE | Type of adverse event | <NULL> | INT | 0 | 613
ADVOTHER | Other adverse event | <NULL> | STR | 0 | 0
AGE | Age | <NULL> | NUM | 1 | 0
AGVHDGUT | aGvHD grade gut | <NULL> | INT | 0 | 85
AGVHDLIV
2:Data in Table 'TREAT'
ID | IDA0 | IDA0B2 | _B2_LDC | _B2_LDM | _B2_IDX | _B2_CRM
107 | 117 | 1800-11-01 | <NULL> | <NULL> | <NULL> | <NULL>
107 | 118 | 1800-11-01 | <NULL> | <NULL> | <NULL> | <NULL>
107 | 119 | 1800-11-01 | <NULL> | <NULL> | <NULL> | <NULL>
107 | 120 | 1800-11-01 | <NULL> | <NULL> | <NULL> | <NULL>
107 | 121 | 1800-11-01 | <NULL> | <NULL> | <NULL> | <NULL>
107 | 122 | 1800-11-01 | <NULL> | <NULL> | <NULL> | <NULL>
107 | 123 | 1800-11-01 | <NULL> | <NULL> | <NULL> | <NULL>
107 | 124 | 1800-11-01 | <NULL> | <NULL> | <NULL> | <NULL>
107 | 125 | 1800-11-01 | <NULL> | <NULL> | <NULL> | <NULL>
107 | 126 | 1800-11-01 | <NULL> | <NULL> | <NULL> | <NULL>
107 | 127 | 1800-11-01 | <NULL> | <NULL> | <NULL> | <NULL>
107 | 128 | 1800-11-01 | <NULL> | <NULL> | <NULL> | <NULL>
Just a series of tables to store both Dictionary and Data ...


ProMISe
Insert Format Records Tools Window Help
mrdm_487465428 : D...
Open
A0_
B0
A0_ : Table
ID
IDA0
203 314
203 315
CODES : Table
LBISET
LBISTR
LBIVAL
94 Chlorambucil 10
94 Cyclosporin 11
94 Daunorubicin 12
13
14
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21
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23
24
25
26
27
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AA_
BA_
CJ_
BB_
BC_
BD_
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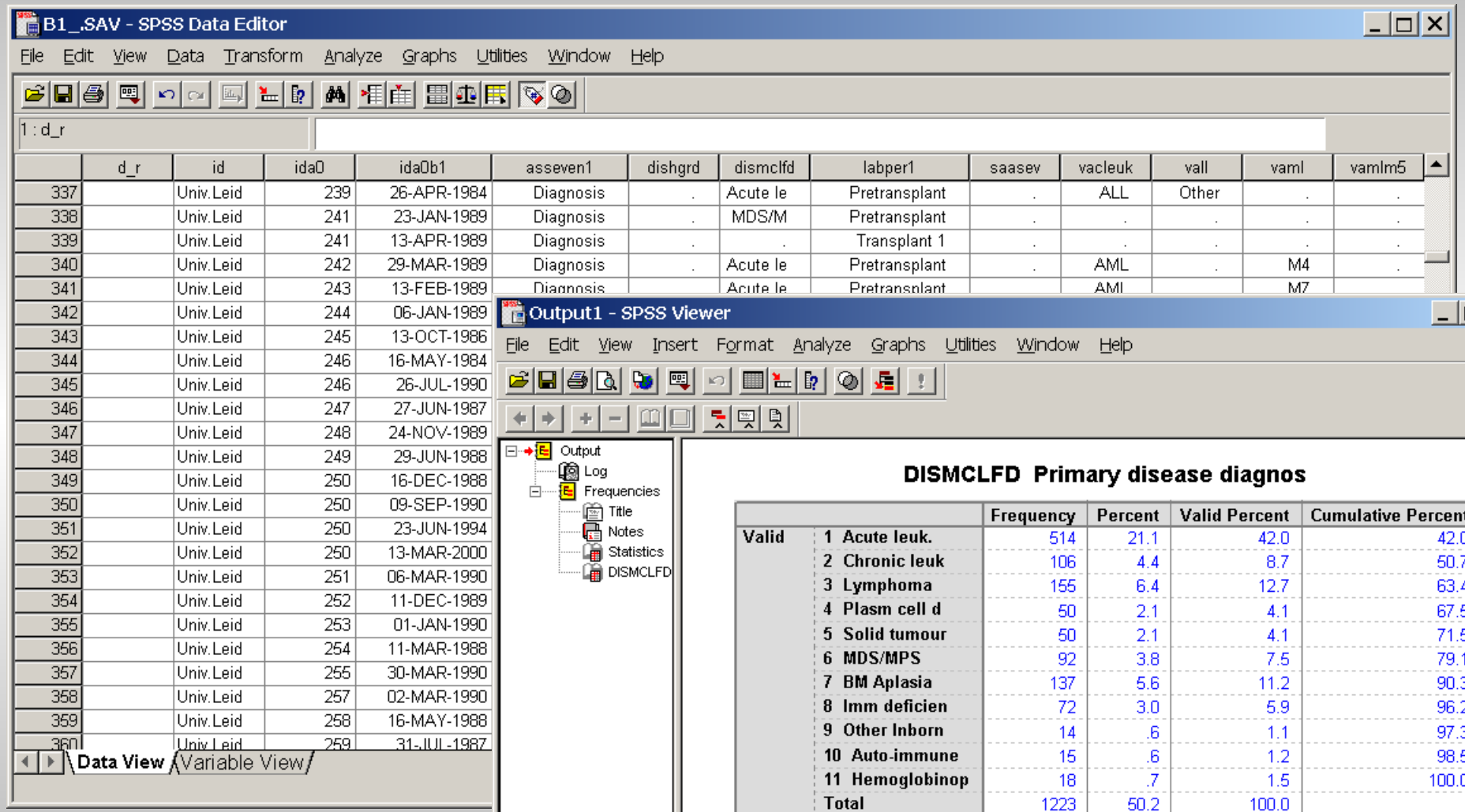
CD_
CE_
CF_
CH_
DA_
BF_
BG_
CI_
BH_
CA_
CB_
CC_
CG_
203 329 1998-08-15
342
343
203 330 1990-10-04
203 330 1998-08-28
203 344
203 330 1999-04-05
203 345
203 346
Record: 1 of 1
Record: 1 of 2434
Complete representation in Access ...
Datasheet View


B1_.SAV - SPSS Data Editor
File Edit View Data Transform Analyze Graphs Utilities Window Help
1 : d_r
d_r id ida0 ida0b1 asseven1 dishgrd dismclfd labper1 saasev vacleuk vall vaml vamlm5
337 Univ.Leid 239 26-APR-1984 Diagnosis . Acute le Pretransplant . ALL Other . .
338 Univ.Leid 241 23-JAN-1989 Diagnosis . MDS/M Pretransplant . . . . .
339 Univ.Leid 241 13-APR-1989 Diagnosis . . Transplant 1 . . . . .
340 Univ.Leid 242 29-MAR-1989 Diagnosis . Acute le Pretransplant . AML . M4 .
341 Univ.Leid 243 13-FEB-1989 Diagnosis . Acute le Pretransplant . AML . M7 .
342 Univ.Leid 244 06-JAN-1989
343 Univ.Leid 245 13-OCT-1986
344 Univ.Leid 246 16-MAY-1984
345 Univ.Leid 246 26-JUL-1990
346 Univ.Leid 247 27-JUN-1987
347 Univ.Leid 248 24-NOV-1989
348 Univ.Leid 249 29-JUN-1988
349 Univ.Leid 250 16-DEC-1988
350 Univ.Leid 250 09-SEP-1990
351 Univ.Leid 250 23-JUN-1994
352 Univ.Leid 250 13-MAR-2000
353 Univ.Leid 251 06-MAR-1990
354 Univ.Leid 252 11-DEC-1989
355 Univ.Leid 253 01-JAN-1990
356 Univ.Leid 254 11-MAR-1988
357 Univ.Leid 255 30-MAR-1990
358 Univ.Leid 257 02-MAR-1990
359 Univ.Leid 258 16-MAY-1988
360 Univ.Leid 259 31-JUL-1987
Data View Variable View
Output1 - SPSS Viewer
File Edit View Insert Format Analyze Graphs Utilities Window Help
Output
Log
Frequencies
Title
Notes
Statistics
DISMCLFD
DISMCLFD Primary disease diagnos
Frequency Percent Valid Percent Cumulative Percent
Valid 1 Acute leuk. 514 21.1 42.0 42.0
2 Chronic leuk 106 4.4 8.7 50.7
3 Lymphoma 155 6.4 12.7 63.4
4 Plasm cell d 50 2.1 4.1 67.5
5 Solid tumour 50 2.1 4.1 71.5
6 MDS/MPS 92 3.8 7.5 79.1
7 BM Aplasia 137 5.6 11.2 90.3
8 Imm deficien 72 3.0 5.9 96.2
9 Other Inborn 14 .6 1.1 97.3
10 Auto-immune 15 .6 1.2 98.5
11 Hemoglobinop 18 .7 1.5 100.0
Total 1223 50.2 100.0
Missing System 1211 49.8
Total 2434 100.0
SPSS Processor is ready

... or SPSS .....

Project realization

- Project "classification" by primary (clinical) purpose…
  * Epidemiological description of target population
  * Unification of (inter)national approaches to one disease
  * Integration of research projects within one clinical area
  * Consensus achievement
  * Questionaire collection
  * Long term data collection with fixed scientific purpose
  * Long term data collection reflecting actual treatment structure (EPF)
  * Unification of scoring systems
  * Clinical trial management and meta data
  * Patient care and safety issues
  * Temporary data collection (EU projects)
  * Partial collection of (phenotypical) data to be linked to genetic data
  * Local support for multi disciplinary approaches
  * National registries integrating many different clinical fields

Project realization

- Project "classification" by primary statistical approach…
  * Single measurement
  * Repeated measurements with a (small) fixed # of repetitions
  * Repeated measurements with variable # of repetitions
  * Presence of "survival context"
  * One-time-only analysis (e.g. clinical trial) or continuous analyses
  * Analysis by statistician or by clinical researcher
  * Data quality control level
  * Focus on case descriptions or summary measures

Project realization

- Project "classification" by IT context…
  * Stand-alone project or one-of-many
  * Need to communicate with other data bases
  * Need to standardize design with other sources of information
  * Accessibility at non-ProMISe level
  * Complexity when represented within other data base contexts
  * Interface requirements to Hospital Information Systems
  * In-house design or external
  * In-house management or external
  * Level of knowledge principle designer
  * Need to import classification systems
  * System load
  * Required level of security

Project realization

- Project "classification" by data management context…
  * Dedicated designer and/or manager or project sharing
  * Central or distributed data entry
  * Organization of data quality checks: a priori and/or post-hoc
  * Level of knowledge principle data manager
  * Need for non-ProMISe data entry (patients, SAE, SUSAR)
  * Need for education and training
  * Dictionary interpretation support (help files, training)
  * Hiding or exposing relational structure: simplicity versus flexibility

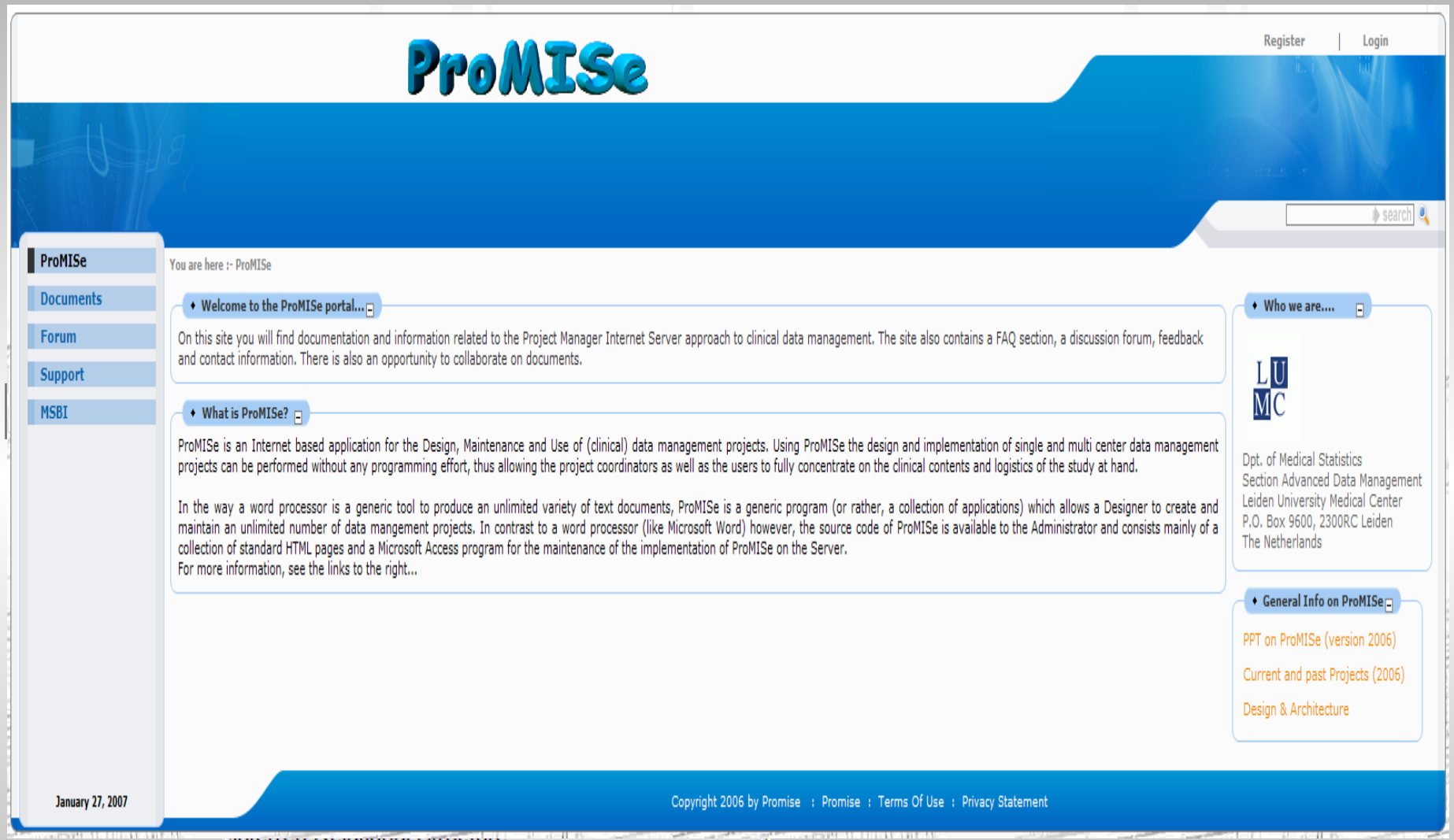
Project realization

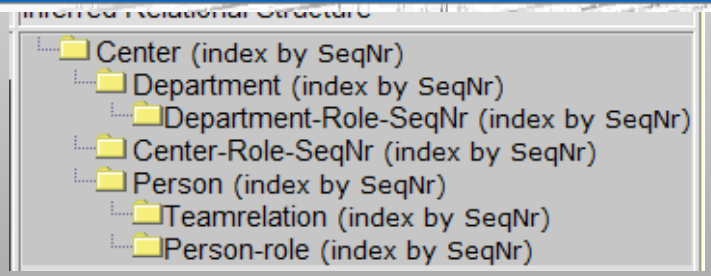
I will now show you a series of different projects realized within ProMISe illustrating the previous concepts

The projects differ in

- Scale
- Purpose
- Clinical complexity
- Security
- Organizational complexity
- Quality requirements
- Methodological approach (observational vs experimental)

Generic ProMISe Projects





European Blood and Marrow Transplant Group

MEMBERS: all membership info

Inferred Relational Structure

- Center (index by SeqNr)
  - Team (index by SeqNr)
    - Activity (index by SeqNr)
    - Accreditation (index by SeqNr)
    - Study (index by SeqNr)
    - Yearly Summaries (index by SeqNr)
    - Audit (index by SeqNr)
  - Person (index by SeqNr)
    - IT ACCESS (index by SeqNr)
    - Role (index by SeqNr)
  - Payment (index by SeqNr)
  - Contract (index by Date/Time)
  - Outreach (index by SeqNr)

ROLES: all roles people have in CLWP projects

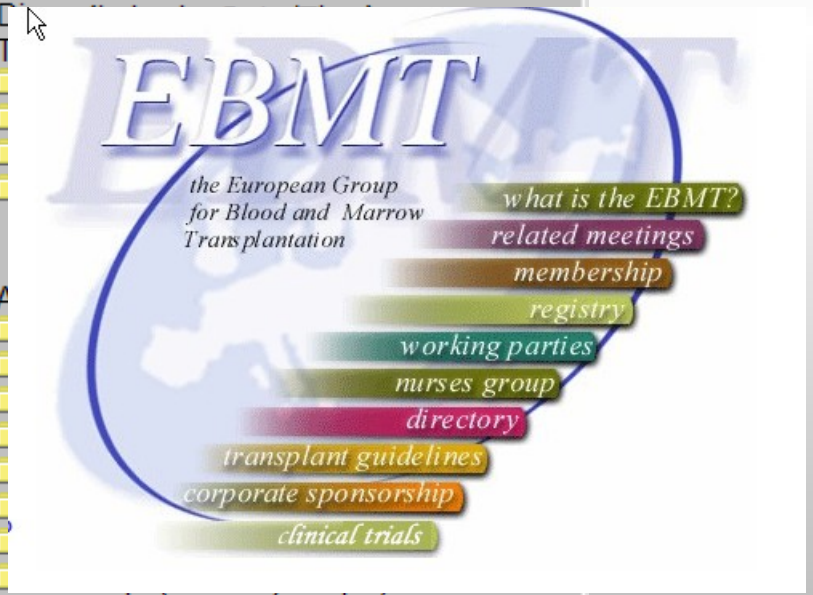
Inferred Relational Structure

- Center (index by SeqNr)
  - Department (index by SeqNr)
    - Department-Role-SeqNr (index by SeqNr)
  - Center-Role-SeqNr (index by SeqNr)
  - Person (index by SeqNr)
    - Teamrelation (index by SeqNr)
    - Person-role (index by SeqNr)

MEDAB: all BM transplants in Europe

Inferred Relational Structure

- Patient (index by SeqNr)
  - Study (index by SeqNr)
  - Antibody (index by SeqNr)
  - Questionnaire (index by SeqNr)
- Asse2 (index by Date/Time)
- Pt-HLA (index by SeqNr)



CLLAG: clinical trial in CLL

Inferred Relational Structure

- Patient (index by SeqNr)
  - FollowUp form (index by Date/Time)
  - SAE form (index by Date/Time)
  - QoL form (index by Date/Time)

MDS2X2: doubly randomized trial in MDS

Inferred Relational Structure

- Patient (index by SeqNr)
  - Treat (index by Date/Time)
  - Assessment (index by Date/Time)
  - SAE or SAE follow up (index by Date/Time)

MMVAR: european trial together with industry

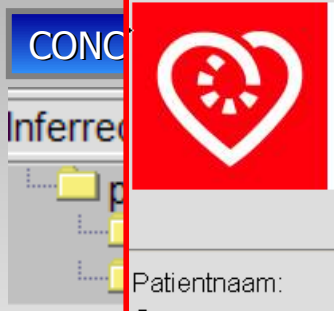
Inferred Relational Structure

- patient (index by SeqNr)
  - treatment (index by Date/Time)
  - assessment (index by Date/Time)
    - adverse event (index by SeqNr)

RICMAC: Reduced Intensity trial in MDS

Inferred Relational Structure

- Patient (index by SeqNr)
  - Follow up (index by Date/Time)
  - SAE or SAE follow up (index by Date/Time)



Concor

Patientnaam:	R. Regeer	Geboortedatum:	1968/02/28	
Concor-nr:	418	Promise-nr:	1061167	DNA afg:
Registr. Zkhs:	Leids Universitair Medisch Centrum [Leiden] (106)	Patientnummer:	8122415	
2e Zkhs:	()	Patientnummer:		

Datum	*	EPCC	Omschrijving	ICD9	ICD10	HE
1971/05/19 00	exact date	09.29.01	Aortic coarctation,		Q25.1	***
{date unknown}	exact date	09.15.22	Bicuspid aortic valve,		Q23.1	
1971/05/19 01	exact date	05.04.02	ASD within oval fossa (secundum),		Q21.1	
1974/07/12 00	exact date	12.18.00	Coarctation / hypoplasia of aorta repair,		?	
1974/07/12 01	exact date	10.14.01	Systemic hypertension,		I10	
2001/11/07 00	exact date	15.35.03	Residual aortic regurgitation,		Q23.1	

* : Zekerheid van de datum
HE : Hoofdevent

Opmerkingen

Aanvullingen

Datum laatste contact cardioloog:
Datum laatste contact CONCOR:
Datum laatste wijziging:
Niet meer onder behandeling?:

ORTHOPAEDICS

LROI: National Registry of all Hip & Knee implants

Inferred Relational Structure

- patient (index by SeqNr)
  - hip operation (index by Date/Time)
  - knee operation (index by Date/Time)
  - assessment (index by Date/Time)

RODA: Regional Registry of Hip & Knee implants (pilot)

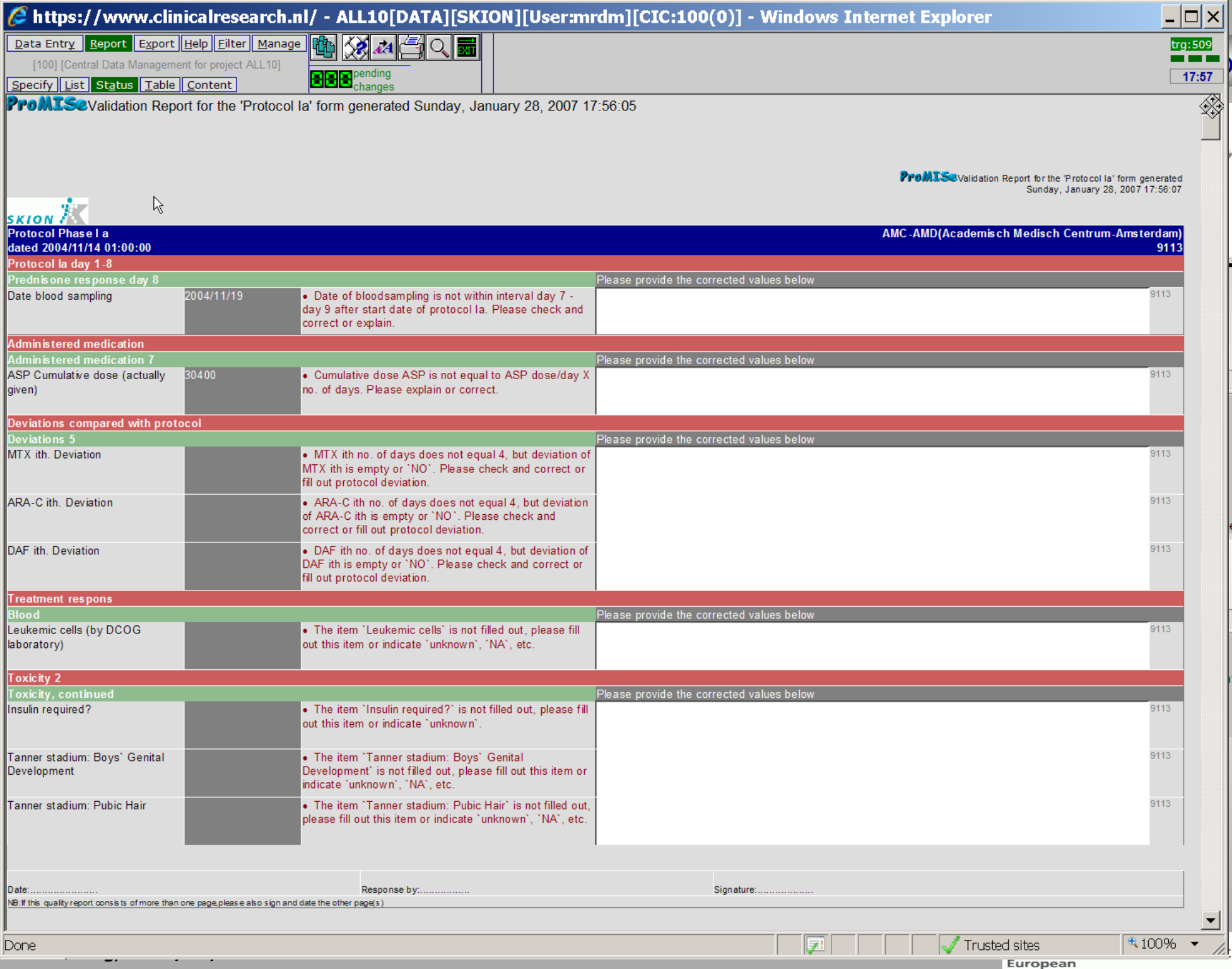
Inferred Relational Structure

- operatie (index by SeqNr)

RESEARCH: all implants in dpt of orthopaedics of the LUMC (unification of all academic research)

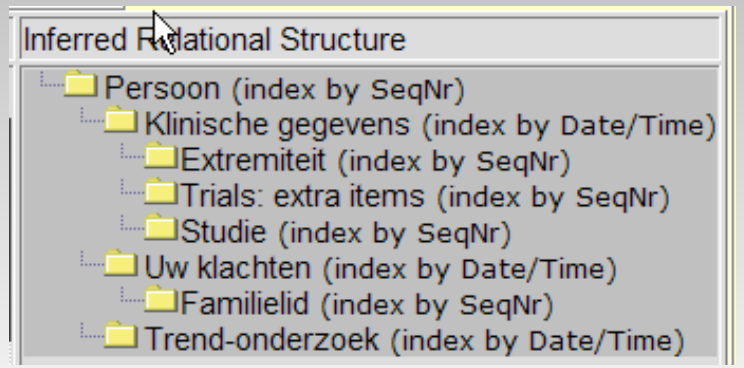
Inferred Relational Structure

- patient (index by SeqNr)
  - wrist-treatment (index by Date/Time)
  - elbow-treatment (index by Date/Time)
  - shoulder-treatment (index by Date/Time)
  - hip-treatment (index by Date/Time)
  - knee-treatment (index by Date/Time)
  - ankle-treatment (index by Date/Time)
  - wrist-assessment (index by Date/Time)
  - elbow-assessment (index by Date/Time)
  - shoulder-assessment (index by Date/Time)
  - hip-assessment (index by Date/Time)
  - knee-assessment (index by Date/Time)
  - ankle-assessment (index by Date/Time)
  - general-assessments (index by Date/Time)
  - General treatment (index by Date/Time)

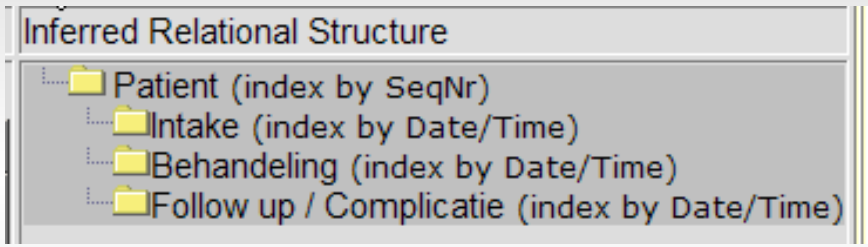

https://www.clinicalresearch.nl/ - ALL10[DATA][SKION][User:mrdm][CIC:100(0)] - Windows Internet Explorer
Data Entry Report Export Help Filter Manage
[100] [Central Data Management for project ALL10]
Specify List Status Table Content
pending changes
trg:509
17:57
ProMISe Validation Report for the 'Protocol Ia' form generated Sunday, January 28, 2007 17:56:05
ProMISe Validation Report for the 'Protocol Ia' form generated Sunday, January 28, 2007 17:56:07
SKION
Protocol Phase I a
dated 2004/11/14 01:00:00
AMC -AMD(Academisch Medisch Centrum-Amsterdam)
9113
Protocol Ia day 1-8
Prednisone response day 8
Please provide the corrected values below
Date blood sampling
2004/11/19
• Date of bloodsampling is not within interval day 7 - day 9 after start date of protocol Ia. Please check and correct or explain.
Administered medication
Administered medication 7
Please provide the corrected values below
ASP Cumulative dose (actually given)
30400
• Cumulative dose ASP is not equal to ASP dose/day X no. of days. Please explain or correct.
Deviations compared with protocol
Deviations 5
Please provide the corrected values below
MTX ith. Deviation
• MTX ith no. of days does not equal 4, but deviation of MTX ith is empty or `NO`. Please check and correct or fill out protocol deviation.
ARA-C ith. Deviation
• ARA-C ith no. of days does not equal 4, but deviation of ARA-C ith is empty or `NO`. Please check and correct or fill out protocol deviation.
DAF ith. Deviation
• DAF ith no. of days does not equal 4, but deviation of DAF ith is empty or `NO`. Please check and correct or fill out protocol deviation.
Treatment respons
Blood
Please provide the corrected values below
Leukemic cells (by DCOG laboratory)
• The item `Leukemic cells` is not filled out, please fill out this item or indicate `unknown`, `NA`, etc.
Toxicity 2
Toxicity, continued
Please provide the corrected values below
Insulin required?
• The item `Insulin required?` is not filled out, please fill out this item or indicate `unknown`.
Tanner stadium: Boys` Genital Development
• The item `Tanner stadium: Boys` Genital Development` is not filled out, please fill out this item or indicate `unknown`, `NA`, etc.
Tanner stadium: Pubic Hair
• The item `Tanner stadium: Pubic Hair` is not filled out, please fill out this item or indicate `unknown`, `NA`, etc.
9113
Date:.....
Response by:.....
Signature:.....
NB:If this quality report consists of more than one page,please also sign and date the other page(s)
Done
Trusted sites
100%

NEUROLOGY

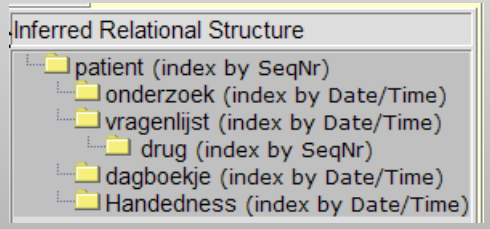
TREND: unification of all Dutch research on Complex Regional Pain Syndrome (CRPS1)

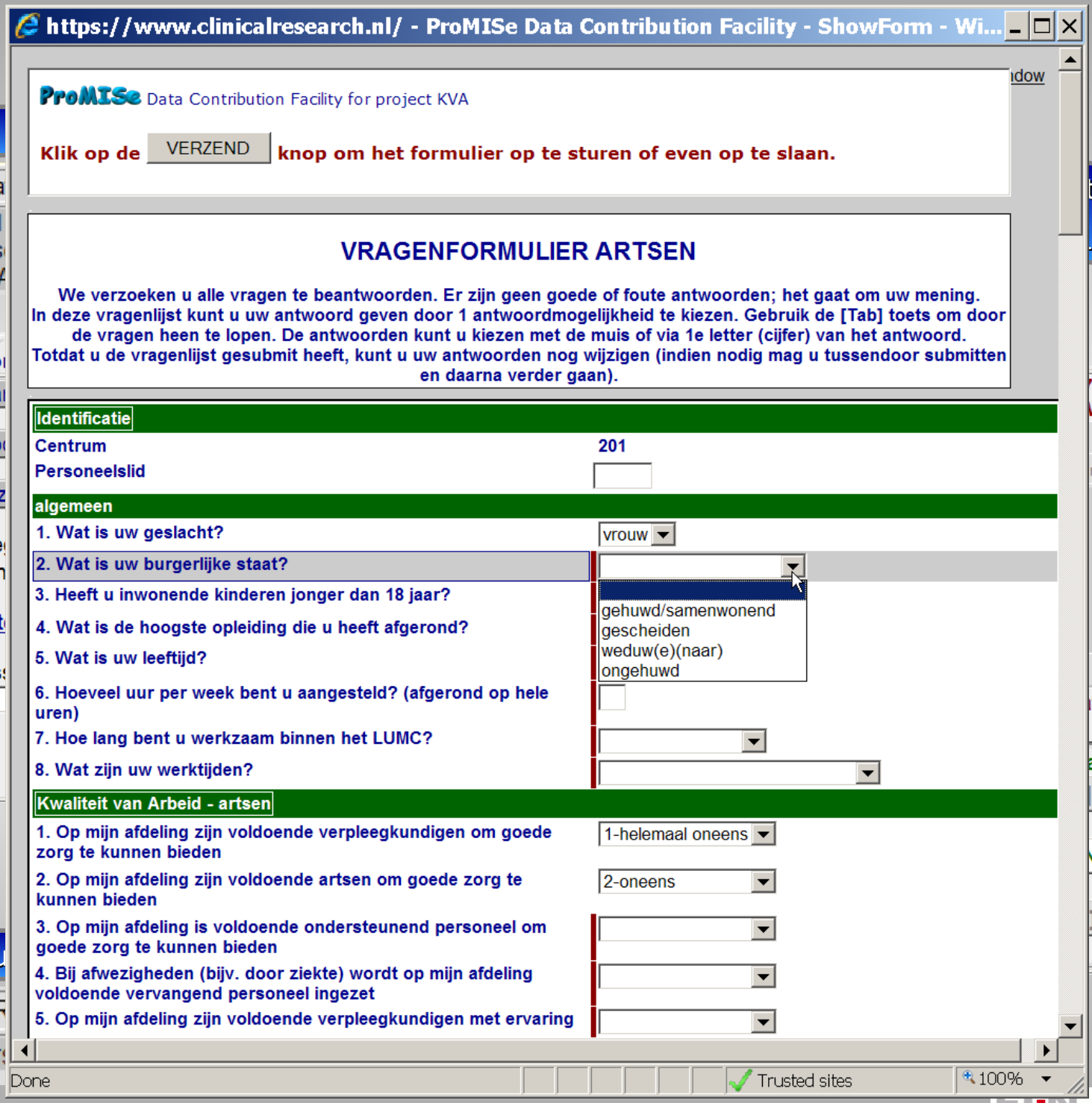


QSN: Dutch national registry on neuromodulation



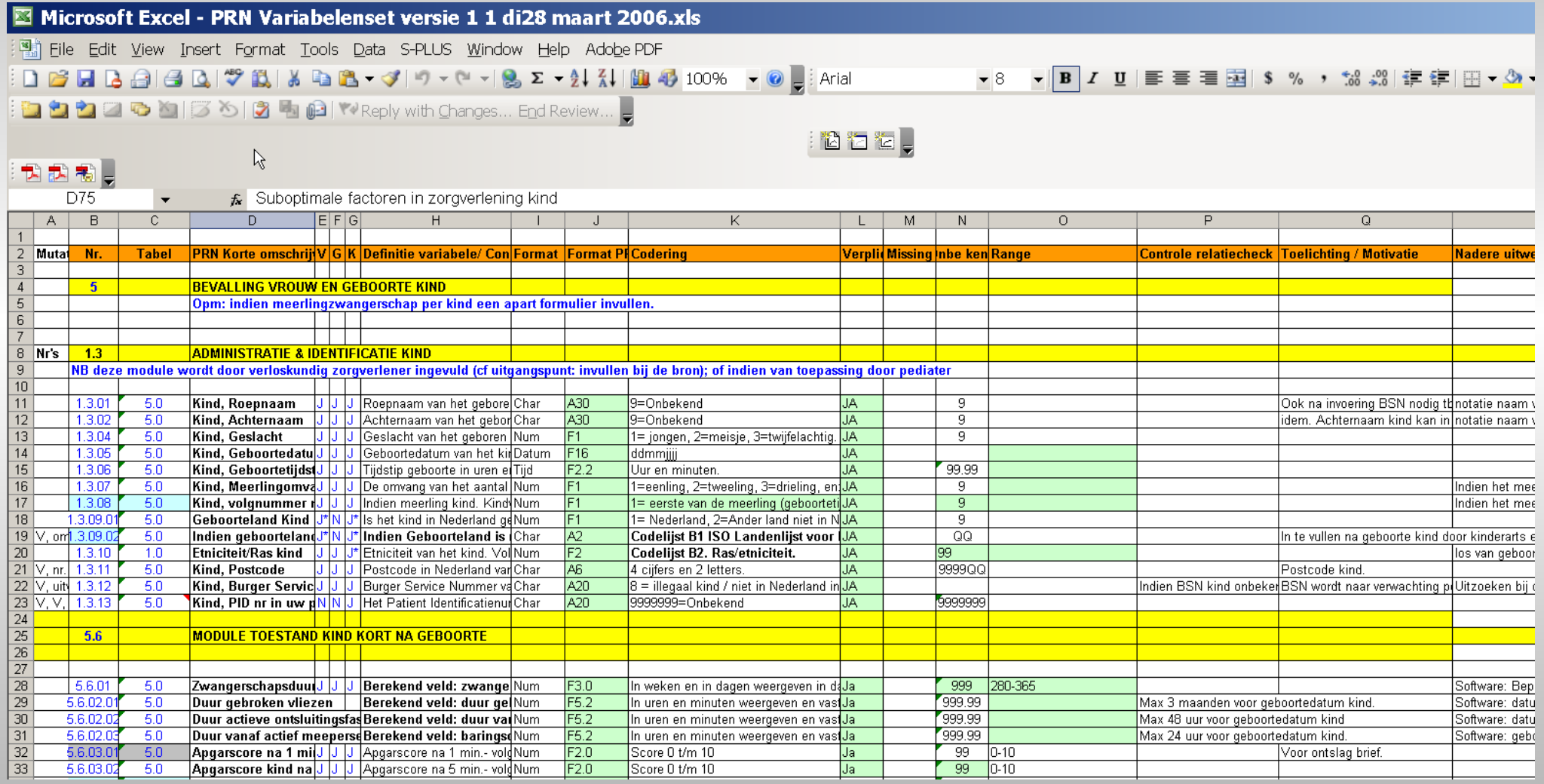
SCOPA: local research project into Parkinsons Disease (long term followup)




https://www.clinicalresearch.nl/ - ProMISe Data Contribution Facility - ShowForm - Wi...
ProMISe Data Contribution Facility for project KVA
Klik op de VERZEND knop om het formulier op te sturen of even op te slaan.
VRAGENFORMULIER ARTSEN
We verzoeken u alle vragen te beantwoorden. Er zijn geen goede of foute antwoorden; het gaat om uw mening.
In deze vragenlijst kunt u uw antwoord geven door 1 antwoordmogelijkheid te kiezen. Gebruik de [Tab] toets om door de vragen heen te lopen. De antwoorden kunt u kiezen met de muis of via 1e letter (cijfer) van het antwoord.
Totdat u de vragenlijst gesubmit heeft, kunt u uw antwoorden nog wijzigen (indien nodig mag u tussendoor submitten en daarna verder gaan).
Identificatie
Centrum
201
Personeelslid
algemeen
1. Wat is uw geslacht?
vrouw
2. Wat is uw burgerlijke staat?
gehuwd/samenwonend
gescheiden
weduw(e)(naar)
ongehuwd
3. Heeft u inwonende kinderen jonger dan 18 jaar?
4. Wat is de hoogste opleiding die u heeft afgerond?
5. Wat is uw leeftijd?
6. Hoeveel uur per week bent u aangesteld? (afgerond op hele uren)
7. Hoe lang bent u werkzaam binnen het LUMC?
8. Wat zijn uw werktijden?
Kwaliteit van Arbeid - artsen
1. Op mijn afdeling zijn voldoende verpleegkundigen om goede zorg te kunnen bieden
1-helemaal oneens
2. Op mijn afdeling zijn voldoende artsen om goede zorg te kunnen bieden
2-oneens
3. Op mijn afdeling is voldoende ondersteunend personeel om goede zorg te kunnen bieden
4. Bij afwezigheden (bijv. door ziekte) wordt op mijn afdeling voldoende vervangend personeel ingezet
5. Op mijn afdeling zijn voldoende verpleegkundigen met ervaring
Done
Trusted sites
100%

SPRN: Dutch foundation for national perinatal registries

STICHTING Perinatale Registratie NEDERLAND



Microsoft Excel - PRN Variabelenset versie 1 1 di28 maart 2006.xls

File Edit View Insert Format Tools Data S-PLUS Window Help Adobe PDF

Reply with Changes... End Review...

D75 Suboptimale factoren in zorgverlening kind

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	
1																		
2	Mutat	Nr.	Tabel	PRN Korte omschrij	V	G	K	Definitie variabele/ Con	Format	Format Pl	Codering	Verplic	Missing	nbe ken	Range	Controle relatiecheck	Toelichting / Motivatie	Nadere uitwe
3																		
4		5		BEVALLING VROUW EN GEBOORTE KIND														
5				Opm: indien meerlingzwangerschap per kind een apart formulier invullen.														
6																		
7																		
8	Nr's	1.3		ADMINISTRATIE & IDENTIFICATIE KIND														
9		NB deze module wordt door verloskundig zorgverlener ingevuld (cf uitgangspunt: invullen bij de bron); of indien van toepassing door pediater																
10																		
11		1.3.01	5.0	Kind, Roepnaam	J	J	J	Roepnaam van het gebore	Char	A30	9=Onbekend	JA		9			Ook na invoering BSN nodig t	notatie naam v
12		1.3.02	5.0	Kind, Achternaam	J	J	J	Achternaam van het gebor	Char	A30	9=Onbekend	JA		9			idem. Achternaam kind kan in	notatie naam v
13		1.3.04	5.0	Kind, Geslacht	J	J	J	Geslacht van het geboren	Num	F1	1= jongen, 2=meisje, 3=twijfelachtig.	JA		9				
14		1.3.05	5.0	Kind, Geboortedatu	J	J	J	Geboortedatum van het kir	Datum	F16	ddmmjjjj	JA						
15		1.3.06	5.0	Kind, Geboortetijdst	J	J	J	Tijdstip geboorte in uren e	Tijd	F2.2	Uur en minuten.	JA		99.99				
16		1.3.07	5.0	Kind, Meerlingomva	J	J	J	De omvang van het aantal	Num	F1	1=eenling, 2=tweeling, 3=drieling, en	JA		9				Indien het mee
17		1.3.08	5.0	Kind, volgnummer r	J	J	J	Indien meerling kind. Kind	Num	F1	1= eerste van de meerling (geboorteti	JA		9				Indien het mee
18		1.3.09.01	5.0	Geboorteland Kind	J*	N	J*	Is het kind in Nederland ge	Num	F1	1= Nederland, 2=Ander land niet in N	JA		9				
19	V, om	1.3.09.02	5.0	Indien geboorteland	J*	N	J*	Indien Geboorteland is	Char	A2	Codelijst B1 ISO Landenlijst voor	JA		QQ			In te vullen na geboorte kind door kinderarts e	
20		1.3.10	1.0	Etniciteit/Ras kind	J	J	J*	Etniciteit van het kind. Vol	Num	F2	Codelijst B2. Ras/etniciteit.	JA		99				los van geboor
21	V, nr.	1.3.11	5.0	Kind, Postcode	J	J	J	Postcode in Nederland var	Char	A6	4 cijfers en 2 letters.	JA		9999QQ			Postcode kind.	
22	V, uit	1.3.12	5.0	Kind, Burger Servic	J	J	J	Burger Service Nummer va	Char	A20	8 = illegaal kind / niet in Nederland in	JA				Indien BSN kind onbeker	BSN wordt naar verwachting p	Uitzoeken bij
23	V, V,	1.3.13	5.0	Kind, PID nr in uw p	N	N	J	Het Patient Identificatienur	Char	A20	9999999=Onbekend	JA		9999999				
24																		
25		5.6		MODULE TOESTAND KIND KORT NA GEBOORTE														
26																		
27																		
28		5.6.01	5.0	Zwangerschapsduur	J	J	J	Berekend veld: zwange	Num	F3.0	In weken en in dagen weergeven in da	Ja		999	280-365			Software: Bep
29		5.6.02.01	5.0	Duur gebroken vliezen				Berekend veld: duur ge	Num	F5.2	In uren en minuten weergeven en vast	Ja		999.99		Max 3 maanden voor geboortedatum kind.		Software: datu
30		5.6.02.02	5.0	Duur actieve ontsluitingsfas				Berekend veld: duur va	Num	F5.2	In uren en minuten weergeven en vast	Ja		999.99		Max 48 uur voor geboortedatum kind		Software: datu
31		5.6.02.03	5.0	Duur vanaf actief meeperse				Berekend veld: baringsd	Num	F5.2	In uren en minuten weergeven en vast	Ja		999.99		Max 24 uur voor geboortedatum kind.		Software: gebo
32		5.6.03.01	5.0	Apgarscore na 1 mi	J	J	J	Apgarscore na 1 min.- volg	Num	F2.0	Score 0 t/m 10	Ja		99	0-10		Voor ontslag brief.	
33		5.6.03.02	5.0	Apgarscore kind na	J	J	J	Apgarscore na 5 min.- volg	Num	F2.0	Score 0 t/m 10	Ja		99	0-10			

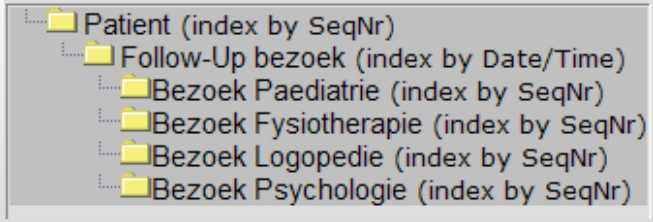
PREVCD: European project on prevention of Caeliac Disease

NEONAT:Neonatal research data base for Nijmegen University

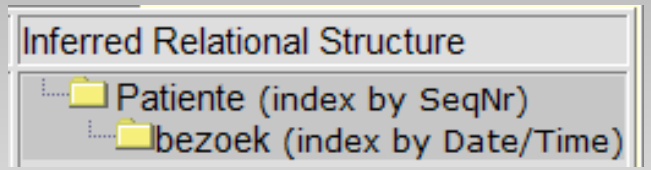
- Neonatology
- Paediatrics
- Physiotherapy
- Logopaedics
- Psychology

UMC St Radboud
met mensen kennis

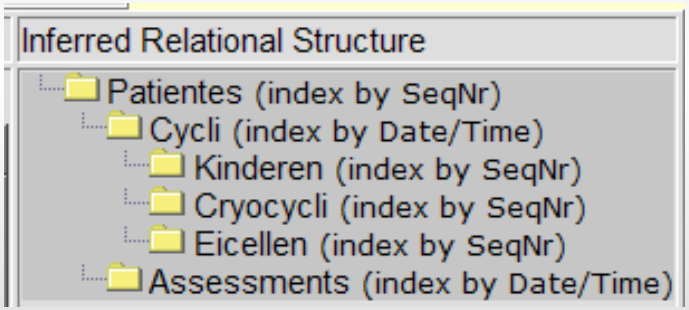
Inferred Relational Structure



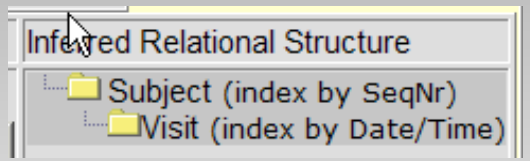
CRYOPRES: local cryopreservation registry overlapping patient care and research



IVF: local IVF registry overlapping patient care and research

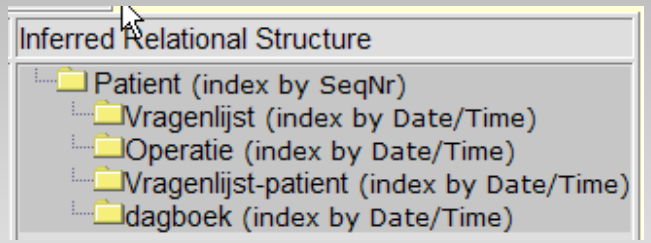


ALBENDA: randomized and cohort study in Indonesia supporting Dutch laboratories



NEUROSURGERY

SCIATICA / MAST: national randomized clinical trials



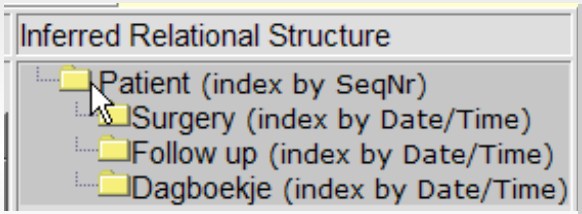
BMC Musculoskelet Disord. 2005; 6: 8.
Published online 2005 February 11. doi: 10.1186/1471-2474-6-8.

Prolonged conservative treatment or 'early' surgery in sciatica caused by a lumbar disc herniation: rationale and design of a randomized trial [ISRCT 26872154]

Wilco C Peul,[1,2] Hans C van Houwelingen,[1] Wilbert B van der Hout,[3] Ronald Brand,[1] Just AH Eekhof,[4] Joseph ThJ Tans,[5] Ralph TWM Thomeer,[1] and Bart W Koes[6]

[1]Department of Neurosurgery, Leiden University Medical Center, PO Box 9600, 2300 RC Leiden, The Netherlands

DELPHI: international randomized clinical trial



BMC Musculoskelet Disord. 2006; 7: 14.
Published online 2006 February 16. doi: 10.11

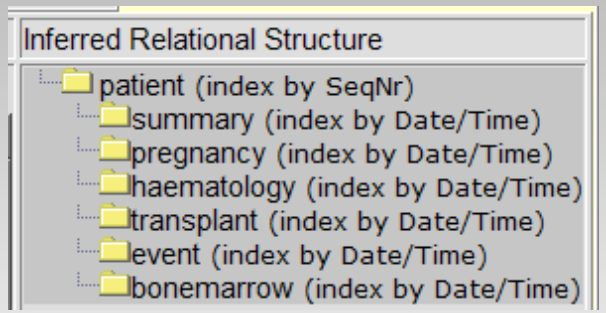
Rationale and design of T international randomized craniocervical treatment, trial comparing 'early' sur treatment [ISRCTN650768

Jasper FC Wolfs,[1] Wilco C Peul, Tulder,[3] Ronald Brand,[4] Hans JC Thomeer[1]

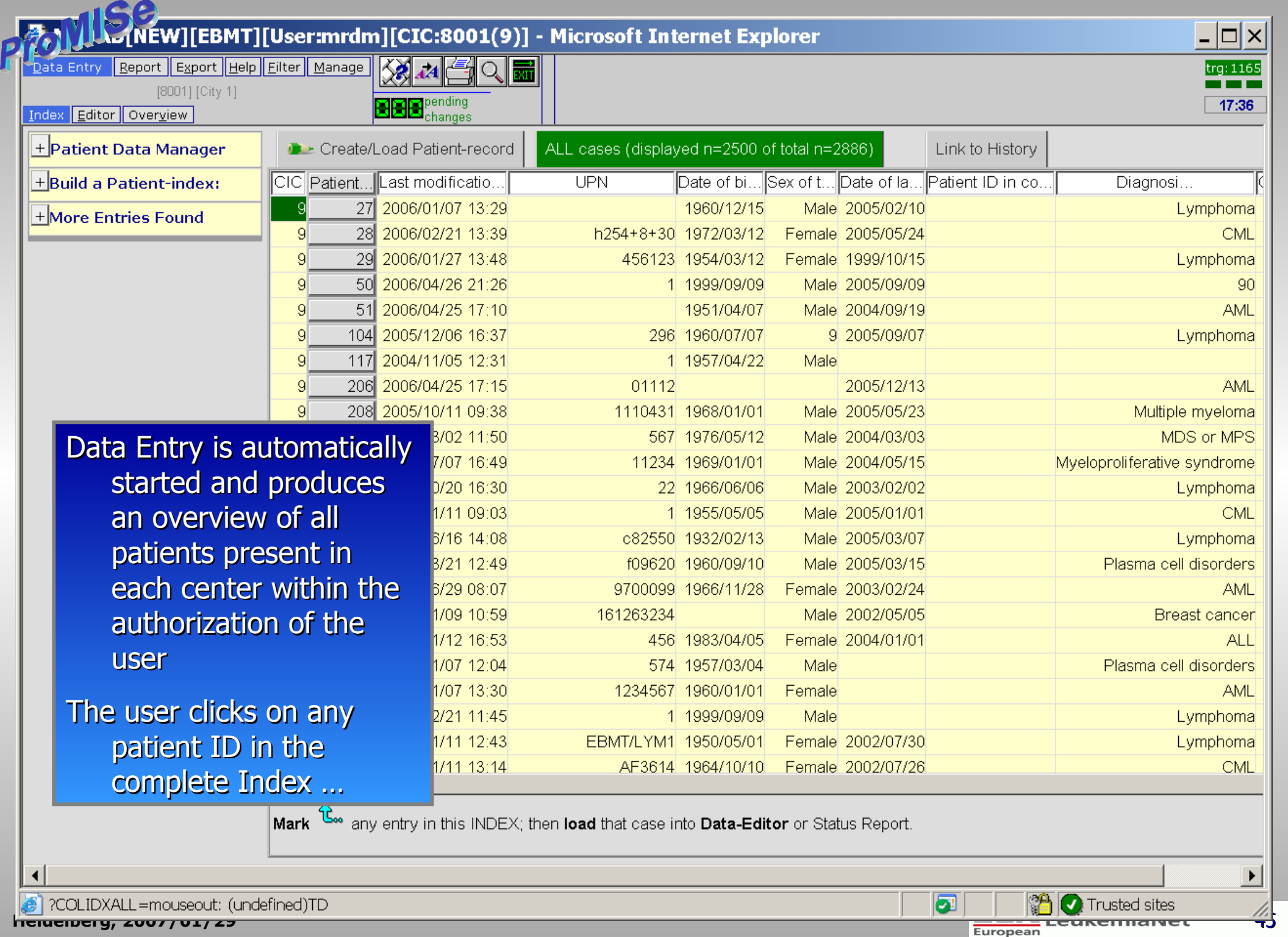
Database

All data collected of patients participating in this trial are registered in a database under the ProMISe data management system of the Department of Medical Statistics of the LUMC. Database access is secure and limited to the trial coordinator, the trial data manager and the principal statistician. At patient enrollment into the trial, a unique study identification number is issued. The database will not contain any information directly identifying the study subject. However, to avoid errors during data collection in the follow-up of the patient, the patient's initials (first character of first name and first character of last name) will be entered as well as the gender and date of birth of the patient. The local hospital number of the patient is also part of the registration. The investigator in each participating hospital will maintain a list in which the correspondence between the true identity of the subject and its study number is documented. Follow-up data sent from each participating hospital to the central data management will only contain the study ID of the subject but not any data directly revealing the identity of the subject. It is the responsibility of each local hospital research coordinator to ensure the integrity of the correspondence between the Study ID and the true identity of the patient. The data manager will enter follow up data and verify that the date of birth of the follow up data forms is identical to the date of birth on the entry form. Discrepancies are to be solved by the local coordinator. This system ensures that only a local physician can infer the identity of any participating subject.

SCNIR: Hannover-based European Registry for Neutropenia

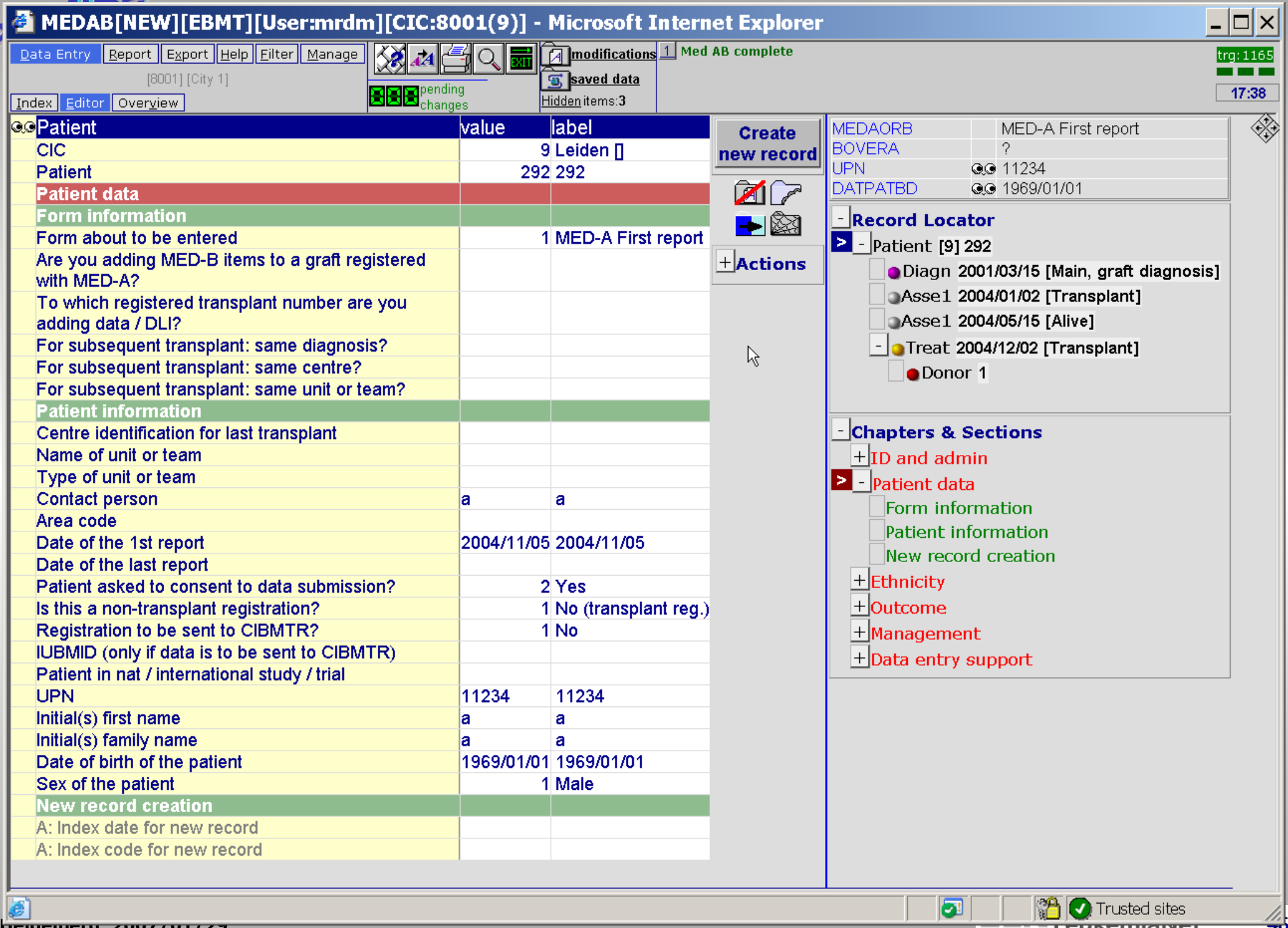


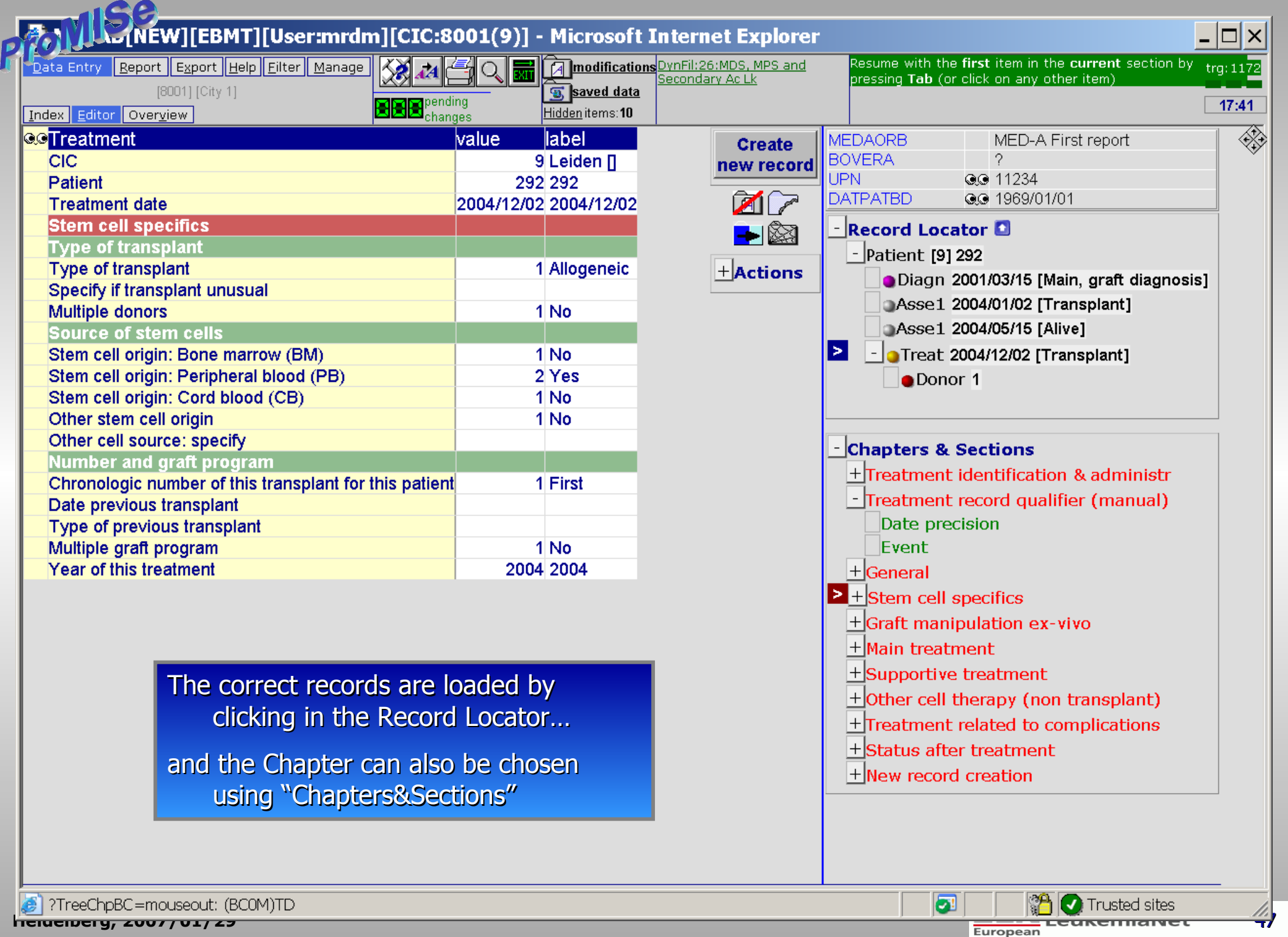
Some screenshots

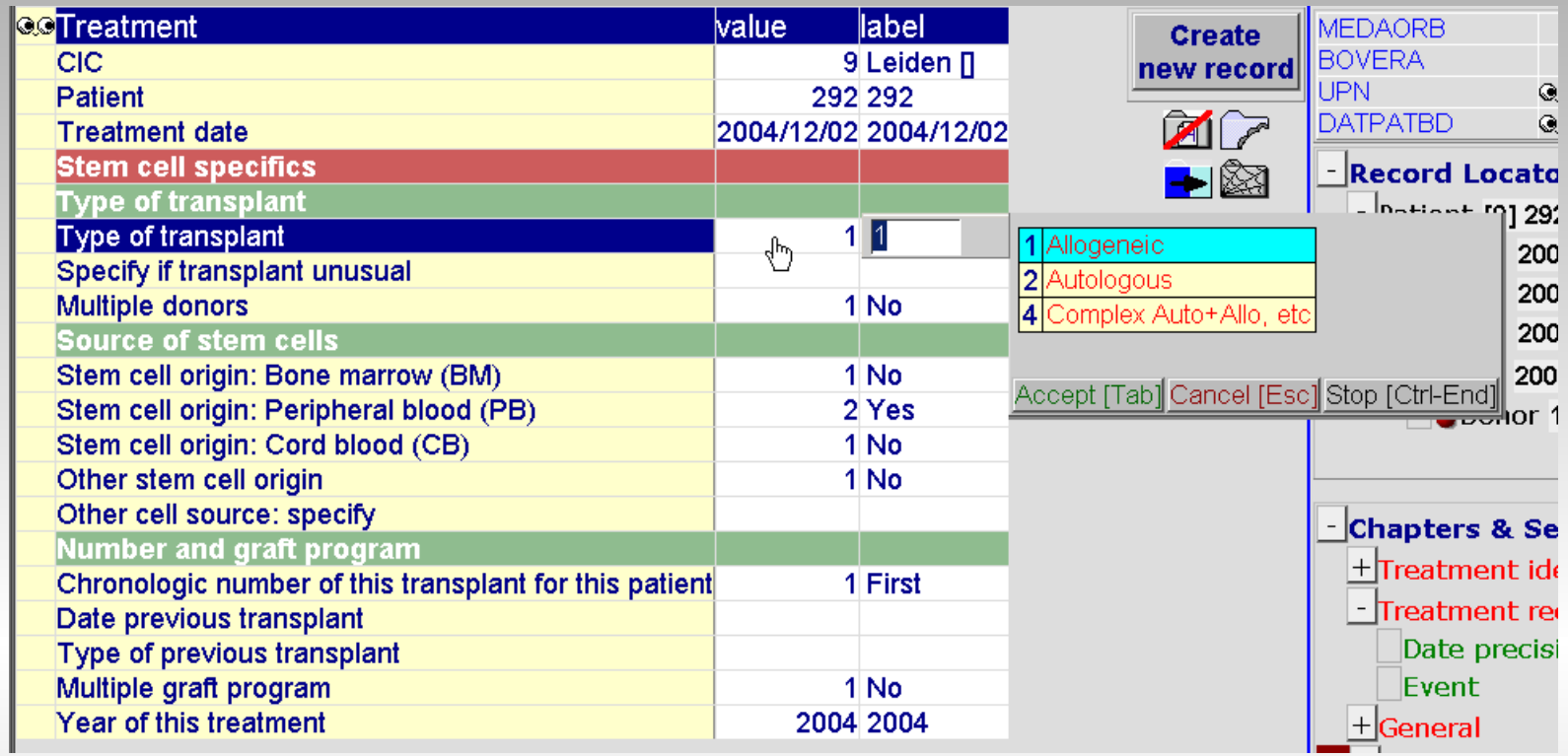


Data Entry is automatically started and produces an overview of all patients present in each center within the authorization of the user

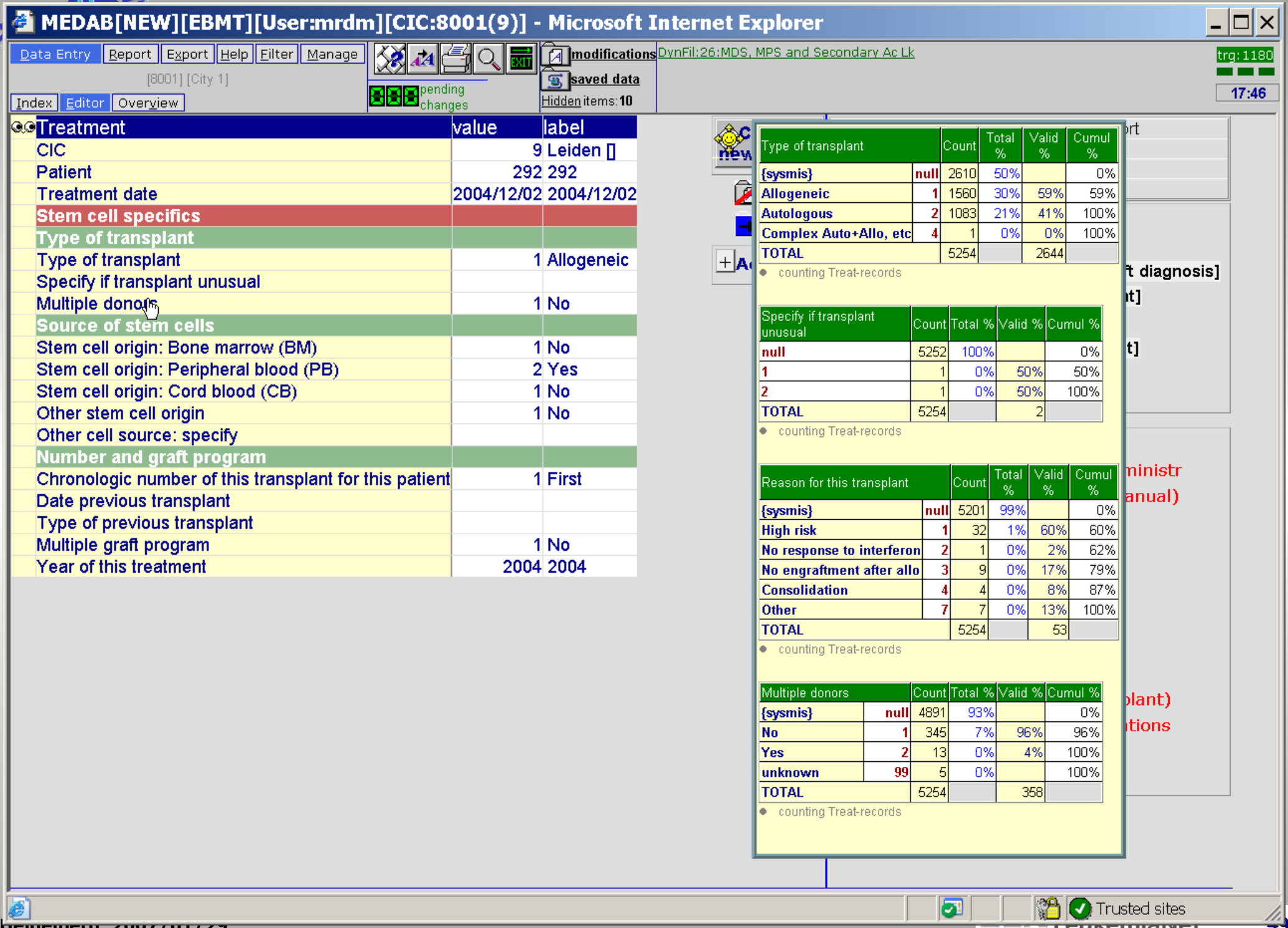
The user clicks on any patient ID in the complete Index ...

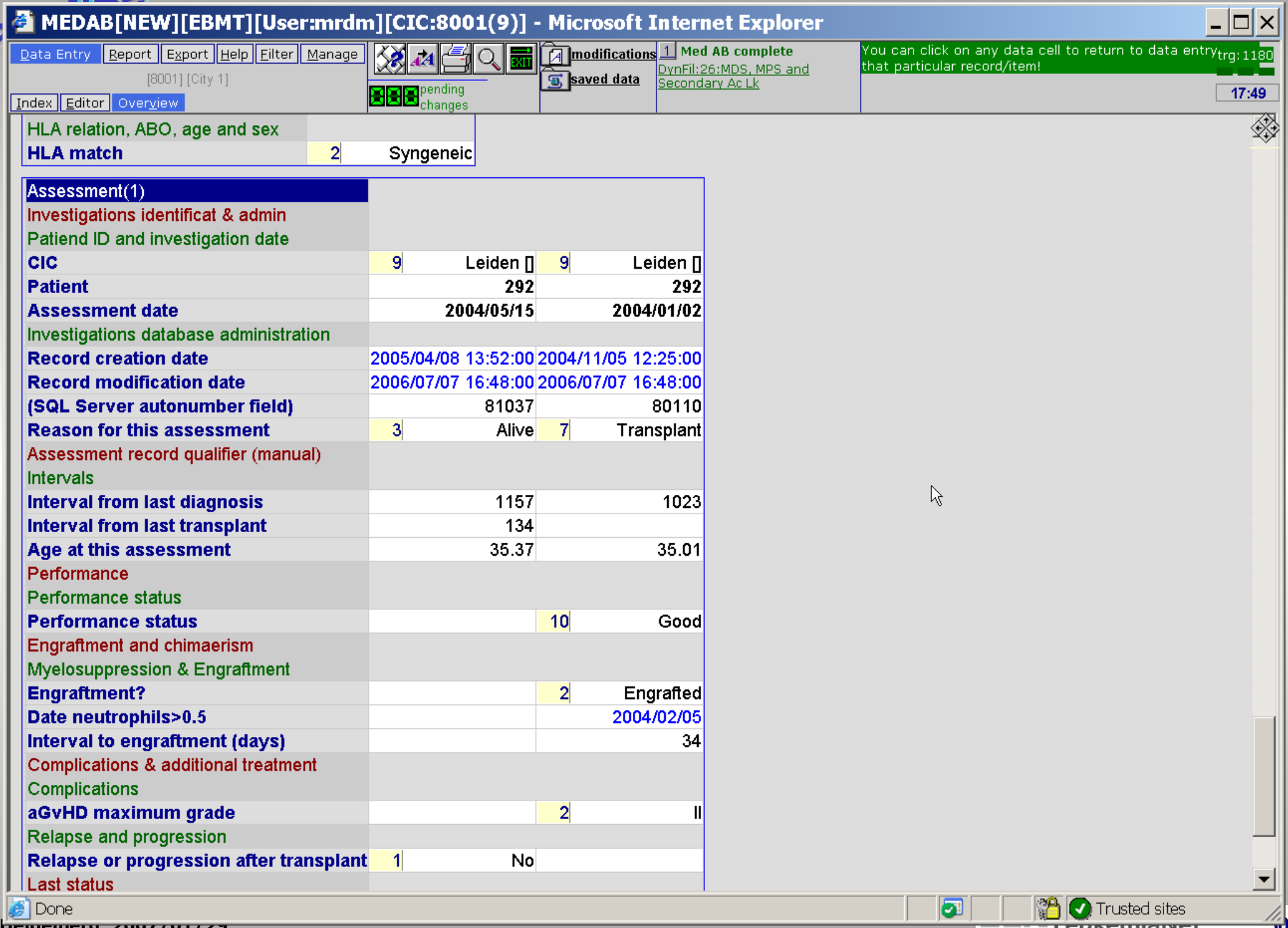

MEDAB[NEW][EBMT][User:mrdm][CIC:8001(9)] - Microsoft Internet Explorer
Data Entry
Report
Export
Help
Filter
Manage
[8001] [City 1]
Index
Editor
Overview
pending changes
modifications
saved data
Hidden items:3
1 Med AB complete
trg: 1165
17:38
Patient
value
label
CIC 9 Leiden []
Patient 292 292
Patient data
Form information
Form about to be entered 1 MED-A First report
Are you adding MED-B items to a graft registered with MED-A?
To which registered transplant number are you adding data / DLI?
For subsequent transplant: same diagnosis?
For subsequent transplant: same centre?
For subsequent transplant: same unit or team?
Patient information
Centre identification for last transplant
Name of unit or team
Type of unit or team
Contact person a a
Area code
Date of the 1st report 2004/11/05 2004/11/05
Date of the last report
Patient asked to consent to data submission? 2 Yes
Is this a non-transplant registration? 1 No (transplant reg.)
Registration to be sent to CIBMTR? 1 No
IUBMID (only if data is to be sent to CIBMTR)
Patient in nat / international study / trial
UPN 11234 11234
Initial(s) first name a a
Initial(s) family name a a
Date of birth of the patient 1969/01/01 1969/01/01
Sex of the patient 1 Male
New record creation
A: Index date for new record
A: Index code for new record
Create new record
Actions
MEDAORB MED-A First report
BOVERA ?
UPN 11234
DATPATBD 1969/01/01
Record Locator
Patient [9] 292
Diagn 2001/03/15 [Main, graft diagnosis]
Asse1 2004/01/02 [Transplant]
Asse1 2004/05/15 [Alive]
Treat 2004/12/02 [Transplant]
Donor 1
Chapters & Sections
ID and admin
Patient data
Form information
Patient information
New record creation
Ethnicity
Outcome
Management
Data entry support
Trusted sites

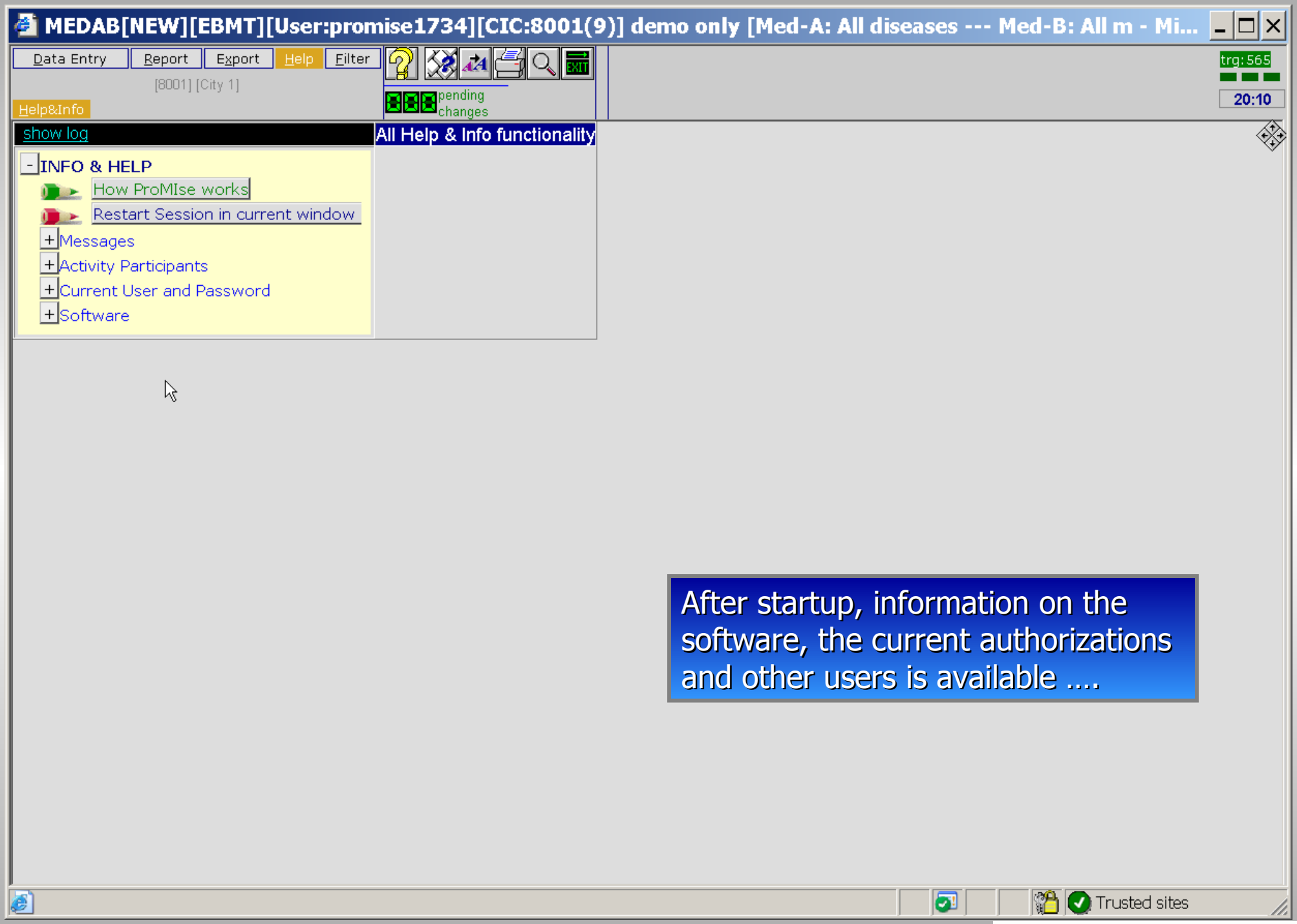

[NEW][EBMT][User:mrdm][CIC:8001(9)] - Microsoft Internet Explorer
Data Entry
Report
Export
Help
Filter
Manage
[8001] [City 1]
Index
Editor
Overview
modifications
saved data
pending changes
Hidden items: 10
DynFil:26:MDS, MPS and Secondary Ac Lk
Resume with the first item in the current section by pressing Tab (or click on any other item)
trg: 1172
17:41
Treatment | value | label
CIC 9 Leiden []
Patient 292 292
Treatment date 2004/12/02 2004/12/02
Stem cell specifics
Type of transplant
Type of transplant 1 Allogeneic
Specify if transplant unusual
Multiple donors 1 No
Source of stem cells
Stem cell origin: Bone marrow (BM) 1 No
Stem cell origin: Peripheral blood (PB) 2 Yes
Stem cell origin: Cord blood (CB) 1 No
Other stem cell origin 1 No
Other cell source: specify
Number and graft program
Chronologic number of this transplant for this patient 1 First
Date previous transplant
Type of previous transplant
Multiple graft program 1 No
Year of this treatment 2004 2004
Create new record
Actions
MEDAORB MED-A First report
BOVERA ?
UPN 11234
DATPATBD 1969/01/01
Record Locator
Patient [9] 292
Diagn 2001/03/15 [Main, graft diagnosis]
Asse1 2004/01/02 [Transplant]
Asse1 2004/05/15 [Alive]
Treat 2004/12/02 [Transplant]
Donor 1
Chapters & Sections
Treatment identification & administr
Treatment record qualifier (manual)
Date precision
Event
General
Stem cell specifics
Graft manipulation ex-vivo
Main treatment
Supportive treatment
Other cell therapy (non transplant)
Treatment related to complications
Status after treatment
New record creation
The correct records are loaded by clicking in the Record Locator…
and the Chapter can also be chosen using "Chapters&Sections"
?TreeChpBC=mouseout: (BCOM)TD
Trusted sites



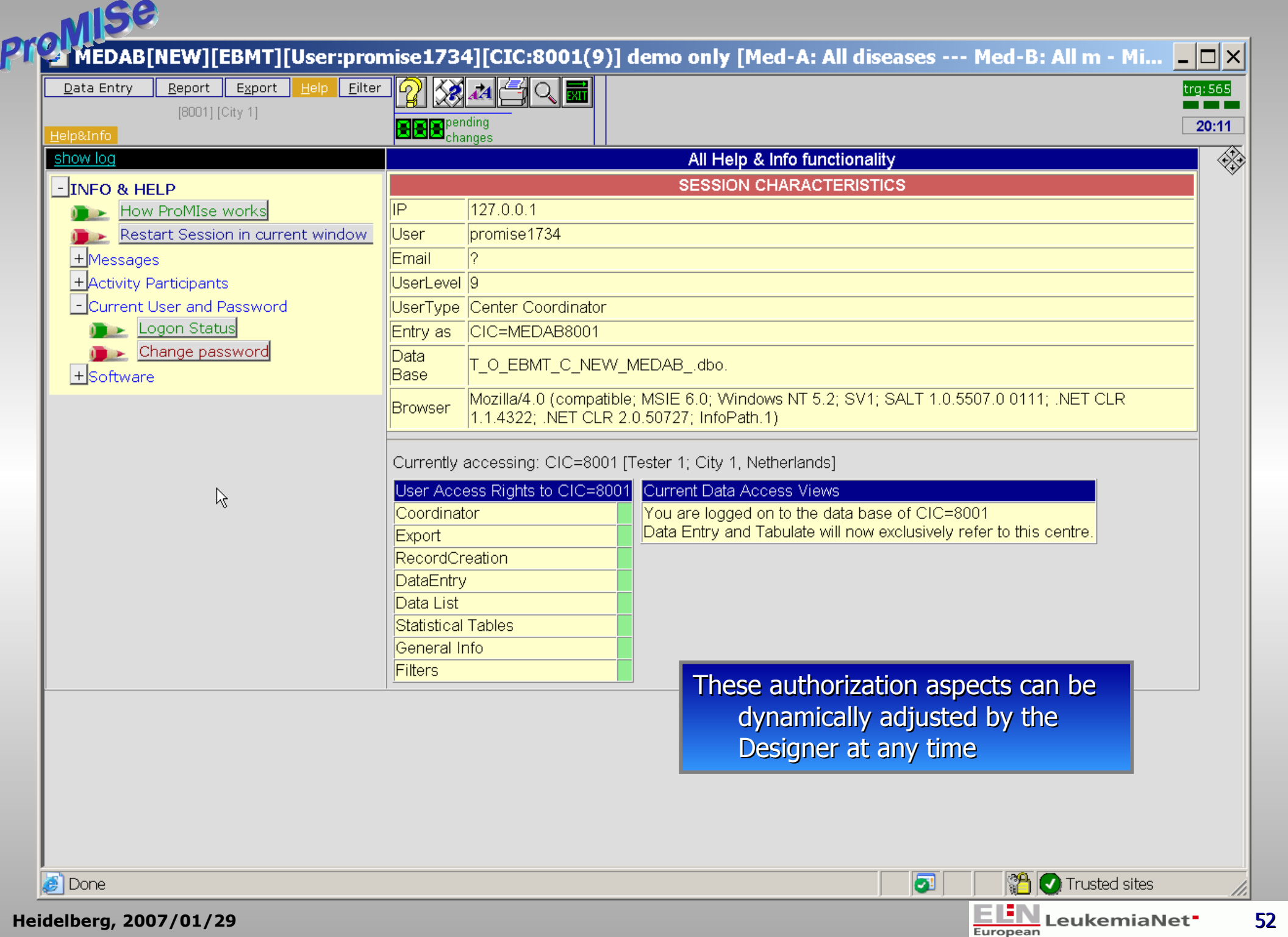
Data Modification is initiated by a mouse click on the item to be modified and then continues sequentially

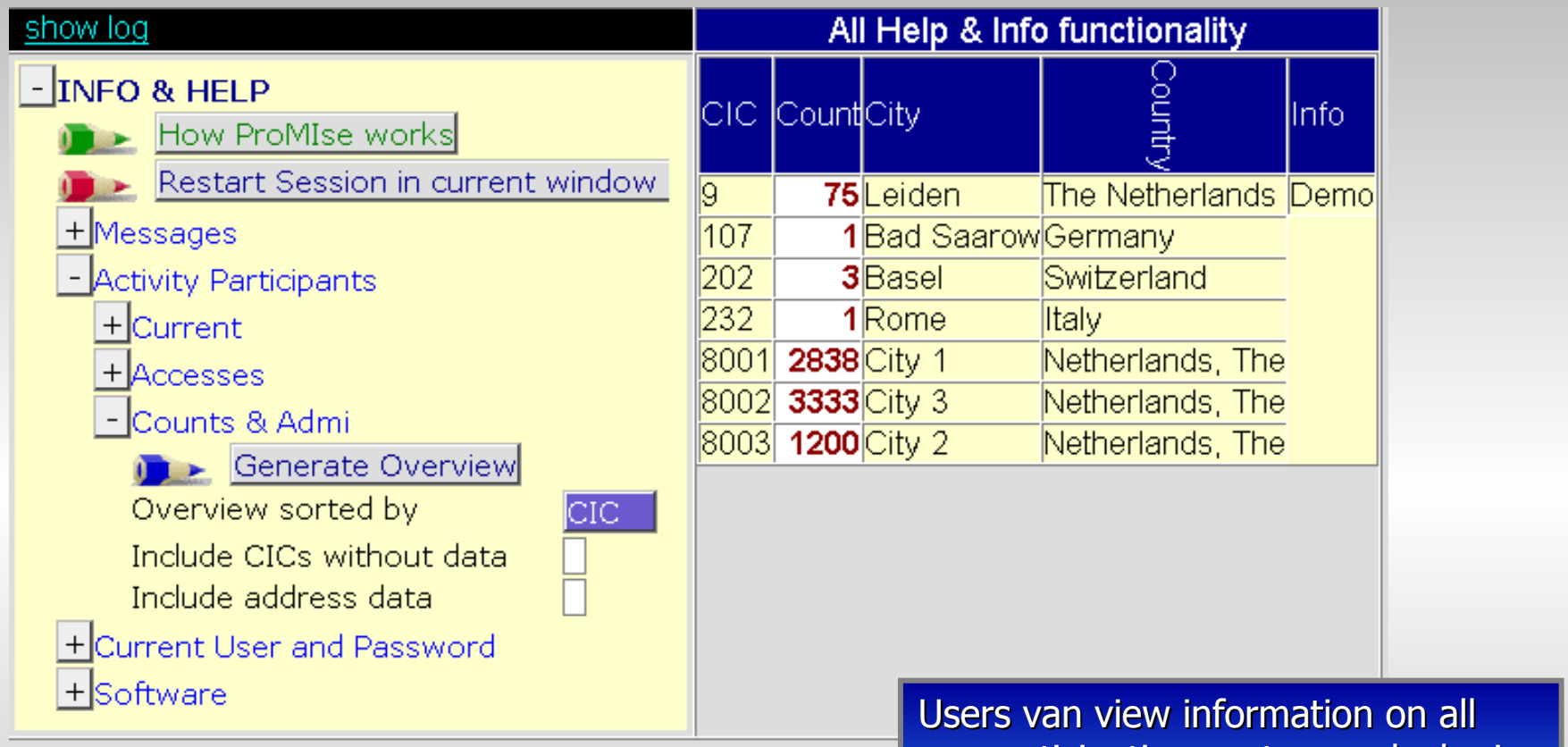

MEDAB[NEW][EBMT][User:mrdm][CIC:8001(9)] - Microsoft Internet Explorer
Data Entry
Report
Export
Help
Filter
Manage
[8001] [City 1]
Index
Editor
Overview
pending changes
modifications
saved data
Hidden items: 10
DynFil:26:MDS, MPS and Secondary Ac Lk
trg: 1180
17:46
Treatment
value
label
CIC 9 Leiden []
Patient 292 292
Treatment date 2004/12/02 2004/12/02
Stem cell specifics
Type of transplant
Type of transplant 1 Allogeneic
Specify if transplant unusual
Multiple donors 1 No
Source of stem cells
Stem cell origin: Bone marrow (BM) 1 No
Stem cell origin: Peripheral blood (PB) 2 Yes
Stem cell origin: Cord blood (CB) 1 No
Other stem cell origin 1 No
Other cell source: specify
Number and graft program
Chronologic number of this transplant for this patient 1 First
Date previous transplant
Type of previous transplant
Multiple graft program 1 No
Year of this treatment 2004 2004
Type of transplant | Count | Total % | Valid % | Cumul %
{sysmis} null 2610 50% 0%
Allogeneic 1 1560 30% 59% 59%
Autologous 2 1083 21% 41% 100%
Complex Auto+Allo, etc 4 1 0% 0% 100%
TOTAL 5254 2644
counting Treat-records
Specify if transplant unusual | Count | Total % | Valid % | Cumul %
null 5252 100% 0%
1 1 0% 50% 50%
2 1 0% 50% 100%
TOTAL 5254 2
counting Treat-records
Reason for this transplant | Count | Total % | Valid % | Cumul %
{sysmis} null 5201 99% 0%
High risk 1 32 1% 60% 60%
No response to interferon 2 1 0% 2% 62%
No engraftment after allo 3 9 0% 17% 79%
Consolidation 4 4 0% 8% 87%
Other 7 7 0% 13% 100%
TOTAL 5254 53
counting Treat-records
Multiple donors | Count | Total % | Valid % | Cumul %
{sysmis} null 4891 93% 0%
No 1 345 7% 96% 96%
Yes 2 13 0% 4% 100%
unknown 99 5 0% 100%
TOTAL 5254 358
counting Treat-records
Trusted sites


MEDAB[NEW][EBMT][User:mrdm][CIC:8001(9)] - Microsoft Internet Explorer
Data Entry
Report
Export
Help
Filter
Manage
[8001] [City 1]
Index
Editor
Overview
pending changes
modifications
saved data
1 Med AB complete
DynFil:26:MDS, MPS and Secondary Ac Lk
You can click on any data cell to return to data entry that particular record/item!
trg: 1180
17:49
HLA relation, ABO, age and sex
HLA match 2 Syngeneic
Assessment(1)
Investigations identificat & admin
Patiend ID and investigation date
CIC 9 Leiden [] 9 Leiden []
Patient 292 292
Assessment date 2004/05/15 2004/01/02
Investigations database administration
Record creation date 2005/04/08 13:52:00 2004/11/05 12:25:00
Record modification date 2006/07/07 16:48:00 2006/07/07 16:48:00
(SQL Server autonumber field) 81037 80110
Reason for this assessment 3 Alive 7 Transplant
Assessment record qualifier (manual)
Intervals
Interval from last diagnosis 1157 1023
Interval from last transplant 134
Age at this assessment 35.37 35.01
Performance
Performance status
Performance status 10 Good
Engraftment and chimaerism
Myelosuppression & Engraftment
Engraftment? 2 Engrafted
Date neutrophils>0.5 2004/02/05
Interval to engraftment (days) 34
Complications & additional treatment
Complications
aGvHD maximum grade 2 II
Relapse and progression
Relapse or progression after transplant 1 No
Last status
Done
Trusted sites

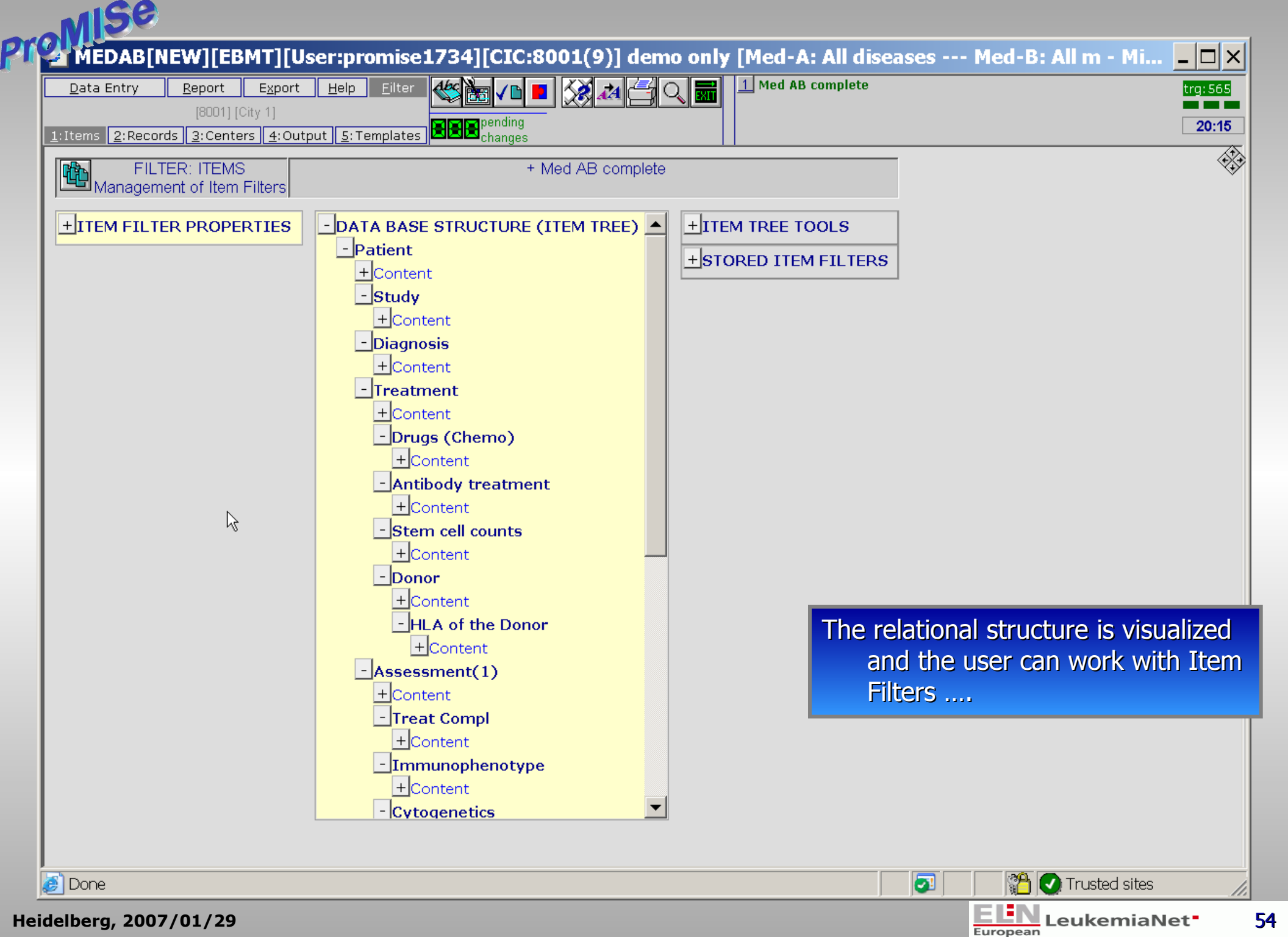


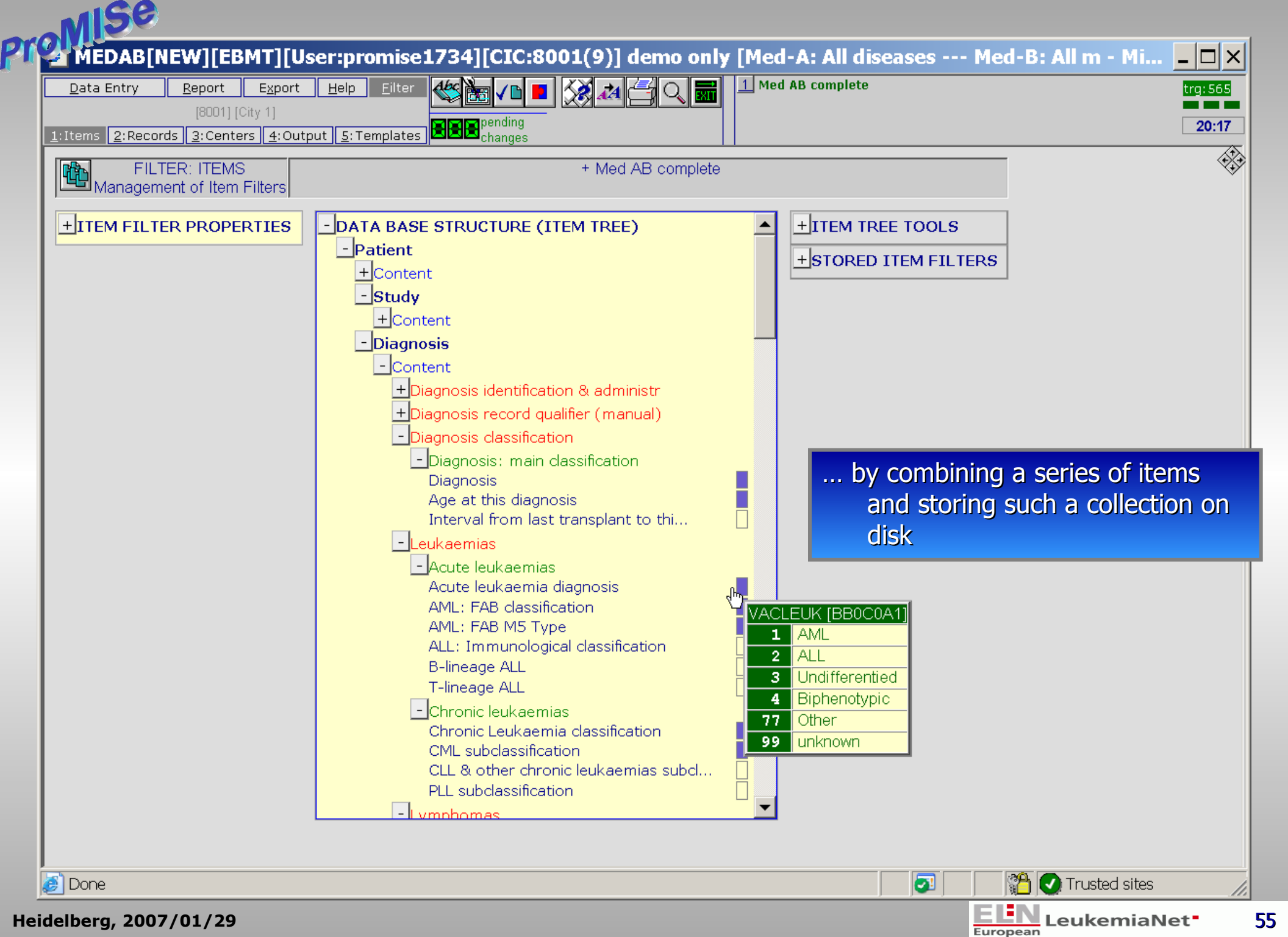
After startup, information on the software, the current authorizations and other users is available ....

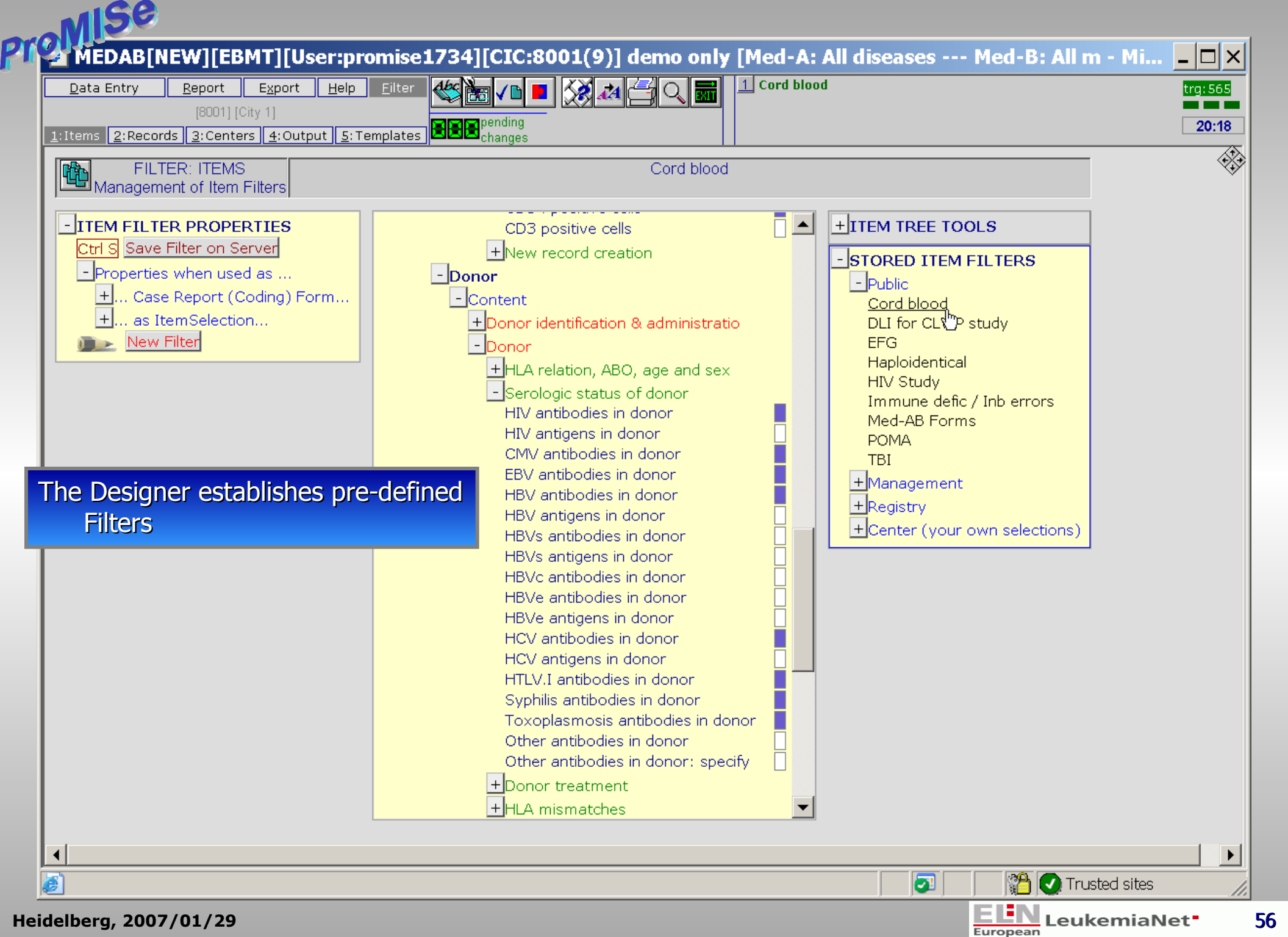

MEDAB[NEW][EBMT][User:promise1734][CIC:8001(9)] demo only [Med-A: All diseases --- Med-B: All m - Mi...
Data Entry
Report
Export
Help
Filter
[8001] [City 1]
Help&Info
pending changes
trg: 565
20:11
show log
All Help & Info functionality
INFO & HELP
How ProMIse works
Restart Session in current window
Messages
Activity Participants
Current User and Password
Logon Status
Change password
Software
SESSION CHARACTERISTICS
IP 127.0.0.1
User promise1734
Email ?
UserLevel 9
UserType Center Coordinator
Entry as CIC=MEDAB8001
Data Base T_O_EBMT_C_NEW_MEDAB_.dbo.
Browser Mozilla/4.0 (compatible; MSIE 6.0; Windows NT 5.2; SV1; SALT 1.0.5507.0 0111; .NET CLR 1.1.4322; .NET CLR 2.0.50727; InfoPath.1)
Currently accessing: CIC=8001 [Tester 1; City 1, Netherlands]
User Access Rights to CIC=8001
Coordinator
Export
RecordCreation
DataEntry
Data List
Statistical Tables
General Info
Filters
Current Data Access Views
You are logged on to the data base of CIC=8001
Data Entry and Tabulate will now exclusively refer to this centre.
These authorization aspects can be dynamically adjusted by the Designer at any time
Done
Trusted sites



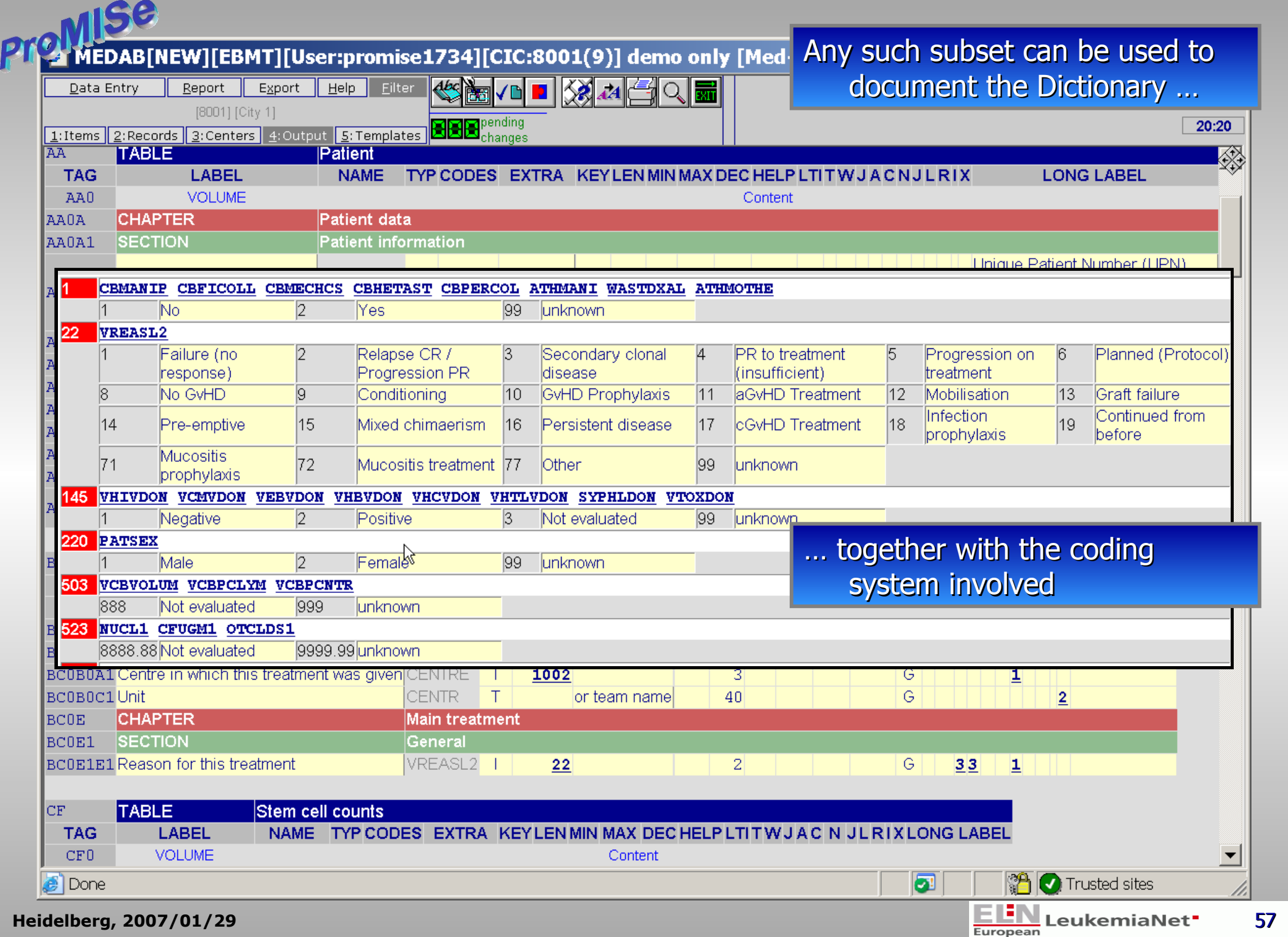
Users van view information on all participating centers and who is actually accessing the data (subject to authorization)

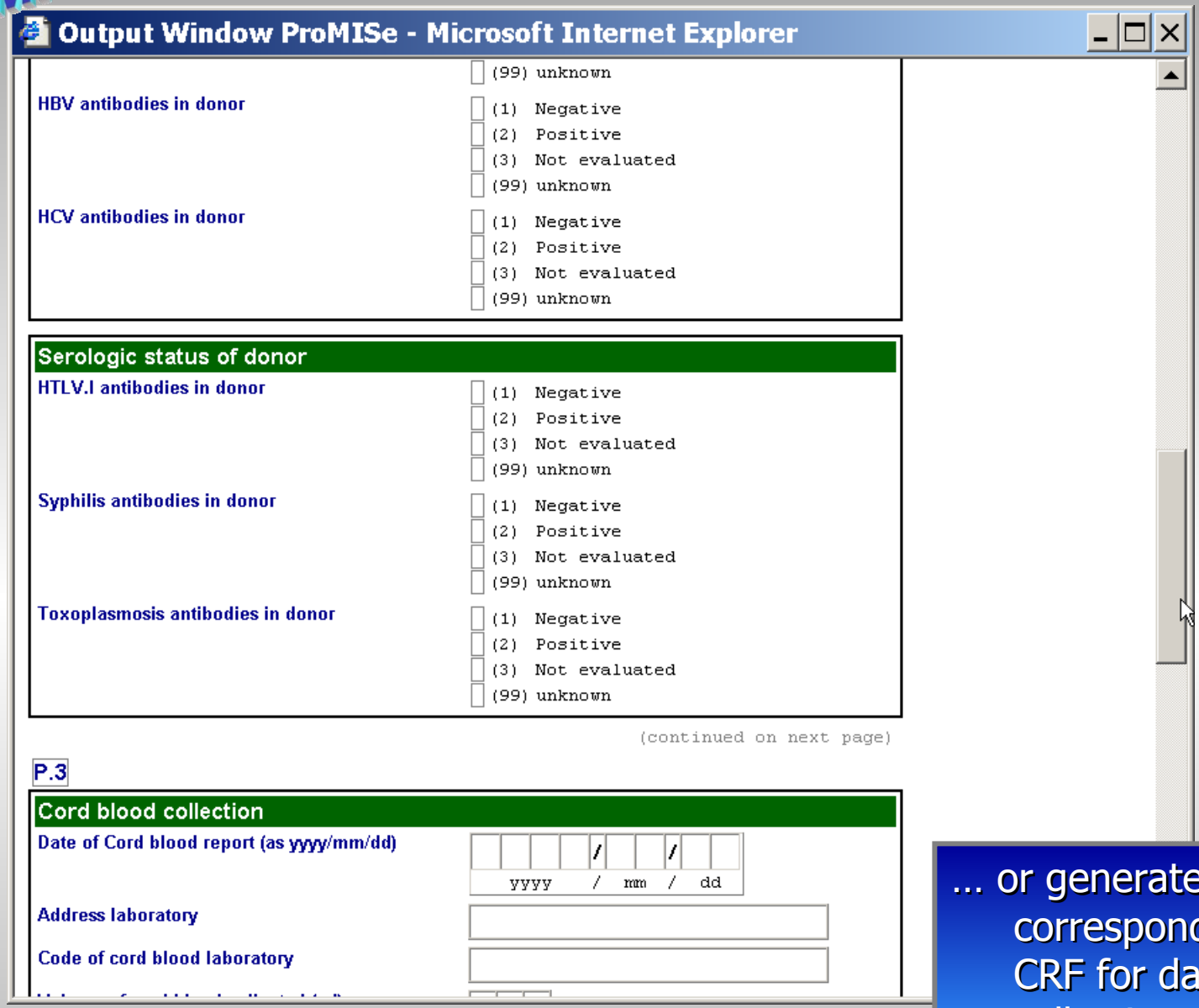

ProMISe
MEDAB[NEW][EBMT][User:promise1734][CIC:8001(9)] demo only [Med-A: All diseases --- Med-B: All m - Mi...
Data Entry
Report
Export
Help
Filter
[8001] [City 1]
1:Items
2:Records
3:Centers
4:Output
5:Templates
pending changes
1 Med AB complete
trg:565
20:15
FILTER: ITEMS
Management of Item Filters
+ Med AB complete
+ITEM FILTER PROPERTIES
-DATA BASE STRUCTURE (ITEM TREE)
-Patient
+Content
-Study
+Content
-Diagnosis
+Content
-Treatment
+Content
-Drugs (Chemo)
+Content
-Antibody treatment
+Content
-Stem cell counts
+Content
-Donor
+Content
-HLA of the Donor
+Content
-Assessment(1)
+Content
-Treat Compl
+Content
-Immunophenotype
+Content
-Cytogenetics
+ITEM TREE TOOLS
+STORED ITEM FILTERS
The relational structure is visualized and the user can work with Item Filters ....
Done
Trusted sites


MEDAB[NEW][EBMT][User:promise1734][CIC:8001(9)] demo only [Med-A: All diseases --- Med-B: All m - Mi...
Data Entry
Report
Export
Help
Filter
[8001] [City 1]
1:Items
2:Records
3:Centers
4:Output
5:Templates
pending changes
1 Med AB complete
trg:565
20:17
FILTER: ITEMS
Management of Item Filters
+ Med AB complete
+ITEM FILTER PROPERTIES
-DATA BASE STRUCTURE (ITEM TREE)
-Patient
+Content
-Study
+Content
-Diagnosis
-Content
+Diagnosis identification & administr
+Diagnosis record qualifier (manual)
-Diagnosis classification
-Diagnosis: main classification
Diagnosis
Age at this diagnosis
Interval from last transplant to thi...
-Leukaemias
-Acute leukaemias
Acute leukaemia diagnosis
AML: FAB classification
AML: FAB M5 Type
ALL: Immunological classification
B-lineage ALL
T-lineage ALL
-Chronic leukaemias
Chronic Leukaemia classification
CML subclassification
CLL & other chronic leukaemias subcl...
PLL subclassification
-Lymphomas
+ITEM TREE TOOLS
+STORED ITEM FILTERS
VACLEUK [BB0C0A1]
1 AML
2 ALL
3 Undifferentied
4 Biphenotypic
77 Other
99 unknown
... by combining a series of items and storing such a collection on disk
Done
Trusted sites



The Designer establishes pre-defined Filters


ProMISe
MEDAB[NEW][EBMT][User:promise1734][CIC:8001(9)] demo only [Med
Data Entry
Report
Export
Help
Filter
[8001] [City 1]
1:Items
2:Records
3:Centers
4:Output
5:Templates
pending changes
20:20
Any such subset can be used to document the Dictionary ...
AA TABLE Patient
TAG LABEL NAME TYP CODES EXTRA KEY LEN MIN MAX DEC HELP LTI T W J A C N J L R I X LONG LABEL
AA0 VOLUME Content
AA0A CHAPTER Patient data
AA0A1 SECTION Patient information
Unique Patient Number (UPN)
1 CBMANIP CBFICOLL CBMECHCS CBHETAST CBPERCOL ATHMANI WASTDXAL ATHMOTHE
1 No 2 Yes 99 unknown
22 VREASL2
1 Failure (no response) 2 Relapse CR / Progression PR 3 Secondary clonal disease 4 PR to treatment (insufficient) 5 Progression on treatment 6 Planned (Protocol)
8 No GvHD 9 Conditioning 10 GvHD Prophylaxis 11 aGvHD Treatment 12 Mobilisation 13 Graft failure
14 Pre-emptive 15 Mixed chimaerism 16 Persistent disease 17 cGvHD Treatment 18 Infection prophylaxis 19 Continued from before
71 Mucositis prophylaxis 72 Mucositis treatment 77 Other 99 unknown
145 VHIVDON VCMVDON VEBVDON VHBVDON VHCVDON VHTLVDON SYPHLDON VTOXDON
1 Negative 2 Positive 3 Not evaluated 99 unknown
220 PATSEX
1 Male 2 Female 99 unknown
503 VCBVOLUM VCBPCLYM VCBPCNTR
888 Not evaluated 999 unknown
523 NUCL1 CFUGM1 OTCLDS1
8888.88 Not evaluated 9999.99 unknown
... together with the coding system involved
BC0B0A1 Centre in which this treatment was given CENTRE I 1002 3 G 1
BC0B0C1 Unit CENTR T or team name 40 G 2
BC0E CHAPTER Main treatment
BC0E1 SECTION General
BC0E1E1 Reason for this treatment VREASL2 I 22 2 G 3 3 1
CF TABLE Stem cell counts
TAG LABEL NAME TYP CODES EXTRA KEY LEN MIN MAX DEC HELP LTI T W J A C N J L R I X LONG LABEL
CF0 VOLUME Content
Done
Trusted sites

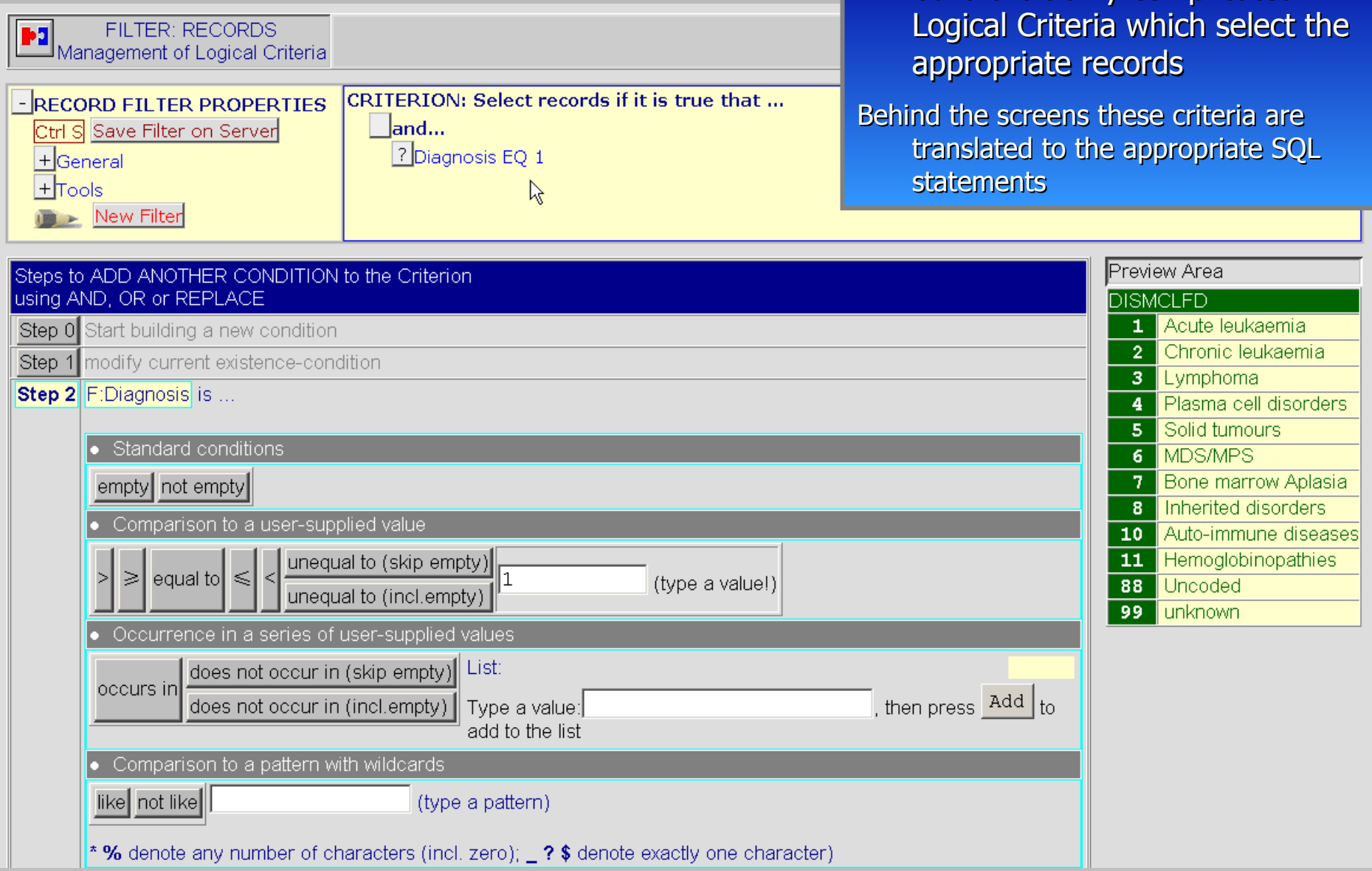


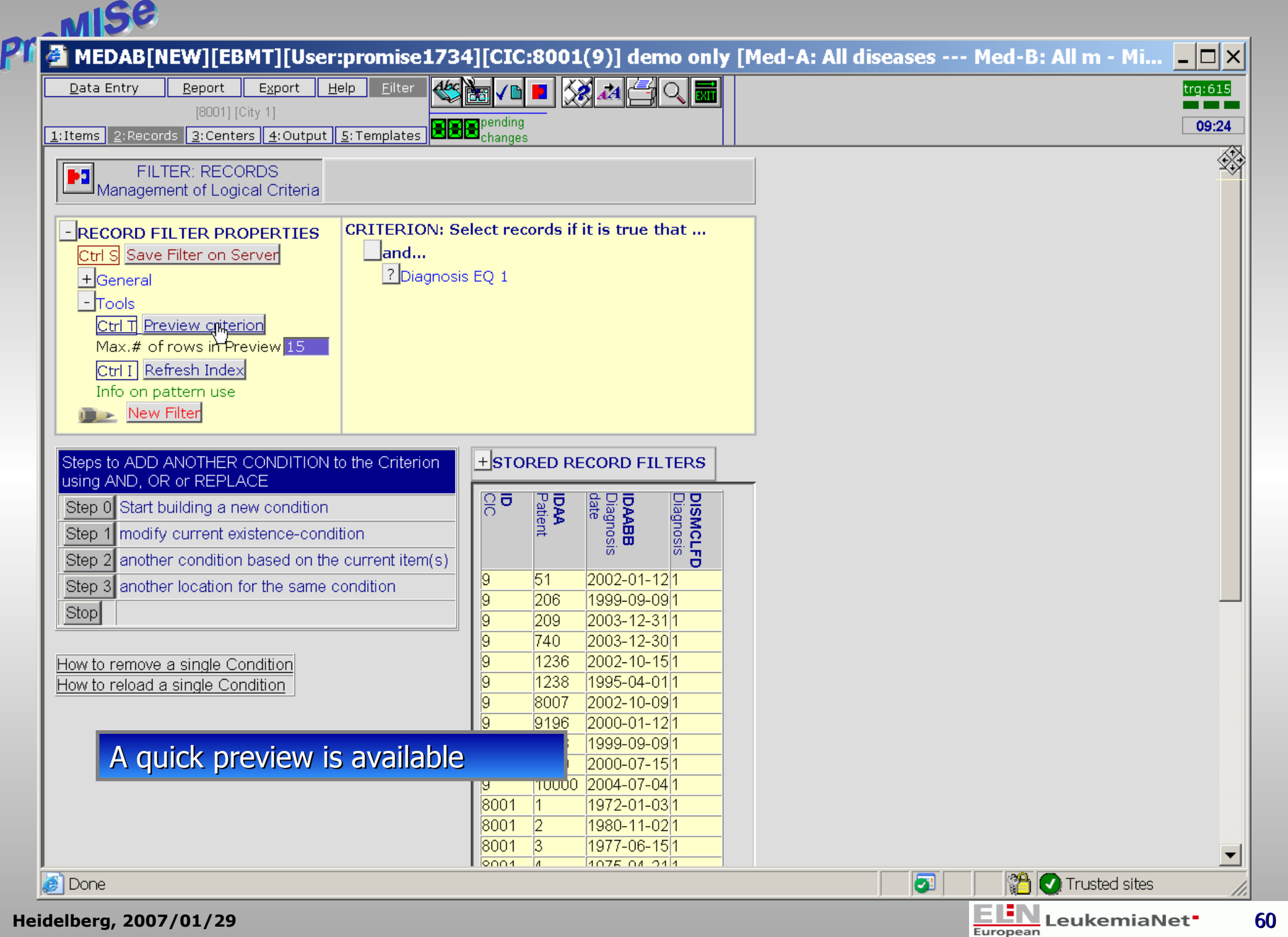
... or generate the corresponding paper CRF for data collection

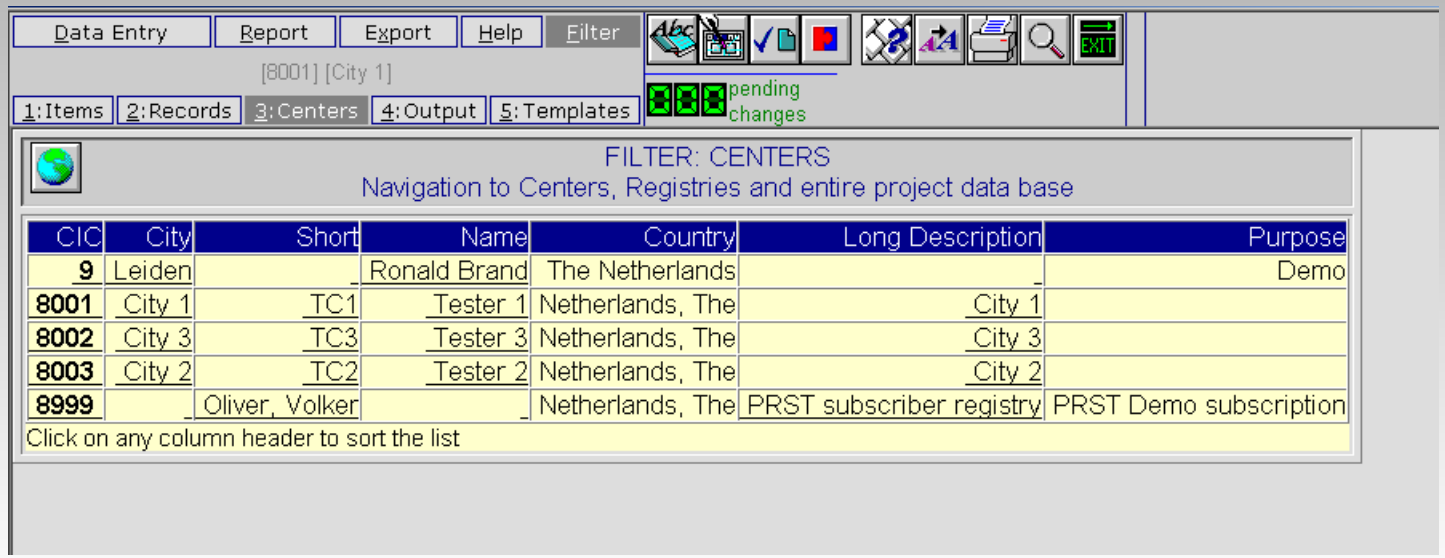
ProMISe

The Record Filter allows the user to build arbitrarily complicated Logical Criteria which select the appropriate records

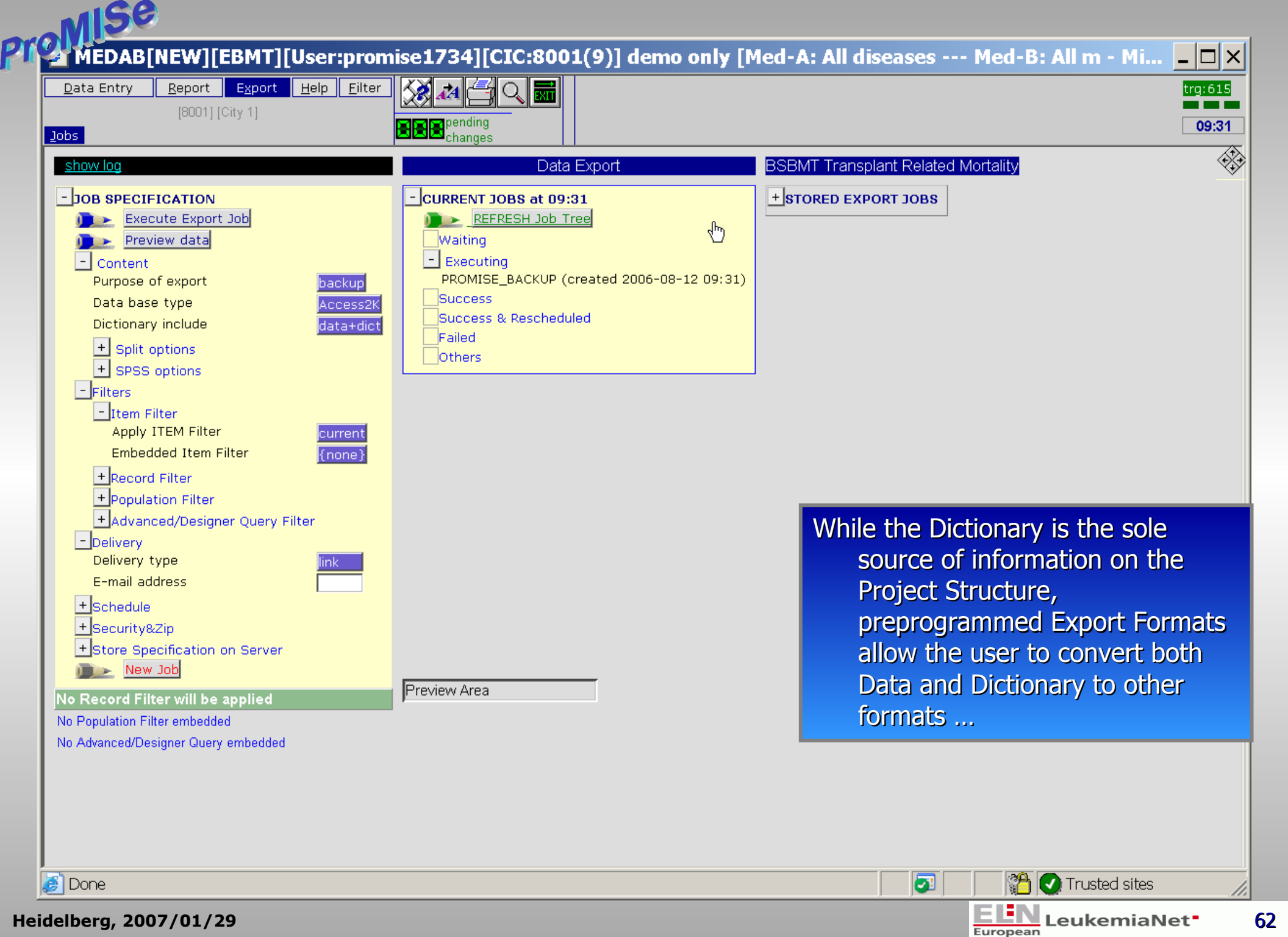
Behind the screens these criteria are translated to the appropriate SQL statements

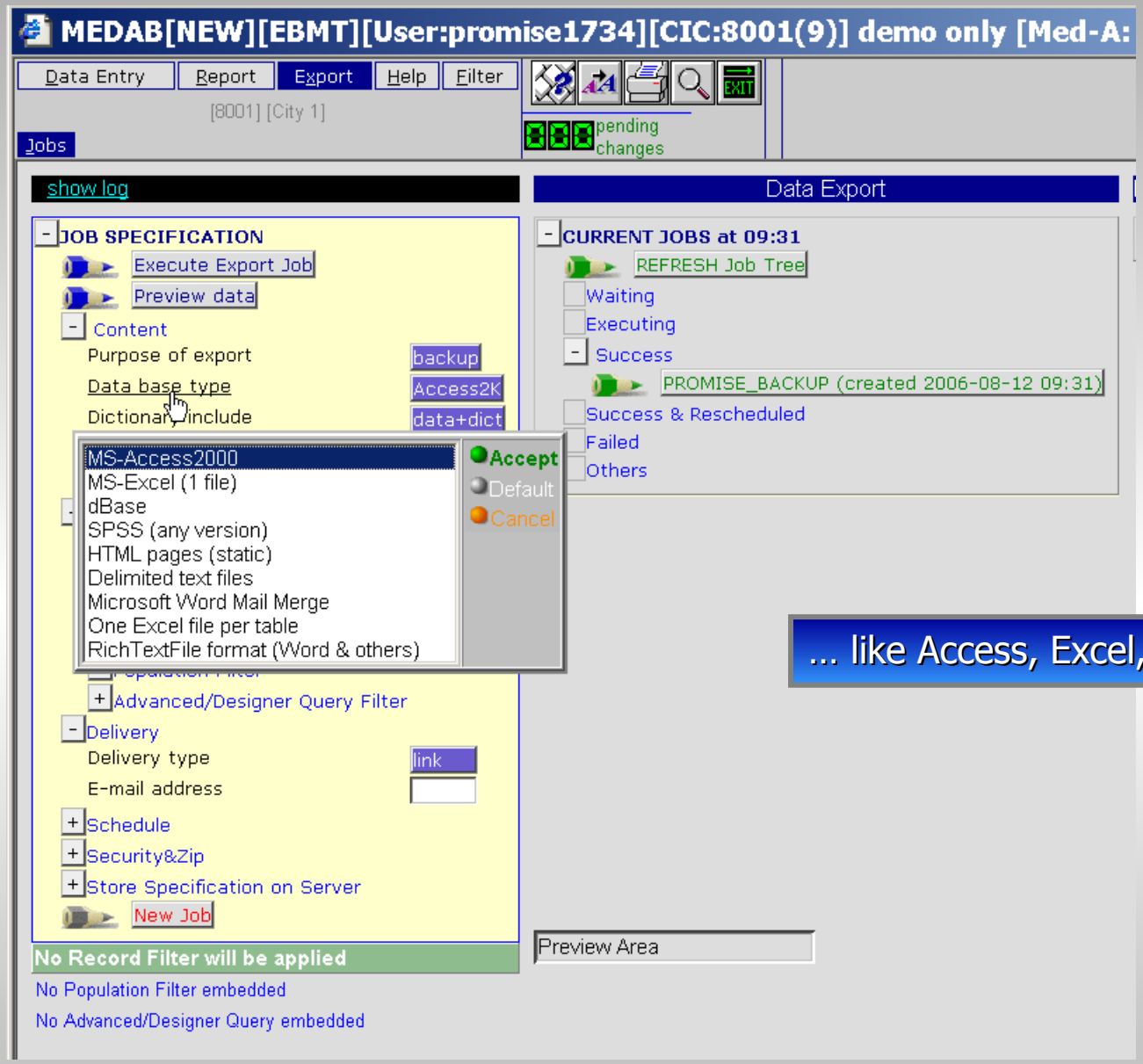



MEDAB[NEW][EBMT][User:promise1734][CIC:8001(9)] demo only [Med-A: All diseases --- Med-B: All m - Mi...
Data Entry
Report
Export
Help
Filter
[8001] [City 1]
1:Items
2:Records
3:Centers
4:Output
5:Templates
pending changes
trq:615
09:24
FILTER: RECORDS
Management of Logical Criteria
RECORD FILTER PROPERTIES
Ctrl S Save Filter on Server
General
Tools
Ctrl T Preview criterion
Max.# of rows in Preview 15
Ctrl I Refresh Index
Info on pattern use
New Filter
CRITERION: Select records if it is true that ...
and...
Diagnosis EQ 1
Steps to ADD ANOTHER CONDITION to the Criterion using AND, OR or REPLACE
Step 0 Start building a new condition
Step 1 modify current existence-condition
Step 2 another condition based on the current item(s)
Step 3 another location for the same condition
Stop
How to remove a single Condition
How to reload a single Condition
STORED RECORD FILTERS
ID CIC
IDAA Patient
IDAABB Diagnosis date
DISMCLFD Diagnosis
9 51 2002-01-12 1
9 206 1999-09-09 1
9 209 2003-12-31 1
9 740 2003-12-30 1
9 1236 2002-10-15 1
9 1238 1995-04-01 1
9 8007 2002-10-09 1
9 9196 2000-01-12 1
1999-09-09 1
2000-07-15 1
9 10000 2004-07-04 1
8001 1 1972-01-03 1
8001 2 1980-11-02 1
8001 3 1977-06-15 1
A quick preview is available
Done
Trusted sites

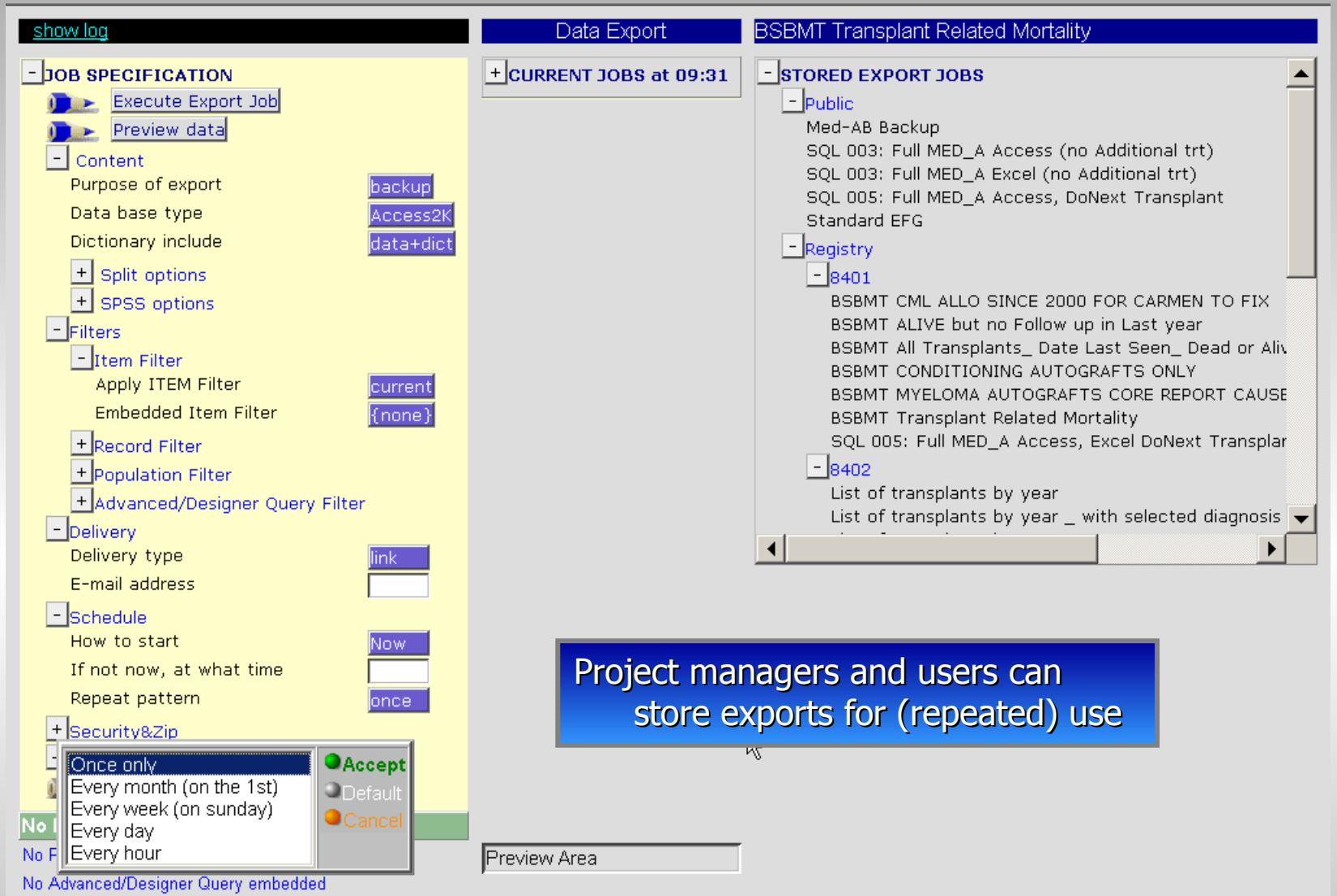


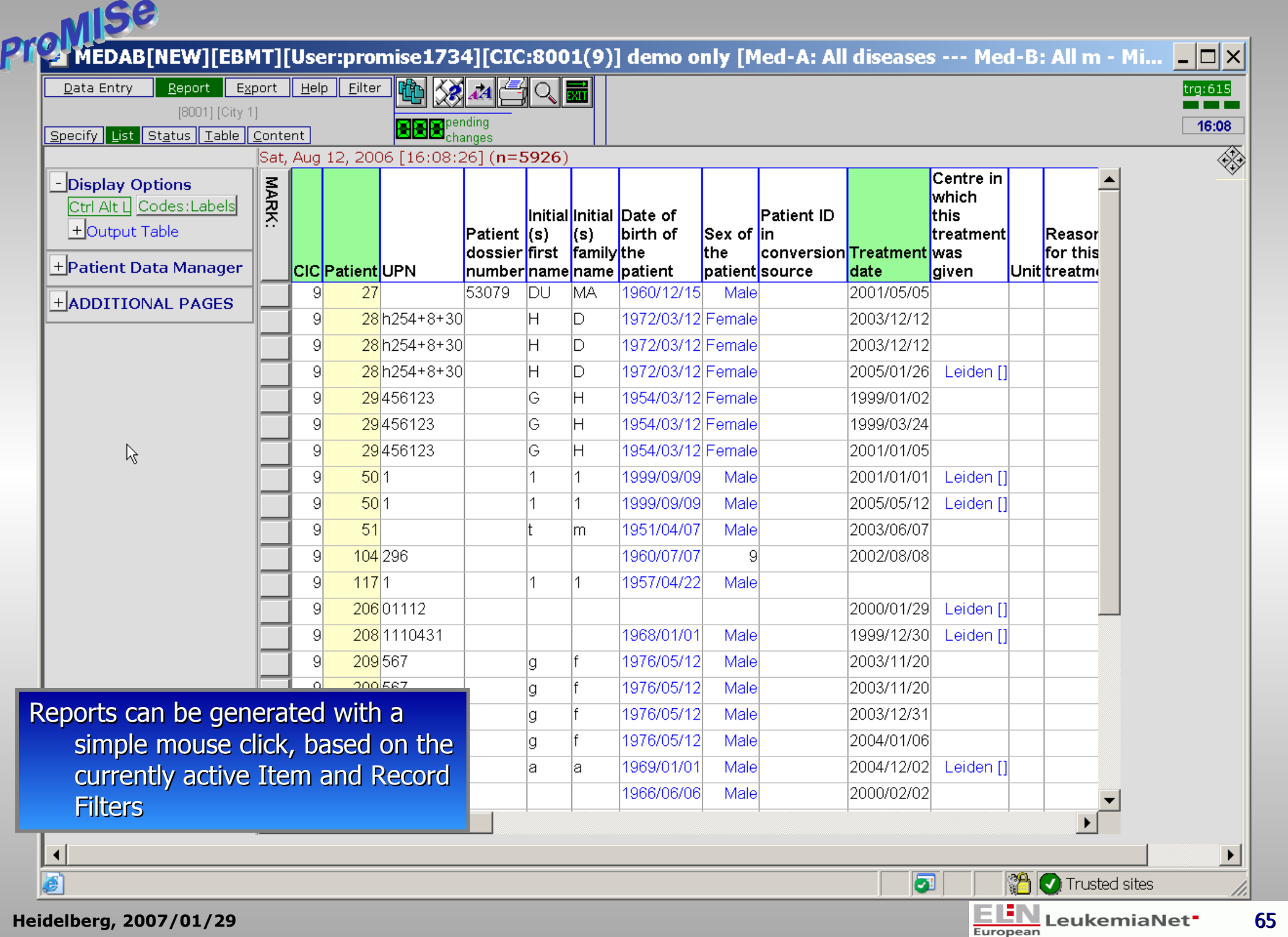
The third Filter chooses the Center to access, subject of course to the user's authorization level

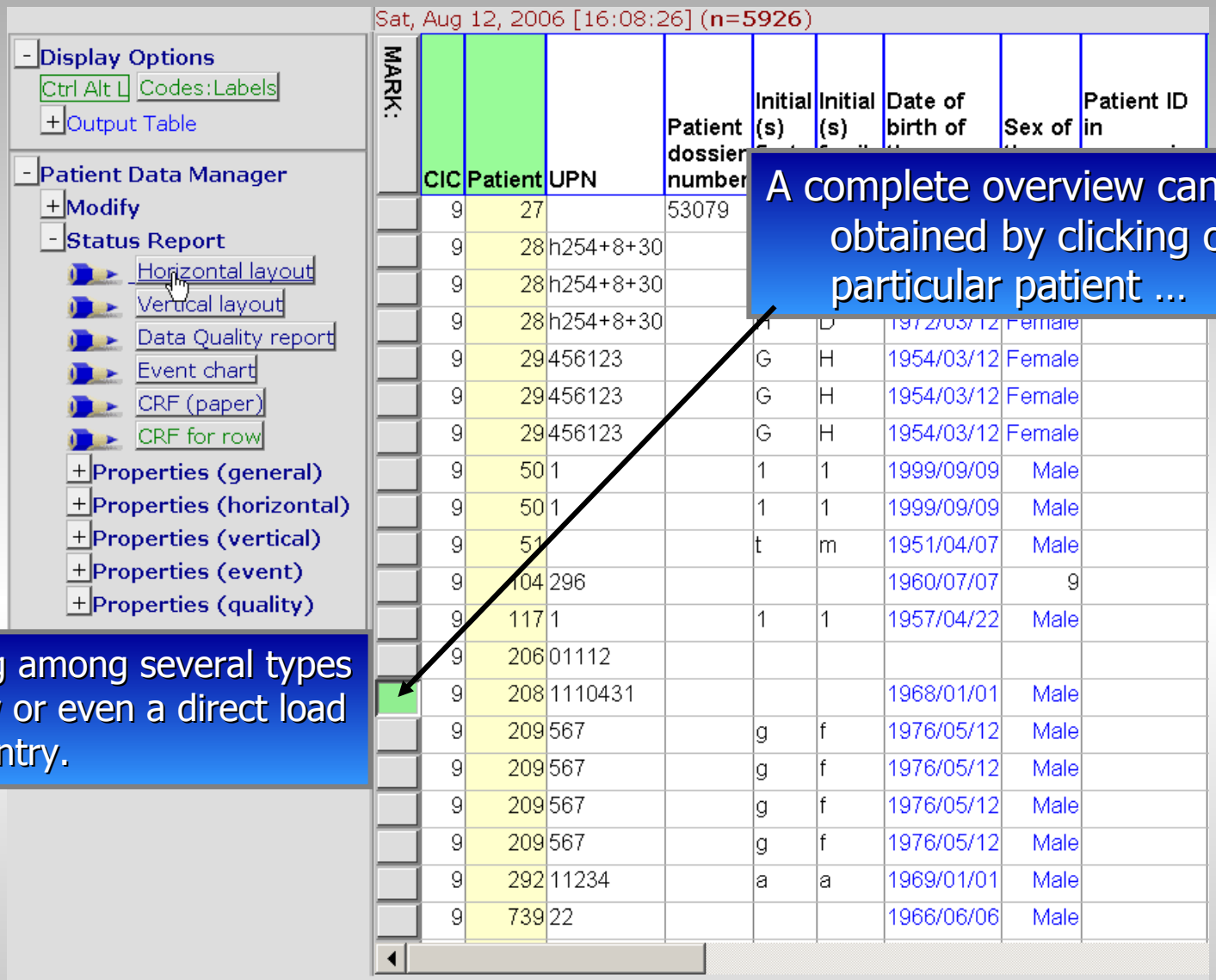

MEDAB[NEW][EBMT][User:promise1734][CIC:8001(9)] demo only [Med-A: All diseases --- Med-B: All m - Mi...
Data Entry
Report
Export
Help
Filter
[8001] [City 1]
Jobs
pending changes
trg:615
09:31
show log
Data Export
BSBMT Transplant Related Mortality
JOB SPECIFICATION
Execute Export Job
Preview data
Content
Purpose of export
backup
Data base type
Access2K
Dictionary include
data+dict
Split options
SPSS options
Filters
Item Filter
Apply ITEM Filter
current
Embedded Item Filter
{none}
Record Filter
Population Filter
Advanced/Designer Query Filter
Delivery
Delivery type
link
E-mail address
Schedule
Security&Zip
Store Specification on Server
New Job
CURRENT JOBS at 09:31
REFRESH Job Tree
Waiting
Executing
PROMISE_BACKUP (created 2006-08-12 09:31)
Success
Success & Rescheduled
Failed
Others
STORED EXPORT JOBS
No Record Filter will be applied
No Population Filter embedded
No Advanced/Designer Query embedded
Preview Area
While the Dictionary is the sole source of information on the Project Structure, preprogrammed Export Formats allow the user to convert both Data and Dictionary to other formats ...
Done
Trusted sites

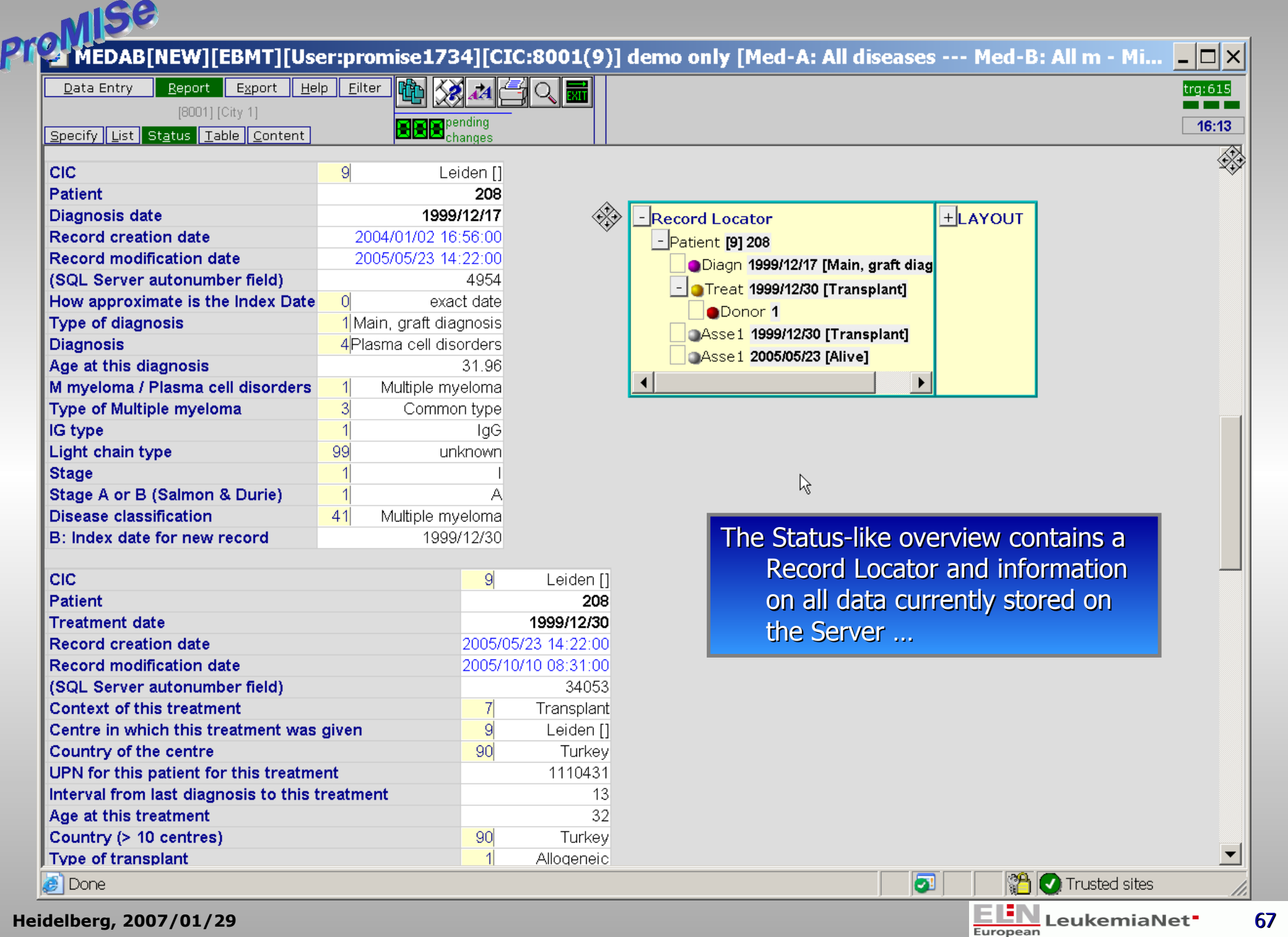


... like Access, Excel, SPSS, Word etc


show log
Data Export
BSBMT Transplant Related Mortality
JOB SPECIFICATION
Execute Export Job
Preview data
Content
Purpose of export
backup
Data base type
Access2K
Dictionary include
data+dict
Split options
SPSS options
Filters
Item Filter
Apply ITEM Filter
current
Embedded Item Filter
{none}
Record Filter
Population Filter
Advanced/Designer Query Filter
Delivery
Delivery type
link
E-mail address
Schedule
How to start
Now
If not now, at what time
Repeat pattern
once
Security&Zip
Once only
Every month (on the 1st)
Every week (on sunday)
Every day
Every hour
Accept
Default
Cancel
No Advanced/Designer Query embedded
CURRENT JOBS at 09:31
Preview Area
STORED EXPORT JOBS
Public
Med-AB Backup
SQL 003: Full MED_A Access (no Additional trt)
SQL 003: Full MED_A Excel (no Additional trt)
SQL 005: Full MED_A Access, DoNext Transplant
Standard EFG
Registry
8401
BSBMT CML ALLO SINCE 2000 FOR CARMEN TO FIX
BSBMT ALIVE but no Follow up in Last year
BSBMT All Transplants_ Date Last Seen_ Dead or Aliv
BSBMT CONDITIONING AUTOGRAFTS ONLY
BSBMT MYELOMA AUTOGRAFTS CORE REPORT CAUSE
BSBMT Transplant Related Mortality
SQL 005: Full MED_A Access, Excel DoNext Transplar
8402
List of transplants by year
List of transplants by year _ with selected diagnosis
Project managers and users can
store exports for (repeated) use


ProMISe
MEDAB[NEW][EBMT][User:promise1734][CIC:8001(9)] demo only [Med-A: All diseases --- Med-B: All m - Mi...
Data Entry
Report
Export
Help
Filter
[8001] [City 1]
Specify
List
Status
Table
Content
pending changes
trq:615
16:08
Sat, Aug 12, 2006 [16:08:26] (n=5926)
Display Options
Ctrl Alt L
Codes:Labels
Output Table
Patient Data Manager
ADDITIONAL PAGES
MARK:
CIC
Patient
UPN
Patient dossier number
Initial (s) first name
Initial (s) family name
Date of birth of the patient
Sex of the patient
Patient ID in conversion source
Treatment date
Centre in which this treatment was given
Unit
Reason for this treatm
9 27 53079 DU MA 1960/12/15 Male 2001/05/05
9 28 h254+8+30 H D 1972/03/12 Female 2003/12/12
9 28 h254+8+30 H D 1972/03/12 Female 2003/12/12
9 28 h254+8+30 H D 1972/03/12 Female 2005/01/26 Leiden []
9 29 456123 G H 1954/03/12 Female 1999/01/02
9 29 456123 G H 1954/03/12 Female 1999/03/24
9 29 456123 G H 1954/03/12 Female 2001/01/05
9 50 1 1 1 1999/09/09 Male 2001/01/01 Leiden []
9 50 1 1 1 1999/09/09 Male 2005/05/12 Leiden []
9 51 t m 1951/04/07 Male 2003/06/07
9 104 296 1960/07/07 9 2002/08/08
9 117 1 1 1 1957/04/22 Male
9 206 01112 2000/01/29 Leiden []
9 208 1110431 1968/01/01 Male 1999/12/30 Leiden []
9 209 567 g f 1976/05/12 Male 2003/11/20
g f 1976/05/12 Male 2003/11/20
g f 1976/05/12 Male 2003/12/31
g f 1976/05/12 Male 2004/01/06
a a 1969/01/01 Male 2004/12/02 Leiden []
1966/06/06 Male 2000/02/02
Reports can be generated with a simple mouse click, based on the currently active Item and Record Filters
Trusted sites


Sat, Aug 12, 2006 [16:08:26] (n=5926)
Display Options
Ctrl Alt L
Codes:Labels
Output Table
Patient Data Manager
Modify
Status Report
Horizontal layout
Vertical layout
Data Quality report
Event chart
CRF (paper)
CRF for row
Properties (general)
Properties (horizontal)
Properties (vertical)
Properties (event)
Properties (quality)
MARK:
CIC
Patient
UPN
Patient dossier number
Initial (s)
Initial (s)
Date of birth of
Sex of
Patient ID in
A complete overview can be obtained by clicking on the particular patient …
… and choosing among several types of overview or even a direct load into Data Entry.


MEDAB[NEW][EBMT][User:promise1734][CIC:8001(9)] demo only [Med-A: All diseases --- Med-B: All m - Mi...
Data Entry
Report
Export
Help
Filter
[8001] [City 1]
Specify
List
Status
Table
Content
pending changes
trq:615
16:13
CIC 9 Leiden []
Patient 208
Diagnosis date 1999/12/17
Record creation date 2004/01/02 16:56:00
Record modification date 2005/05/23 14:22:00
(SQL Server autonumber field) 4954
How approximate is the Index Date 0 exact date
Type of diagnosis 1 Main, graft diagnosis
Diagnosis 4 Plasma cell disorders
Age at this diagnosis 31.96
M myeloma / Plasma cell disorders 1 Multiple myeloma
Type of Multiple myeloma 3 Common type
IG type 1 IgG
Light chain type 99 unknown
Stage 1 I
Stage A or B (Salmon & Durie) 1 A
Disease classification 41 Multiple myeloma
B: Index date for new record 1999/12/30
Record Locator
Patient [9] 208
Diagn 1999/12/17 [Main, graft diag
Treat 1999/12/30 [Transplant]
Donor 1
Asse1 1999/12/30 [Transplant]
Asse1 2005/05/23 [Alive]
LAYOUT
The Status-like overview contains a Record Locator and information on all data currently stored on the Server ...
CIC 9 Leiden []
Patient 208
Treatment date 1999/12/30
Record creation date 2005/05/23 14:22:00
Record modification date 2005/10/10 08:31:00
(SQL Server autonumber field) 34053
Context of this treatment 7 Transplant
Centre in which this treatment was given 9 Leiden []
Country of the centre 90 Turkey
UPN for this patient for this treatment 1110431
Interval from last diagnosis to this treatment 13
Age at this treatment 32
Country (> 10 centres) 90 Turkey
Type of transplant 1 Allogeneic
Done
Trusted sites

ProMISe

CONCR[PROD][MEST][User:mrdm][CIC:1(1)] [clindev2003][443] - Microsoft Internet Explorer

Data Entry | Report | Export | Help | Filter | Manage

DESIGNER TEST CONTAINER [#1]

ProMISe contains a simple language that can be used by a HTML

Concor

Patientnaam:	R. Regeer	Geboortedatum:	1968/02/28	
Concor-nr:	418	Promise-nr:	1061167	DNA afg:
Registr. Zkhs:	Leids Universitair Medisch Centrum [Leiden] (106)	Patientnummer:	8122415	
2e Zkhs:	()	Patientnummer:		

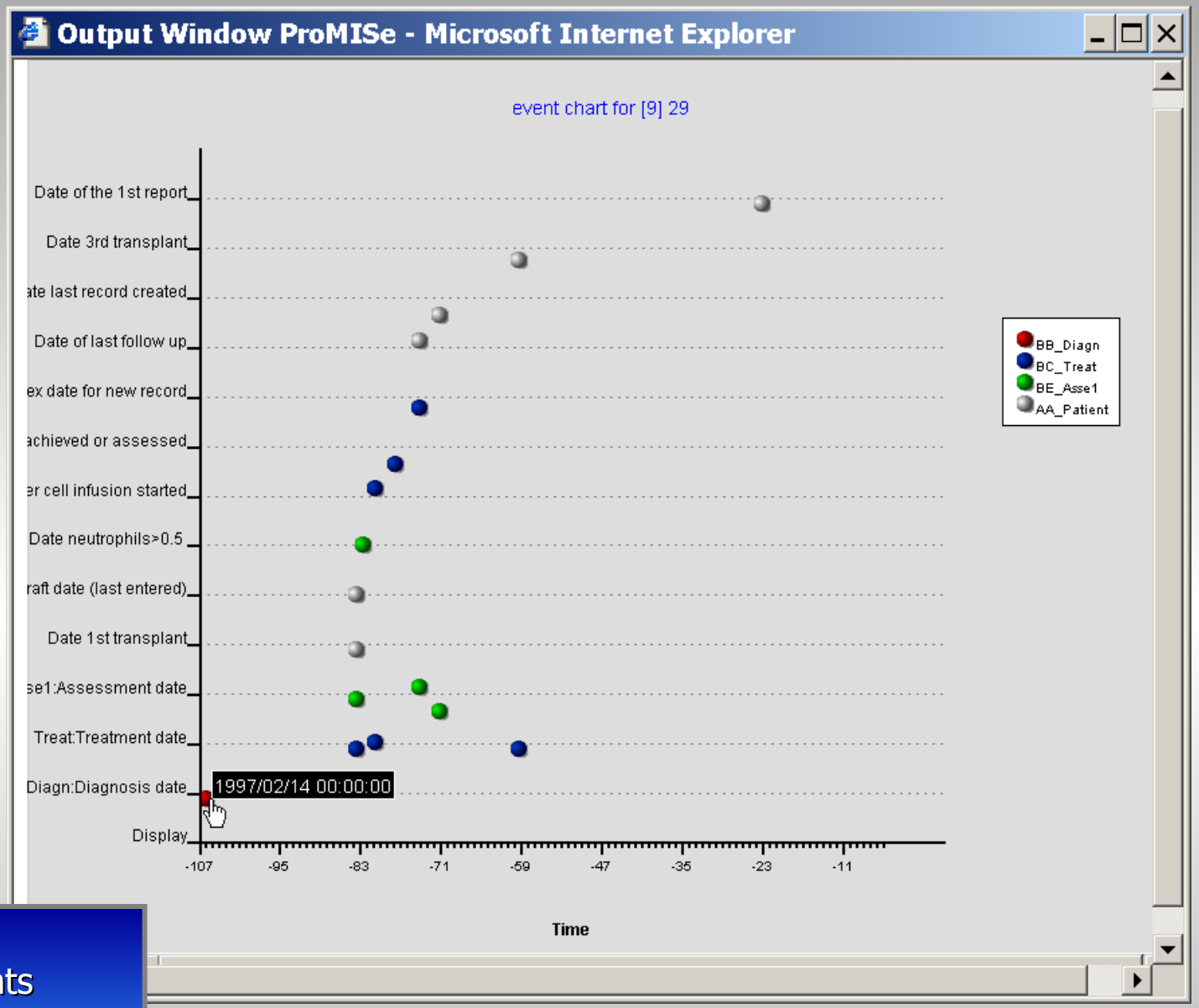
Datum	*	EPCC	Omschrijving	ICD9	ICD10	HE
1971/05/19 00	exact date	09.29.01	Aortic coarctation,		Q25.1	***
{date unknown}	exact date	09.15.22	Bicuspid aortic valve,		Q23.1	
1971/05/19 01	exact date	05.04.02	ASD within oval fossa (secundum),		Q21.1	
1974/07/12 00	exact date	12.18.00	Coarctation / hypoplasia of aorta repair,		?	
1974/07/12 01	exact date	10.14.01	Systemic hypertension,		I10	
2001/11/07 00	exact date	15.35.03	Residual aortic regurgitation,		Q23.1	

* : Zekerheid van de datum
HE : Hoofdevent

Opmerkingen

Aanvullingen

Datum laatste contact cardioloog:
Datum laatste contact CONCOR:
Datum laatste wijziging:
Niet meer onder behandeling?:



- A special graphical representation of all events experienced by a patient is directly linked to the overview

MEDAB[NEW][EBMT][User:promise1734][CIC:8001(9)] demo only [Med-A: All diseases --- Med-B: All m - Mi...

Data Entry | Report | Export | Help | Filter

[8001] [City 1]

Specify | List | Status | Table | Content

Save | 885 pending changes

trg:634

16:20

Saturday August 12 2006 16:19

TABLES

Show all tables

Jump to ...

DISMCLFD [Diagnosis]

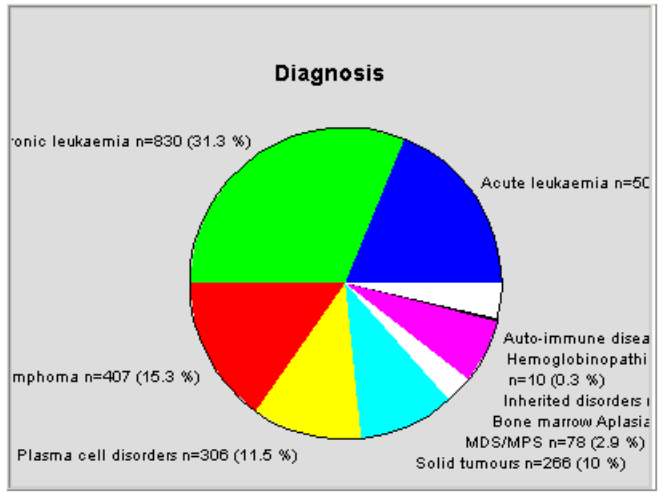
Modify visible graph(s) ...

type of chart pie

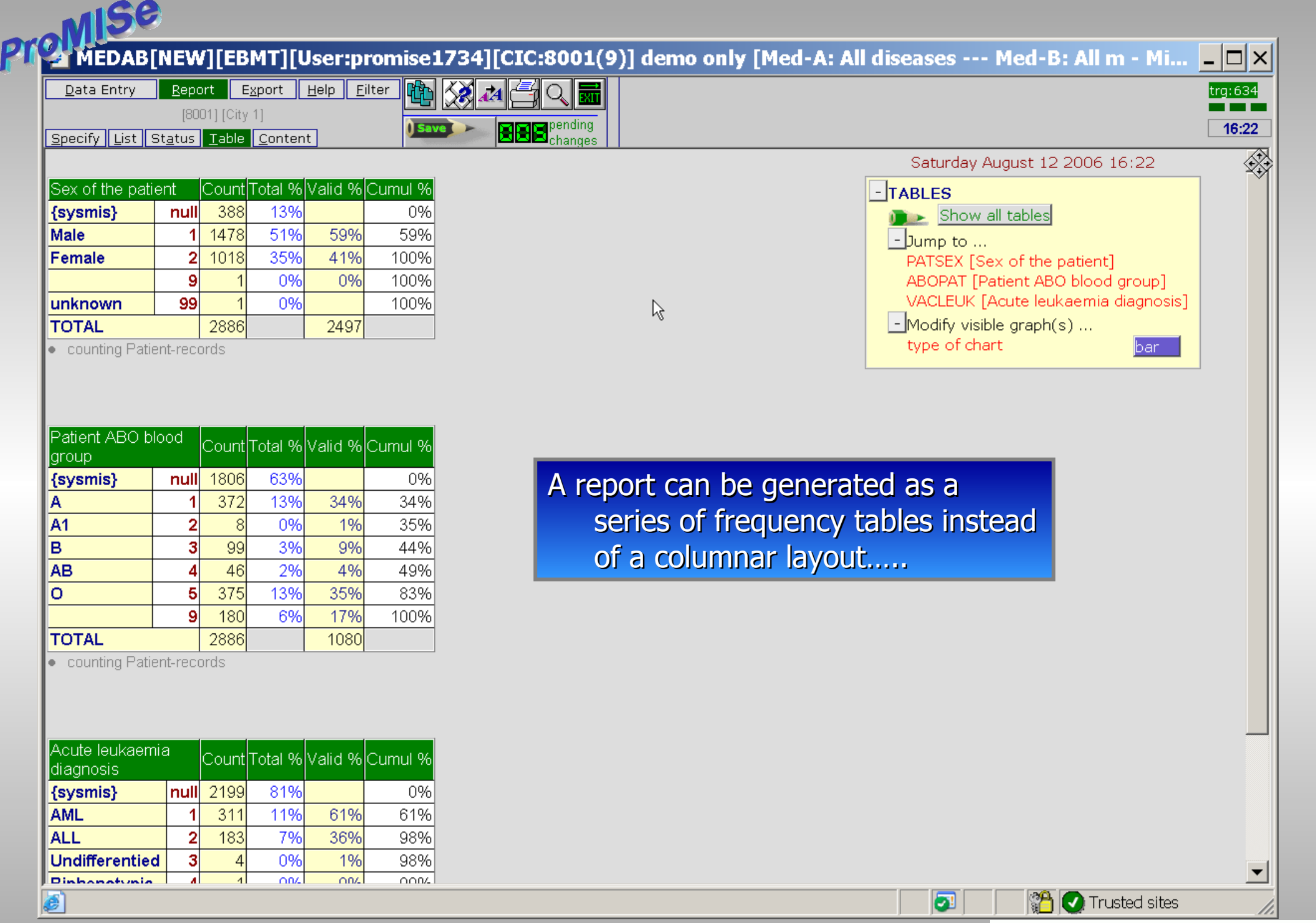
Diagnosis		Count	Total %	Valid %	Cumul %
{sysmis}	null	50	2%		0%
Acute leukaemia	1	501	19%	19%	19%
Chronic leukaemia	2	830	31%	31%	50%
Lymphoma	3	407	15%	15%	66%
Plasma cell disorders	4	306	11%	12%	77%
Solid tumours	5	266	10%	10%	87%
MDS/MPS	6	78	3%	3%	90%
Bone marrow Aplasia	7	184	7%	7%	97%
Inherited disorders	8	11	0%	0%	97%
	9	10	0%	0%	98%
Auto-immune diseases	10	4	0%	0%	98%
Hemoglobinopathies	11	53	2%	2%	100%
Uncoded	88	5	0%		100%
TOTAL		2705		2650	

counting Diagn-records

Output Window ProMISe - Micr...



When the header of a column in the report is clicked, a frequency table appears with a graphical representation



Sex of the patient		Count	Total %	Valid %	Cumul %
{sysmis}	null	388	13%		0%
Male	1	1478	51%	59%	59%
Female	2	1018	35%	41%	100%
	9	1	0%	0%	100%
unknown	99	1	0%		100%
TOTAL		2886		2497	

• counting Patient-records

Patient ABO blood group		Count	Total %	Valid %	Cumul %
{sysmis}	null	1806	63%		0%
A	1	372	13%	34%	34%
A1	2	8	0%	1%	35%
B	3	99	3%	9%	44%
AB	4	46	2%	4%	49%
O	5	375	13%	35%	83%
	9	180	6%	17%	100%
TOTAL		2886		1080	

• counting Patient-records

Acute leukaemia diagnosis		Count	Total %	Valid %	Cumul %
{sysmis}	null	2199	81%		0%
AML	1	311	11%	61%	61%
ALL	2	183	7%	36%	98%
Undifferentied	3	4	0%	1%	98%
Biphenotypic	4	1	0%	0%	00%

In addition a graphical representation appears, optionally comparing the current center with its "complement" .....

MEDAB[NEW][EBMT][

Data Entry | Report | Export

[8001] [City 1]

Specify | List | Status | Table | Content

Save | 005 pending changes

17:13

Saturday August 12 2006 17:14

Sex of the patient		Count	Total %	Valid %	Cumul %
{sysmis}	null	0	0%		0%
Male	1	1478	59%	59%	59%
Female	2	1018	41%	41%	100%
	9	1	0%	0%	100%
unknown	99	1	0%		100%
TOTAL		2498		2497	

• counting Patient-records

TABLES

Show all tables

Jump to ...

PATSEX [Sex of the patient]

ABOPAT [Patient ABO blood group]

VACLEUK [Acute leukaemia diagnosis]

Modify visible graph(s) ...

type of chart: pie

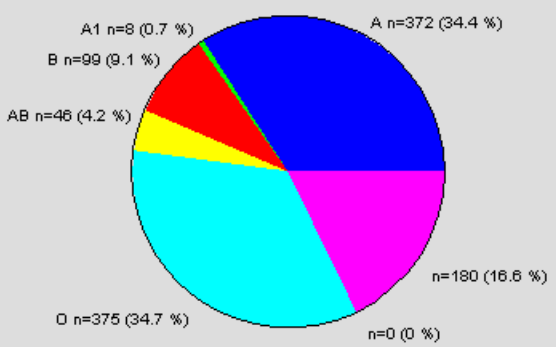
Patient ABO blood group		Count	Total %	Valid
{sysmis}	null	0	0%	
A	1	372	34%	34
A1	2	8	1%	1
B	3	99	9%	9
AB	4	46	4%	4
O	5	375	35%	35
	8	0	0%	
	9	180	17%	17
unknown	99	0	0%	
TOTAL		1080		10

• counting Patient-records

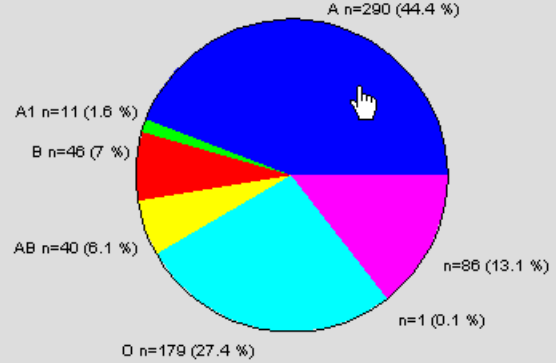
Acute leukaemia diagnosis		Count	Total %	Valid
{sysmis}	null	0	0%	
AML	1	311	61%	61%

Output Window ProMISe - Microsoft Internet Explorer

Local distribution

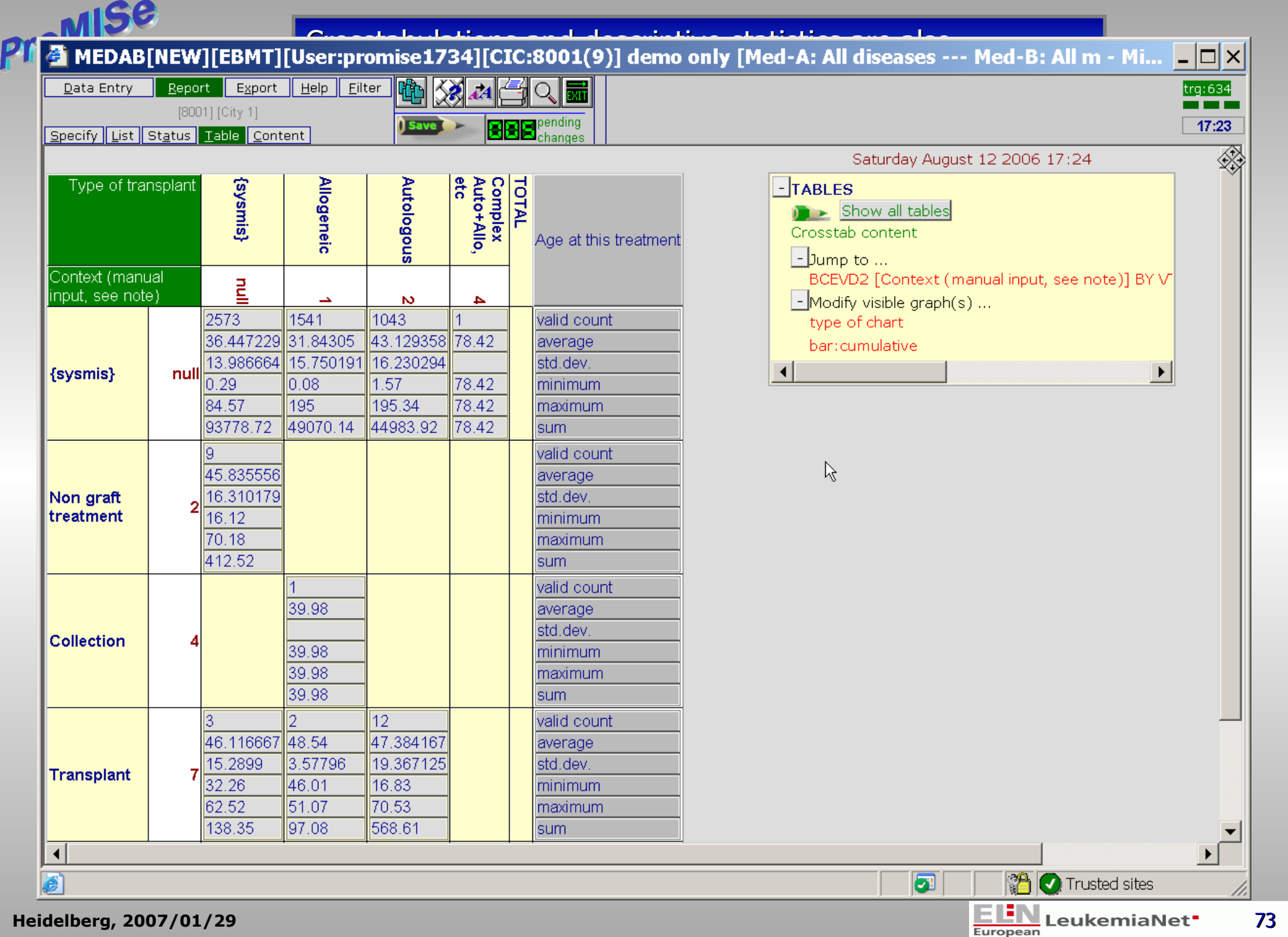


Complement distribution



Local distribution | Complement distribution

Trusted sites

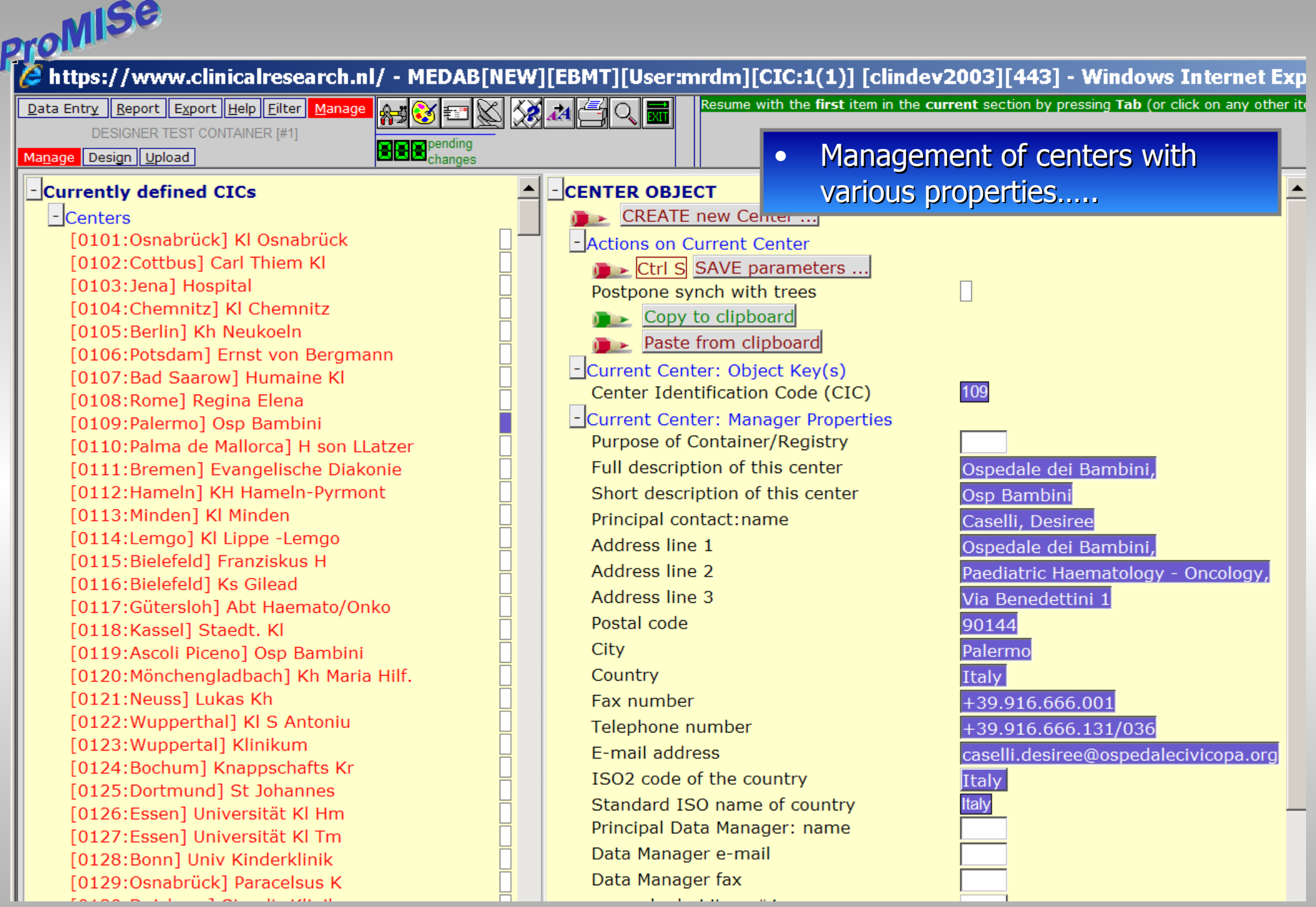


Type of transplant		{sysmis}	Allogeneic	Autologous	Complex Auto+Allo, etc	TOTAL	Age at this treatment
Context (manual input, see note)		null	1	2	4		
{sysmis}	null	2573	1541	1043	1		valid count
		36.447229	31.84305	43.129358	78.42		average
		13.986664	15.750191	16.230294			std.dev.
		0.29	0.08	1.57	78.42		minimum
		84.57	195	195.34	78.42		maximum
		93778.72	49070.14	44983.92	78.42		sum
Non graft treatment	2	9					valid count
		45.835556					average
		16.310179					std.dev.
		16.12					minimum
		70.18					maximum
		412.52					sum
Collection	4		1				valid count
			39.98				average
							std.dev.
			39.98				minimum
			39.98				maximum
			39.98				sum
Transplant	7	3	2	12			valid count
		46.116667	48.54	47.384167			average
		15.2899	3.57796	19.367125			std.dev.
		32.26	46.01	16.83			minimum
		62.52	51.07	70.53			maximum
		138.35	97.08	568.61			sum

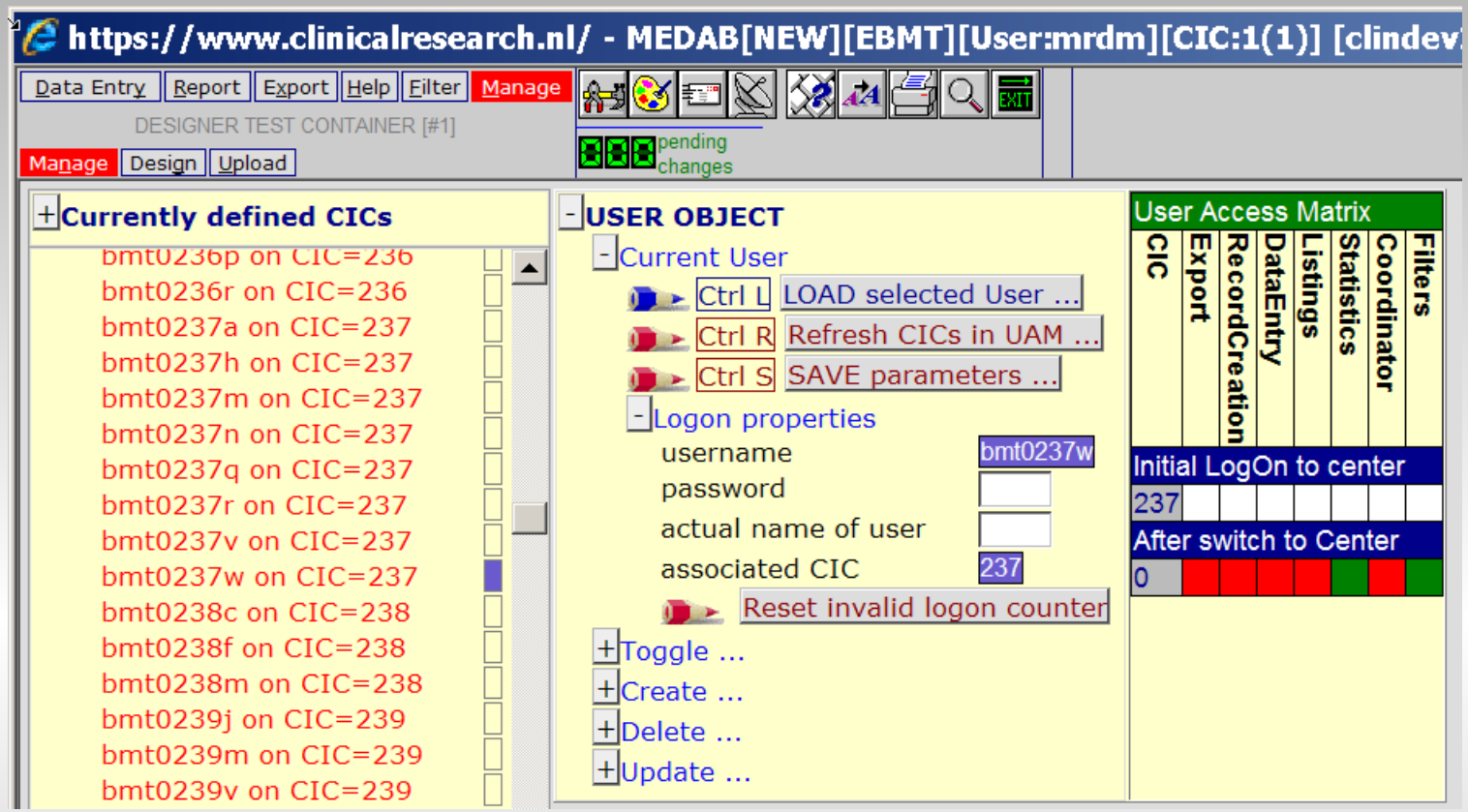
The **Manager** of the project can maintain all production aspects of a project that need adjustment remotely including ..

- Participating Centers
- User authorization
- System performance
- Data sharing with other projects
- Project-wide parameters

The system is "self-repairing" and remembers the queries issued to enhance its efficiency

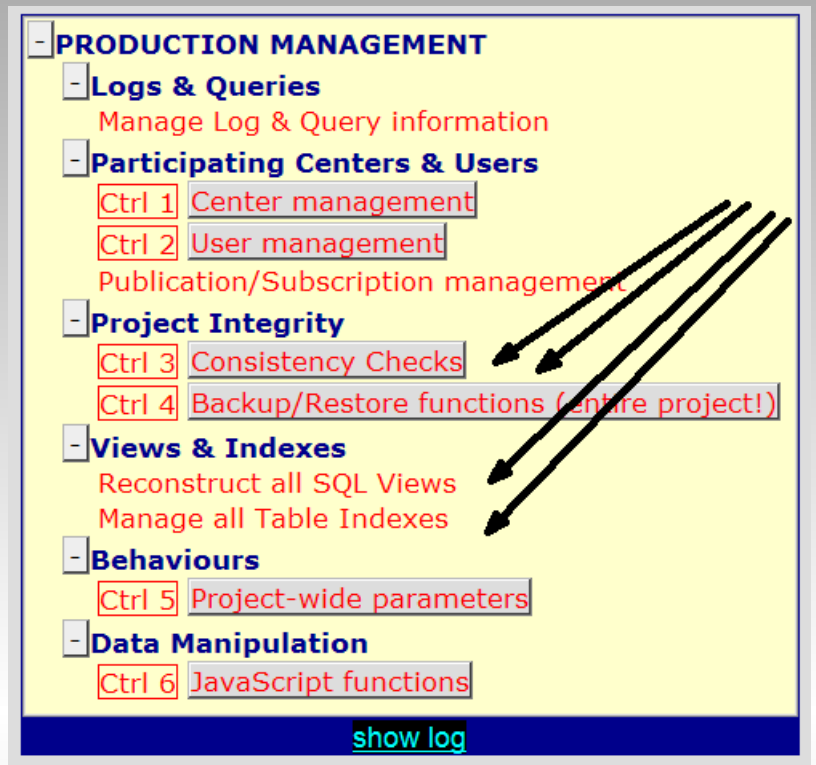


- Management of centers with various properties.....



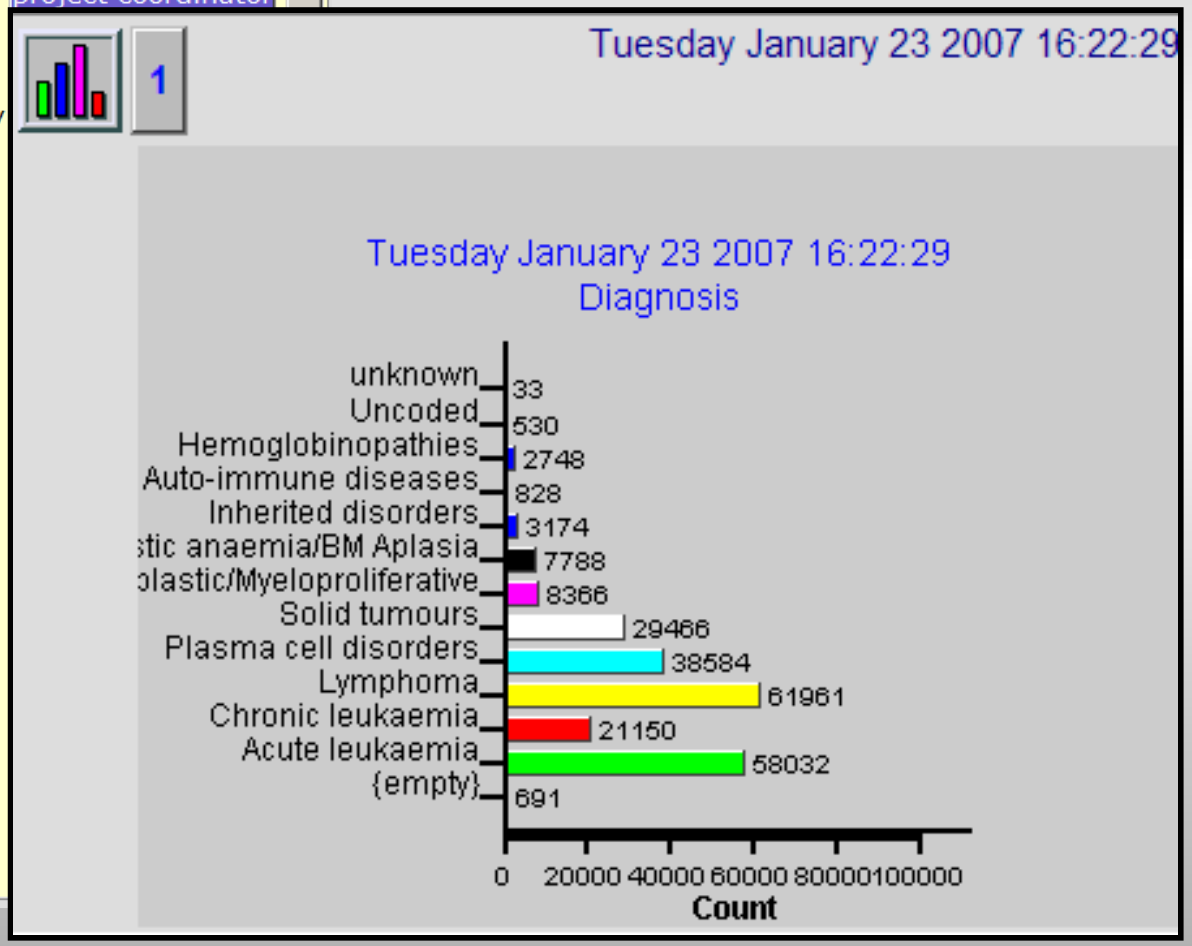
- ... and users authorized to access them
- Support of detailed authorization when allowing switching from one center to another in one session

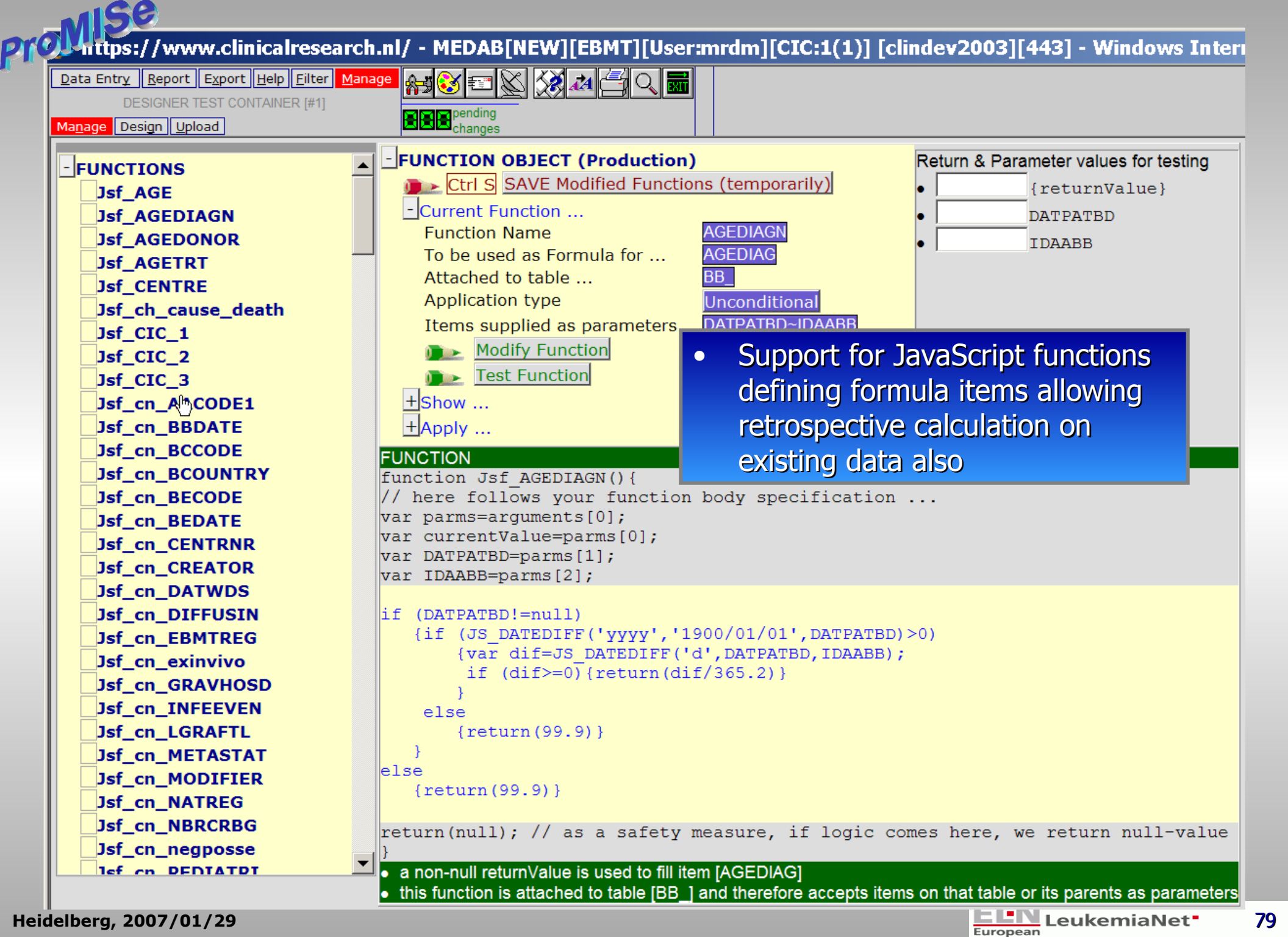
- Infrastructure is "self-repairing" through internal consistency checks
- Manager can make full additional backups and store them locally for added safety
- Table indexes can be defined for increase in speed if certain types of queries are known to be used very often



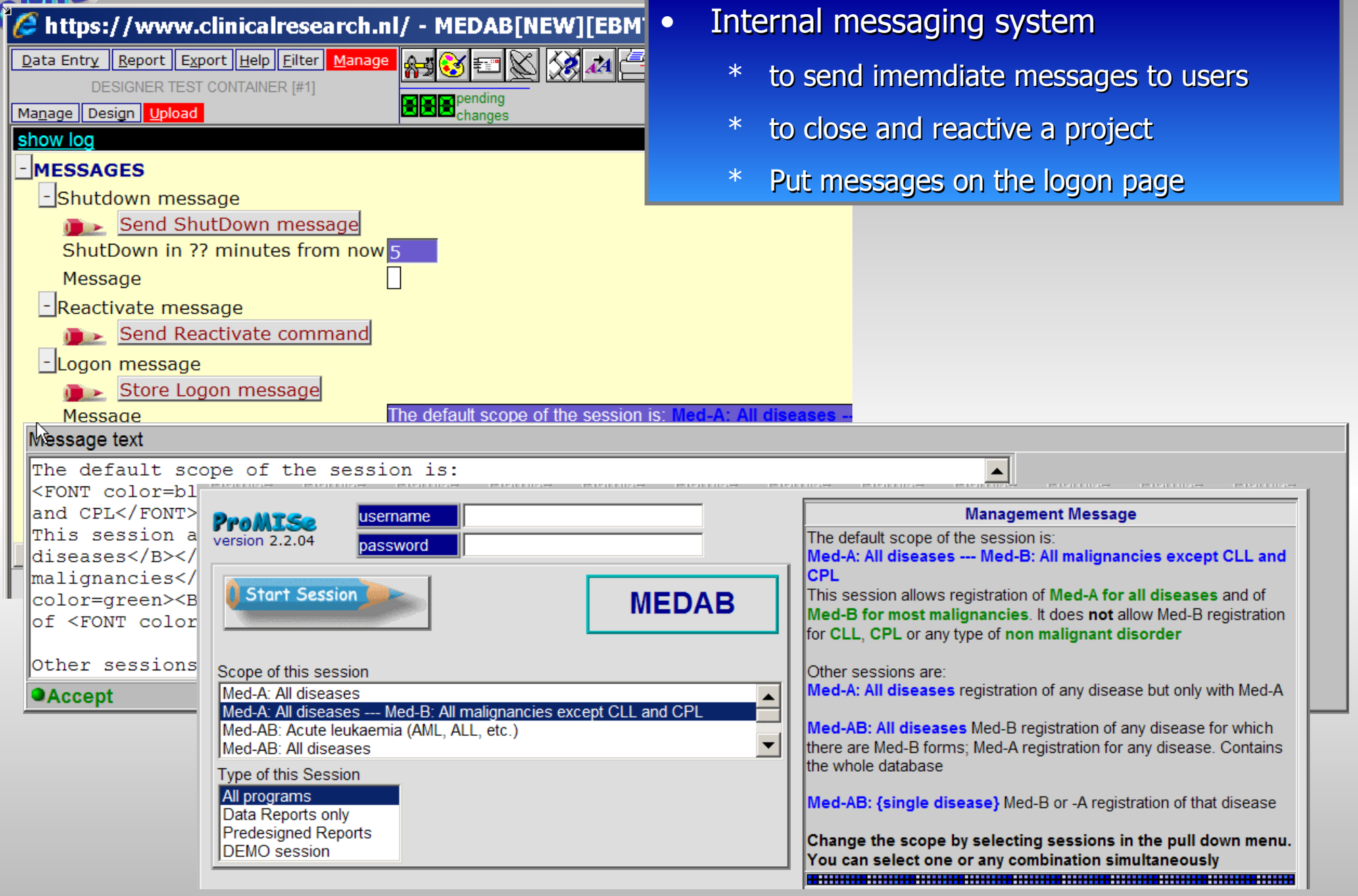
- **BEHAVIOURS**
  - Ctrl S UPDATE ALL PROPERTIES ...
  - Parameters
    - General
    - Data Entry
    - Reports & Exports
    - Additional structures
      - Additional CIC (IDX) support — 3rd
      - Automatic Country support — automatic
    - Locking & Monitoring structure
      - Modification Lock Support — project coordinator
      - Analysis/Report Lock Support
      - Synchronization Lock Support
      - PINcode support for Data Contribution Facility
  - Actions
    - Auto-start DataEntry
    - Auto-create user for new center
    - Frequency Chart on logon page
      - Graph item(s)
      - CIC
      - Height in pixels
      - Width in pixels
      - Type of graph(s)
  - Authorization Defaults
    - DEMO version access (max.auth.level)
    - DEMO version password (optional)
    - Security Level
    - On logon to any Container (CIC=0,2,3,...9)
    - On logon to any CIC (>=10)
    - Password Expiration
  - Publication/Subscription
    - Subscription parameters

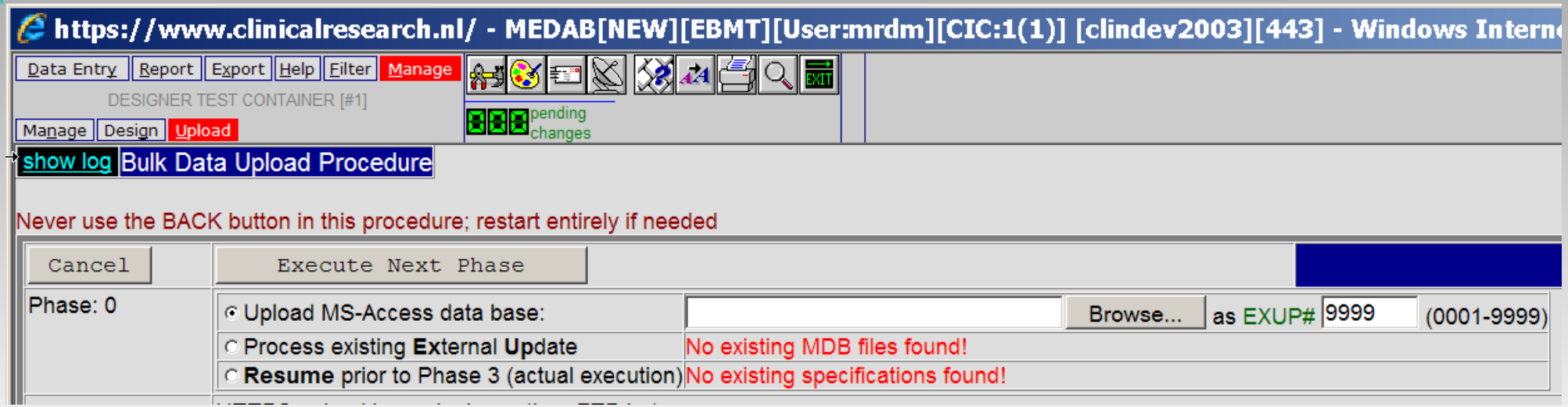
- Special parameters allow fine tuning of projects beyond the standard behaviour assummed by ProMISe



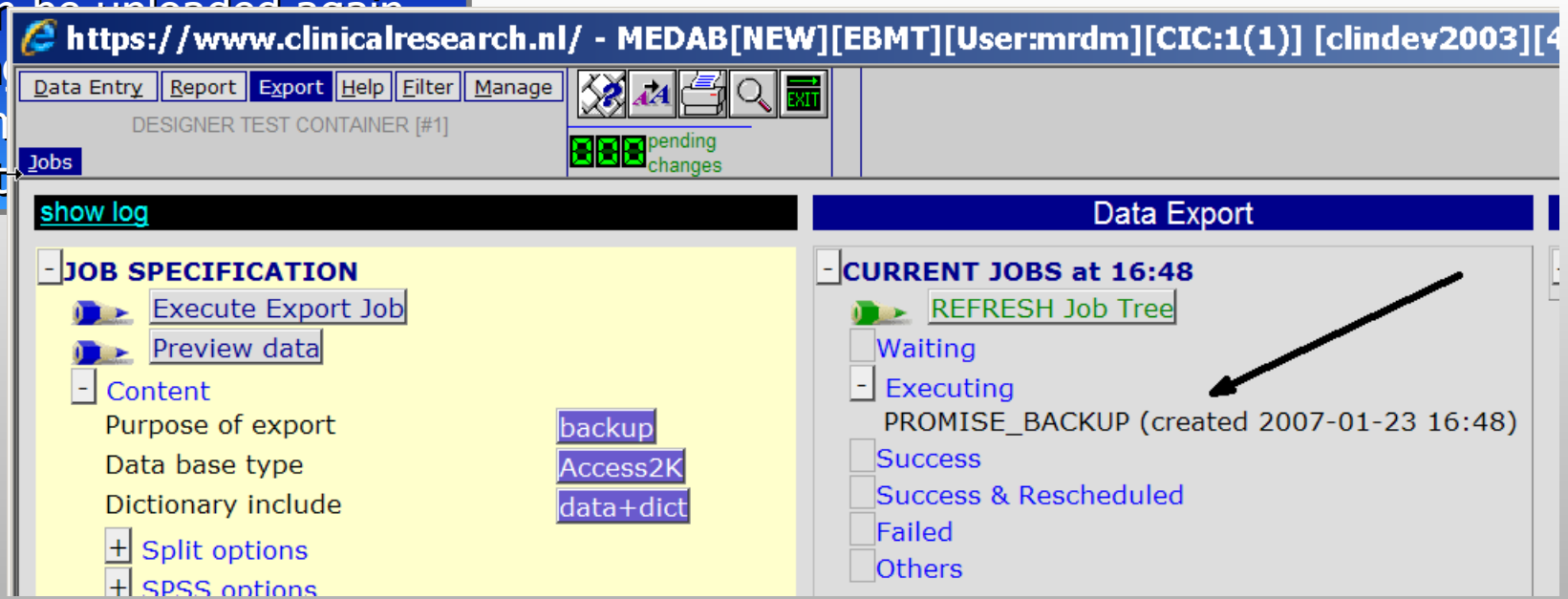

https://www.clinicalresearch.nl/ - MEDAB[NEW][EBMT][User:mrdm][CIC:1(1)] [clindev2003][443] - Windows Inter
Data Entry
Report
Export
Help
Filter
Manage
DESIGNER TEST CONTAINER [#1]
Manage
Design
Upload
pending changes
FUNCTIONS
Jsf_AGE
Jsf_AGEDIAGN
Jsf_AGEDONOR
Jsf_AGETRT
Jsf_CENTRE
Jsf_ch_cause_death
Jsf_CIC_1
Jsf_CIC_2
Jsf_CIC_3
Jsf_cn_ANCODE1
Jsf_cn_BBDATE
Jsf_cn_BCCODE
Jsf_cn_BCOUNTRY
Jsf_cn_BECODE
Jsf_cn_BEDATE
Jsf_cn_CENTRNR
Jsf_cn_CREATOR
Jsf_cn_DATWDS
Jsf_cn_DIFFUSIN
Jsf_cn_EBMTREG
Jsf_cn_exinvivo
Jsf_cn_GRAVHOSD
Jsf_cn_INFEEVEN
Jsf_cn_LGRAFTL
Jsf_cn_METASTAT
Jsf_cn_MODIFIER
Jsf_cn_NATREG
Jsf_cn_NBRCRBG
Jsf_cn_negposse
FUNCTION OBJECT (Production)
Ctrl S
SAVE Modified Functions (temporarily)
Current Function ...
Function Name
AGEDIAGN
To be used as Formula for ...
AGEDIAG
Attached to table ...
BB_
Application type
Unconditional
Items supplied as parameters
DATPATBD~IDAABB
Modify Function
Test Function
Show ...
Apply ...
Return & Parameter values for testing
{returnValue}
DATPATBD
IDAABB
• Support for JavaScript functions defining formula items allowing retrospective calculation on existing data also
FUNCTION
function Jsf_AGEDIAGN(){
// here follows your function body specification ...
var parms=arguments[0];
var currentValue=parms[0];
var DATPATBD=parms[1];
var IDAABB=parms[2];
if (DATPATBD!=null)
{if (JS_DATEDIFF('yyyy','1900/01/01',DATPATBD)>0)
{var dif=JS_DATEDIFF('d',DATPATBD,IDAABB);
if (dif>=0){return(dif/365.2)}
}
else
{return(99.9)}
}
else
{return(99.9)}
return(null); // as a safety measure, if logic comes here, we return null-value
}
• a non-null returnValue is used to fill item [AGEDIAG]
• this function is attached to table [BB_] and therefore accepts items on that table or its parents as parameters

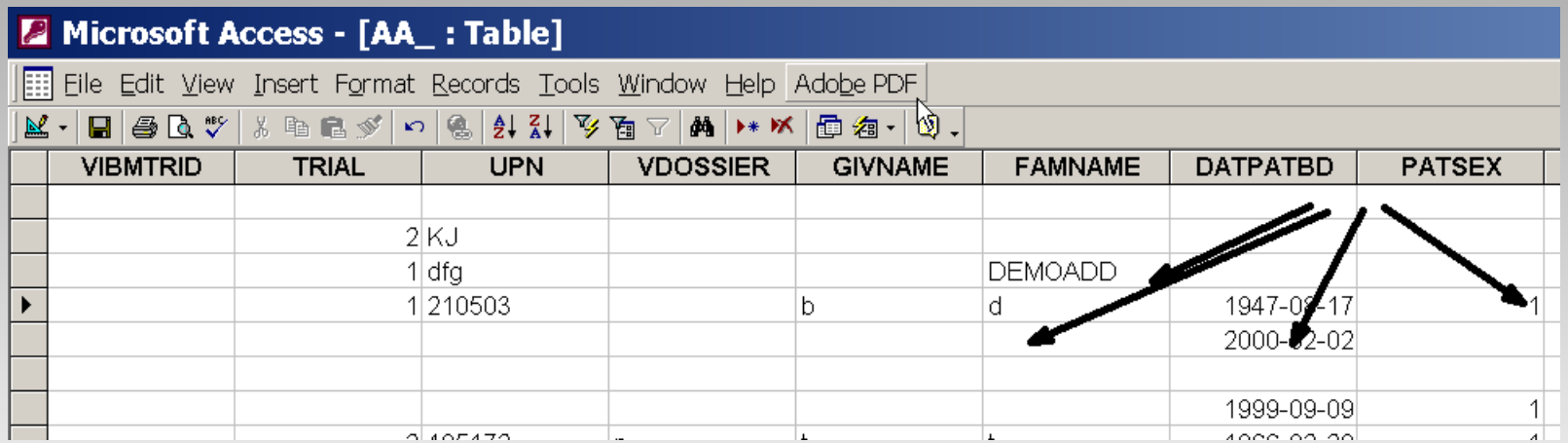
- Internal messaging system
  - to send imemdiate messages to users
  - to close and reactive a project
  - Put messages on the logon page



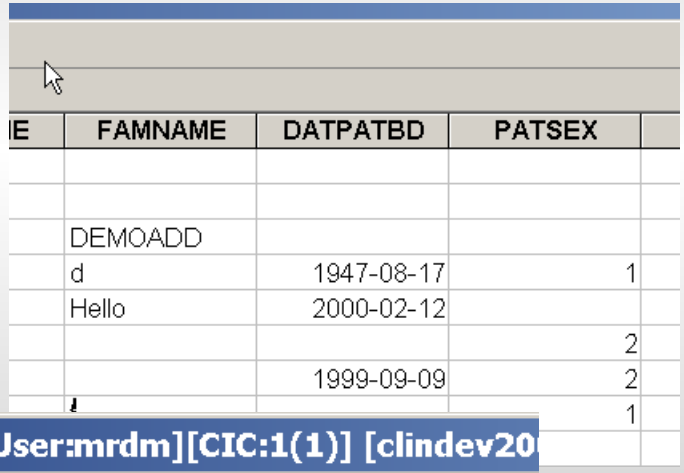


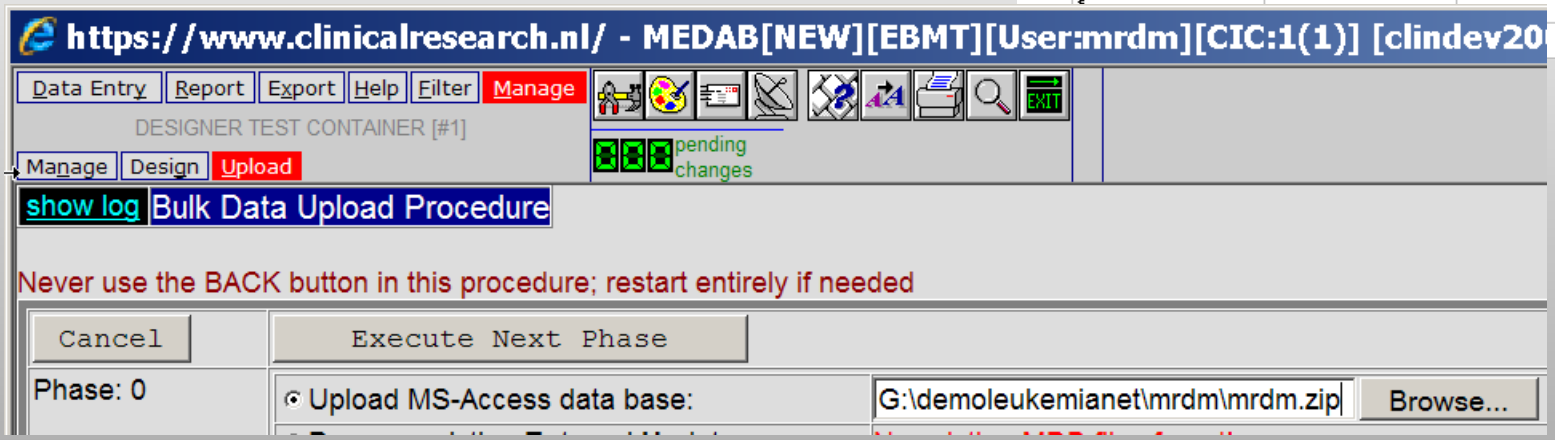
- After EXPORTING (a part of) the data, the resulting MS-Access MDB file can be uploaded again (after adding data) and in base almost

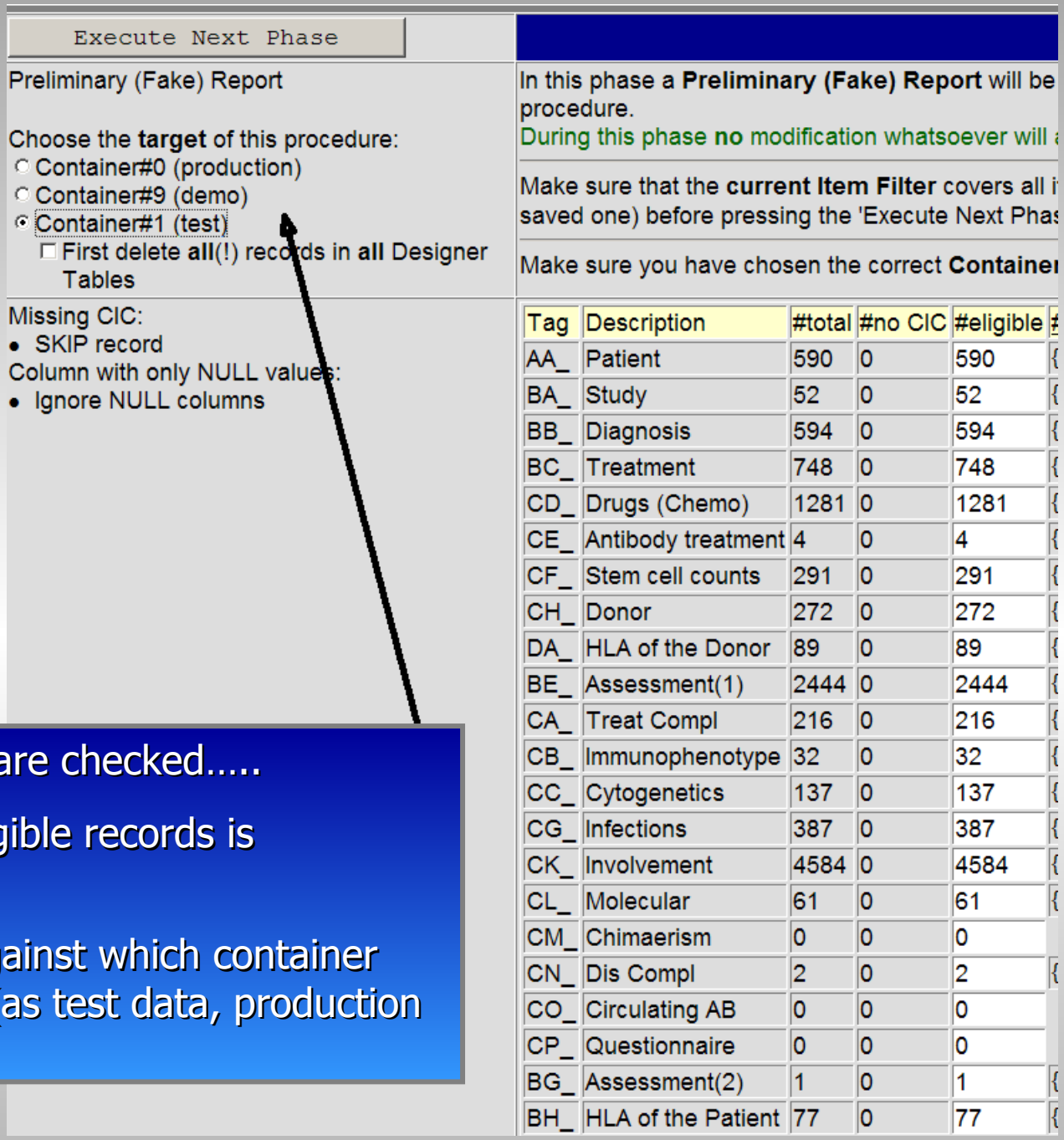




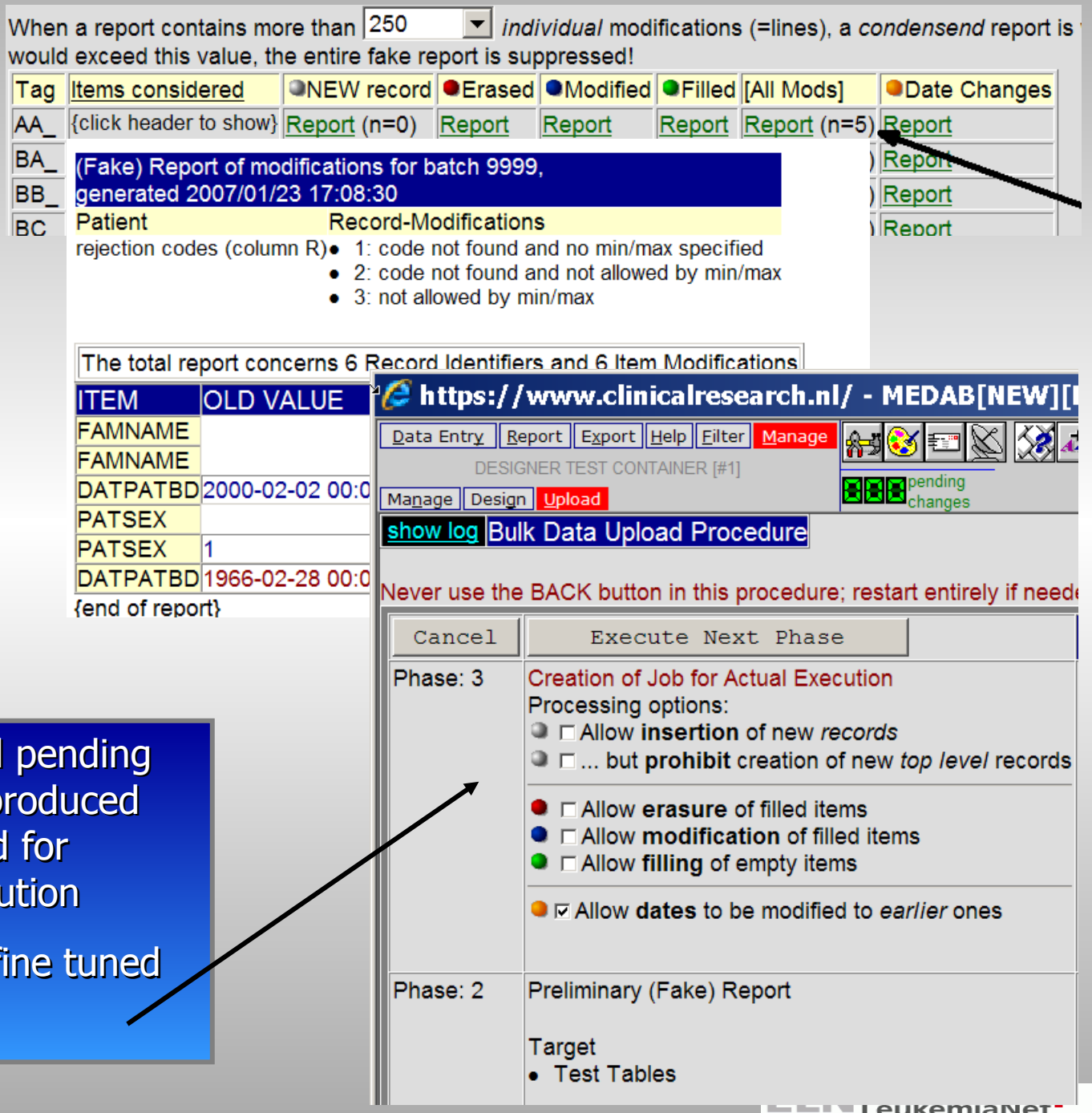
- In Access we add, modify and delete some fields….
- … and then zip the file again and upload it…..



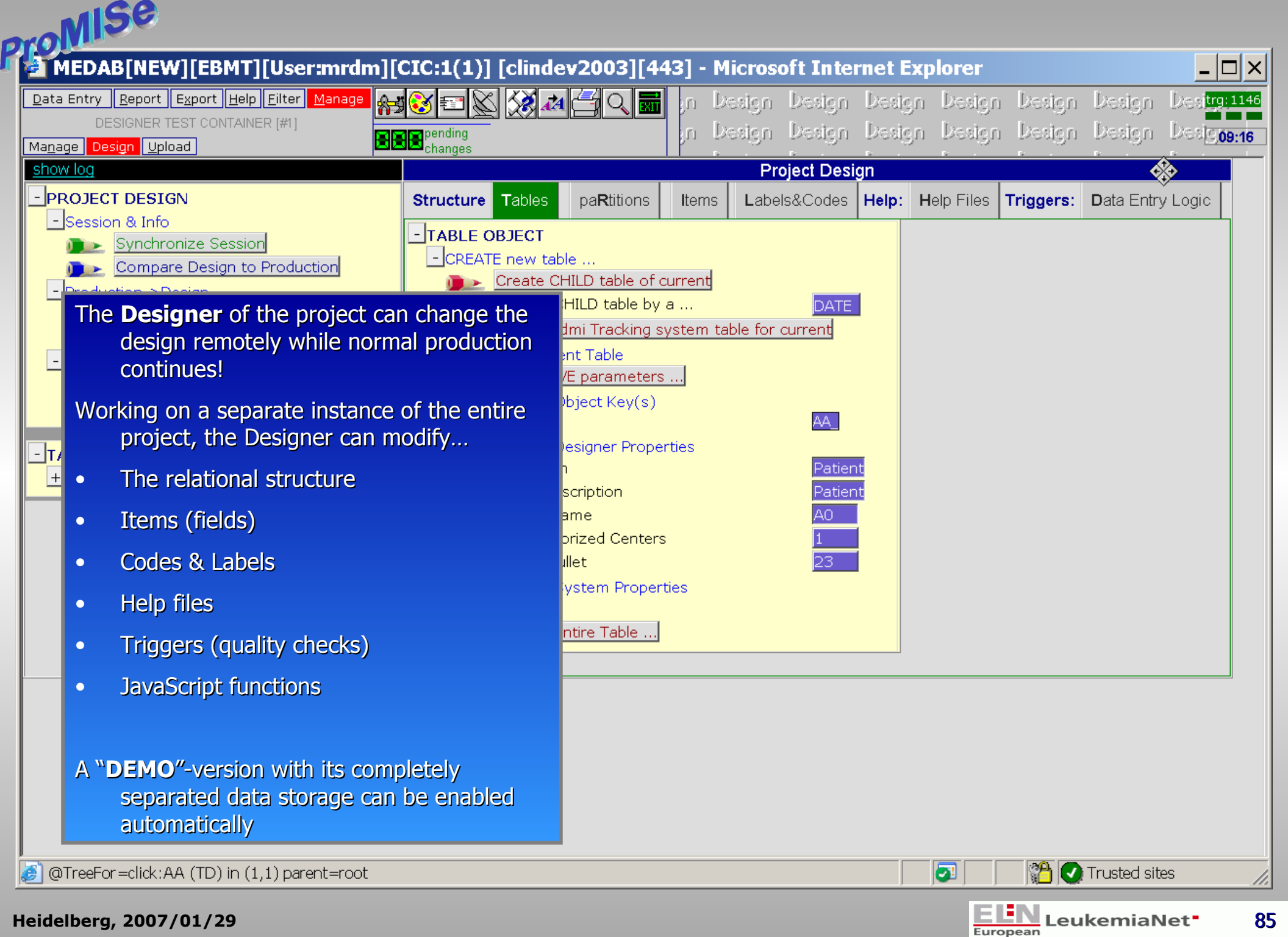




- Contents of the uploaded file are checked…..
- …. And an overview of the eligible records is produced….
- Then the Manager chooses against which container the data should be uploaded (as test data, production data or demo data)



- Finally overviews of all pending modifications can be produced (and even downloaded for analysis) prior to execution
- Actual upload can be fine tuned

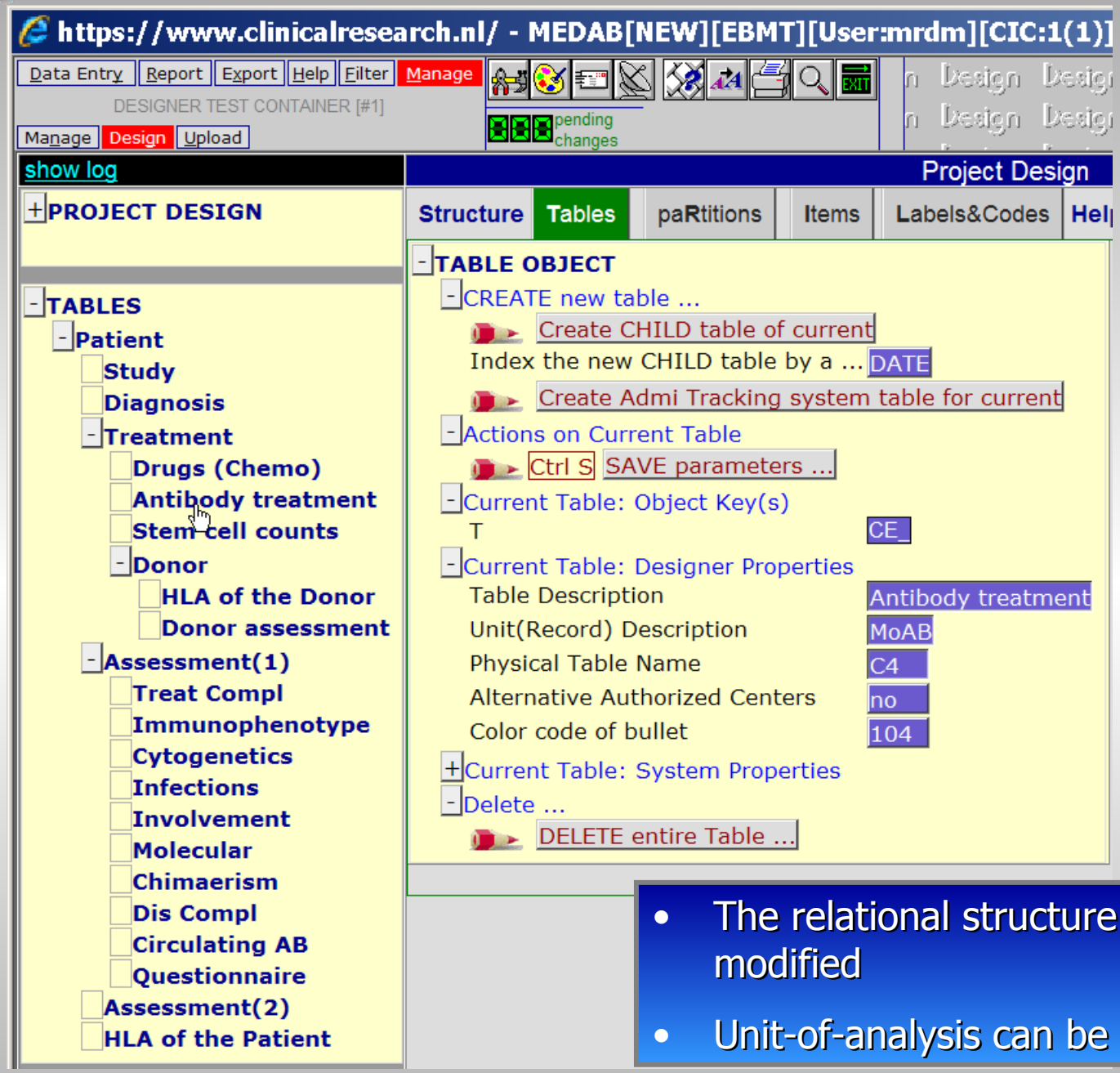


The **Designer** of the project can change the design remotely while normal production continues!

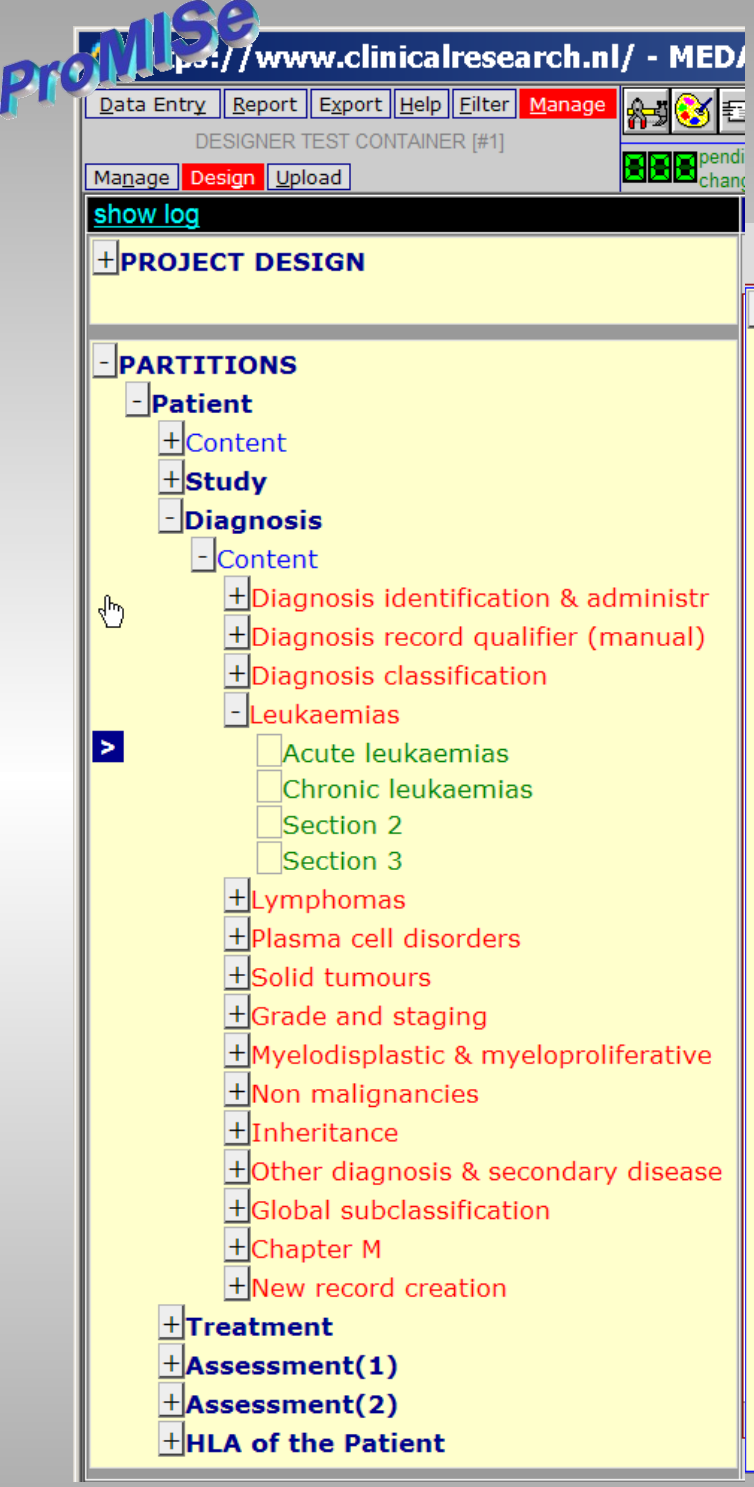
Working on a separate instance of the entire project, the Designer can modify…

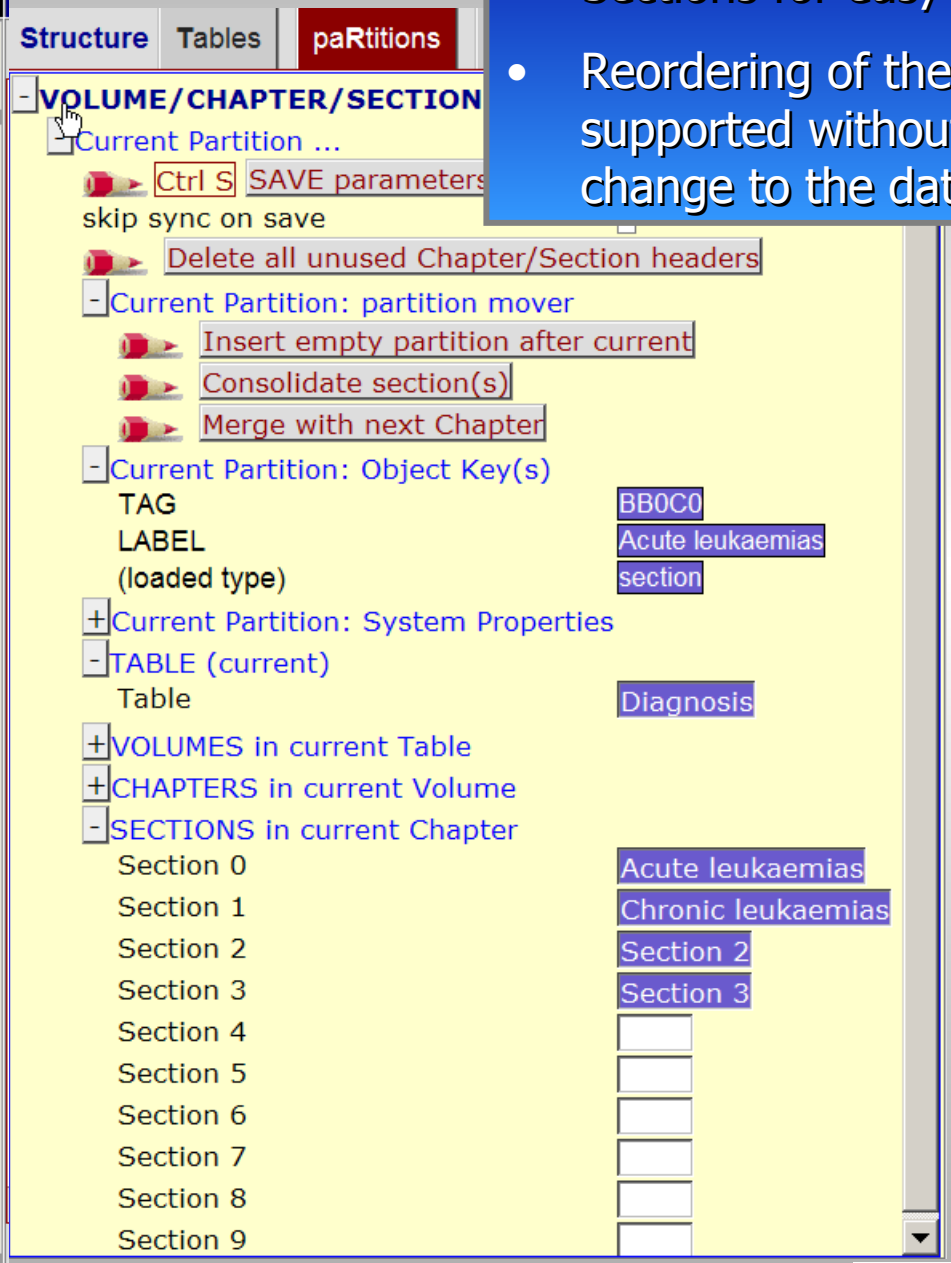
- The relational structure
- Items (fields)
- Codes & Labels
- Help files
- Triggers (quality checks)
- JavaScript functions

A "**DEMO**"-version with its completely separated data storage can be enabled automatically

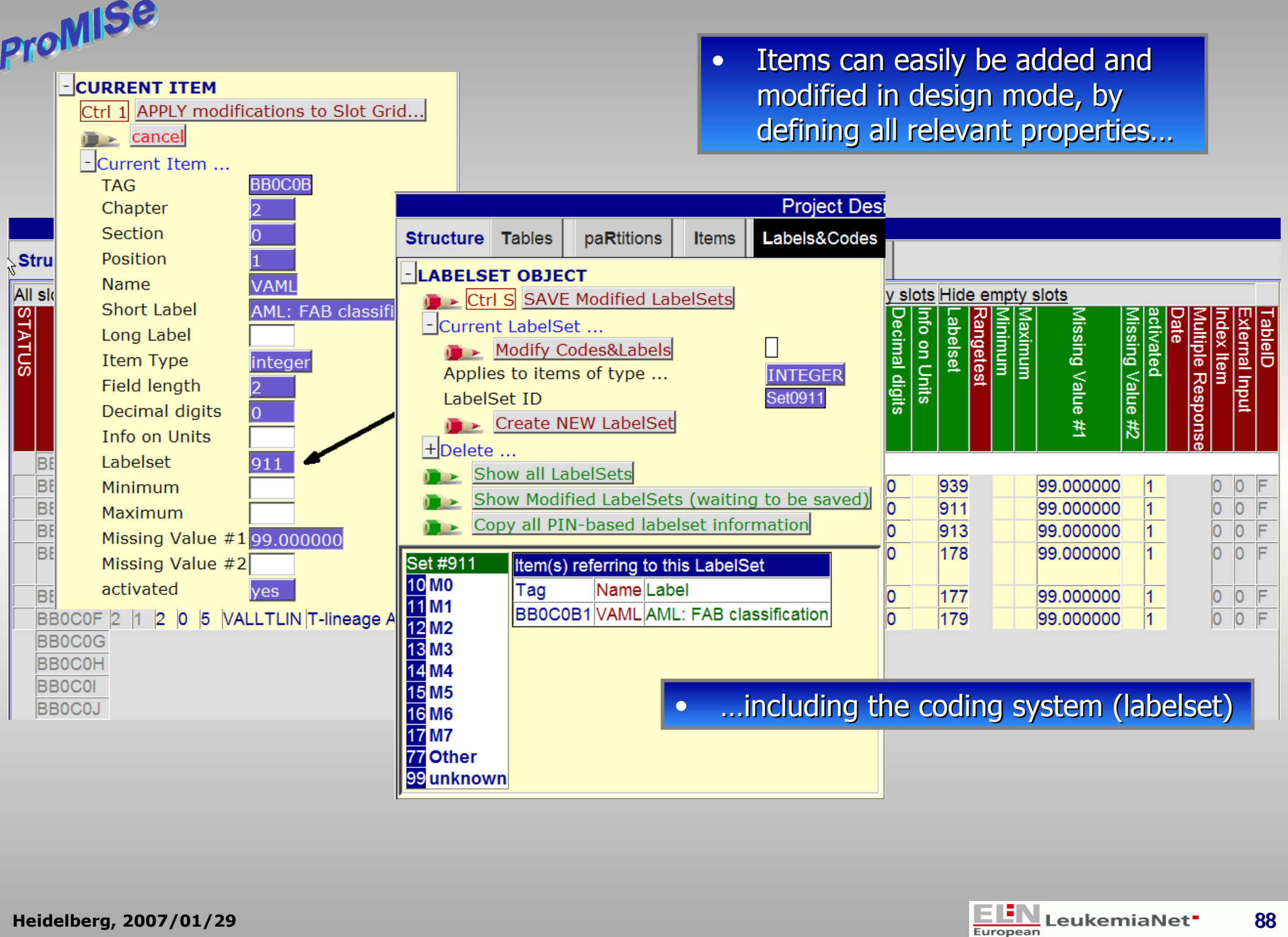


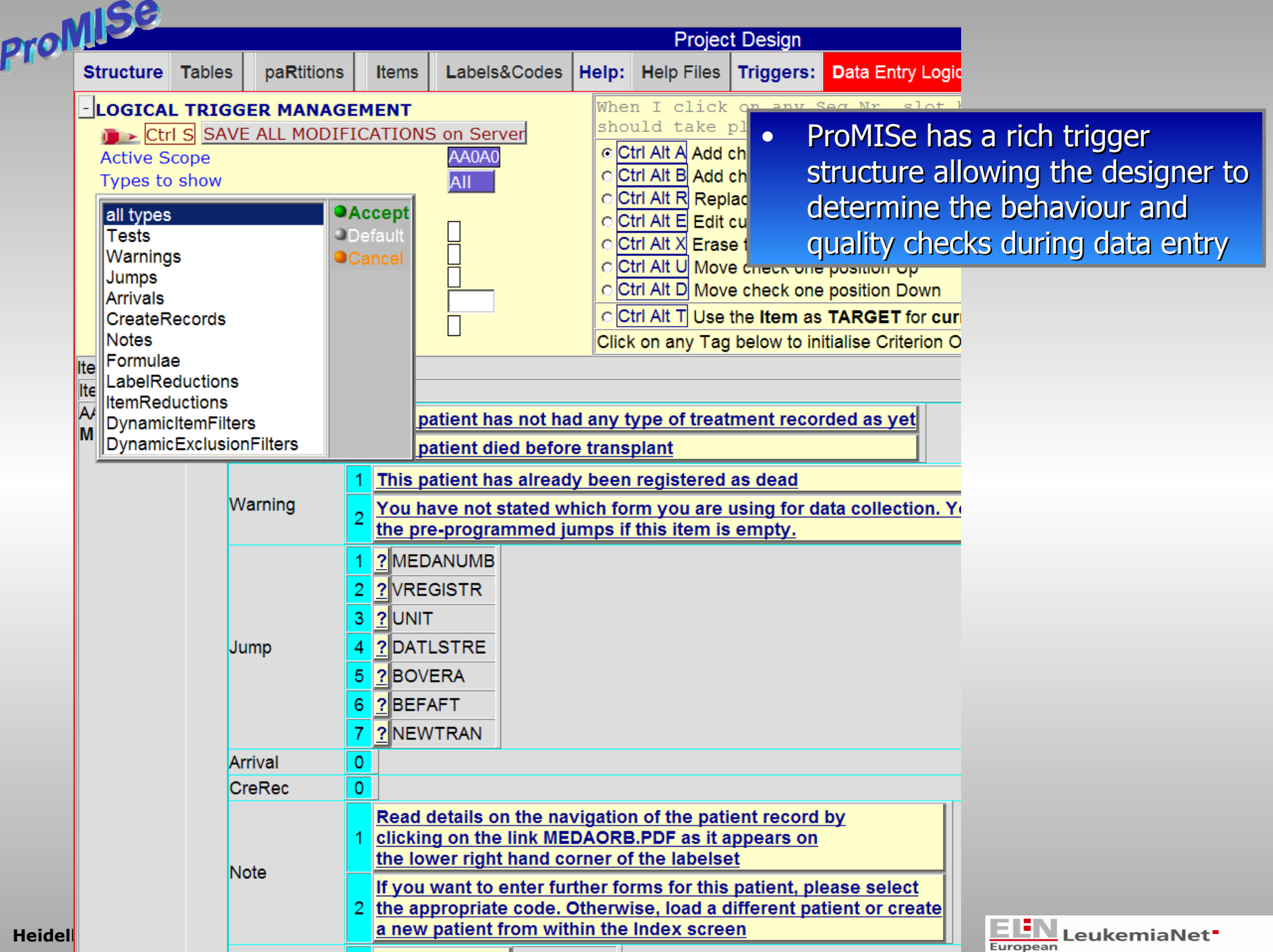
- The relational structure can be modified
- Unit-of-analysis can be defined



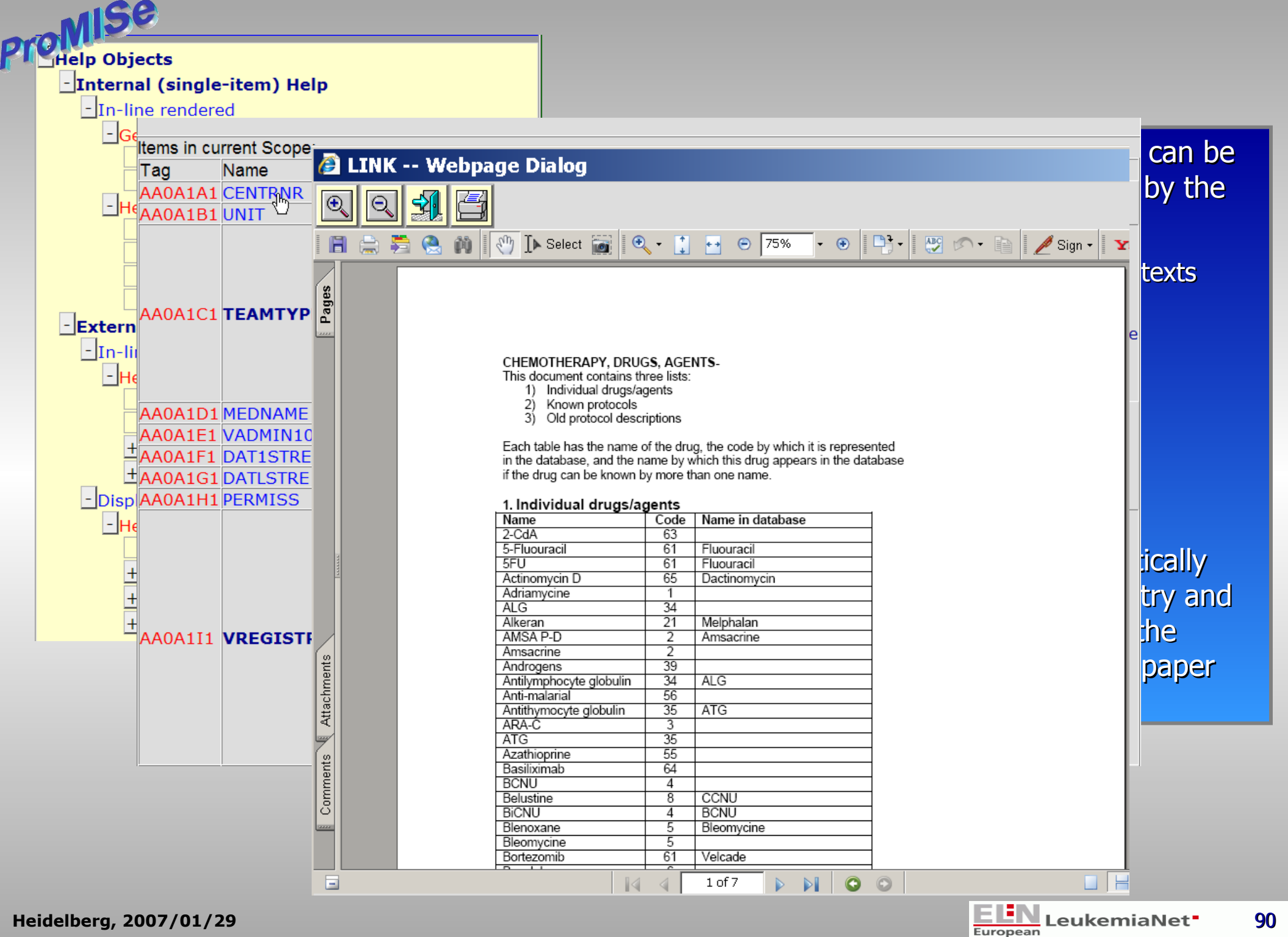


- The items in each table can be organized into Chapters and Sections for easy reference
- Reordering of these partitions supported without physical change to the data base


ProMISe
CURRENT ITEM
Ctrl 1
APPLY modifications to Slot Grid...
cancel
Current Item ...
TAG BB0C0B
Chapter 2
Section 0
Position 1
Name VAML
Short Label AML: FAB classifi
Long Label
Item Type integer
Field length 2
Decimal digits 0
Info on Units
Labelset 911
Minimum
Maximum
Missing Value #1 99.000000
Missing Value #2
activated yes
Project Desi
Structure
Tables
paRtitions
Items
Labels&Codes
LABELSET OBJECT
Ctrl S
SAVE Modified LabelSets
Current LabelSet ...
Modify Codes&Labels
Applies to items of type ... INTEGER
LabelSet ID Set0911
Create NEW LabelSet
Delete ...
Show all LabelSets
Show Modified LabelSets (waiting to be saved)
Copy all PIN-based labelset information
Set #911
10 M0
11 M1
12 M2
13 M3
14 M4
15 M5
16 M6
17 M7
77 Other
99 unknown
Item(s) referring to this LabelSet
Tag Name Label
BB0C0B1 VAML AML: FAB classification
y slots
Hide empty slots
STATUS
Decimal digits
Info on Units
Labelset
Rangetest
Minimum
Maximum
Missing Value #1
Missing Value #2
activated
Date
Multiple Response
Index Item
External Input
TableID
BB0C0F 2 1 2 0 5 VALLTLIN T-lineage A
BB0C0G
BB0C0H
BB0C0I
BB0C0J
• Items can easily be added and modified in design mode, by defining all relevant properties...
• ...including the coding system (labelset)



- ProMISe has a rich trigger structure allowing the designer to determine the behaviour and quality checks during data entry


Help Objects
Internal (single-item) Help
In-line rendered
Items in current Scope
Tag
Name
AA0A1A1 CENTRNR
AA0A1B1 UNIT
AA0A1C1 TEAMTYP
AA0A1D1 MEDNAME
AA0A1E1 VADMIN1C
AA0A1F1 DAT1STRE
AA0A1G1 DATLSTRE
AA0A1H1 PERMISS
AA0A1I1 VREGISTR
LINK -- Webpage Dialog
Select
75%
Sign
Pages
Attachments
Comments
CHEMOTHERAPY, DRUGS, AGENTS-
This document contains three lists:
1) Individual drugs/agents
2) Known protocols
3) Old protocol descriptions
Each table has the name of the drug, the code by which it is represented in the database, and the name by which this drug appears in the database if the drug can be known by more than one name.
1. Individual drugs/agents
Name | Code | Name in database
2-CdA | 63 |
5-Fluouracil | 61 | Fluouracil
5FU | 61 | Fluouracil
Actinomycin D | 65 | Dactinomycin
Adriamycine | 1 |
ALG | 34 |
Alkeran | 21 | Melphalan
AMSA P-D | 2 | Amsacrine
Amsacrine | 2 |
Androgens | 39 |
Antilymphocyte globulin | 34 | ALG
Anti-malarial | 56 |
Antithymocyte globulin | 35 | ATG
ARA-C | 3 |
ATG | 35 |
Azathioprine | 55 |
Basiliximab | 64 |
BCNU | 4 |
Belustine | 8 | CCNU
BiCNU | 4 | BCNU
Blenoxane | 5 | Bleomycine
Bleomycine | 5 |
Bortezomib | 61 | Velcade
1 of 7
can be
by the
texts
tically
try and
the
paper

ProMISe2: summary

ProMISe2 is a self-learning and programmer-independent environment …

- to design and manage any clinical study
- from any place in the world
- offering a secure storage of privacy sensitive data
- in industry-standard data bases
- with automatically generated web pages
- for data entry & output via secure Internet
- with conversion to other data base systems or statistical software.

Just like …

- a text-editor is a generic tool to write anything from a simple letter to a complicated book
- ProMISe2 is a tool to create any clinical data management environment, from simple studies to complicated ongoing disease registrations or clinical trials

Conclusions from 8 years development & production experience

- It is possible to design generic software for Internet based multi center data management projects that is …
  * tailored to the needs of data managers, statisticians and clinicians in various situations
  * to be maintained by a single person
  * to safeguard the link between protocol logistics, data base structure and statistical analyses
  * to allow a non-information scientist to create and maintain complex large scale projects
  * to convinces research organisations to accept a fixed interface in return for fast development and mutual benefit
- It is however required to maintain an overview of all projects realized in order to assess which improvements can and should be implemented so running projects are not "harmed" but instead may benefit from them

Acknowledgement

- A major part of the development of ProMISe has been financed by the EBMT; its European data base is currently the largest project run by the software
- The dedication of the EBMT to run its permanent registry with high data quality and (future) clinical trials efficiently as well as the desire to link its data in a flexible way to other scientific projects, has triggered the development of most of the features in ProMISe
- Other projects and scientific organizations have already benefited from these long term investments

E-mail: R.BRAND@LUMC.NL