



Project Manager Internet Server3

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

Ronald Brand & Henk Jan van der Wijk

**Professor of Good Research Data Management, Biostatistician
& Scientific Programmer**

**Department of Medical Statistics, section Advanced Data Management
Leiden University Medical Center**



Objectives of the Section Advanced Data Management, LUMC

- Full integration of data management and statistics as a support structure for clinical scientific research in the broadest sense of the word
- Providing generic, cost effective and user friendly data management infrastructures to clinical researchers, data managers, patients and statisticians
- Fine tuning of the data collection to the scientific use of the data by researchers, statisticians and data managers
- Broad support by an independent Department of Biostatistics with knowledge of both data management and statistical methodologies for the analysis of outcome parameters and peer review in multi center situations

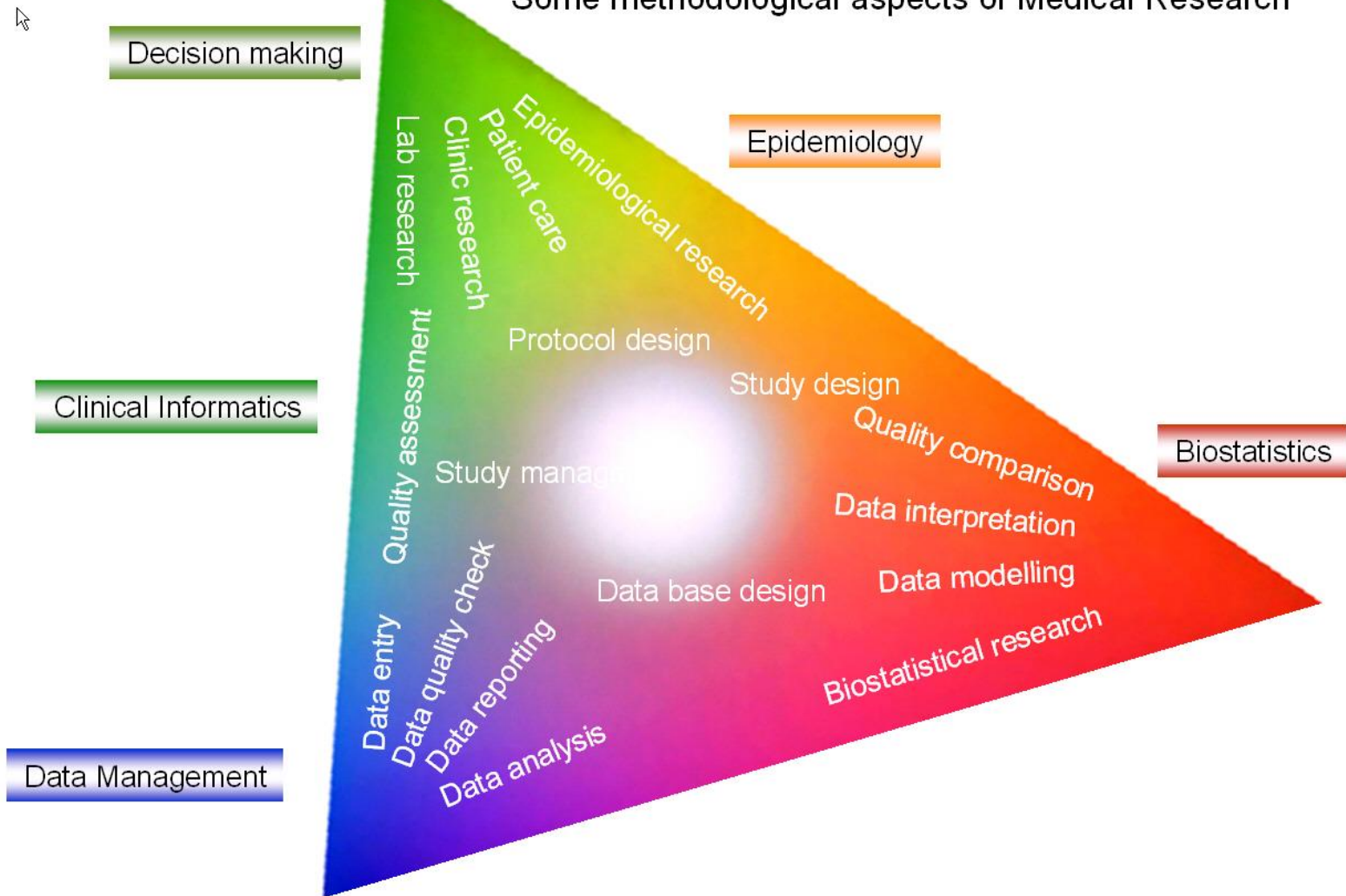


Objectives of the Section Advanced Data Management, LUMC

- Since the inception of ProMISe, the software in use to build infrastructures for clinical research, we have done that for **35** research organizations in the Netherlands and abroad in over **200** projects, with **15.000** users on-line in **480.000** sessions working on over **5.000.000** patient and followup records and an audit trail of over **100.000.000** modifications to data elements.
- Subjects are e.g. bone marrow transplantation, cardiology, perinatology, pediatrics, internal medicine, orthopedics, psychiatry, neurology, neurosurgery, ophthalmology, gynecology, general surgery, traumatology and oncology
- Also policy-supporting registrations as a mortality audit in collaboration with the Dutch Insurance Companies, incident alerts, the nationwide orthopedic implants registry and quality comparisons of hospitals like the DSCA
- We study for example prostheses, pacemakers, heart defects, decision trees, aneurysms, traumas, Parkinson patients, hernias, blood transfusions, neuro modulation, migraine and colorectal tumors.



Some methodological aspects of Medical Research



Integration, coordination and unification



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 and Security

- 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
- All connections encrypted and secure
- Entire approach NEN7510 certified by Lloyds Quality Register
- Complete user management with the possibility of fine tuning access rights, scope of sessions, data locking, strong authentication



CONCOR: National Registry of cardiac events among patients with inborn cardiac malformations

Currently 13.600 patients, 60.000 events

DIPR: National Registry of all cardiac implants (pacemakers)

Currently 194.000 patients, 260.000 procedures



CONCOR
Congenital Cor Vitia

Homepage
Background
Organisation
Centers
Methodology
Progress
Newsletters
Research projects
F.A.Q.
For researchers
Links

National registry and DNA-bank of adult patients with congenital heart disease

Meld u aan !
(only for Dutch inhabitants)

phone: +31-20-5668679
mobile: +31-6-13940558
e-mail: info@concor.net

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?:

Generates EPD-like patient overviews for inclusion in patient files

CIDR: National Registry of all PCTA and THVI procedures

ORTHOPAEDICS

LROI: National Registry of all Hip & Knee implants

Currently 116.000 hips, 83.000 knees

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



QUALITY REGISTERS

DSCA

DSCA: Dutch Surgical Colorectal Audit

Currently 26.000 colon/rectum surgical procedures

DS?A: Dutch Surgical Audit: quality indicators among hospitals

Support from Ministry & Insurers for 8 additional Quality Registers

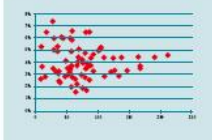


ProMISe

De dataverzameling van de DSCA is gebaseerd op het datamanagementsysteem ProMISe (Project Manager Internet Server) van de afdeling Medische Statistiek en Bio-informatica, sectie Advanced Data Management (ADM) van het Leids Universitair Medisch Centrum. ProMISe biedt een generieke infrastructuur voor medisch datamanagement over het internet en heeft strengbeveiligde webbased datamanagement mogelijk gemaakt in meer dan honderd projecten met zo'n 5.000 gebruikers in vele ziekenhuizen in Nederland en in Europa. De sectie ADM en de architectuur van alle ProMISe projecten zijn onlangs door Lloyd's gecertificeerd volgens de NEN-7511 norm. De sectie ADM ontwerpt en ondersteunt met ProMISe uiteenlopende projecten zoals langlopende (inter)nationale registraties, clinical trials en questionnaires, maar ook kleine academische registraties met als uitgangspunt de structurering en inbedding in het wetenschappelijk onderzoek en de kwaliteitscontrole. Belangrijke begrippen bij het ontwerpen van projecten zijn analyseerbaarheid, efficiency, kwaliteitsborging, veranderbaarheid, veiligheid en privacybewaking. Bij de implementatie van de DSCA en een aantal andere ProMISe projecten wordt de sectie ADM ondersteund door de Stichting IVZ. Nadere informatie over ProMISe is te vinden op www.msbi.nl/promise.

orectal Audit

2009
registratie;
kwaliteit van zorg



DUTCH INSTITUTE FOR CLINICAL AUDITING

DSCA | DUCA | DBCA | DLSA

NIEUWS

Breast cancer; Lung cancer; esophagus cancer

All clinical trials within the Surgery Data Centre

+/- 8000 patients and > 50.000 follow up records

TRAUMA SURGERY



National and regional registries of all accidents in the Netherlands

>330.000 incidents, fully classified according to AIS score

Acute Zorgnetwerken

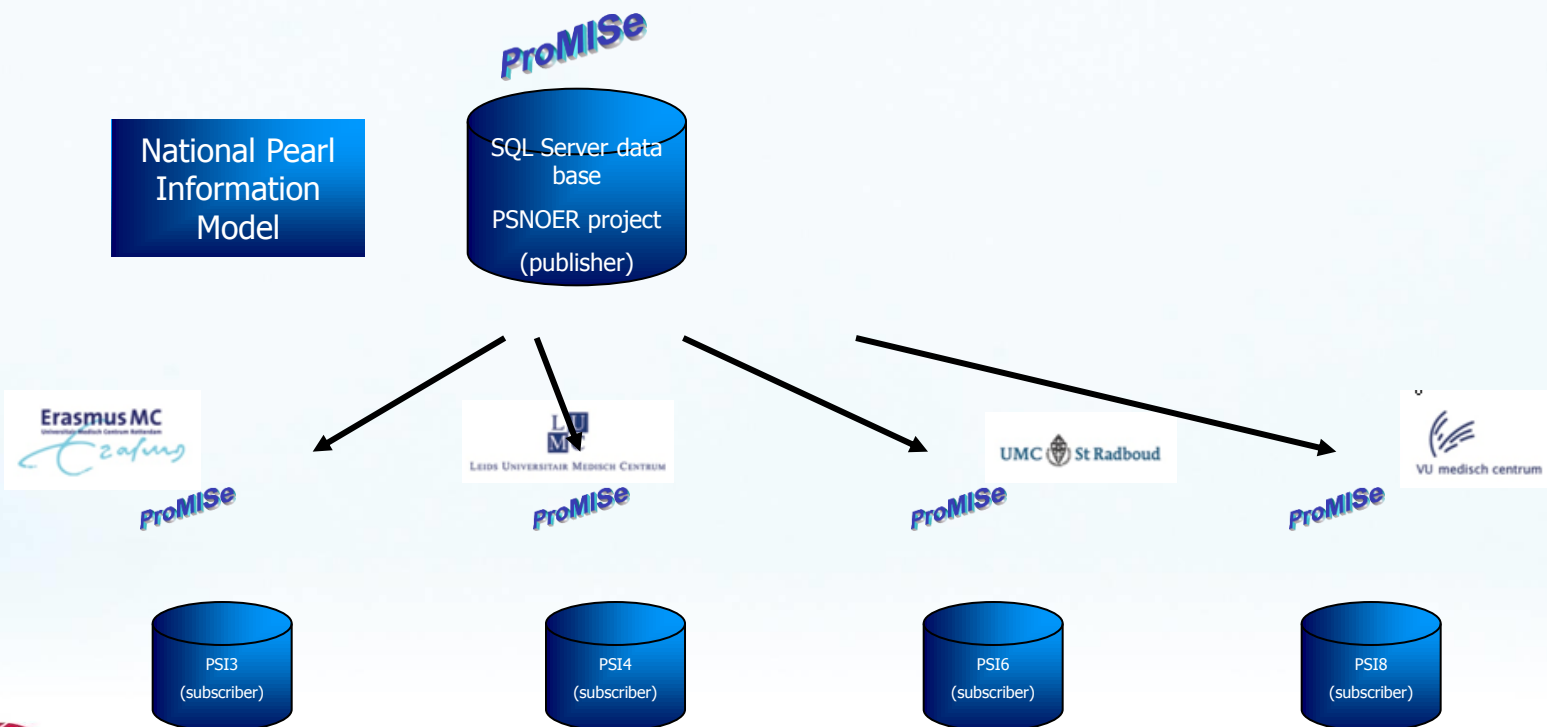


| DIAGNOSE GEGEVENS | |
|--------------------|-------------|
| Diagnose regio | 63 Abdom |
| Diagnose categorie | 2991 Spleen |
| AIS-code | |
| Omschrijving | |

| | |
|---------|--|
| 5442102 | [Abdom] {Spleen} contusion (hematoma) NFS |
| 5442122 | [Abdom] {Spleen} contusion (hematoma) minor (superficial; subcapsular; <= 50% surface area; OIS Gr |
| 5442143 | [Abdom] {Spleen} contusion (hematoma) major (subcapsular > 50% surface area or expanding) OIS Gr |
| 5442202 | [Abdom] {Spleen} laceration NFS |
| 5442222 | [Abdom] {Spleen} laceration minor (superficial) OIS Grade I or II |
| 5442243 | [Abdom] {Spleen} laceration moderate (no hilar or segmental parenchymal disruption or destruction) OIS |
| 5442264 | [Abdom] {Spleen} laceration major (involving segmental parenchymal disruption or destruction with no h |
| 5442285 | [Abdom] {Spleen} laceration massive (with hilar disruption) OIS Grade V |
| 5442403 | [Abdom] {Spleen} rupture ('fracture') NFS |
| 5442992 | [Abdom] {Spleen} NFS |

Hierarchical coding systems with stepwise refinement

PSI: String of Pearls Initiative





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

- 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

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





ProMISe: summary

ProMISe 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 ...

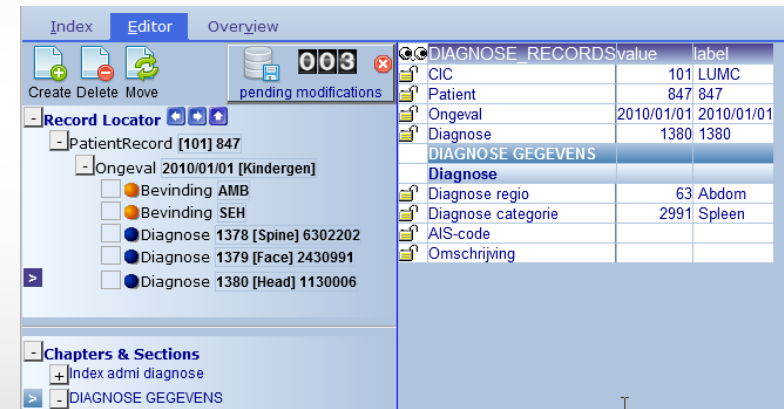
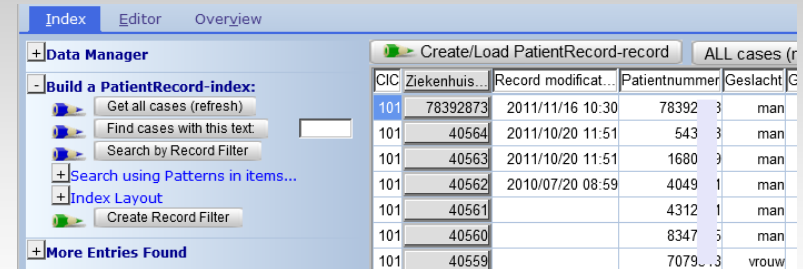
- a text-editor is a generic tool to write anything from a simple letter to a complicated book
- ProMISe is a tool to create any clinical data management environment, from simple studies to complicated ongoing disease registrations or clinical trials



ProMISE features: Data Entry



- Index to all cases (or any selection)
 - * Quickly find cases based on (partial) texts
 - * Complex criterion selector
 - * Pattern searches in and sorting any item
 - * History of previously loaded cases
- Data Entry Editor
 - * Full relational overview of all records for a case
 - * Quick overview of chapters and sections
 - * Full quality checking during data modifications
- Overview in different formats including quality checks
 - * Status, quality and time track overviews
 - * Overview of pending modifications
 - * Overview of current values on server



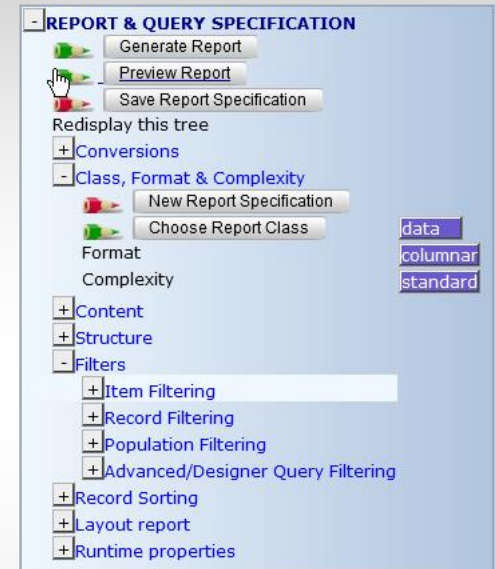


ProMISe features: Reports



- Specification

- * Status, columnar, quality, survival, descriptive statistics
- * Different complexity levels
 - Simple: just select items and optionally record filters
 - Advanced: menu guided specification of complex queries
 - Designer: arbitrary T-SQL
 - Stored functions, procedures and views
 - Post-processing after save of modifications
 - Fully automatic Microsoft Webservice creation
 - Log reports: retrieve info on any modification to any data item
- * Store any specification for private or public use
 - Share queries with other users or centers
 - Auto-run specification

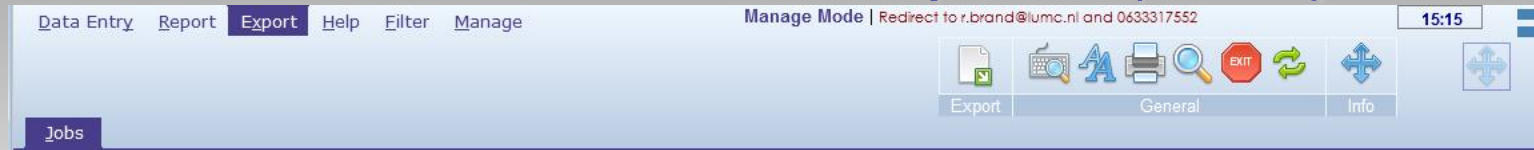


- Output

- * Columnar reports: switch between codes and labels; linked to Data Entry and frequency reports
- * Descriptive statistics: linked to Columnar reports
- * Quality reports: document all conditions not (yet) fulfilled



ProMISE features: Exports (Jobs)



- Specification

- * Multiple purposes

- Backup (with relational structure)
 - Report (rectangular result set of arbitrary query)
 - Run+Mail
 - Arbitrary T-SQL jobs
 - SQL-backup
 - Complete Dictionary (meta-data)
 - ProMISE Excel Prototyper (Designer tool for non-ProMISE experts)

- * Multiple formats

- MS-Access; Excel; SPSS; XML; CSV

- * Options

- Automatic split by Center or Registry
 - Removal of identification of Center or Case
 - Excel exports contain library of useful data management tools

- Specification

- * Filtering

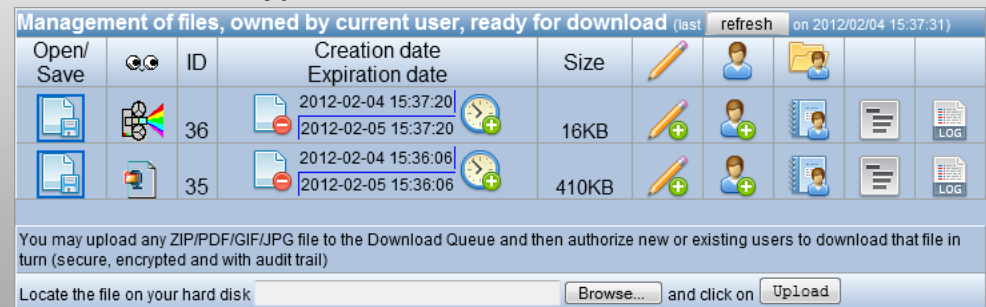
- Arbitrary selection of items
 - Ad-hoc application and/or embedding of record and population filters
 - All exports can be based on advanced or designer queries instead of original relational structure

- * Scheduling

- One-time run; daily, weekly or monthly runs

- Output

- * Zipped with optional password
 - * Placed in Secure Download Facility
 - * Encrypted and audited download

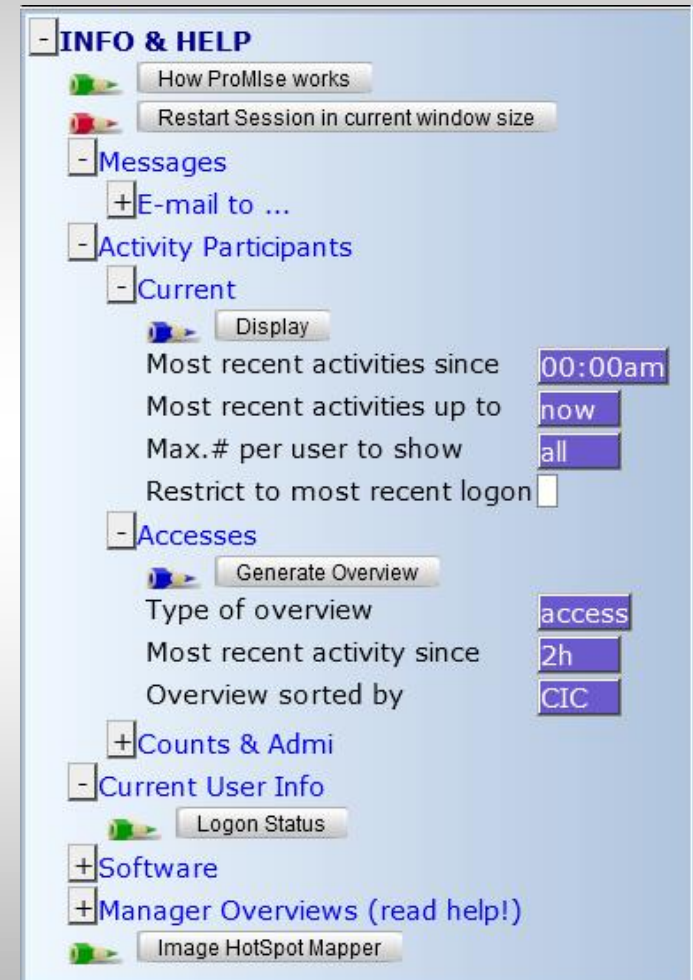




ProMISE features: Help



- Server based e-mails to other users with optional screenshot attachments
- Overview of activities of users
- Overview of project access by users
- Special manager overviews of meta data
- Utility to make arbitrary graphics “clickable” and produce codes for data entry





ProMISE features: Item Filters



- Define and store subsets of Items
 - * Apply these filters to Reports, Exports, Data Entry and Uploads
 - * Store as private or public for reuse
- Define additional properties as...
 - * Paper Coding Forms (pCRF)
 - Empty forms
 - Pre-filled with data from Server
 - * Electronic Coding Forms (eCRF)
 - Automatically generated patient questionnaires
 - Full quality checking
 - Automatic e-mailing of web forms
 - Useful for Randomization, SAE reporting and Quality of Life questionnaires
 - * Server to Server communication (sCRF)
 - In combination with web services data exchange between other servers and the ProMISE project

Patient
Patientnummer
Geslacht (0) vrouw (1) man
Geboortedatum
yyyy / mm / dd

Gegevens ongeval
Oorzaak ongeval (categorie) (1) Onbekend (2) Toegebracht door anderen (4) Verkeer (5) Bedrijfsongeval (6) Prive (8) Sport (9) Zelfmutilatie (11) Anders
Plaats herkomst {add.[1]}

1 = ander (onbekend) ziekenhuis 2=LUMC 3=huisarts 4=plaats ongeval
5=onbekend 6=anders 7=Diaconessenhuis Leiden 8=Rijnland Leiderdorp
9=Bronovo 10=MCH Westeinde 11=MCH Ahoze Leidschendam
12=Hagaziekenhuis/Leyweg 13=Hagaziekenhuis/Sportlaan 14=RdGG Delft
15= t Lange Land 16=Groene Hart, Gouda 17=Rijnland, Alphen ad Rijn
18=Ziekenhuis andere regio 19=Ziekenhuis buitenland

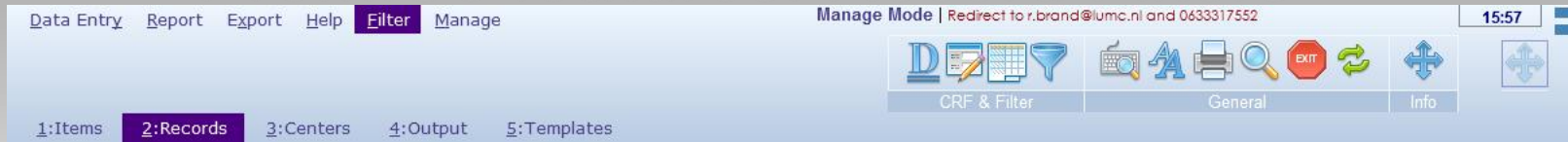
= always required = currently required = currently not required = modified after initialisation

Patient
 Patientnummer
 Geslacht {empty} vrouw man
 Geboortedatum
Gegevens ongeval
Oorzaak ongeval (categorie) {empty}
Plaats herkomst {empty}

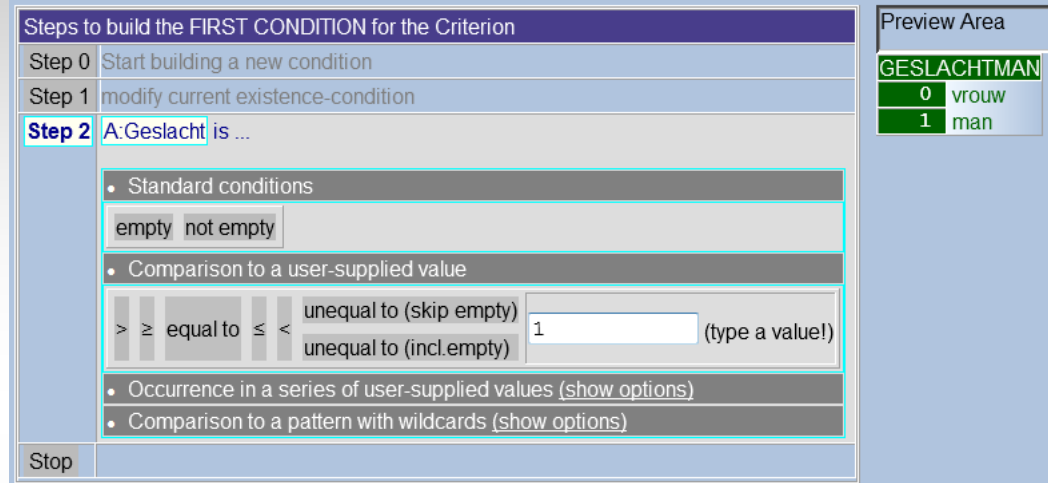
= always required = currently required = currently not required = modified after initialisation



ProMISe features: Record Filters



- Define criteria of arbitrary complexity
 - * Point and click
 - * Completely menu guided
 - * Graphically displayed
- Execute
 - * Preview during building
 - * Turn into index for Data Entry
 - * Embed in Reports/Exports
- Storage
 - * Temporary during session
 - * In a private/public library for re-use





ProMISe features: Center Filters

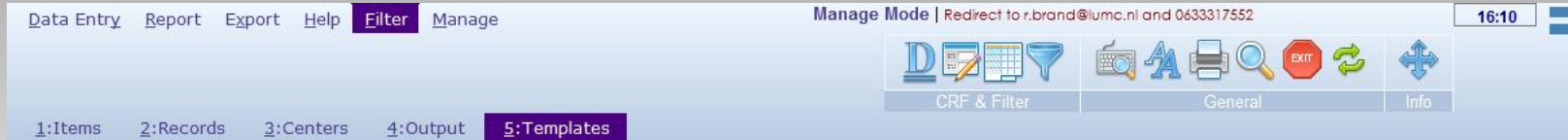


- Switch to any center or registry or study within authorization scope
 - * All actions automatically restrict to the Cluster switched to
 - * Data managers can be authorized to enter data on behalf of other centers
 - * Fine tuning of authorizations after switching


| | | |
|-----|---|--------------------------|
| 132 | - | * Traumacentrum Zwolle |
| 134 | - | * Traumacentrum AMC |
| 150 | ? | St. Elisabeth Ziekenhuis |
| 152 | ? | TweeSteden Ziekenhuis |
| 153 | ? | Jeroen Bosch Ziekenhuis |
| 154 | ? | Bernhoven Ziekenhuis Oss |
| 155 | ? | Franciscus Ziekenhuis |
| 156 | ? | Ziekenhuis Lievensberg |
| 157 | ? | Amphia Ziekenhuis Moleng |
| 158 | ? | Sint Anna Ziekenhuis |
| 159 | ? | Elkerliek Ziekenhuis |



ProMISe features: Template Filters



- Arbitrary HTML source code specification with automatic mail merge substitution
 - * Define letters of discharge with free layout



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?:

TAGS

Show

Global

- F2,H Include HTML source file
- F2,5 Evaluate JavaScript
- F2,X Activate XLS file & DQ-XML

Records...

- F2,F Get first record
- F2,L Get last record
- F2,N Get next record
- F2,P Get previous record
- F2,O Insert complete record loop

Items...

- F2,V Insert value of item
- F2,D Insert label of value
- F2,I Declare item
- F2,C Insert complete item loop
- F2,0 Insert NAME of item
- F2,1 Insert short label of item
- F2,2 Insert long label of item

Layout ...

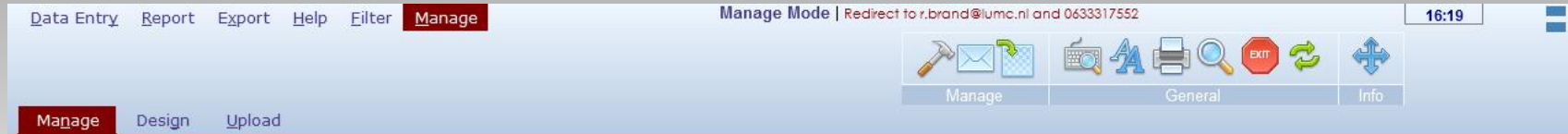
- F2,S CSS STYLE element
- F2,G Insert image
- F2,A Insert pagebreak
- F2,3 Insert Chapter header
- F2,4 Insert Section header

Flow...

- F2,B label (to jump to)
- F2,J Conditional jump to label
- F2,E Jump on Error/Warning
- F2,Y Ignore Dynamic Filters
- F2,R Apply Active Item Filter
- F2,6 Start global counter



ProMISe features: Project Management

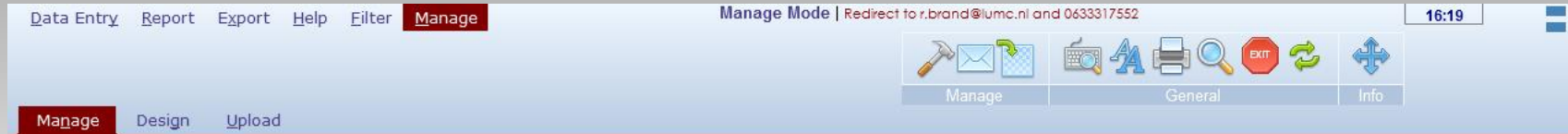


- Center management
 - * Define actual centers
 - * Define Registries (virtual centers)
 - * Define Studies for use in the Dashboard Facility
- User Management
 - * Define users (accounts)
 - * Specify contact details (e-mail, SMS)
 - * Specify exact authorizations
 - * Specify roles within the project
- Log file Management
 - * Optimize all audit trails
 - * Store off-line for efficiency
- Complete set of consistency checks
- Fine tune behavior of the project by specification of around 100 Project Wide Parameters
- Javascript Function Editor
 - * Specify arbitrary complex functions for use in Triggers, Criteria and web forms

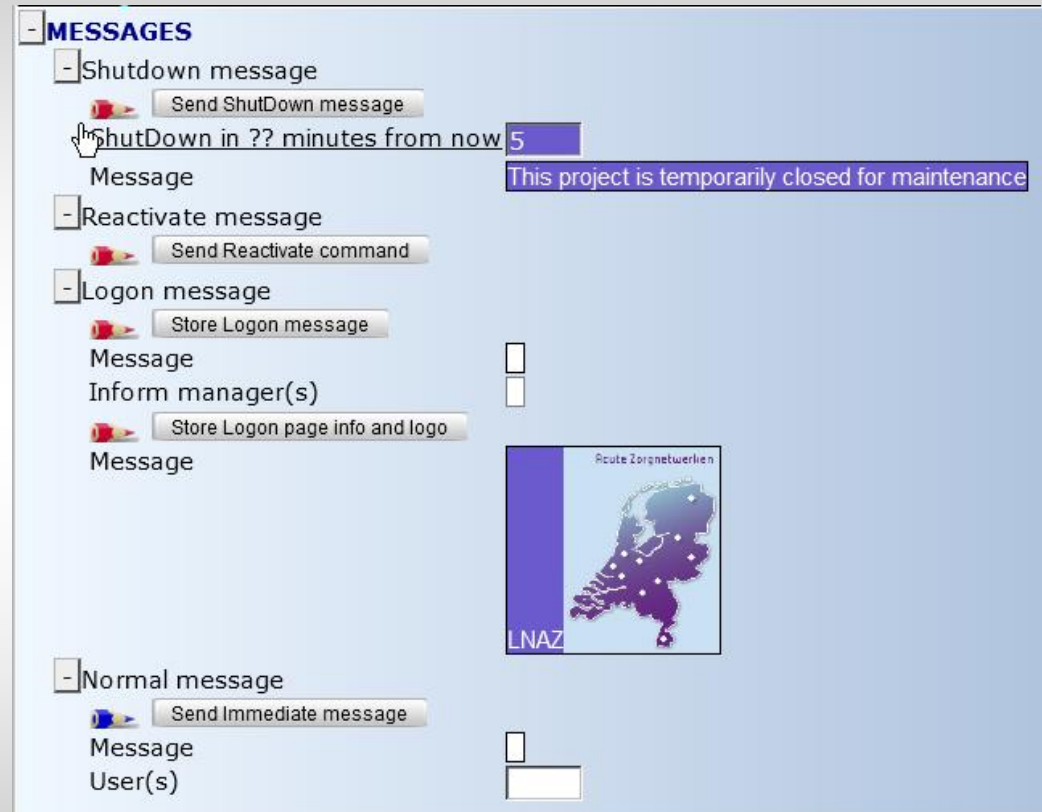




ProMISe features: Project Messaging

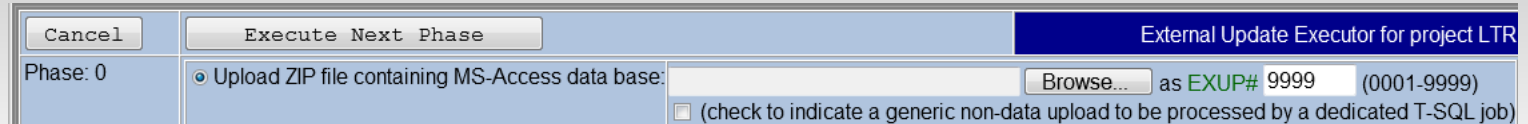
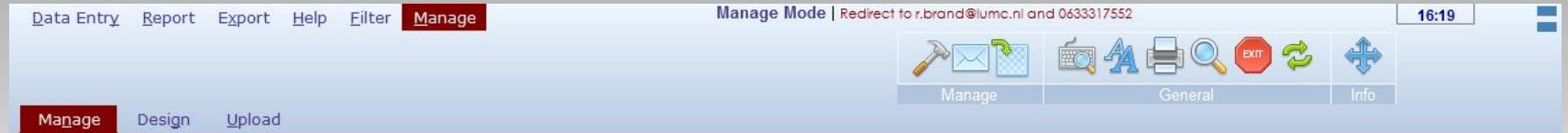


- Shutdown project for maintenance
- Reactivate project
- Store any logon message on the logon page
 - * Automatically inform other managers about this message
- Store permanent information on logon page
 - * Text
 - * Logo
- Send messages directly to users
 - * Pops up within ProMISe session
 - * User must acknowledge reading the message





ProMISe features: Data Upload (Import)



- Fully documented and flexible data upload utility
 - * Reads MS-Access and XML exports back into the ProMISe project
 - XML / XSD allows for type checking at the source (for example when Hospital Information Systems are exporting data)
 - * Full log trial as if data were entered by keyboard
 - * Complete reporting on modifications before the actual execution
 - * Reports can be converted to MS-Access / Excel for analysis
 - * Fine tuning of type of modifications allowed (fill empty; modify filled; erase filled; new records allowed)
 - * Upload of arbitrary tables (non-ProMISe tables) can be performed by Managers
 - Specialized T-SQL jobs can process for example periodic updates of external dictionary information like updated coding systems



ProMISe features: Project Design



- **Tables**
 - * Add tables to the relational structure of the project
 - * Flag tables with specific colored bullets
 - * Enable CRF flow support
- **Partitions**
 - * Group all items into logical Chapters and Sections
 - * Give descriptions with short and long headers and in up to 9 language alternatives
- **Items**
 - * Add/modify items and specify properties
 - Type; length; minimum/maximum; missing values; short and long descriptions in up to 9 alternative languages; coding system; indication of units
 - * Move among sections and chapters
 - * Import definitions from other projects
- **Labels & Codes**
 - * Define codes and labels for coded items with short and long labels in up to 9 alternative languages (or synonyms)



ProMISe features: Project Design (2)



- Help files

- * Internal help files tied to one specific item

- Pictures
 - Short explanations
 - (un)rendered text, typed in by Designer allowing HTML
 - Links to other help files or websites rendered automatically as buttons

- * External help files tied to one or more items

- Supported types: .ASC, .TXT, .GIF, .JPG, .AVI, .WMV, .MP\$, .MOV, .HTM, .PDF, .DOC, .XLS
 - The name of the file matches automatically to items with the same (partial) name
 - Files can be tied to code sets
 - GIF files can be made click-sensitive and produce codes as alternative to text based input

- Data Entry logic (“triggers”)

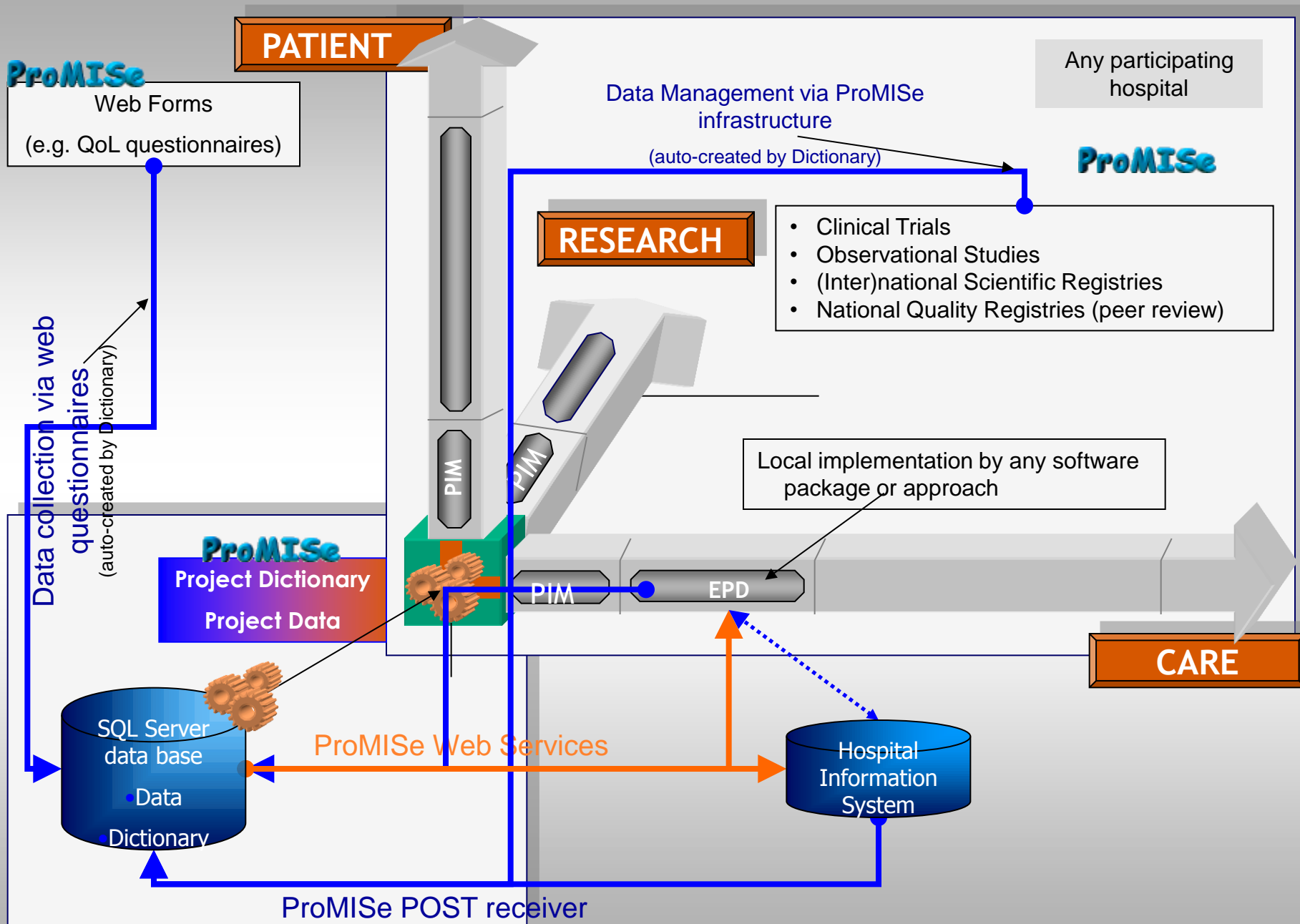
- * Arbitrary criteria to test for inadmissible values; warnings or notifications
 - * Adjusting data entry flow by conditional jumps to specific items
 - * Conditional hide/show subsets of codes depending on values already entered
 - * Conditional hide/show of items or sections depending on values already entered
 - * Automated creation of records in the relational structure based on logical criteria
 - * Support for automatically evaluated formulae based on logical criteria
 - * All triggers have counterparts to “program” behavior of questionnaires



Example of a complex national research infrastructure


- Features

- * One central Dictionary covering 8 (rare) diseases
- * Each University Hospital subscribes to the common Dictionary
- * Four hospitals extend their local copy with local Dictionaries
- * Data are obtained by real-time conversion from Hospital Information Systems as well as manual input



Authentication

ProMISe Logon Procedure: information requested -- Webpage Dialog

| | |
|---|---|
| This project requires a ProMISe Session Key which you should receive in a few moments via SMS |  628039 (required) |
| If you work regularly on this PC and declare this computer to be in a safe environment, you may choose to register the IP address of this computer (10.160.9.99) as a safe PC to logon from with this username. If you do so, you will not be prompted for a Session Key anymore when using this computer with the current username until your password changes or expires. | <input checked="" type="checkbox"/> (check to declare safe) |
| Please confirm/change your e-mail address to the ProMISe Server for internal administration purposes and direct communication of important messages | r.brand@lumc.nl |

Continue logon procedure

Frequency tables and summary measures

Specify List Status **Table** Content

| Oorzaak ongeval (categorie) | Count | Total % | Valid % | Cumul % | mean | count | std.dev. | minimum | maximum | sum | |
|-----------------------------|-------|---------|---------|---------|------|------------|----------|----------|---------|-----|-----|
| {sysmis} | null | 23930 | 56% | | 0% | 0.022987 | 23231 | 0.149864 | 0 | 1 | 534 |
| Onbekend | 1 | 1458 | 3% | | 0% | 0.024005 | 1458 | 0.153119 | 0 | 1 | 35 |
| Toegebracht door anderen | 2 | 640 | 1% | 4% | 4% | 0.032813 | 640 | 0.178285 | 0 | 1 | 21 |
| Verkeer | 4 | 3789 | 9% | 22% | 25% | 0.017683 | 3789 | 0.131813 | 0 | 1 | 67 |
| Bedrijfsongeval | 5 | 432 | 1% | 2% | 28% | 0.020833 | 432 | 0.142992 | 0 | 1 | 9 |
| Prive | 6 | 10928 | 25% | 62% | 90% | 0.032394 | 10928 | 0.177052 | 0 | 1 | 354 |
| Sport | 8 | 1540 | 4% | 9% | 98% | 0.003247 | 1540 | 0.056906 | 0 | 1 | 5 |
| Zelfmutilatie | 9 | 183 | 0% | 1% | 100% | 0.054645 | 183 | 0.227909 | 0 | 1 | 10 |
| Anders | 11 | 84 | 0% | 0% | 100% | 0.047619 | 84 | 0.214238 | 0 | 1 | 4 |
| TOTAL | | 42984 | | 17596 | | Overleden? | | | | | |

• counting Ongeval-records

| Oorzaak ongeval (categorie) | Count | Total % | Valid % | Cumul % | mean | count | std.dev. | minimum | maximum | sum | |
|-----------------------------|-------|---------|---------|---------|------|------------|----------|----------|----------|-----|--------------|
| {sysmis} | null | 23930 | 56% | | 0% | 0.979741 | 21508 | 0.061698 | 0.001575 | 1 | 21072.275989 |
| Onbekend | 1 | 1458 | 3% | | 0% | 0.984967 | 1408 | 0.028614 | 0.137922 | 1 | 1386.833918 |
| Toegebracht door anderen | 2 | 640 | 1% | 4% | 4% | 0.971079 | 614 | 0.134842 | 0.000017 | 1 | 596.242256 |
| Verkeer | 4 | 3789 | 9% | 22% | 25% | 0.974875 | 3585 | 0.088678 | 0.003164 | 1 | 3494.925525 |
| Bedrijfsongeval | 5 | 432 | 1% | 2% | 28% | 0.975881 | 423 | 0.101021 | 0.025206 | 1 | 412.797835 |
| Prive | 6 | 10928 | 25% | 62% | 90% | 0.979768 | 10595 | 0.043732 | 0.00623 | 1 | 10380.645737 |
| Sport | 8 | 1540 | 4% | 9% | 98% | 0.99277 | 1519 | 0.03912 | 0.040427 | 1 | 1508.017714 |
| Zelfmutilatie | 9 | 183 | 0% | 1% | 100% | 0.938953 | 167 | 0.187967 | 0.000349 | 1 | 156.805222 |
| Anders | 11 | 84 | 0% | 0% | 100% | 0.973074 | 79 | 0.094652 | 0.179353 | 1 | 76.872819 |
| TOTAL | | 42984 | | 17596 | | P-survival | | | | | |

• counting Ongeval-records

If a scoring system is also implemented (as a Javascript formula or as SQL post processing) we can compare the observed death rate ($1-0.032=0.978$) with the expected one under International classification (0.980)

Simple survival analysis

Data Entry Report Export Help Filter Manage [52][[PRODUCTION][?]] Manage Mode | Redirect to r.brand@lumc.nl and 0633317552 22:11

Report General Info

Specify List Status Table Content 1 Initial

DATA REPORTS ronald::demo survival

REPORT & QUERY SPECIFICATION

Generate Report
Save Advanced Query

Redisplay this tree

- + Conversions
- Class, Format & Complexity
 - New Report Specification
 - Choose Report Class
 - data
 - survival
 - advanced
 - Format
 - Complexity
- + Content
- + Survival Structure
 - Date item #0
 - OT Ongevalsdatum en tijd
 - Private:CIC=1:Valide datum ongeval
 - start
 - Date item #1
 - Datum ontslag
 - Private:CIC=1:In leven
 - censored
 - Date item #2
 - Datum en tijdstip overlijden
 - Public:Overleden
 - uncensored
 - Date item #3
 - {none}
 - censored
 - Date item #4
 - {none}
 - censored

Continue by Constructing the Advanced Query

STORED REPORT SPECIFICATIONS

- The actual Survival Analysis has to be specified as an Advanced Query!
- Use the branch **Simple Survival Setup** if you are not familiar with advanced queries and you need help with a basic survival specification.

Final Query

- In the Final Query (#E) we select Records from ...

- #A: ONGEVAL-RECORDS (but only if: `Valide datum ongeval`)
 - ... adding info (using minimum {DATUMONTSLAG}#B) and ...
 - ... matching records (possibly none) with the same [CIC,PatientRecord] from ...
- #B: ONGEVAL-RECORDS (but only if: `In leven`)
 - ... adding info (using minimum {DATUMOVERLEDEN}#C) and ...
 - ... matching records (possibly none) with the same [CIC,PatientRecord] from ...
- #C: ONGEVAL-RECORDS (but only if: `Overleden`)

Immediate conversion of results (to any software, e.g. Excel)

Sat, Feb 04, 2012 [10:32:16] (n=1145)

Display Options
 Ctrl Alt L Codes:Labels
 + Output Table

Data Manager

ADDITIONAL PAGES

| MARK: | ID_ | IDAA_ | ~START1 | ~CENS2 | TIME~CENS2 | ~UNCENS3 | TIME~UNCENS3 | CIC | Ziekenhuis patientnummer | Ongeval | Oorzaak ongeval (categorie) | Letselaard | Vervoer | OT Ongevalsdatum en tijd | Datum ontslag | Datum en tijdstip overlijden |
|-------|----------|------------|------------|--------|------------|----------|--------------|----------|--------------------------|---------|-----------------------------|------------|---------------------|--------------------------|---------------------|------------------------------|
| | 101 847 | 2010/01/01 | 2006/01/02 | -1460 | | | | 101 847 | 2010/01/01 | Anders | Scherp | ambulance | 2010/01/01 12:00:00 | 2006/01/02 | | |
| | 101 2332 | 2007/12/07 | 2007/12/07 | 0 | | | | 101 2332 | 2007/12/07 | | Stomp | ambulance | 2007/12/07 03:06:00 | 2007/12/07 | | |
| | 101 3404 | 2008/07/20 | 2008/07/23 | 3 | | | | 101 3404 | 2008/07/20 | | Stomp | ambulance | 2008/07/20 00:00:00 | 2008/07/23 | | |
| | 101 3606 | 2008/06/26 | 2008/06/26 | 0 | | | | 101 3606 | 2008/06/26 | | Stomp | ambulance | 2008/06/26 19:03:00 | 2008/06/26 | | |
| | 101 4514 | 2007/03/27 | 2007/04/03 | 7 | | | | 101 4514 | 2007/03/27 | | Stomp | ambulance | 2007/03/27 10:35:00 | 2007/04/03 | | |
| | 101 4661 | 2007/01/20 | 2007/01/23 | 3 | | | | 101 4661 | 2007/01/20 | | Stomp | ambulance | 2007/01/20 00:00:00 | 2007/01/23 | | |
| | 101 5674 | 2007/03/08 | 2007/03/12 | 4 | | | | 101 5674 | 2007/03/08 | | Stomp | ambulance | 2007/03/08 13:58:00 | 2007/03/12 | | |
| | 101 5708 | 2007/02/18 | 2006/11/05 | -105 | 2007/02/18 | 0 | | 101 5708 | 2007/02/18 | | Stomp | ambulance | 2007/02/18 00:00:00 | 2007/02/18 | 2007/02/18 14:45:00 | |

Sheet1 - Microsoft Excel

File Home Insert Page Layout Formulas Data Review View Developer Add-Ins Load Test Team

Clipboard Font Alignment Number Styles

Normal Bad Good Neutral Calculation
 Check Cell Explanatory... Input Linked Cell Note

| | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | |
|----|-------|-----|-------|---------|--------|----------|----------|----------|-----|----------|---------|-----------|------------|-----------|---------------------|---------------|-----------------------|-----|------|
| 1 | MARK: | ID_ | IDAA_ | ~START1 | ~CENS2 | TIME~CEN | ~UNCENS3 | TIME~UNC | CIC | Ziekenhu | Ongeval | Oorzaak o | Letselaarc | Vervoer | OT Ongevalsdatum er | Datum ontslag | Datum en tijdstip ove | CIC | Ziel |
| 2 | | 101 | 847 | 40179 | 38719 | -1460 | | | 101 | 847 | 40179 | Anders | Scherp | ambulance | 2010-01-01 | 38719 | | 101 | |
| 3 | | 101 | 2332 | 39423 | 39423 | 0 | | | 101 | 2332 | 39423 | | Stomp | ambulance | 2007-12-07 | 39423 | | 101 | |
| 4 | | 101 | 3404 | 39649 | 39652 | 3 | | | 101 | 3404 | 39649 | | Stomp | ambulance | 2008-07-20 | 39652 | | 101 | |
| 5 | | 101 | 3606 | 39625 | 39625 | 0 | | | 101 | 3606 | 39625 | | Stomp | ambulance | 2008-06-26 | 39625 | | 101 | |
| 6 | | 101 | 4514 | 39168 | 39175 | 7 | | | 101 | 4514 | 39168 | | Stomp | ambulance | 2007-03-27 | 39175 | | 101 | |
| 7 | | 101 | 4661 | 39102 | 39105 | 3 | | | 101 | 4661 | 39102 | | Stomp | ambulance | 2007-01-20 | 39105 | | 101 | |
| 8 | | 101 | 5674 | 39149 | 39153 | 4 | | | 101 | 5674 | 39149 | | Stomp | ambulance | 2007-03-08 | 39153 | | 101 | |
| 9 | | 101 | 5708 | 39131 | 39026 | -105 | 39131 | 0 | 101 | 5708 | 39131 | | Stomp | ambulance | 2007-02-18 | 39131 | 2007-02-18 | 101 | |
| 10 | | 101 | 6623 | 39126 | 39128 | 2 | | | 101 | 6623 | 39126 | | Stomp | ambulance | 2007-02-13 | 39128 | | 101 | |
| 11 | | 101 | 7012 | 39514 | 39516 | 2 | | | 101 | 7012 | 39514 | | Stomp | ambulance | 2008-03-07 | 39516 | | 101 | |
| 12 | | 101 | 8558 | 39083 | 39084 | 1 | | | 101 | 8558 | 39083 | | Stomp | ambulance | 2007-01-01 | 39084 | | 101 | |
| 13 | | 101 | 8559 | 39083 | 39101 | 18 | | | 101 | 8559 | 39083 | | Stomp | ambulance | 2007-01-01 | 39101 | | 101 | |
| 14 | | 101 | 8560 | 39083 | 39094 | 11 | | | 101 | 8560 | 39083 | | Stomp | ambulance | 2007-01-01 | 39094 | | 101 | |
| 15 | | 101 | 8563 | 39085 | 39084 | 0 | | | 101 | 8563 | 39085 | | Stomp | ambulance | 2007-01-01 | 39084 | | 101 | |

Data for Survival

https://ronald.clinicalresearch.nl/ - LTR[REGIS][LNAZ][S][mrdm_MC_GLOBAL_man][CIC:1(1)] [ronald - Windows Internet Explorer] Manage Mode | Redirect to r.brand@lumc.nl and 063317552 10:36

Data Entry Report Export Help Filter Manage

Specify List Status Table Content

SURVIVAL

- Preparations
 - Ctrl 7 Analyze in R (Statistical Portal)
 - Ctrl 8 Show/Export status/time table
 - Ctrl 9 Clear Graph
 - Model fit log
- Analysis
- Display parameters

| n | ID | IDAA | S | Time | Start | End | Cens | |
|-------|------|------|----|------------|----------|---------------------|---------------------|------|
| 101 | 847 | -1 | -1 | 2010-01-01 | 12:00:00 | 00:00:00 | | 1131 |
| 1101 | 2332 | 0 | 0 | 2007-12-07 | 03:06:00 | 00:00:00 | 2007-12-07 00:00:00 | 21 |
| 2101 | 3404 | 0 | 3 | 2008-07-20 | 00:00:00 | 00:00:00 | 2008-07-23 00:00:00 | 21 |
| 3101 | 3606 | 0 | 0 | 2008-06-26 | 19:03:00 | 00:00:00 | 2008-06-26 00:00:00 | 21 |
| 4101 | 4514 | 0 | 7 | 2007-03-27 | 10:35:00 | 00:00:00 | 2007-04-03 00:00:00 | 21 |
| 5101 | 4661 | 0 | 3 | 2007-01-20 | 00:00:00 | 00:00:00 | 2007-01-23 00:00:00 | 21 |
| 6101 | 5674 | 0 | 4 | 2007-03-08 | 13:58:00 | 00:00:00 | 2007-03-12 00:00:00 | 21 |
| 7101 | 5708 | 1 | 0 | 2007-02-18 | 00:00:00 | 2007-02-18 14:45:00 | 00:00:00 | 21 |
| 8101 | 6623 | 0 | 2 | 2007-02-13 | 10:05:00 | 00:00:00 | 2007-02-15 00:00:00 | 21 |
| 9101 | 7012 | 0 | 2 | 2008-03-07 | 00:00:00 | 00:00:00 | 2008-03-09 00:00:00 | 21 |
| 10101 | 8558 | 0 | 1 | 2007-01-01 | 06:12:00 | 00:00:00 | 2007-01-02 00:00:00 | 21 |
| 11101 | 8559 | 0 | 18 | 2007-01-01 | 00:00:00 | 00:00:00 | 2007-01-19 00:00:00 | 21 |
| 12101 | 8560 | 0 | 11 | 2007-01-01 | 12:19:00 | 00:00:00 | 2007-01-12 00:00:00 | 21 |
| 13101 | 8562 | 0 | 9 | 2007-01-03 | 00:00:00 | 00:00:00 | 2007-01-12 00:00:00 | 21 |

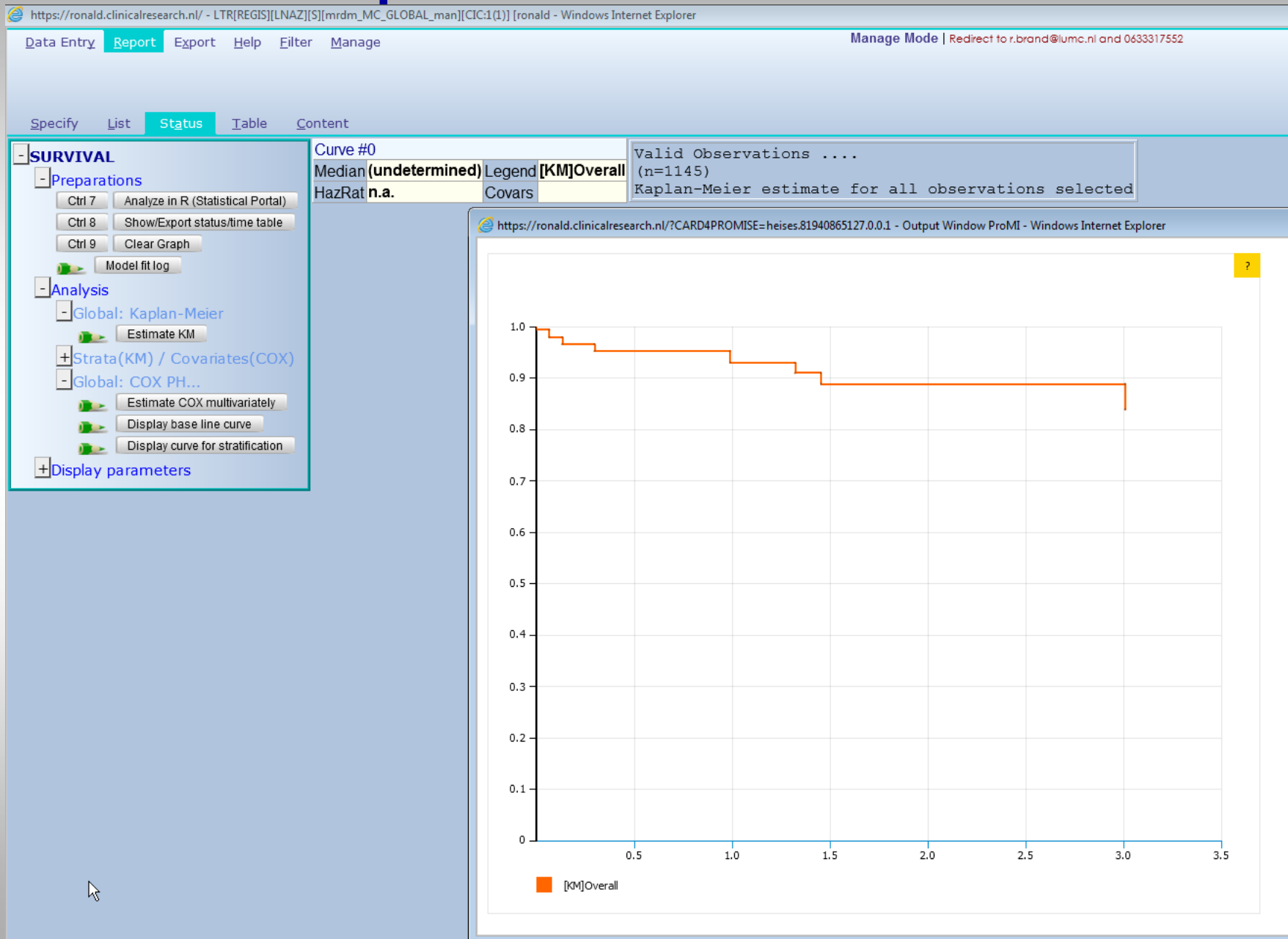
File Home Insert Page Layout Formulas Data Review View Developer Add-Ins Load Test Team

Clipboard Font Alignment Number

| | A | B | C | D | E | F | G | H | I | J | K | L |
|----|----|-----|------|----|------|---------|---------|---------|----|---|---|---|
| 1 | n | ID | IDAA | S | Time | Start | End | Cens | | | | |
| 2 | | 101 | 847 | -1 | -1 | 00:00.0 | | | 11 | 3 | 1 | |
| 3 | 1 | 101 | 2332 | 0 | 0 | 06:00.0 | | 00:00.0 | | 2 | 1 | |
| 4 | 2 | 101 | 3404 | 0 | 3 | 00:00.0 | | 00:00.0 | | 2 | 1 | |
| 5 | 3 | 101 | 3606 | 0 | 0 | 03:00.0 | | 00:00.0 | | 2 | 1 | |
| 6 | 4 | 101 | 4514 | 0 | 7 | 35:00.0 | | 00:00.0 | | 2 | 1 | |
| 7 | 5 | 101 | 4661 | 0 | 3 | 00:00.0 | | 00:00.0 | | 2 | 1 | |
| 8 | 6 | 101 | 5674 | 0 | 4 | 58:00.0 | | 00:00.0 | | 2 | 1 | |
| 9 | 7 | 101 | 5708 | 1 | 0 | 00:00.0 | 45:00.0 | | | 2 | 1 | |
| 10 | 8 | 101 | 6623 | 0 | 2 | 05:00.0 | | 00:00.0 | | 2 | 1 | |
| 11 | 9 | 101 | 7012 | 0 | 2 | 00:00.0 | | 00:00.0 | | 2 | 1 | |
| 12 | 10 | 101 | 8558 | 0 | 1 | 12:00.0 | | 00:00.0 | | 2 | 1 | |
| 13 | 11 | 101 | 8559 | 0 | 18 | 00:00.0 | | 00:00.0 | | 2 | 1 | |
| 14 | 12 | 101 | 8560 | 0 | 11 | 19:00.0 | | 00:00.0 | | 2 | 1 | |
| 15 | 13 | 101 | 8562 | 0 | 9 | 00:00.0 | | 00:00.0 | | 2 | 1 | |
| 16 | 14 | 101 | 8564 | 0 | 5 | 08:00.0 | | 00:00.0 | | 2 | 1 | |
| 17 | 15 | 101 | 8565 | 0 | 0 | 36:00.0 | | 00:00.0 | | 2 | 1 | |
| 18 | 16 | 101 | 8566 | 0 | 14 | 05:00.0 | | 00:00.0 | | 2 | 1 | |
| 19 | 17 | 101 | 8567 | 0 | 1 | 00:00.0 | | 00:00.0 | | 2 | 1 | |
| 20 | 18 | 101 | 8568 | 0 | 35 | 50:00.0 | | 00:00.0 | | 2 | 1 | |

Quick and dirty export to any software....

Kaplan Meier curve



Simple split by risk factor

Valid Observations
(n=2059)

| Variable | Avg | SD | RefVal | RefLab | Coeff=Effect of: |
|----------|--------|--------|--------|--------|----------------------|
| 1 | 0.0146 | 0.1198 | 0 | nee | [ja] versus [RefVal] |

Iteration History...

-2 Log Likelihood = 771.3436

(NULL Model)

-2 Log Likelihood = 816.5098

-2 Log Likelihood = 762.5088

-2 Log Likelihood = 760.9334

-2 Log Likelihood = 760.8973

-2 Log Likelihood = 760.8973

(Converged)

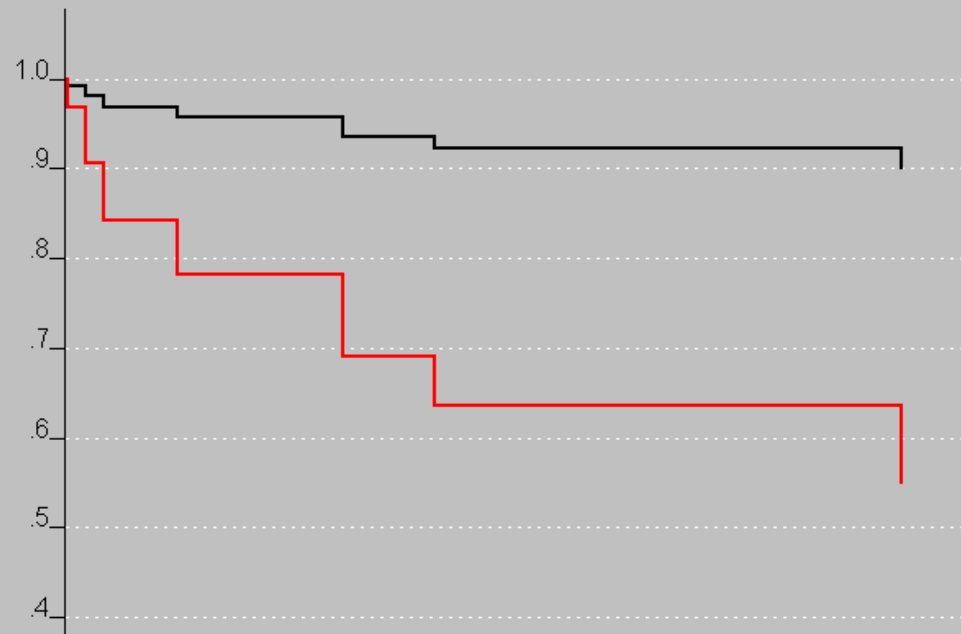
Overall Model Fit...

Chi Square= 10.4463; df=1;p= 0.0012

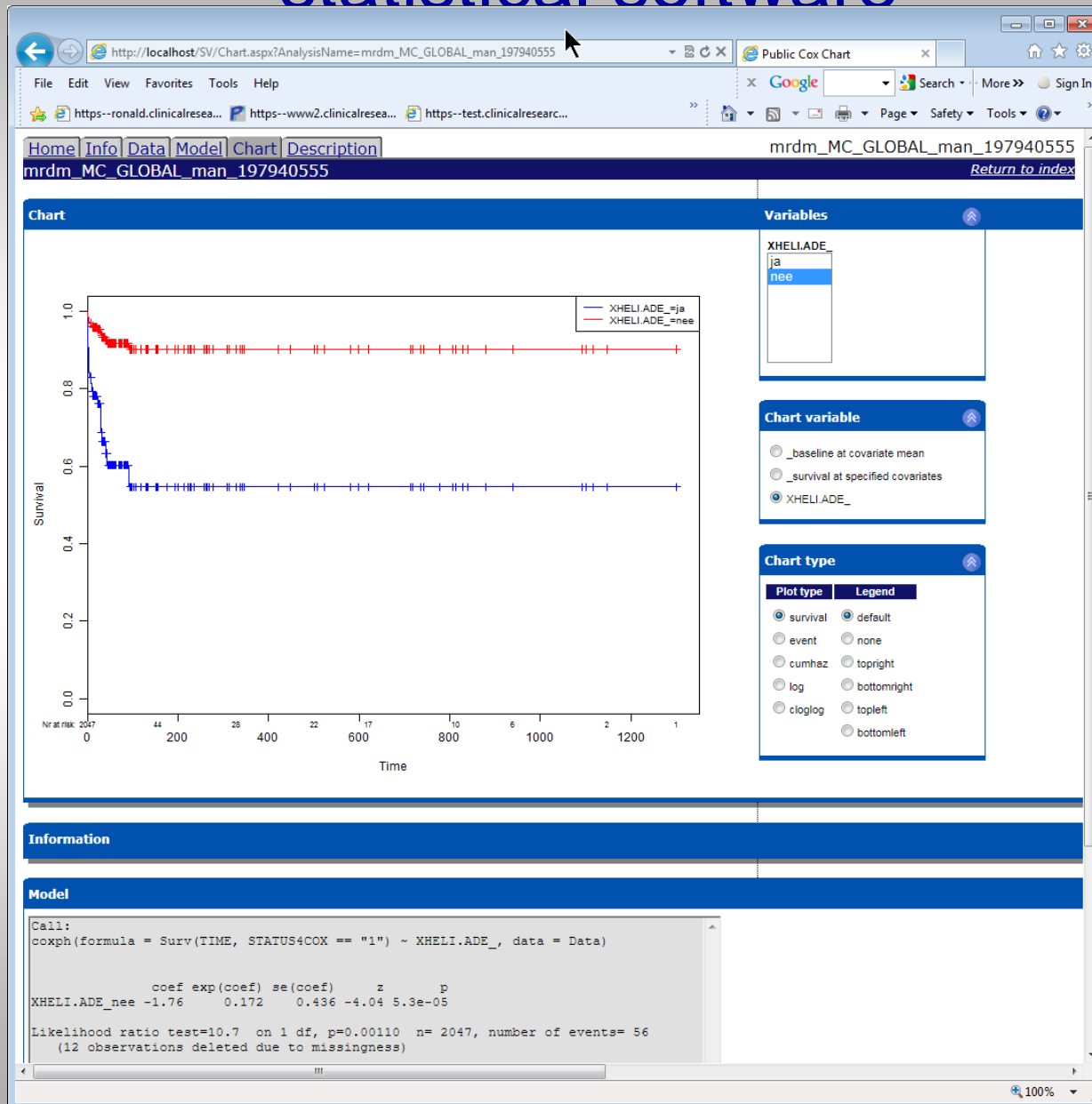
| Var | Coeff. | StdErr | p | HazRatio | Lo95% | Hi95% |
|-----|--------|--------|--------|---------------|--------|---------|
| 1 | 1.7389 | 0.4352 | 0.0001 | 5.6912 | 2.4359 | 13.2965 |

Model fitted and baseline (at predictor RefV

Output Window ProMISe - Windows Internet Explorer



Possibility to link to professional statistical software



Simple Frequency tables

Specify List Status **Table** Content

Diagnose frequentie verdelingen

| Diagnose regio | Count | Total % | Valid % | Cumul % |
|----------------|-------|---------|---------|---------|
| Skin | 59 | 292 | 3% | 3% |
| Leg | 60 | 1871 | 18% | 21% |
| Arm | 61 | 1197 | 12% | 32% |
| Spine | 62 | 1346 | 13% | 45% |
| Abdom | 63 | 372 | 4% | 49% |
| Thorax | 64 | 955 | 9% | 58% |
| Neck | 65 | 83 | 1% | 59% |
| Face | 66 | 1275 | 12% | 71% |
| Head | 67 | 3009 | 29% | 100% |
| TOTAL | | 10400 | | |

• counting Diagnose-records

| Groepsindeling voor ISS berekening | Count | Total % | Valid % | Cumul % |
|------------------------------------|-------|---------|---------|---------|
| 1 | 3102 | 30% | 30% | 30% |
| 2 | 697 | 7% | 7% | 37% |
| 3 | 2537 | 24% | 24% | 61% |
| 4 | 899 | 9% | 9% | 70% |
| 5 | 1383 | 13% | 13% | 83% |
| 6 | 1782 | 17% | 17% | 100% |
| TOTAL | | 10400 | | |

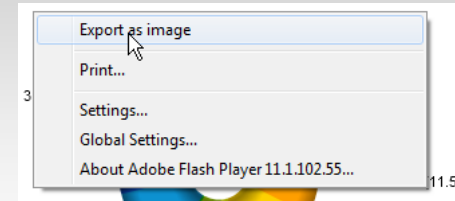
• counting Diagnose-records

https://www.clinicalresearch.nl/?CARD4PROMISE=heises....

Diagnose regio

Groepsindeling voor ISS berekening

Charts can be saved as graphics



Counts and percentages

ITEMS ELIGIBLE FOR REPORTS

- PATIENT_RECORDS
 - + Inhoud
 - ONGEVAL-RECORDS
 - ONGEVAL-RECORDS
 - + Index admi ongeval
 - ONGEVAL GEGEVENS
 - Gegevens ongeval
 - Oorzaak ongeval (categorie)
 - Oorzaak ongeval (detail)
 - Plaats herkomst
 - Verwijzer
 - Letselaard
 - Beschrijving / toedracht ongeval

Unselect
 Select for Descriptive Statistics Table (mean etc)
 Select for Frequency table
 Crosstabulate other items with this item (Vertically)

Accept
 Default
 Cancel

Diagnose frequentie verdelingen

| Letselaard | Stomp | Scherp | | TOTAL |
|-------------------|-------|--------|-------|-------|
| Verwijzer | 2 | 3 | 8 | |
| huisarts | 1 | 93% | 7% | 100% |
| 112 | 2 | 100% | | 100% |
| politie/brandweer | 4 | 100% | | 100% |
| | 10 | 96% | 4% | 100% |
| | 11 | 95% | 4% 0% | 100% |
| | 12 | 89% | 11% | 100% |
| | 888 | 72% | 28% | 100% |
| TOTAL | | 96% | 4% 0% | 100% |

counting {Ongeval}-records

Turn into percentages with a click

Friday February 03 2012 22:46

TABLES

Show all tables

Crosstab content counts

counts: show counts (whether value is valid or not)
 valid: only count valid values
 row %%: show only row percentages
 col %%: show only column percentages
 row %%+count: include counts and row percentages of valid values
 col %%+count: include counts and column percentages of valid values

User management and authorisation levels

- CURRENTLY DEFINED USERS

Search in (user)name,email,mobile:

- Active Users
 - + Manager (A)
 - + Designer (A)
 - Production (A)
 - + Center (Prod-A)
 - Registry (Prod-A)
 - ltr99rb on CIC=99
 - + Demo (A)
 - + Download (A)
- + Anonymous Users
- + Expired Users
- + Deactivated Users
- Unclassified Users

actual name unknown
 unknown and expired
 authorisation expired
 active
 blocked (10 invalid passwords)
 deactivated (by manager)

- USER OBJECT

- Current User

LOAD selected User ...
 Refresh CICs in UAM ...
 SAVE parameters ...

- Logon properties

username: ltr99rb
 password: *****
 ... notify user on change:
 actual name of user: ronald brand
 e-mail of user: r.brand@lumc.nl
 mobile number: 06
 Special user subtype: Normal
 privacy protection category: None
 TTP encryption category: EncDec
 user allowed on-behalf logon:
 Authentication and IP addresses: IP
 Authenticated IP addresses:
 IP(-pattern) mask(s):
 IP violators:
 IP(-pattern) block(s):

- (info only)

associated CIC: 99
 Expiration date: 2012-04-01 08:53:57.207
 Invalid logon counter: 0
 User Class (calculated): Registry-Prod-Active
 UserGuid: 513ADEBC-929C-4069

| User Access Matrix | | | | | |
|-------------------------|--------|----------------|-----------|----------|------------|
| CIC | Export | RecordCreation | DataEntry | Listings | Statistics |
| Initial LogOn to center | | | | | |
| 99 | | | | | |
| After switch to Center | | | | | |
| 0 | | | | | |

Dashboard functionalities (trauma project)

eliminate missings W: 500 H: 300 Refresh Study: Study: Automatische selectie van patiënten met een ongeval met ISS > 15 [Items for Study 4001]

| Scope | Complement | Study | FilterBar | Item (*crosstab) |
|-------------------------------------|-------------------------------------|--------------------------|-----------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | P | PATIENT_RECORDS |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | P | Geslacht |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | P | ONGEVAL-RECORDS |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | P | Oorzaak ongeval (categorie) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | P | Letselaard |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | P | Gebruik alcohol |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | P | Gebruik drugs |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | P | Gebruik medicijnen |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P | DIAGNOSE_RECORDS |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | P | Diagnose regio |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | % | ONGEVAL-RECORDS |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | % | Oorzaak ongeval (categorie) *Gebruik alcohol |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | % | Letselaard *Gebruik alcohol |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | % | Gebruik drugs *Gebruik alcohol |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | % | Gebruik medicijnen *Gebruik alcohol |

[Diagnose regio] (within CIC=101 {LUMC} within Studie ISS_15+)

| Category | Count | Percentage |
|------------------------------------|-------|------------|
| head | 34 | 54.8% |
| Face | 8 | 12.9% |
| Spine | 6 | 9.7% |
| Leg | 4 | 6.5% |
| Administratie en overige diagnoses | 1 | 1.6% |
| Skin | 2 | 3.2% |
| Arm | 2 | 3.2% |
| Abdom | 1 | 1.6% |
| Thorax | 2 | 3.2% |
| Neck | 2 | 3.2% |

[Diagnose regio] (outside CIC=101 {LUMC} within Studie ISS_15+)


| Category | Count | Percentage |
|------------------------------------|-------|------------|
| head | 586 | 40.8% |
| Face | 200 | 13.9% |
| Arm | 145 | 10.1% |
| Thorax | 155 | 10.8% |
| Spine | 133 | 9.2% |
| Leg | 139 | 9.7% |
| Abdom | 46 | 3.2% |
| Neck | 5 | 0.3% |
| Administratie en overige diagnoses | 3 | 0.2% |
| Skin | 26 | 1.8% |

TRES: Real-time encryption via TTP

- **Dual Control – Access to identifying data only after authentication by CDMS as well as the Tres software**
- **Separation of duties – CDMS authorizes access to data, TTP authorizes decryption and thereby access to identification**
- **Split Knowledge – TTP has no access to the data and CDMS has no knowledge on decrypt permissions.**

Fully integrated into data management

DEMO VARIOUS FUNCTIONALITIES

Special it 

An item to show referencing cont

An item to conta compatible)

An item to conta

Demo fuzzy date

Reporting

E-mail address

Find data in HI

Identification of p

Information Syst

Date of birth

Last name

First name

Items for TTP-ENCRYPTION (TOPSECRET)

| | | | |
|------------------------------|----------------------------|-----------|---|
| Name patient | b9d05419-76df-4fdb-bd6 ... | John Doe | ⌵ |
| Address patient | b9d05419-76df-4fdb-bd6 ... | Road 1 | ⌵ |
| Social Security Number (BSN) | b9d05419-76df-4fdb-bd6 ... | 123456789 | ⌵ |

Encrypt a value 

Enter value for [Name patient]: 

John Doe 

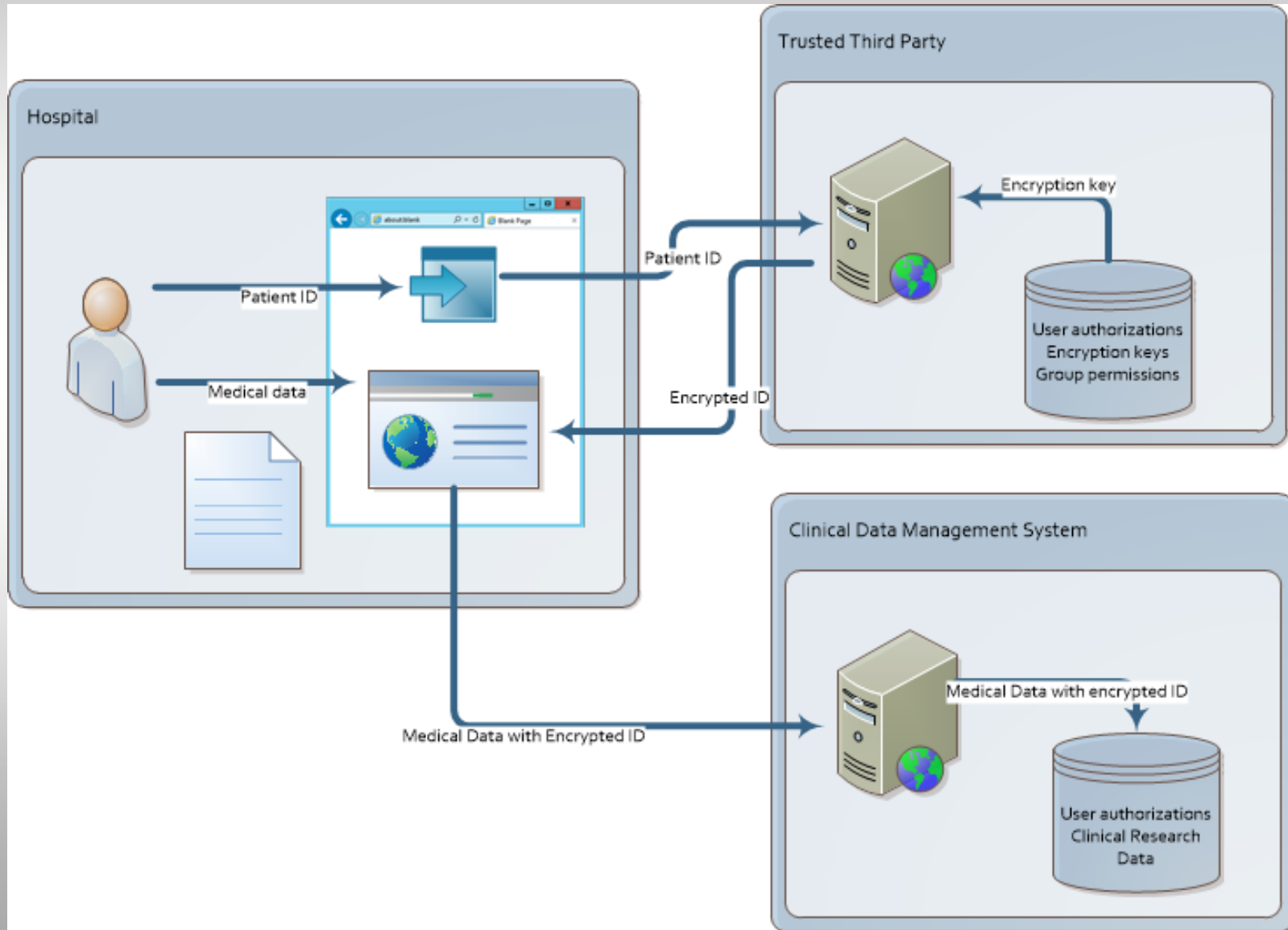
Encrypt **Cancel** **Clear**

No access to encrypted data without TTP authentication

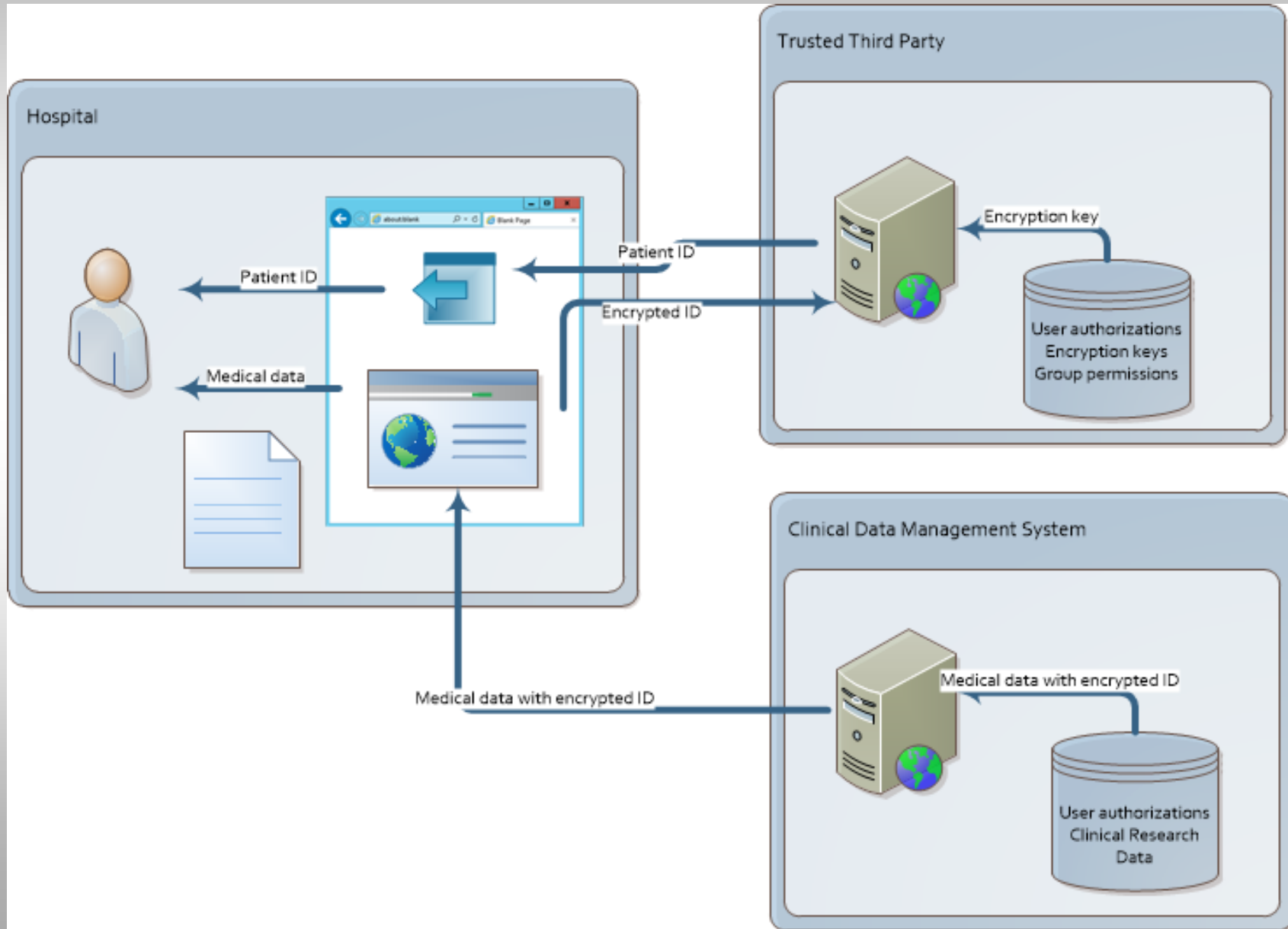
| Items for TTP-ENCRYPTION (TOPSECRET) | | |
|--------------------------------------|----------------------------|----------------------|
| Name patient | f0a2b963-db9e-4f0b-ba6 ... | Not connected to TTP |
| Address patient | | |
| Social Security Number (BSN) | f0a2b963-db9e-4f0b-ba6 ... | Not connected to TTP |

| Items for TTP-ENCRYPTION (TOPSECRET) | | |
|--------------------------------------|----------------------------|--|
| Name patient | f0a2b963-db9e-4f0b-ba6 ... | No decrypt permission.  |
| Address patient | | |
| Social Security Number (BSN) | f0a2b963-db9e-4f0b-ba6 | No decrypt permission.  |

The patient ID is entered in a TTP data entry form, encrypted by the TTP and the encrypted ID is then automatically entered in the CDMS



The patient ID is decrypted by the TTP and displayed in a TTP form .



Research and analysis do not have access to the TTP and thereby no access to patient identifiers and with further limitations in CDMS anonymized access can be provided.

