Project: D o s e I n t e n s i t y as O n c o l o g y S t a n d a r d
C e n t r e   o f   B i o s t a t i s t i c s   a n d   A n a l y s e s

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PROJECT STATUS REPORT II.
Enclosure 2

On-line technology for dose intensity monitoring and health technology assessment

One of the key aims of the project is to provide SW solution, widely accessible for different types of users. In addition to model implementation in hospital information systems, we therefore proposed on-line solution in the form corresponding to common multi-centric registries. That is why the solution is proposed as "DIOS Registry": the output will be used in planned case studies and included in complex project solution.

On-line technology should be accepted as added value that allows namely:
-   easy presentation of the project outputs and tools, international presentations
-   very effective organization of pilot tests and validation
-   organization of multi-centric case studies and projects

On the other hand, on-line technology is not targeted for operation inside hospitals and their information systems. It can get necessary data though exports or manual gathering by data managers. Solution of problems that occur inside health facilities is proposed in different regimes (see enclosure 3 of this report).

Software tools

DIOS registry is primarily an on-line based system for the gathering and analyses of time-stamped clinical information. ("Time-stamped" means that every patient-associated event recorded in the database is tagged with the time it happened or ran). It can be used both retrospectively and prospectively, several application are also devoted to longitudinal collection of data in clinical practice. There are also numerous functions for administrators of clinical trials, including computer assisted randomization, automated reporting of clinical monitoring, etc...
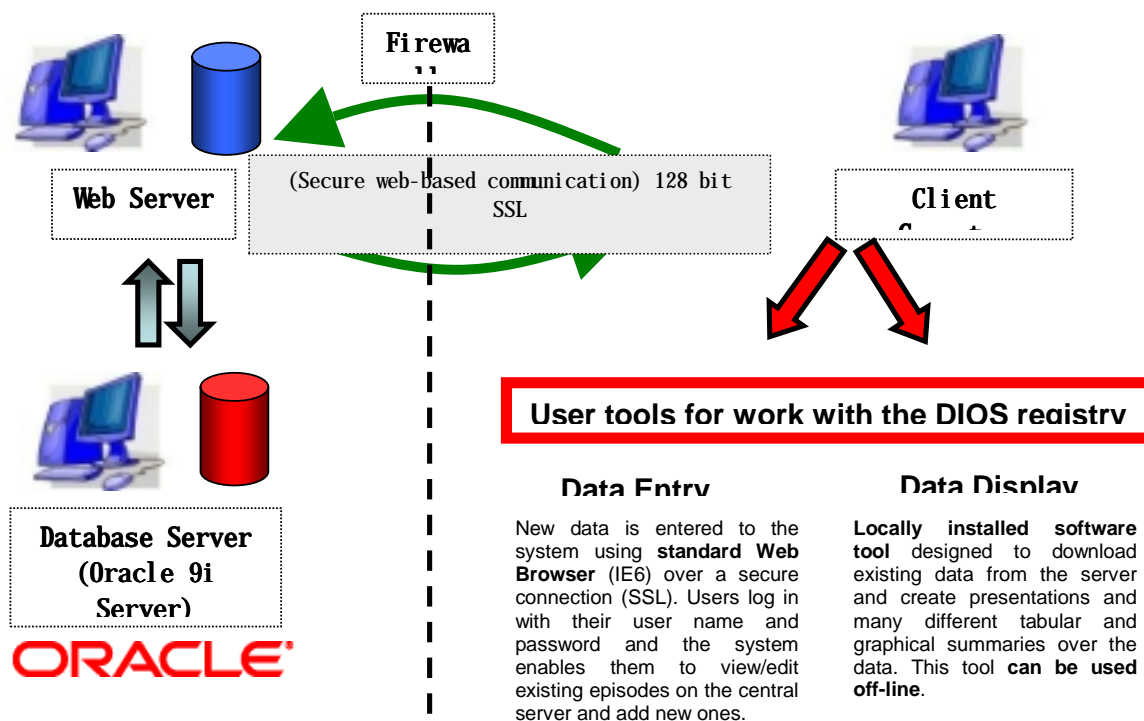
Main advantage of such online solution is a direct centralization of collected data on a shared, fully secured database server. The process of upgrading is also trouble free; web application changes are available immediately to all participating centres. A partial disadvantage is the dependence of this solution on internet. Every data-collecting centre must have reliable and reasonably fast internet connection.

Principally, it is a three-component system:

1. Software background is composed from three independent components that are brought one by one to the process according to progress in data entry. The most important part of the register is the robust central database with on-line access (ORACLE 9i). Clients can enter, view or edit data directly using web forms that meet the data structure of the project.

Project: Dose Intensity as Oncology Standard
Centre of Biostatistics and Analyses

DIOS

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2. The second part consists of communication and access tools that are needed when utilizing the data in practice, and for data management. Clients (clinicians, data managers) can use discussion forum on the web to solve problems, to present important outputs etc... The system supports even multi-centric data management in effective electronic form.

3. The third part consists of automated analytical and presentation tools (data browser, presentation tools, automated summaries). Analytical tools are mainly targeted for clinicians that can use this to gain case reports for individual patient to assess selected group of patients. These tools are typically developed in final phase of registration projects when they are supported by enough complex data.

DATA FLOW DIAGRAM OF THE SYSTEM DIOS REGISTRY

Firewall

(Secure web-based communication) 128 bit SSL

Web Server

Client

Database Server
(Oracle 9i Server)

ORACLE

User tools for work with the DIOS registry

Data Entry

New data is entered to the system using **standard Web Browser** (IE6) over a secure connection (SSL). Users log in with their user name and password and the system enables them to view/edit existing episodes on the central server and add new ones.

Data Display

Locally installed software tool designed to download existing data from the server and create presentations and many different tabular and graphical summaries over the data. This tool **can be used off-line**.

Main advantages of the on-line system:

» Flexibility

» Universality

» Easy to use

» Transparency

» Security

» Exporting functions

» Variability

» Automated presentations

» Statistical functions

» On-line update and data actualization

Flexibility
Thanks to flexible data structure, users can make changes in existing forms for data collection that are generated by the server. This is very useful for adding new fields or reorganizing data collection forms on-the-fly. This system is especially suitable for multicentric data collection, where the entry forms may need to change frequently.

Universality
With DIOS registry system you can connect to various data structures and analyze data from these sources directly.

This system is suitable for application even for complicated multi-centric studies on international level, thanks to its universality and flexibility.

Easy to use
The system respects all requirements to user ergonomics. You can create reports by a single click. The system uses well-arranged set of icons.

Transparency
The user just selects his source of data and this gives him complete overview about current dataset. The system features easy logical data model that is transparent even for first-time users. Moreover, different groups of parameters are differently coloured for better orientation.

Export functions

The system will allow you to export your data from predefined analysis or various parts of the database directly to .xls, .txt or other format.

Variability

Among the most important advantages of the system is the wide variability which allows the user to freely define any available data source, creation of unlimited number of analyses and reports and exports to virtually any format.

Automated presentations

Software DIOS contains set of automated presentation functions, well defined in cooperation with prominent specialists. The user is able to easily display complete report aimed to given problematic without complicated analyses.

Statistical functions

One of the basic functions of the system is displaying basic parameters of descriptive statistics over any parameter. It is possible to create more comprehensive statistical analyses in additional modules like the Automated Presentation Module.

On-line update and data actualization

By one click on the icon you can make data actualization to your local workstation or laptop. Consequently, you can browse your data in off-line mode without internet connection. Also locally installed software for analyzing data can be updated through internet. It's very useful when new version of software becomes available and you have zero delivery costs.

Security

Special chapter bellow.

Proposed DIOS registry solution utilizes web technology and data transfer to the central database, archive and analyses in the coordination centre but data can be simultaneously saved even locally on each centre. Each participating centre is therefore independent, but is sufficiently equipped for data browsing and summary. The registry consists of server and clients with analytical tools and software installed on the client side. The server can use either MS Windows or GNU/Linux operating system. The registry uses Oracle 9i database and ASP technology on the server side. Data can be viewed, entered and modified using MS Internet Explorer 5.5 or higher. The client part of the registry (analytical software) is developed with MS Visual C++ 6.0.

The software for analyses is robust local fully graphic analytical system for analyses and graphical presentations over collected data in MS Windows environment. This component of our own development enables clients to comfortably and simply create presentations, analysis and prearranged data summaries.

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DATA COLLECTION
Basically, data can be collected by two different means:

- Data collection by data managers
- Direct import from primary systems

DATA STORAGE
Each user has data on local hard disk (if data is updated) and simultaneously on the database server. It means that users can use their data without connecting to the central database server.

Security
Data security belongs among the most important questions in every clinically oriented database. It can be divided into three basic parts:
- Place security
- Network security
- Data security

Place security
The whole workplace is well secured and important security elements are present in each room that prevent unauthorized personnel from accessing the building, data and servers.
Security elements:
- 24-hour monitoring (security cameras and personnel)
- entrance identification
- anti-fire system
- alarm movement detectors
- direct connection to police, fire brigades and rescue service
- bullet-proof windows
- armored door with special lock (server rooms, store rooms with clinical data materials)
- air-conditioned server rooms
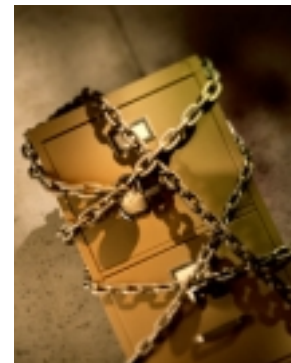
Network security
Network in CBA is based on heterogeneous environment of UNIX-based and Windows-based servers and clients. The network is separated and protected from Internet by a UNIX-based firewall/router with strictly defined firewall rules. All network elements, including servers, are located behind this firewall. The rules are IP-based so that different rules apply for clients and different for servers. In general, outgoing communication is generally enabled (which provides good functionality) and

incoming connections are strictly blocked for the clients and selectively opened for the servers. Moreover, every client and server has installed local firewall that prevents the machine from possible attacks from inside the network. Servers that are communicating only inside the network are separated from internet completely.

Our network segment is part of academic network of MU Brno. This network has well implemented e-mail virus protection (our mail server sends and receives mail through central secured gateway) so that the risk of virus intrusion via e-mail is decreased to minimum possible level.

Data security

Data storage and security is provided by special technical team and is markedly restricted.

Server with ORACLE database is completely separated from external network and access is possible only from local network, protected by firewall.

The system of access rights is defined by database administrator directly in ORACLE environment. Rights of individual users are strictly specified according to needs and professional experience of the user. Only selected users, participating on a given project, have the access rights to internal data of submitter. These users are articled not to share information about data in process to third party and they can be given sanctions.

For data transfer, external disks connected directly to a server are being used.

We provide on-line registers security using four basic elements:

- Organizational and local restriction of access to database servers
- Precise defining of individual users' rights and security of entry accounts administration politics.
- Protocol monitoring of all events, updates or common administration activities over central databases
- Firewall protection of central database and of the whole local network.
- Encryption of all network communication using standard 128-bit SSL protocol.

Data security in ORACLE environment

ORACLE system platform is being secured by three-plied safety model, which is extended using proxy authentication, including certificate Credential proxy X.509 or Distinguished Names (DN), Connection looping for thin and thick client interface JDBC and OCI. Users' identities are safely saved in all plies of application.

Disk capacity

Our database servers are designed to manage and hold large amount of data (hundreds of GB) and are constantly monitored for remaining disk space. Present databases on our servers typically take just tens of MB of disk space, although the system has been successfully tested using a database of about 300 GB in size.