

The EudraTrack/CTS* present and (possible) future

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* New abbreviation: **C**ommunication and **T**racking **S**ystem

Excerpt from the 1st CTS - Activity Report (after takeover from JRC)

- 280 mails received and answered
- 12 procedures reopened and modified
- Preparation of a new CTS client (to be released 4th of March)
 - > delivered for testing purposes end of January 2003
 - > including bug fixes and solution for „Swedish date problem“
 - > 1st time we have relevant source files for executable client
- Technical description of the CTS software
 - > constructed directly from the software level

Activity Report II

- Implementation of mailing lists
 - > remote subscription (since March 2003)
- Preparation and realisation of 1st CTS user meeting at BfArM 13th – 14th January 2003
- Preparation of a demo database
 - > for CADREAC Member States
 - > for training purposes
 - > self-installing, runs on a desktop

Activity Report Summary

- Availability 100 % for the database
 99.9 % for the network
- Some start-up problems with the network, due to the conversion from TESTA1 to TESTA2
- All mails answered within 24 hours
- All agencies have access

Usage of CTS by CADREAC Countries

Technical Solutions

- Distributing of a demo CD (for training purposes) to run CTS on a local desktop without using a network
- Implementing a CADREAC database (CCTS) containing only CADREAC procedures
- Giving CADREAC institutions access to the CTS database
- At the moment in „read only“ mode

Formal prerequisite: signature on letter of confidentiality

and now the problems !!!

Proposal (Evaluation) Topgraf (presented at Ispra 16th April 2002)

Application review: USER INTERFACE

- “One size fits all” application
 - Mail
 - Query System
- “Dense” user interface ←
- Not ready for internationalisation
 - No resource file
 - No initialisation file

*In their own
words !!*



TOPGRAF

Proposal (Evaluation) Topgraf (presented at Ispra 16th April 2002)

Application review: MAINTENABILITY

- Technical documentation doesn't exist
- Component aging
 - Different components for the same task
- Bad structure and style
 - Naming Rules & Variable scope
 - Copy & Paste coding
- Database structure close binding
 - SQL statements embedded in source code
 - Stored procedures used rarely

*In their own
words !!*



TOPGRAF

Restrictions of the Current System (EMR Client 5.3.9)

MRI product index

There is still a contract between JRC and Sweden to service download of MRI but JRC no longer has the database!!

The procedures of JRC given to BfArM/DIMDI only support the collection of relevant data but not the download itself

MRI database and Eudratrack database have mismatched architectures

Data from the JRC Database version 5.3.9
will not be 100% correct

will only be readable, but not editable

needs to be migrated to the new interfaces

Current System (EMR Client 5.3.9)

- Write access
 - > for all clients only one user with write access
 - > the entire database can be destroyed within minutes
- System not scaleable, no abstraction for database access
- User interface not compatible with Windows
 - » some actions are only mouse
 - » based, tabulator functions not understandable, wrong colour
 - » suggests input fields, but input not possible, and and, ... |
 - » nput data not completely visible

Current System (EMR Client 5.3.9)

- 3rd party components (e.g. Visual Basic developing tools) are
 - > no longer available or not compatible
- SQL Server 7.0
 - > no longer supported by Microsoft
- New numbering system
 - > expected to be too expensive (no centralised code table)
- Source code
 - > unique functions are multiplied („copy and paste programming“), expensive to maintain, every modification needs to be performed at several positions, testing of the whole system required

Current System (EMR Client 5.3.9)

- Database
 - > extension nearly not possible, no centralised database access, no logical interfaces, all read and write actions are taken directly via SQL
- Documentation
 - > no or only sparse documentation

To Do List (BfArM/DIMDI Evaluation)

- Source Code (JRC Client 5.3.9) is not completely available
- „Dense“ user interface (cf. explanation next transparency)
- „Buggy“ internationalisation (cf. „Sweden problem“)
- Bad structure and coding style
 - > copy & paste - coding
 - > naming rules & variable scope
- Database is inconsistent (1200 known problems)
- Heavy bandwidth usage
- No formal data - extraction interfaces
- Unused and/or unfinished modules
- User requirements
- Bugs
- Security can easily be broken

Requirements for a New System

- Provides the required functionality
- Runs on all Windows versions starting with Windows 98
- Runs on any network that supports HTTP over TCP/IP
- Using only standard protocols
- Scalable
- Formal interfaces for data extraction, statistics and import of catalogue-data
- Logging of all actions (history function)
- Clear and consistent versioning
- Unit testing right from the start
- User management and system management tools
- Responsive system, even on slower networks
- Validation of all user supplied data (client and server)
- No direct access for users to the database
- Remote administration

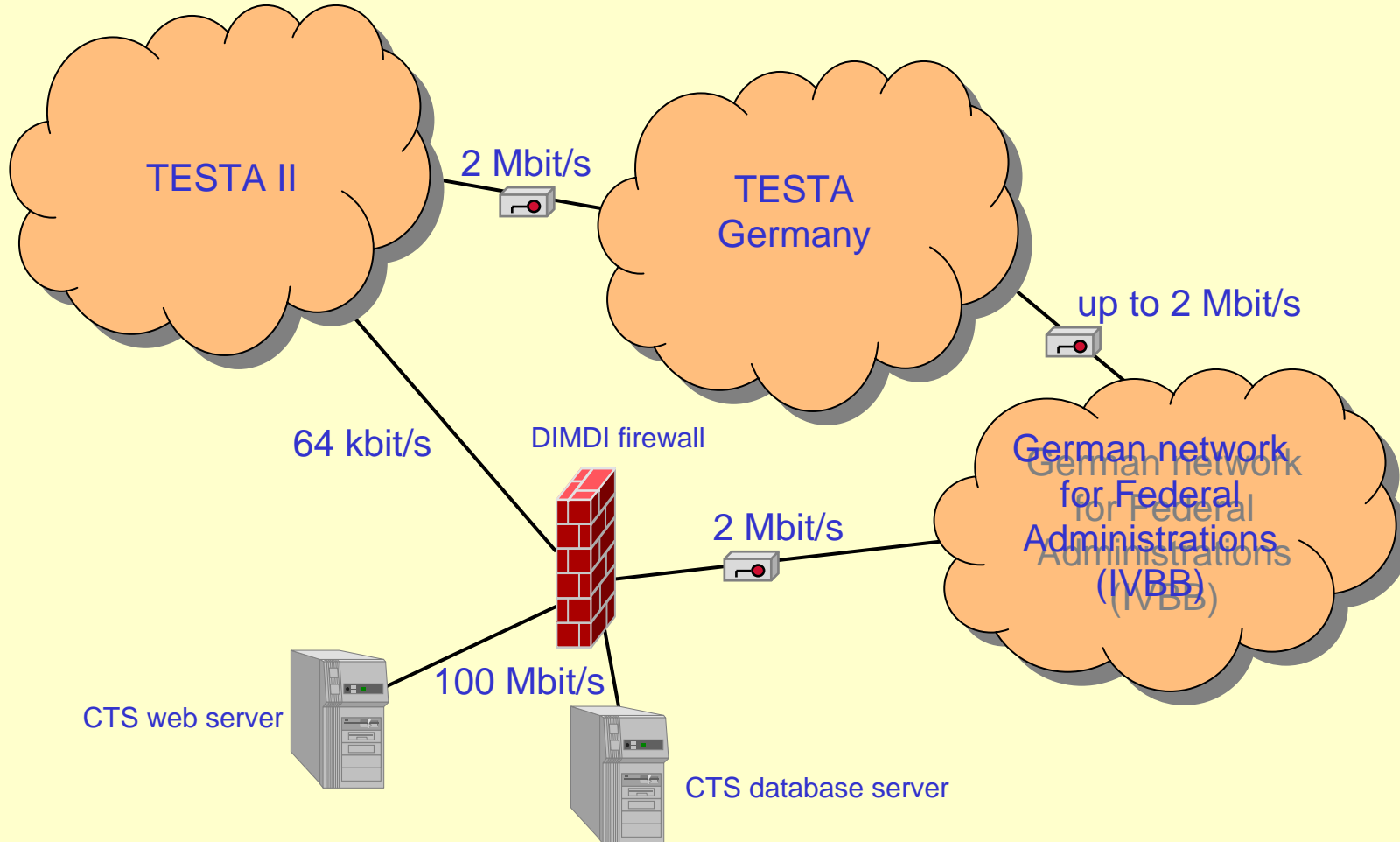
and now the solutions !!!

Meet the users requirements !!

Create a Clean, Extensible Architecture

- a Scalable Server-Environment
 - a Secure Environment
 - a Maintainable System

DIMDI connection to EudraNet: Improvement of Connectivity Speed



First Step: Release and Installation of:

- Win32 client using single file setup
 - » Scheduled release: September 2003
 - » Estimated costs 64,960.00 €
 - » Project started April 2003

Next Step: CTS Next Generation - Client

Next Step: CTS Next Generation - Client

- UI Look and Feel will conform to the Windows-Standard
 - » No more irritating and strange fields/buttons
- Switchable Tabbed- and MDI-User interface

Product Environment: Software I

From the user perspective software runs on the following operating systems:

- » Microsoft Window 98 / 98 SE
- » Microsoft Windows ME
- » Microsoft Windows NT 4.0 SP 6
- » Microsoft Windows 2000 Professional / Server
- » Microsoft Windows XP Home/Professional

The server-components of the system are able to run on the following operating systems:

- » Microsoft Windows 2000 Server
- » Microsoft Windows 2003 Server

Requirements for New Client 5.3.9

(From the 2nd CTS user group meeting 2003 in Cologne)

- Access to database should be possible with the new client version 5.3.9 (Winter 2003) with fallback option
- Solving the problem with the date format (already solved in a test version)
- Type level dialogue should allow only logical and reasonable combinations
- Simplification of configuration of the client (ODBC configuration done automatically)
- Refinement of error handling
- Setting the procedure status (valid - invalid - valid) must be possible

Product Environment: Database III

The Database-components of the system will be able to run on the following Database-systems:

- » Microsoft SQL-Server 2000

Completely new Data-Model

Data-Access only via Stored-Procedures

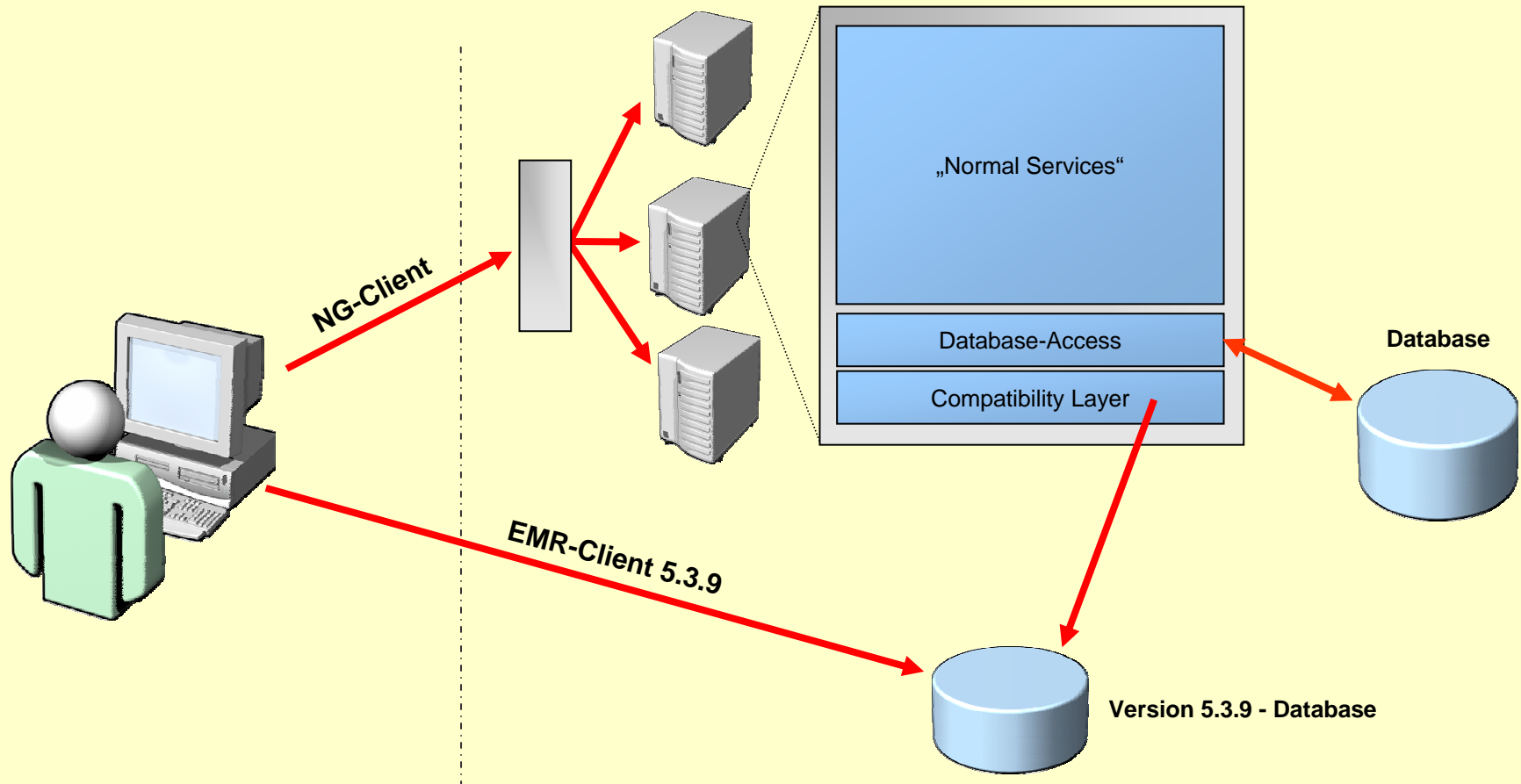
Collision-Detection

Product Environment: Network IV

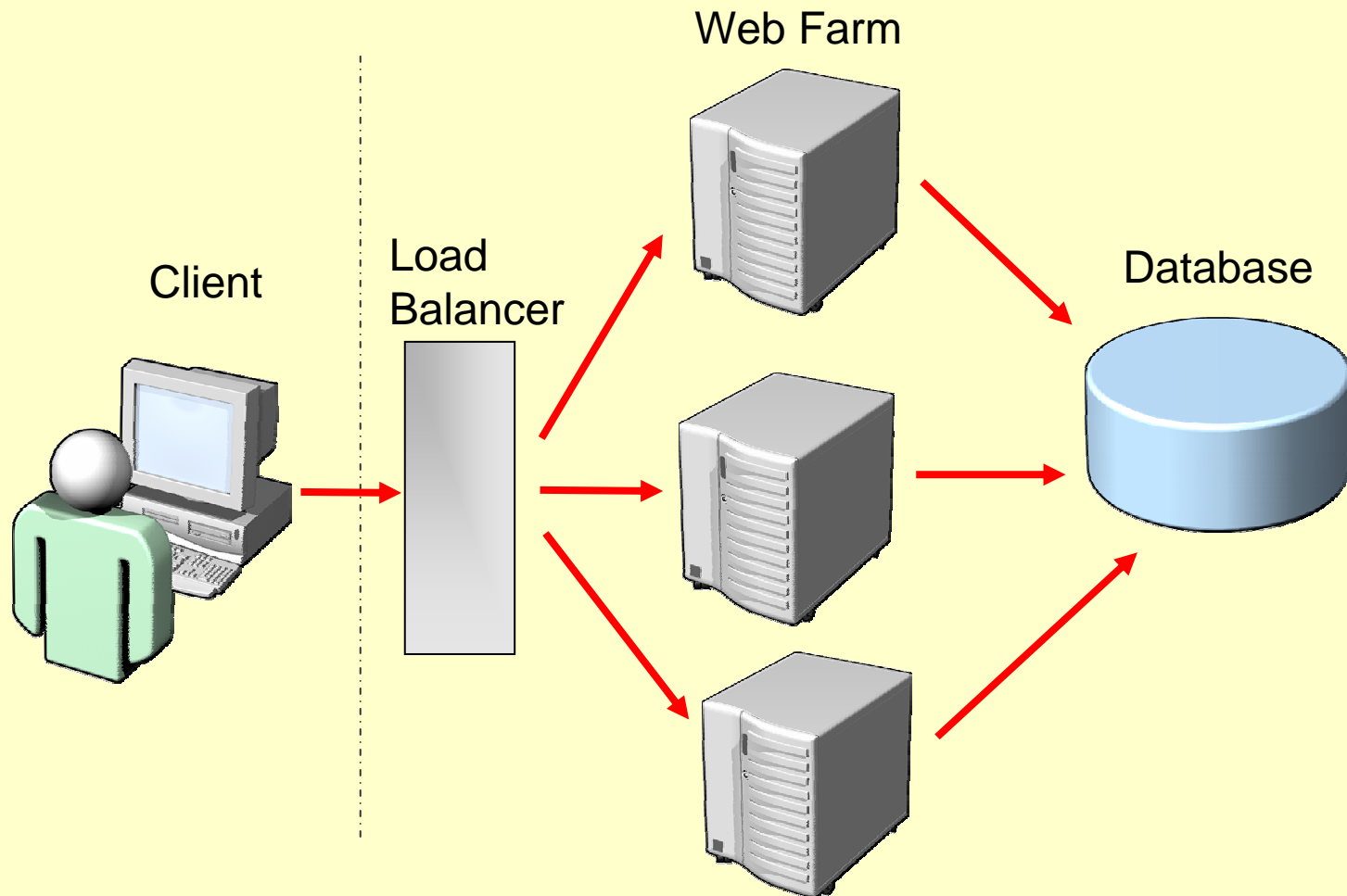
The software can be run on any TCP/IP-network without any special requirements to the network infrastructure. This does not exclude any special preparations, i.e. firewall, etc. that has to do with security in the network.

The software uses only standard protocols, that are “firewall-friendly”, i.e. SOAP over HTTP/1.1 and HTTP/1.1 for the administrative Web-Interface.

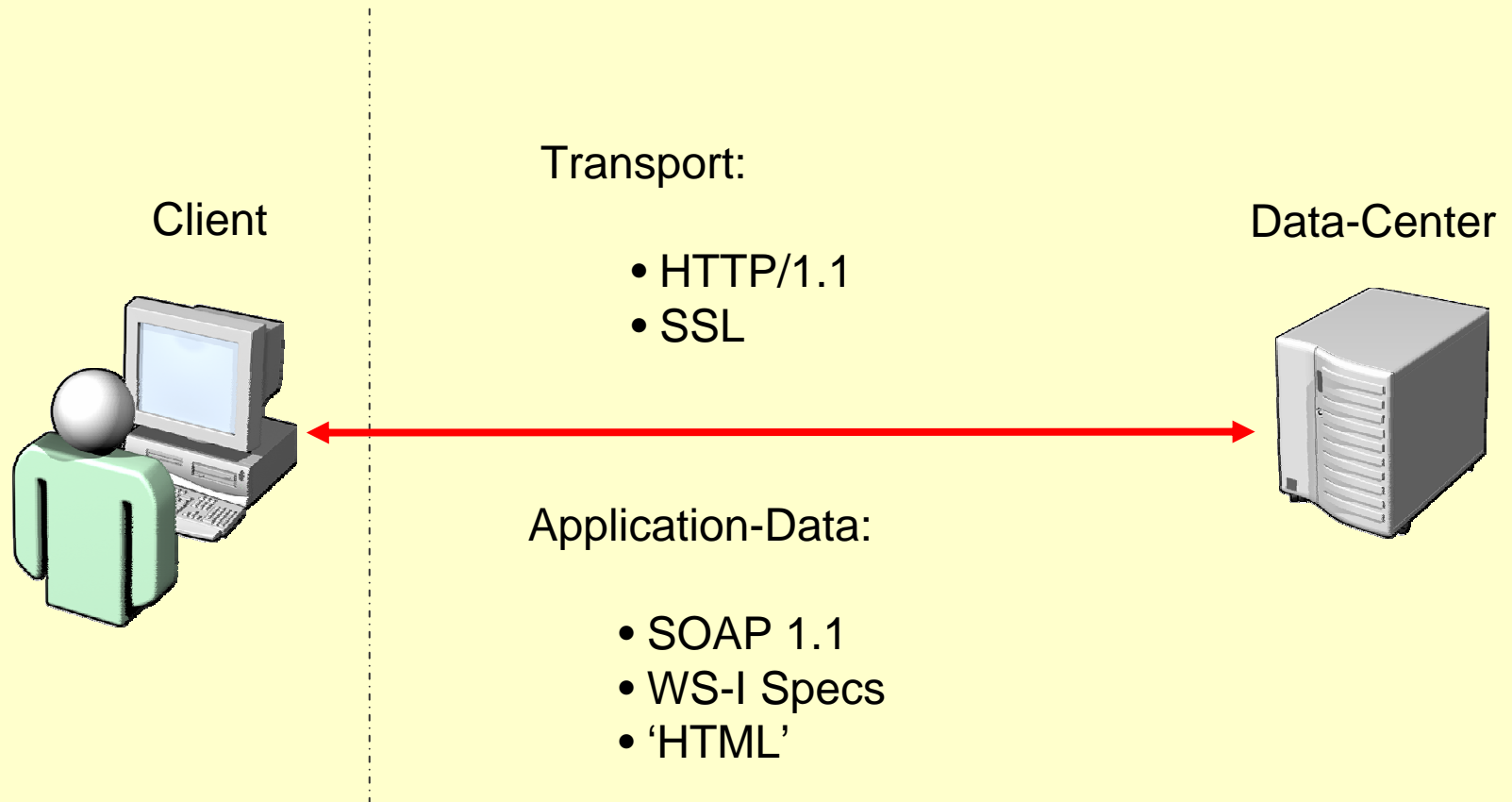
Migration Strategy



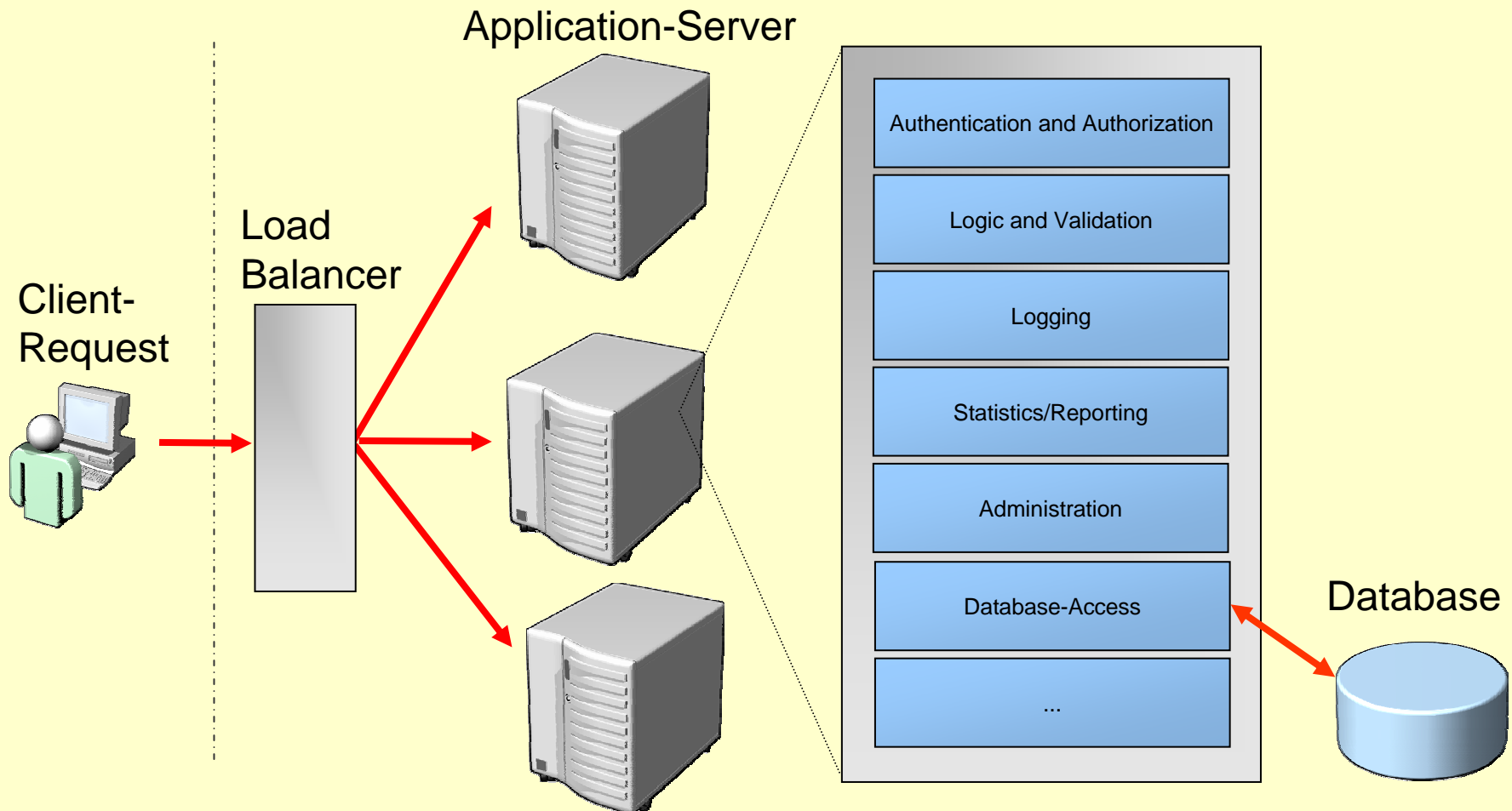
Architecture: Overview



Architecture: Protocols



Architecture: Data-Center



Architecture: Client



- Win32 Client
- Only TCP-Port 80/443 (HTTP/SSL) required
- End-To-End secured communication
- No configuration required
- No DLL-Hell
- Modern GUI
- Windows Look and Feel
- Really easy to update
- Self-Configuring

Client-SW Installation/Updates

- Onetime setup of a Client-PC using CD or downloaded SETUP.EXE
- The client automatically checks for updates
- The client can automatically download and configure the software
- The client software can be updated via CD or downloaded SETUP.EXE
- The update process includes a rollback mechanism

The Client Update Process

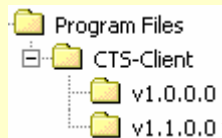
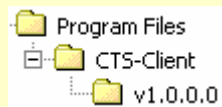
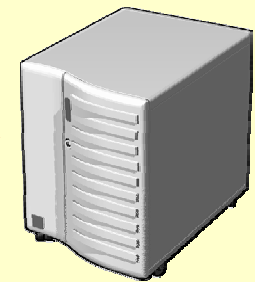
How does it work?

Data Center



New version available?

Yes, download and install it.

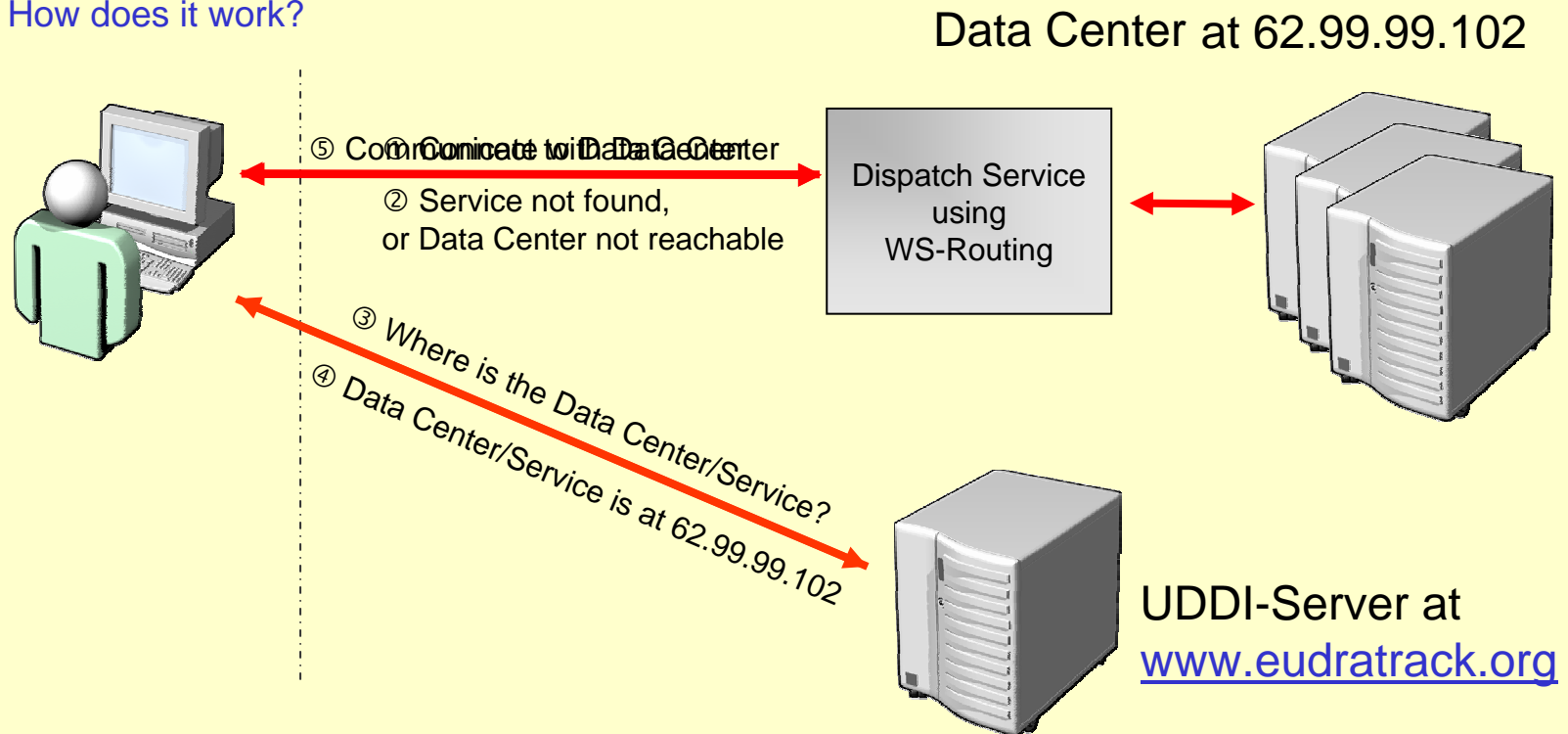


- ✓ Fully automatic download and installation
- ✓ Last versions are kept
- ✓ No Registry changes!
- ✓ No copying of files to Windows- or System32-Directory, aka. DLL-Hell

Self-Configuring Client

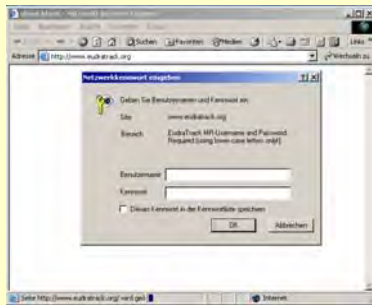
The Client automatically finds the correct server.

How does it work?

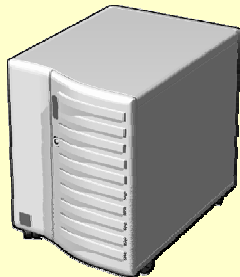


Administration

Web-based Administration for



- Users, Roles, Sites
- Catalog-Management
- Procedure-Manipulation
- Application-Monitoring



Statistics and Reporting

All Statistics defined by the CTS-Usergroup will be available!

- The list of available statistics is server-based
- All statistics will be server-generated
- Various export possibilities

Users will have access to the data through XML-Web-Services, which can be accessed from:

- Microsoft Office: Word, Excel, etc.
- Applications developed by the Agencies

- ✓ Consistent Data
- ✓ Stable Interfaces

Development

- Implementation will use C# and the Microsoft .NET Framework
- Extensive source-code documentation
- Unit-Testing at the Server-side
- Extensive Error-Handling and Logging
- System will be implemented with Localisation in mind (not only date-formats)
- Utilizing GoF-Design Patterns
- Lazy programming: Reduce, Reuse, Recycle
- Layered architecture on the Server-side
- Document/View architecture on the client-side
- Extensible through Plugins
- No use of 3rd Party components without Source-Code

Questions and Answers

- BfArM will closely follow the development process and build a quality assurance team, consisting of Dino Soumpasis and Peter Bachmann.
- Automated Test-Systems will be used.
- Performance-Tests right from the beginning.
- A BfArM-internal Bug-Tracking system will be set up.
- BfArM QA-Team reports to the CTS-Usergroup.
- A CTS-Usergroup QA-Team has to be established.

Milestones

- 10/04 Specialized Specification of the new Variations
- 10/04 Feature-definition completed by the CTS Usergroup
- 10/04 New Data-Model finished
- 12/05 CTS NextGen Server finished
- 30/06 CTS NextGen Client with new Variations finished
- 15/08 Interaction between 5.3.9 and NextGen-Client finished
- 30/08 Beta-Test with CTS Usergroup-Members
- 15/09 Testing Phase at all European Sites
- 01/10 Going Live with new Variations

May/2004* CTS NextGen completely replaces EMR 5.3.9

* Date to be confirmed

We are convinced that.....

- the first step of soft migration is the only possible solution to implement new legislation
- the implementation guarantees the survival of the system
- the implementation increases the quality and the security of CTS
- long-term cost reduction for development and maintenance will arise

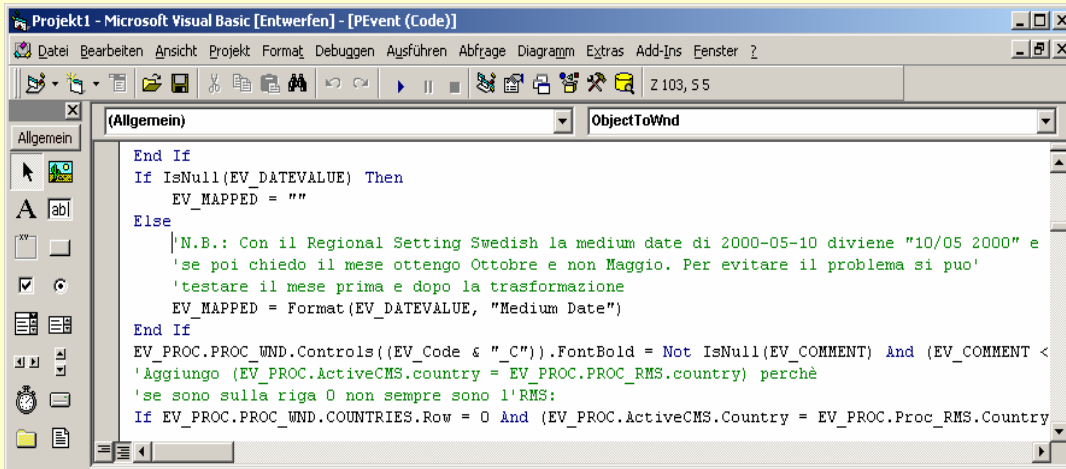
Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)



Thank you for your kind attention

Current System (EMR Client 5.3.9)

e.g.: The so-called „Sweden problem“



```

Projekt1 - Microsoft Visual Basic [Entwerfen] - [PEvent (Code)]
Datei Bearbeiten Ansicht Projekt Format Debuggen Ausführen Abfrage Diagramm Extras Add-Ins Fenster ?
Z 103,55
(Allgemein) ObjectToWnd
Allgemein
End If
If IsNull(EV_DATEVALUE) Then
    EV_MAPPED = ""
Else
    'N.B.: Con il Regional Setting Swedish la medium date di 2000-05-10 diviene "10/05 2000" e
    'se poi chiedo il mese ottengo Ottobre e non Maggio. Per evitare il problema si puo'
    'testare il mese prima e dopo la trasformazione
    EV_MAPPED = Format(EV_DATEVALUE, "Medium Date")
End If
EV_PROC.PROC_WND.Controls((EV_Code & "_C")).FontBold = Not IsNull(EV_COMMENT) And (EV_COMMENT <
'Aggiungo (EV_PROC.ActiveCMS.country = EV_PROC.PROC_RMS.country) perchè
'se sono sulla riga 0 non sempre sono l'RMS:
If EV_PROC.PROC_WND.COUNTRIES.Row = 0 And (EV_PROC.ActiveCMS.Country = EV_PROC.Proc_RMS.Country
  
```

Citation from the
original source code

'N.B.: Con il Regional Setting Swedish la medium date di 2000-05-10 diviene "10/05 2000" e 'se poi chiedo il mese ottengo Ottobre e non Maggio. Per evitare il problema si puo' 'testare il mese prima e dopo la trasformazione

Translation: In the regional setting "Swedish" the medium date "2000-05-10" is changed to "10/05/2000" and then when I check for the date I obtain October instead of May. In order to avoid this problem the month could be tested first and afterwards the transformation.

No more comments on that !!!

Financial Report I

Expected receipts (2002) (3 months; financial annex)	48,660.13 €
Expected receipts (2003) (12 months; financial annex)	194,640.50 €
Total amount	243,300.63 €
20% excess (contractually accorded)	38,928.10 €
Resulting possible financial frame	282,228.73 €

Financial Report II

• Preliminary financing 2002	26,714.71 €
• Current costs 2003	28,539.22 €
• Contractual obligation 2003	98,765.81 €
• Expected max. personnel costs 2003 (depends on engagement of personnel)	120,042.00 €
• Max. disbursements 2003	274,061.74 €
• Max. receipts 2002 & 2003 including 20%	<u>282,228.73 €</u>
• Result (surplus)	8,166.99 €

Financial Report III

(implementing new legislation)

- Expected costs 64,960.00 €
(Distributable costs for Member States)
- BfArM/DIMDI will try to reduce all upcoming costs with regard to personnel and infrastructure
- Concerning all financial issues, please contact head of finance (Mr. Schäfer, BfArM)