

EudraTrack/CTS

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1st CTS - Report (after takeover)

- Activity Report
- Financial Report
- Network (status report)
- CADREAC (technical solutions)
- Proposal for new implementations

Activity Report

- 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

- Implementation of mailing lists
 - > remote subscription (begin of 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
- In the meantime all agencies have access

Financial Report

(overview of 12th February 2002)

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 €

*One invoice will be sent to all Member States for 2002 & 2003 during the 3rd week of February 2003

20% excess (contractually accorded)	38,928.10 €
Resulting possible financial frame	282,228.73 €

Financial Report

(overview of 12th February 2002)

• 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

(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)

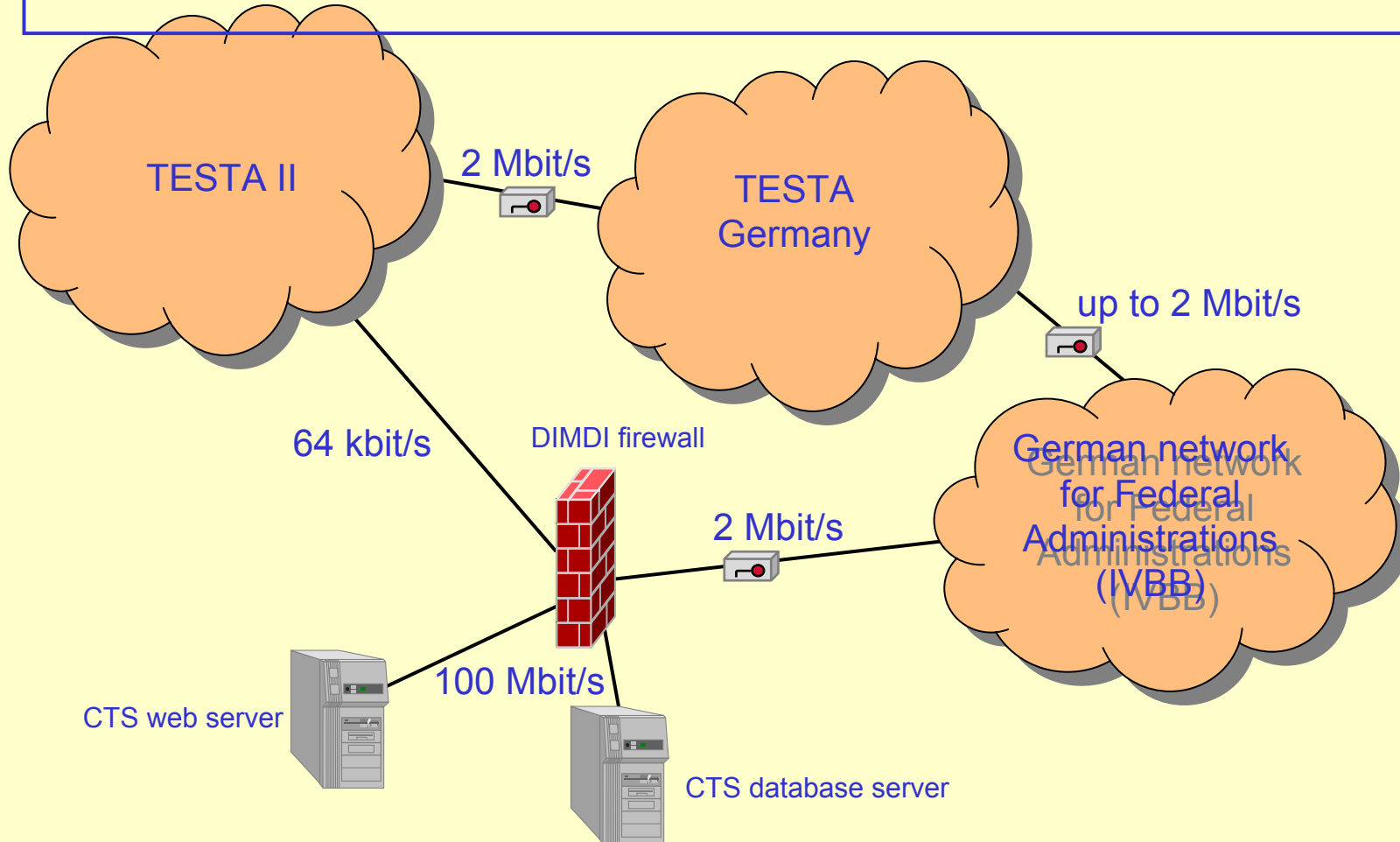
Financial Report

(details)

	A	B	C	D	E	F
1						
2		EudraTrack costs 2002 and 2003				
3						
4						
5		Preliminary financing	Actual costs	Contractual obligation	Max. disbursement	
6		2002	2003	2003	2002 / 2003	
7	Hard- and Software					
8	database server + backup		21.654,88 €			
9	web server + backup			16.891,45 €		
10	software (2x each SQL-Server, Windows 2000 Advanced Server,VPN)					
11	it-infrastructure (fire protection, high availability, maintenance contracts)		6.462,30 €	8.793,15 €		
12	travel costs	786,50 €	422,04 €	2.000,00 €		
13						
14	Staff					
15	projekt management (BfArM / DIMDI)					
16	network/firewall (DIMDI)			55.229,00 €		
17	DB-administration (externer Support)	25.928,21 €		48.720,00 €		
18	software maintenance (externer Support)					
19	helpdesk (system) (DIMDI)					
20	helpdesk (application) (BfArM)			35.258,00 €		
21	administration (BfArM)			29.555,00 €		
22	expenditure on material - office supplies (2,5x)					
23						
24						
25	Network					
26	setup EudraNet			3.036,42 €		
27	EudraNet fee			19.324,79 €		
28	Internet fee					
29						
30	Overall sum 2002 and 2003	26.714,71 €	28.539,22 €	218.807,81 €	274.061,74 €	
31						
32						
33						

DIMDI connection to EudraNet

Connectivity Speed

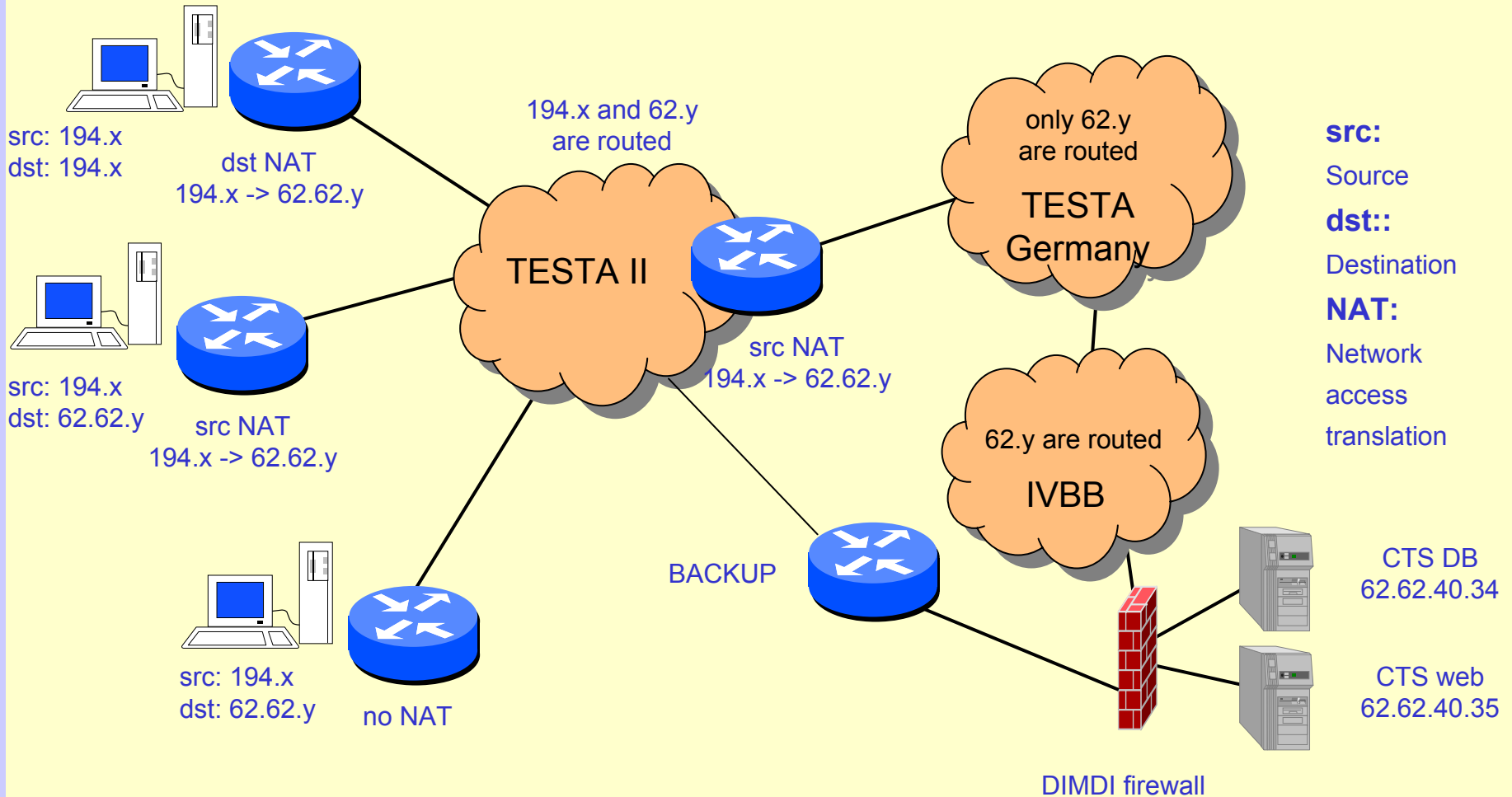


IP Addresses for CTS Servers

database	web	connection	assigned by
194.81.126.201	194.81.126.201	main	EudraNet administration
62.62.40.34	62.62.40.35	main	IVBB from TESTA II pool
62.62.41.128	62.62.41.129	backup	Equant

- TESTA II network is based on 62.62.x addresses
- 19x.y addresses are bequest of TESTA I
- For use of TESTA I addresses, the routers at every agency site must be reconfigured
- This results in three different types of client connections
- **DIMDI is able to connect with three types of client connections depending on routing or network access translation (NAT)**

IP Addressing Scheme (main connection and backup)



Usage of CTS by CADREAC Countries Technical Solutions

Status

- November 2002
 - > Formal request during HoA/HEVRA meeting (27th November 2002) to implement CTS in institutions of CADREAC countries
- Formal requirements
 - > Letter of confidentiality
Responsible: Dr. Paul Weissenberg
Accepted by Dr. Milan Smid (Chair of CADREAC)

Solutions

- Announcing 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
- In „read only“ mode

Formal prerequisite: signature on letter of confidentiality

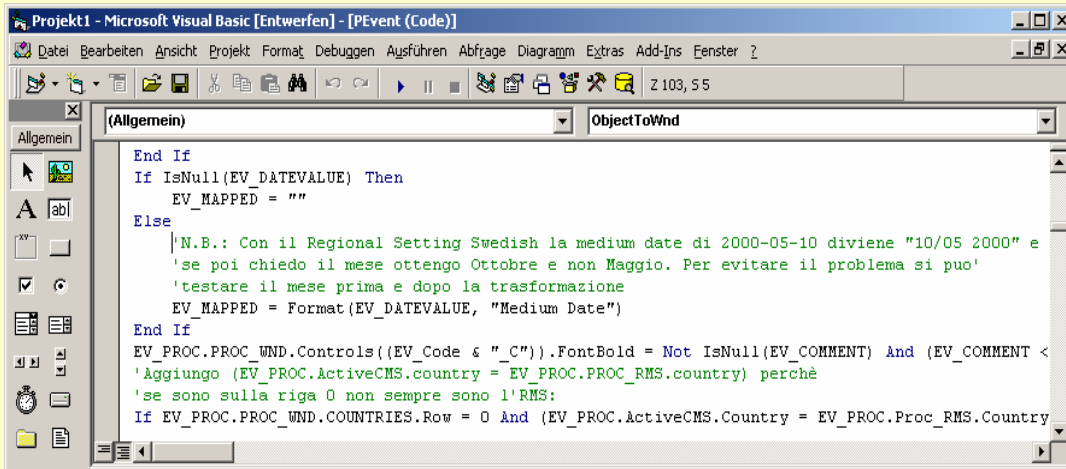
and now the problems !!!

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

Current System (EMR Client 5.3.9)

e.g.: The so-called „Sweden problem“



```

(Allgemein) ObjectToWnd
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 !!!

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, ... input data not completely visible

Current System (EMR Client 5.3.9)

- 3rd party components (e.g. Visual Basic developing tools)
 - > 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

and now the solutions !!!

CTS Next Generation - Client

- Necessity
- Requirements
- Release and installation
- Time schedule

Necessity (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

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 !!*



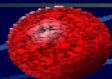
TOPGRAF

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

Proposal **CODE RE-ENGINEERING**

- Interface
- Business Logic
- Data Providers
- **Benefits**
 - Scalability
 - Flexibility

*In their own
words !!*



TOPGRAF

Requirements for New Client 5.3.9

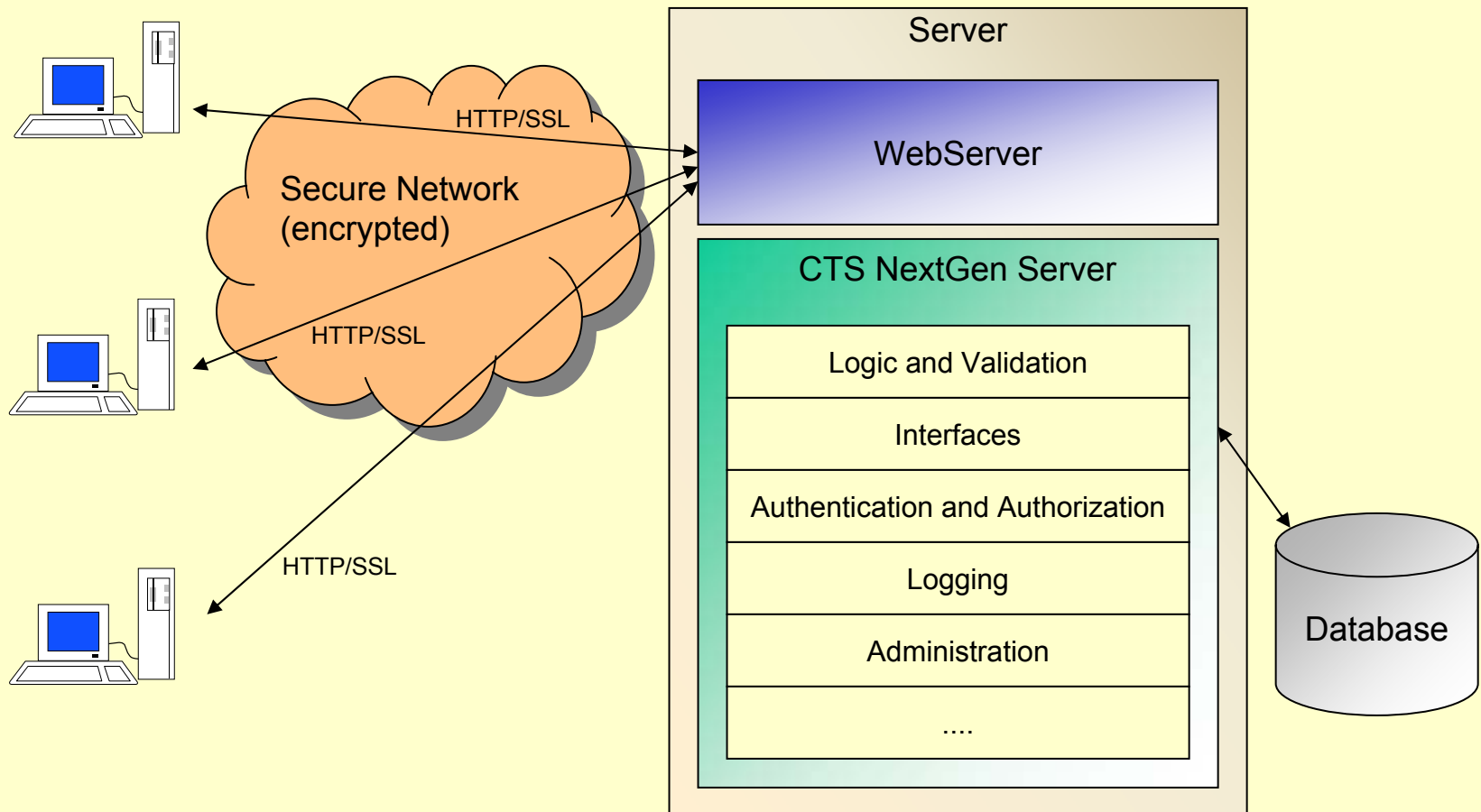
(CTS user group meeting)

- 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

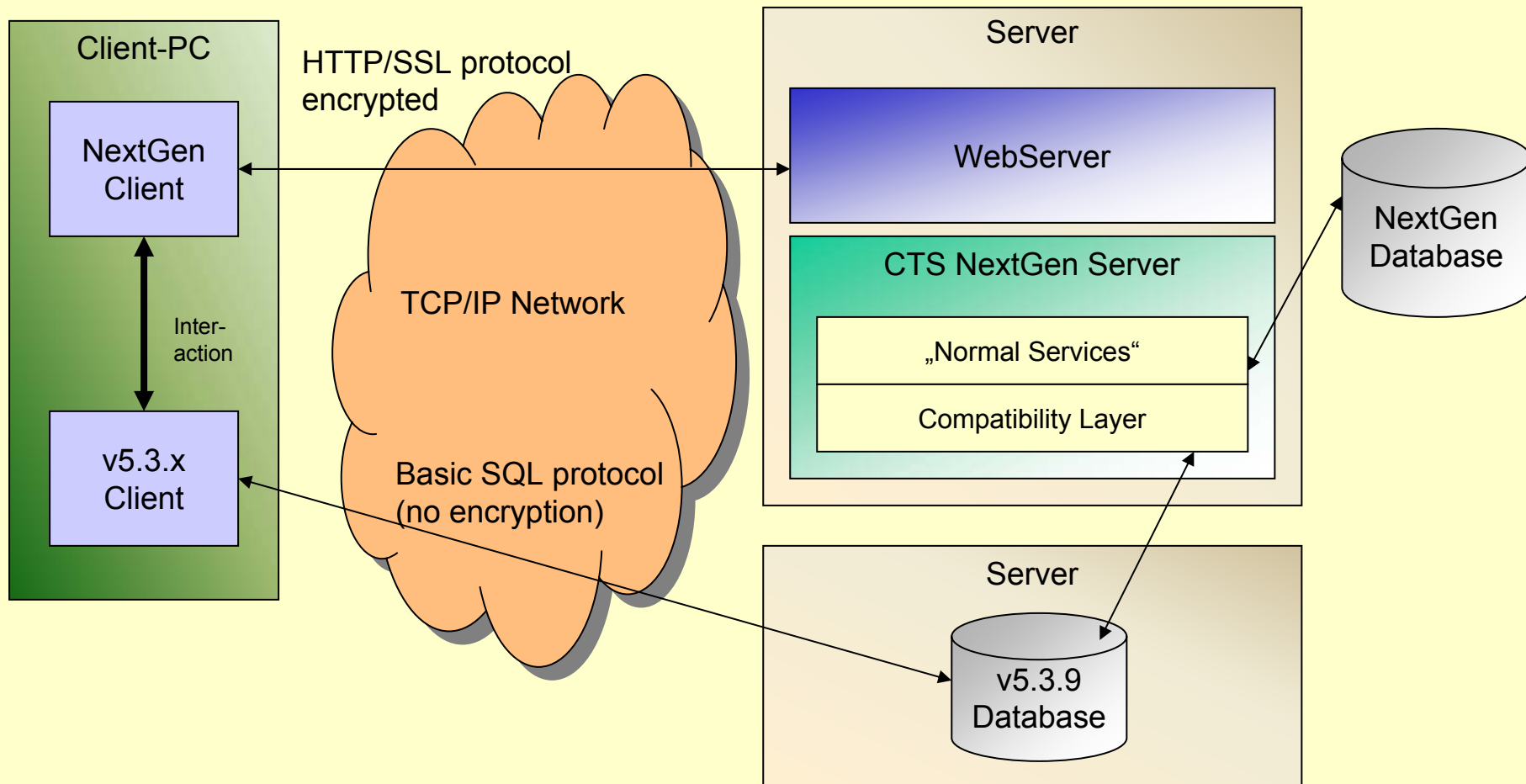
Requirements for a New System

- 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

CTS NextGen Architecture



Migration Strategy



Restrictions

- Data from the JRC Database version 5.3.9
 - > will not be 100% correct
 - > will only be readable, but not editable
- Custom data analysis
 - > needs to be migrated to the new interfaces

Release and Installation

- Win32 client using single file setup
- Scheduled release: September 2003
- Estimated costs 64,960.00 €
- Project start (foreseen) April 2003

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

How to finance the 64,960.00 € ????

HoA/HEVRA Meeting

Thank you for your attention