



Sicherheitskonzepte für Biobanken am Beispiel von GENOMatch



Tembit Software GmbH

11. Dezember 2006

Sicherheitskonzepte in der vernetzten medizinischen Forschung, TMF-Workshop

Inhalt

- GENOMatch
- Sicherheitsanforderungen
- Praktische Beispiele
- GENOMatch Sicherheitskonzept
- 'Vertrauen schaffen'
- Bewertung



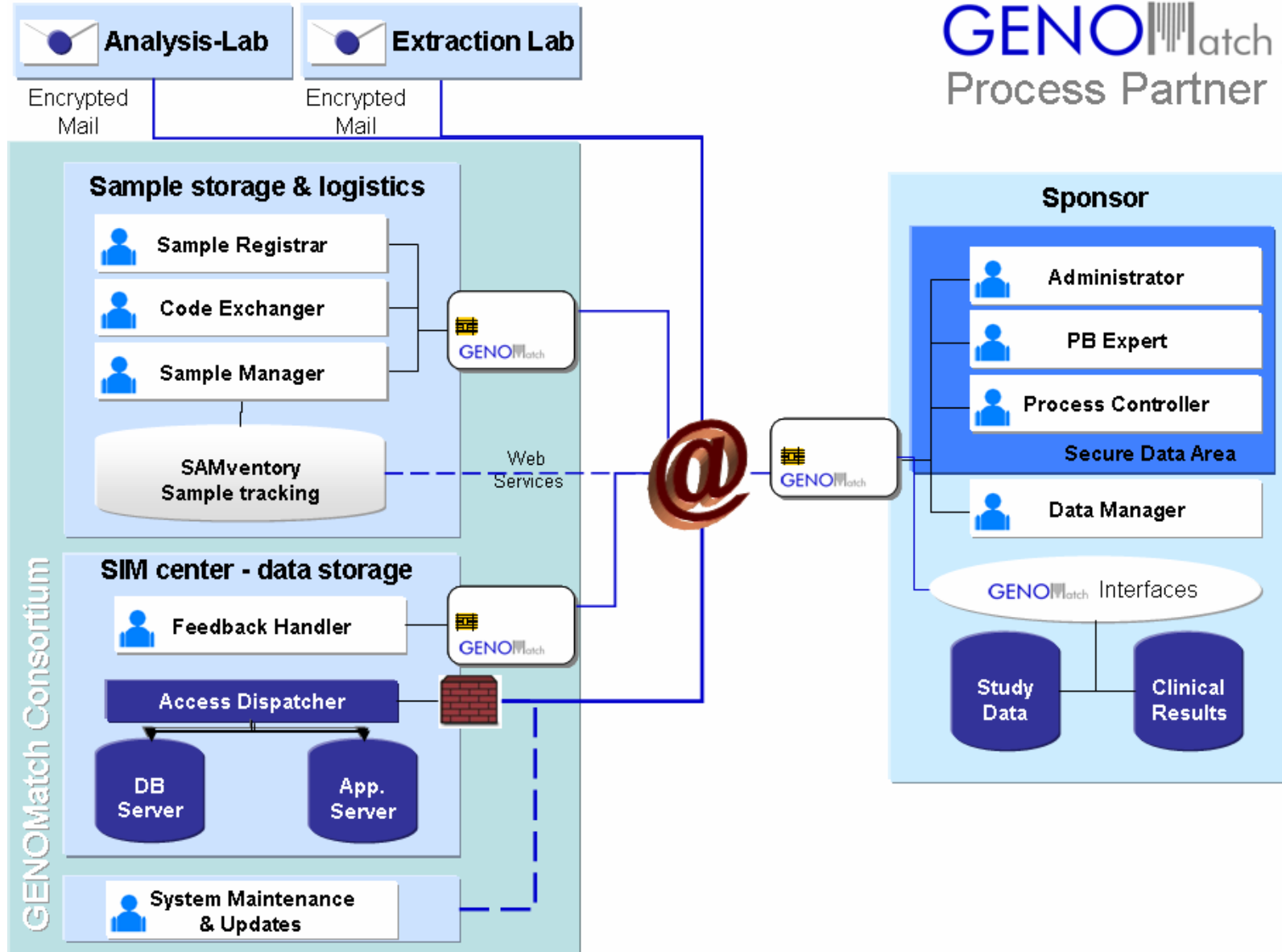
Sicherheitskonzepte für Biobanken am Beispiel von GENOMatch

GENOMatch

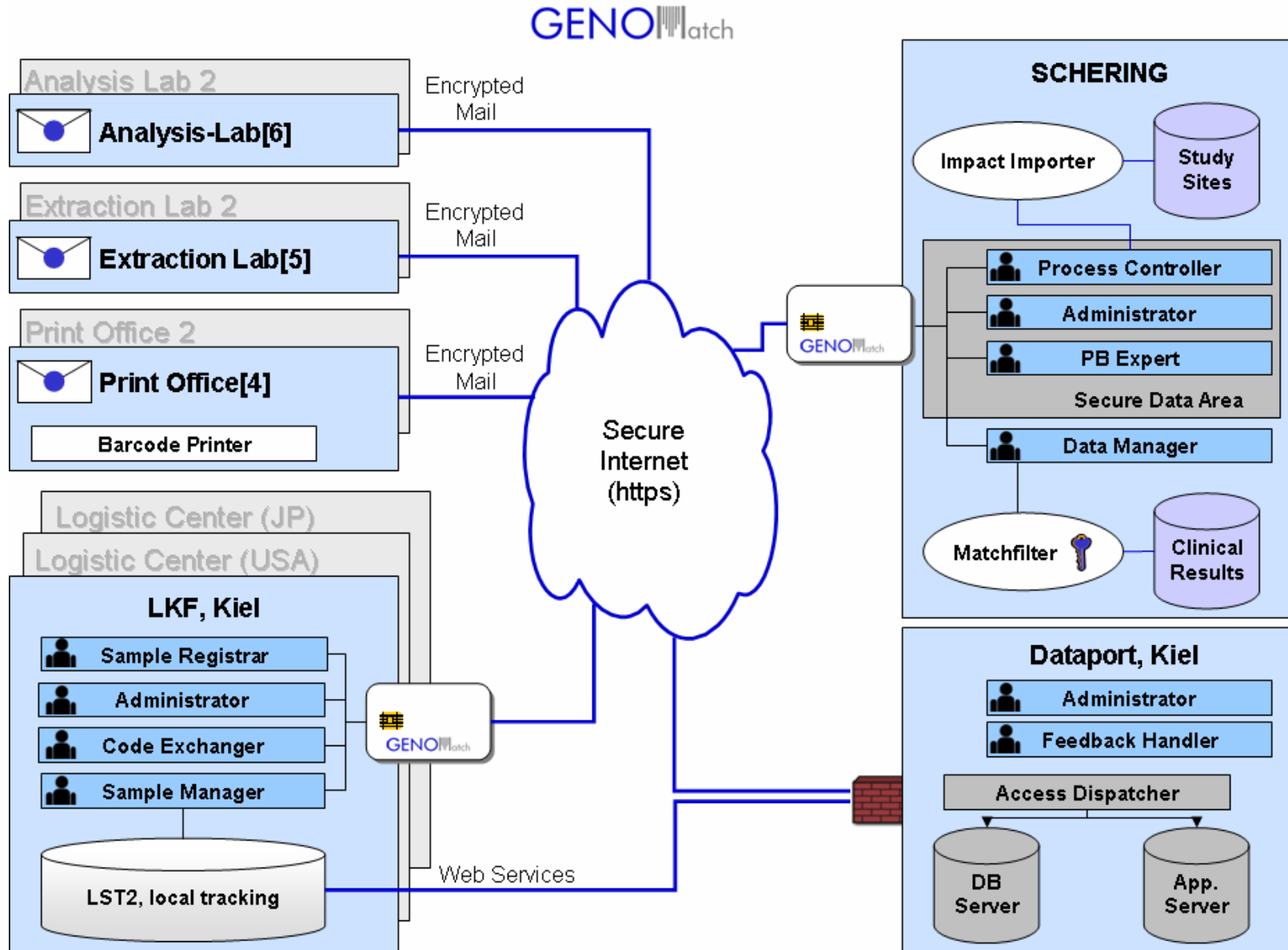
- Internet-basiertes Logistiksystem für pharmakogenetische Substudien (Biobank)
- Projektstart: 03.2003
- Projektende: 12.2004
- Produktiveinsatz: 2 Jahre
- Probenmenge: ca. 5.000
- Speicherung von personenbezogenen, genetischen Daten in pseudonymisierter Form (PN – BC1 – BC2)

GENOMatch

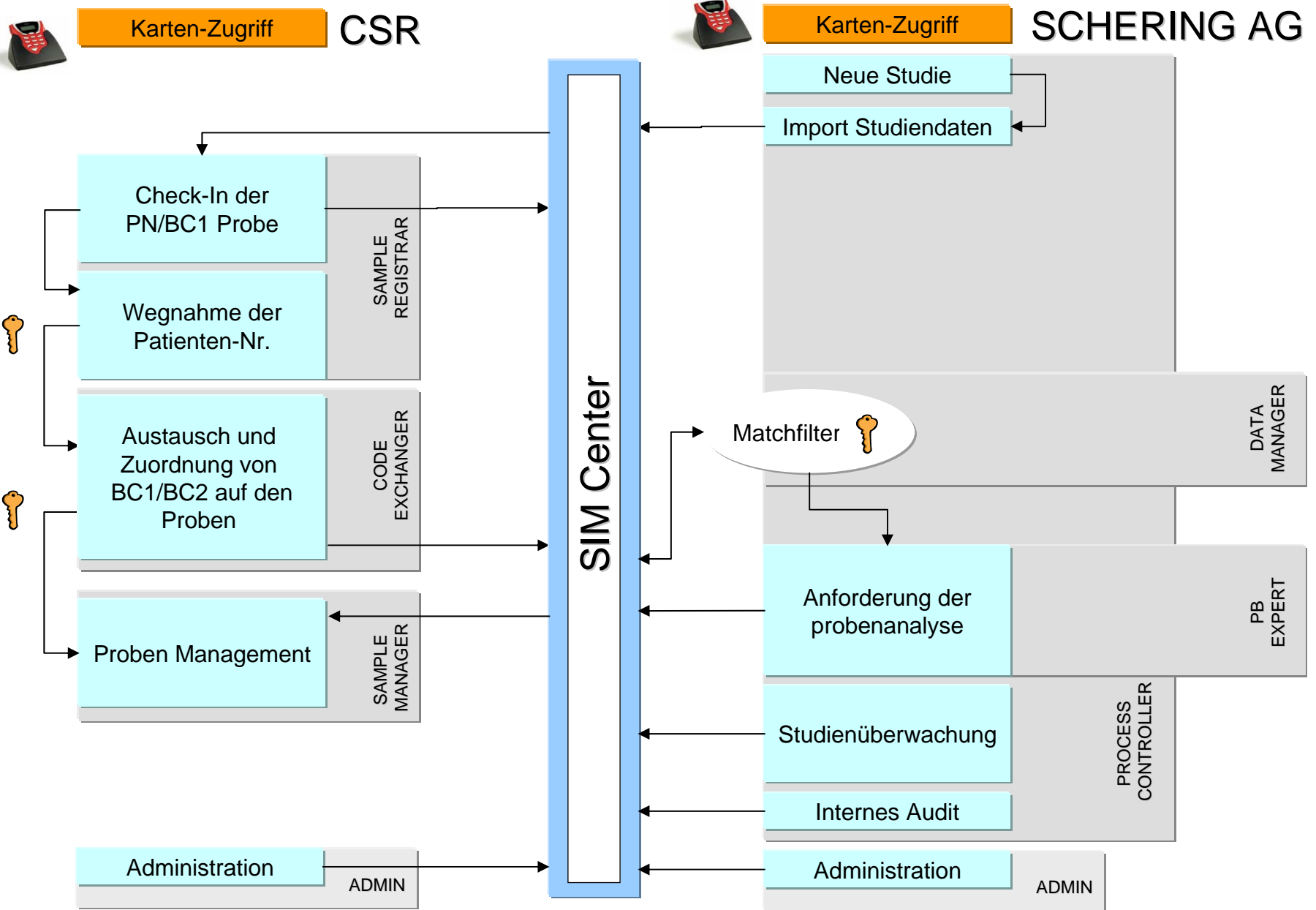
GENOMatch
Process Partner



GENOMatch bei Schering



GENOMatch - Ablauf



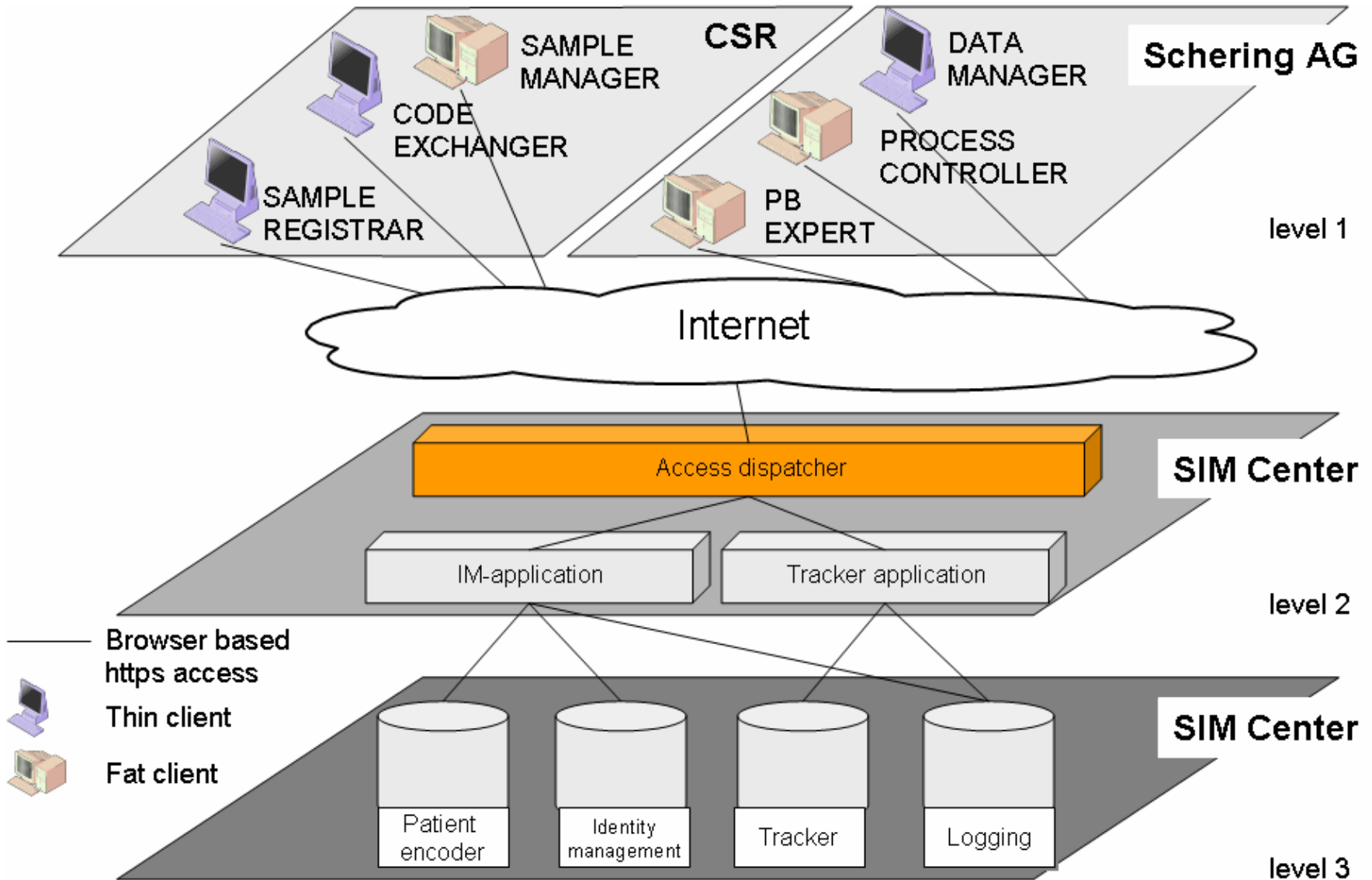
A solid black square positioned to the left of the section header text.

Sicherheitskonzepte für Biobanken am Beispiel von
GENOMatch

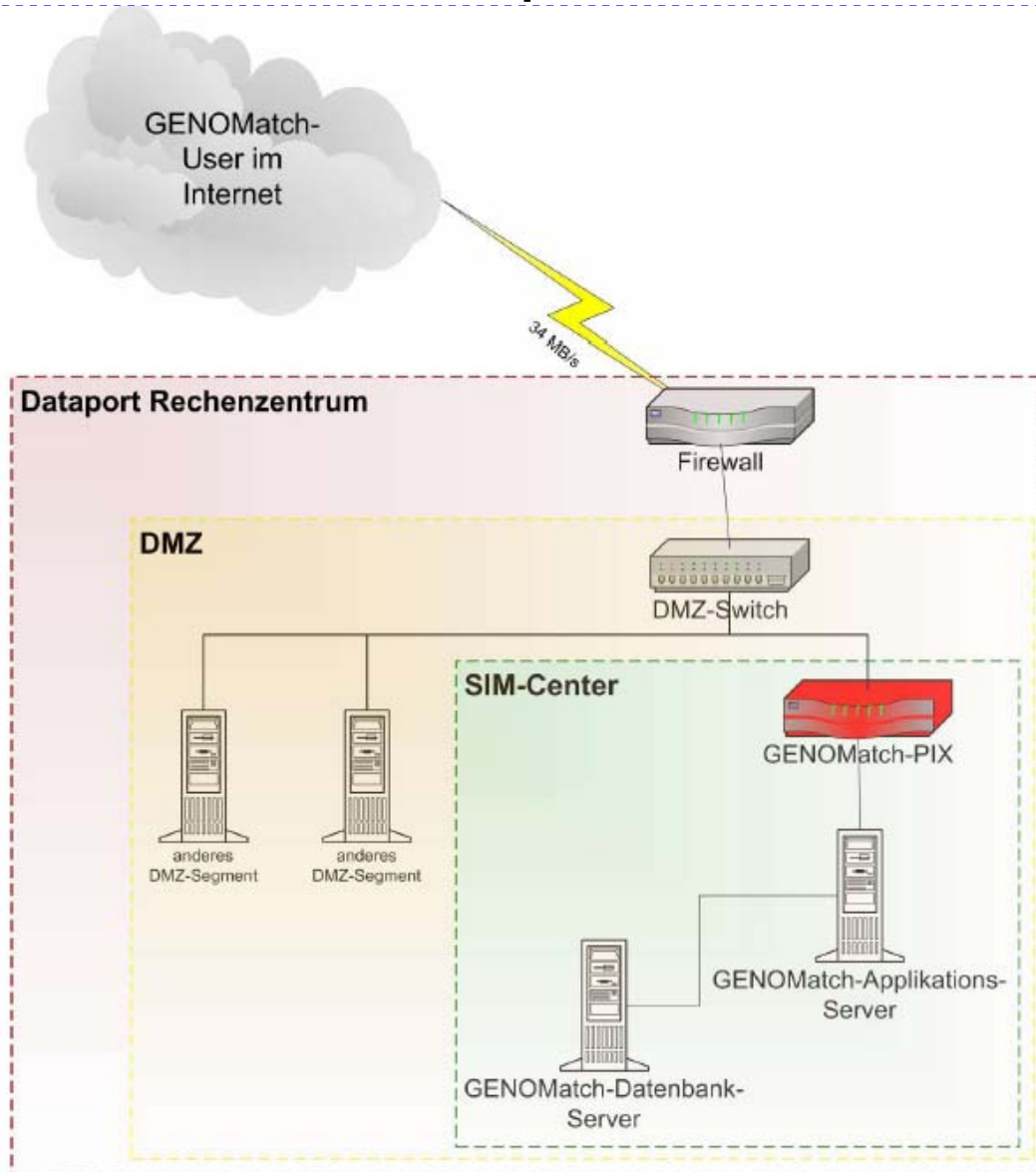
A blue arrow pointing to the right, positioned to the left of the section header text.

Sicherheitsanforderungen

GENOMatch



GENOMatch bei dataport



Sicherheitsanforderungen

- Technologische Sicherheitsanforderungen
 - Smart Card Zugriff
 - Verschlüsselung der Datenübertragung
 - Mail-Verschlüsselung
 - Datenbank Verschlüsselung (partiell)
 - Triple Code Pseudonymisierung
 - Patienten-Feedback
 - Minimale Eingriffe in bestehende Prozesse
- Organisatorische Sicherheitsanforderungen
 - Post-Ident Verfahren
 - Standard Operating Procedures (SOP)
 - Rollentrennung
 - 4-Augen-Prinzip
 - “Secure Data Area”
- Qualitätsanforderungen
 - Konformität nach GCP und CFR21 Part 11 (Validierung & Change Management)



Sicherheitskonzepte für Biobanken am Beispiel von GENOMatch



Praktische Beispiele

Proben Check-in



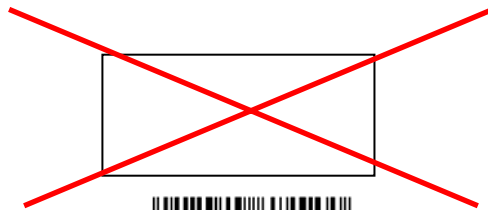
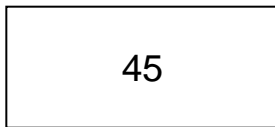
Patientennummer
Barcode 1



Barcode 1




Barcode 2



Proben Check-in


Genomatch Reference System - BC1 to BC2 change - Microsoft Internet Explorer


Adresse <https://www.tembit.de:8443/genomatch/codeex.do?method=verifyBC2Form>



Menu

- Order BC2
- BC1 to BC2 change**
- Mail list
- Home
- Logout

User 		Reference System	
User name	Horst Jensen	Date	08.12.2006
Institution	Sample CSR	Role	CODE EXCHANGER

BC1 to BC2 change 

Step I: Verify BC2

- Please scan BC2 on paper form.

Scan first BC2 on paper form

Scan second BC2 on paper form

Scan BC1 on tube

Scan BC2 on tube

BACK

Fertig Internet

Proben Check-in

GENOMatch - Assign Patient - Microsoft Internet Explorer

Datei Bearbeiten Ansicht Favoriten Extras ?

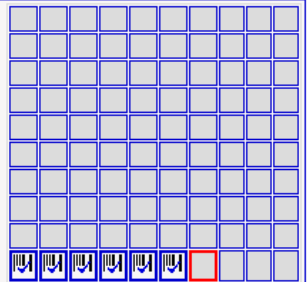
Zurück Suchen Favoriten Adresse <https://www.tembit.de:8443/training/genomatch/assignpat.do>



- Menu
- Study list
- Assign Patient**
- Reassign Patient
- Reassign Trial Site
- Withdraw Patient
- PN/PCI Search
- Assign BC3
- Order BC1
- Verify BC1
- Order BC3
- Verify BC3
- Feedback list
- Confirm Tube Destruction
- Reassign Tube
- Mail list

- My Genomatch
- Home
- Logout

User	
User name	Sample Registrar
Institution	Test CSR
Date	08.12.2006
Role	SAMPLE REGISTRAR
Assign Patient	
Selected study: so-12345 - Quick Test Study	
Rack number: 161	
completed	
(PN: 2004) assigned. (This is 2 of 2 tubes by this patient in this study.)	
Trial site	1833 - Praxis Frühling
Enter patient number	2005
Re-enter patient number	2005
PCI(dd.mm.yyyy)	20.05.1960
Feedback	<input type="checkbox"/>
Scan BC1	0198075567899816
Assign Reset	
6 tubes were assigned.	



Change rack

0.596 sec.


BACK

Proben Check-in

GENOMatch - BC1 to BC2 change - Microsoft Internet Explorer

Datei Bearbeiten Ansicht Favoriten Extras ?

Zurück Suchen Favoriten Adresse <https://www.tembit.de:8443/training/genomatch/bc1tobc2.do>



Menu

- Order BC2
- BC1 to BC2 change**
- BC3 to BC2 change
- Mail list

- My Genomatch
- Home
- Logout

User

User name	Code Exchanger	Date	08.12.2006
Institution	Test CSR	Role	CODE EXCHANGER

BC1 to BC2 change

Step I: Verify BC2

Rack number: 161

completed

- Tube is de-identified.

Scan first BC2 on paper form

Scan second BC2 on paper form

Scan BC1 on tube

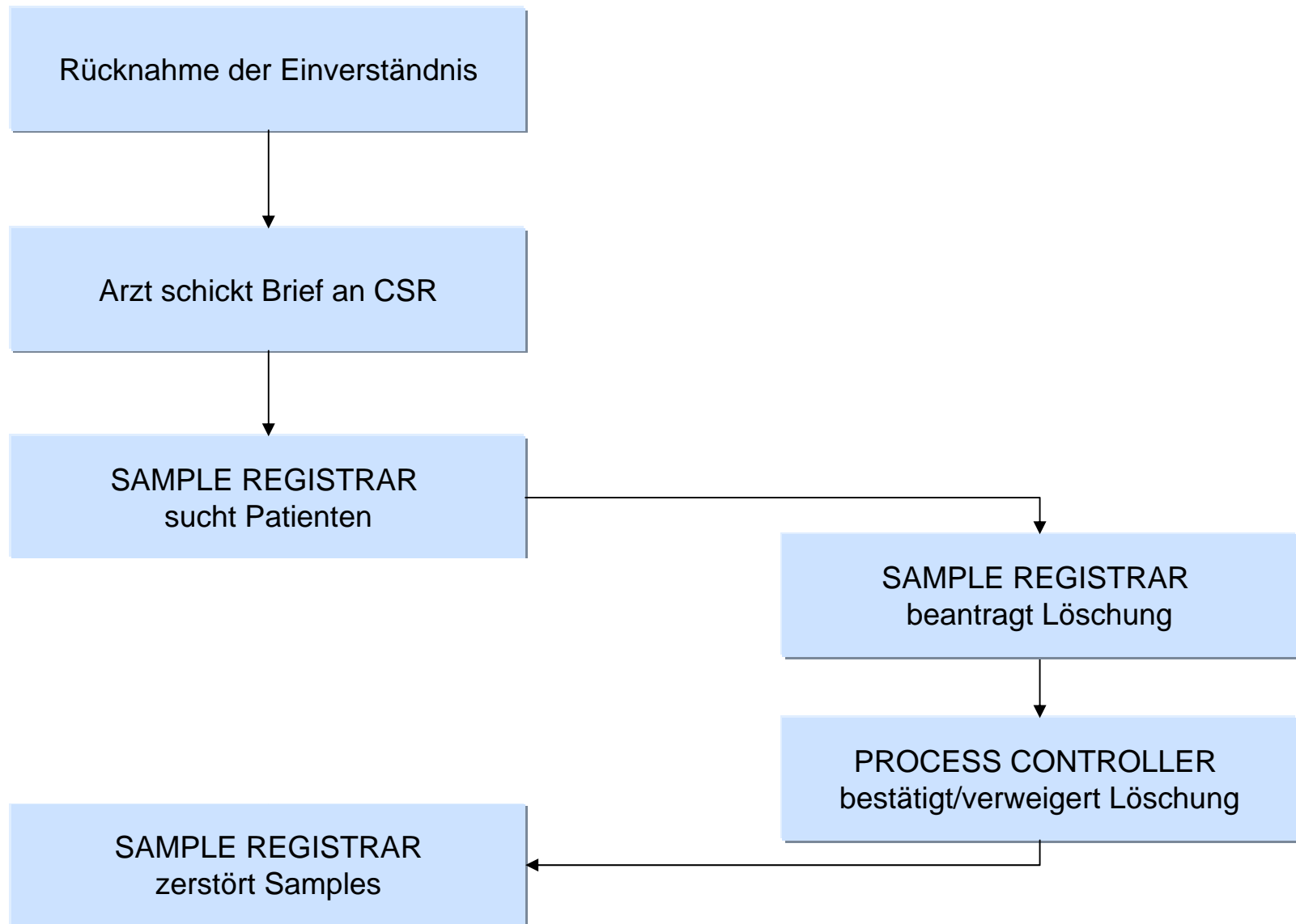
Scan BC2 on tube

1 tube was de-identified.

1.419 sec. BACK

Fertig Internet


Patientenlöschung (4-Augen-Prinzip)



Patientenlöschung (4-Augen-Prinzip)

GENOMatch - Withdraw Patient - Microsoft Internet Explorer

Adresse: <https://www.tembit.de:8443/training/genomatch/samplerreg.do?method=dropoutPatientForm>



Menu

- Study list
- Assign Patient
- Reassign Patient
- Reassign Trial Site
- Withdraw Patient**
- PN/PCI Search
- Assign BC3
- Order BC1
- Verify BC1
- Order BC3
- Verify BC3
- Feedback list
- Confirm Tube Destruction
- Reassign Tube
- Mail list

- My Genomatch
- Home
- Logout

User			
User name	Sample Registrar	Date	12.10.2006
Institution	Test CSR	Role	SAMPLE REGISTRAR

Withdraw Patient

Selected study: so-12345 - Quick Test Study

Enter patient number:

Re-enter patient number:

PCI(dd.mm.yyyy):

Remark (don't write PN or PCI here, this remark will be sent to Process Controller):

0.087 sec. BACK


Internet

Patientenlöschung (4-Augen-Prinzip)

GENOMatch - Confirm Withdraw Patient - Microsoft Internet Explorer

File Bearbeiten Ansicht Favoriten Extras ?

Zurück Suchen Favoriten Adresse <https://www.tembit.de:8443/training/genomatch/predropout.do>



Menu

- Study list
 - Assign Patient
 - Reassign Patient
 - Reassign Trial Site
 - Withdraw Patient**
 - PN/PCI Search
 - Assign BC3
 - Order BC1
 - Verify BC1
 - Order BC3
 - Verify BC3
 - Feedback list
 - Confirm Tube Destruction
 - Reassign Tube
 - Mail list
- My Genomatch
- Home
- Logout

User ?			
User name	Sample Registrar	Date	12.10.2006
Institution	Test CSR	Role	SAMPLE REGISTRAR

Confirm Withdraw Patient ?

Selected study: [so-12345 - Quick Test Study ?](#)

Are you sure that you want to withdraw this patient?

PN: 1120

PCI: 11.02.1988

With remark: Patient asked for deletion

REQUEST PATIENT'S WITHDRAWAL

0.445 sec. BACK

Fertig Internet


Patientenlöschung (4-Augen-Prinzip)

GENOMatch - Withdrawal requested - Microsoft Internet Explorer

File Edit View Favorites Extras ?

Back Forward Stop Home Search Favorites Refresh Print Mail Stop Close

Adresse <https://www.tembit.de:8443/training/genomatch/samplerreg.do?method=requestDropout&pn=1120&>



Menu

- Study list
- Assign Patient
- Reassign Patient
- Reassign Trial Site
- Withdraw Patient**
- PN/PCI Search
- Assign BC3
- Order BC1
- Verify BC1
- Order BC3
- Verify BC3
- Feedback list
- Confirm Tube Destruction
- Reassign Tube
- Mail list

- My Genomatch
- Home
- Logout

User ?			
User name	Sample Registrar	Date	12.10.2006
Institution	Test CSR	Role	SAMPLE REGISTRAR

Withdrawal requested ?

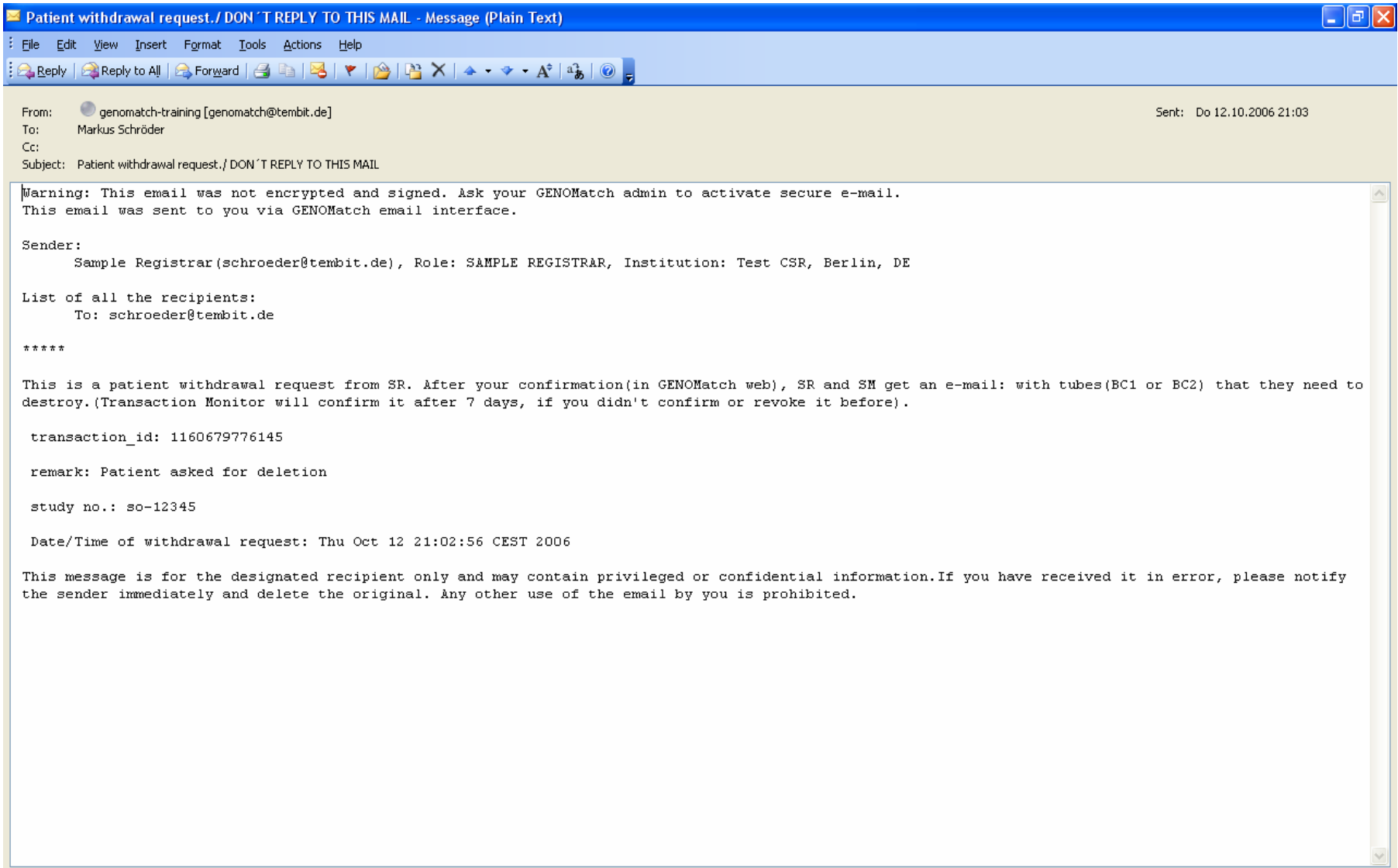
- Withdrawal requested. You will get confirmation by e-mail after Process Controller confirms your request.

[Back to study overview](#)

1.645 sec. BACK

Fertig Internet

Patientenlöschung (4-Augen-Prinzip)



The screenshot shows an email client window titled "Patient withdrawal request./ DON'T REPLY TO THIS MAIL - Message (Plain Text)". The window has a menu bar (File, Edit, View, Insert, Format, Tools, Actions, Help) and a toolbar with icons for Reply, Reply to All, Forward, and other actions. The email content is as follows:

From: genomatch-training [genomatch@tembit.de] Sent: Do 12.10.2006 21:03
To: Markus Schröder
Cc:
Subject: Patient withdrawal request./ DON'T REPLY TO THIS MAIL

Warning: This email was not encrypted and signed. Ask your GENOMatch admin to activate secure e-mail.
This email was sent to you via GENOMatch email interface.

Sender:
Sample Registrar(schroeder@tembit.de), Role: SAMPLE REGISTRAR, Institution: Test CSR, Berlin, DE

List of all the recipients:
To: schroeder@tembit.de

This is a patient withdrawal request from SR. After your confirmation(in GENOMatch web), SR and SM get an e-mail: with tubes(BC1 or BC2) that they need to destroy.(Transaction Monitor will confirm it after 7 days, if you didn't confirm or revoke it before).

transaction_id: 1160679776145

remark: Patient asked for deletion

study no.: so-12345


Date/Time of withdrawal request: Thu Oct 12 21:02:56 CEST 2006

This message is for the designated recipient only and may contain privileged or confidential information.If you have received it in error, please notify the sender immediately and delete the original. Any other use of the email by you is prohibited.

Patientenlöschung (4-Augen-Prinzip)

GENOMatch - Reassign/Withdrawal - Microsoft Internet Explorer

Adresse: <https://www.tembit.de:8443/training/genomatch/process.do?method=transactionList>



Menu

- Study list
- Add Study
- Institution list
- User list
- Add Institution
- Impact import
- Analysis constants
- Tube constants
- Reassign/Withdrawal**
- Tube Reassign
- Expired tubes list
- Billing
- Audit
- Audit types
- QA Audit
- Mail list

- My Genomatch
- Home
- Logout

User ?						
User name	Process Controller	Date	12.10.2006			
Institution	SAG GENOMatch Test	Role	PROCESS CONTROLLER			

Reassign/Withdrawal ?						
Study no.	Type	Date	Initiator	Trans. id	Remark	Confirm/Revoke
so-12345	withdrawal	12.10.2006 21:02	Registrar , SR	1160679776145	Patient asked for deletion	<input type="text"/> <input type="button" value="Submit"/>
so-12345	reassign	26.09.2006 12:59	Registrar , SR	1159268371870	Mistype	confirmed by TM


0.122 sec. BACK

Patientenlöschung (4-Augen-Prinzip)

GENOMatch - Reassign/Withdrawal - Microsoft Internet Explorer

Datei Bearbeiten Ansicht Favoriten Extras ?

Zurück Suchen Favoriten Adresse <https://www.tembit.de:8443/training/genomatch/confirmtransaction.do>



Menu

- Study list
- Add Study
- Institution list
- User list
- Add Institution
- Impact import
- Analysis constants
- Tube constants
- Reassign/Withdrawal**
- Tube Reassign
- Expired tubes list
- Billing
- Audit
- Audit types
- QA Audit
- Mail list

- My Genomatch
- Home
- Logout

User

User name	Process Controller	Date	12.10.2006
Institution	SAG GENOMatch Test	Role	PROCESS CONTROLLER

Reassign/Withdrawal

Study no.	Type	Date	Initiator	Trans. id	Remark	Confirm/Revoke
• confirmed.						
so-12345	withdrawal	12.10.2006 21:02	Registrar , SR	1160679776145	Patient asked for deletion	confirmed
so-12345	reassign	26.09.2006 12:59	Registrar , SR	1159268371870	Mistype	confirmed by TM

1.111 sec. BACK

Fertig Internet

Patientenlöschung (4-Augen-Prinzip)

Please destroy tubes with following BC1:/ DON'T REPLY TO THIS MAIL - Message (Plain Text)

File Edit View Insert Format Tools Actions Help

Reply Reply to All Forward

From: genomatch-training [genomatch@tembit.de] Sent: Do 12.10.2006 21:08
To: Markus Schröder
Cc:
Subject: Please destroy tubes with following BC1:/ DON'T REPLY TO THIS MAIL

Warning: This email was not encrypted and signed. Ask your GENOMatch admin to activate secure e-mail.
This email was sent to you via GENOMatch email interface.

Sender:
Process Controller(schroeder@tembit.de), Role: PROCESS CONTROLLER, Institution: SAG GENOMatch Test, Berlin, DE

List of all the recipients:
To: schroeder@tembit.de
Cc: schroeder@tembit.de

PC confirmed your patient withdrawal request. Please destroy tubes with following BC1: (Attention: BC1 is 14-digit but on the tube 16-digit with 01 or 02 infront of it.)

42050056198764
60895505978015

transaction_id: 1160679776145

Date/Time of withdrawal request: Thu Oct 12 21:02:56 CEST 2006


This message is for the designated recipient only and may contain privileged or confidential information.If you have received it in error, please notify the sender immediately and delete the original. Any other use of the email by you is prohibited.

Patientenlöschung (4-Augen-Prinzip)

GENOMatch - Confirm Tube Destruction - Microsoft Internet Explorer

Datei Bearbeiten Ansicht Favoriten Extras ?

Zurück Suchen Favoriten Adresse <https://www.tembit.de:8443/training/genomatch/samplerreg.do?method=confirmBC1DropoutForm>



Menu

- Study list
- Assign Patient
- Reassign Patient
- Reassign Trial Site
- Withdraw Patient
- PN/PCI Search
- Assign BC3
- Order BC1
- Verify BC1
- Order BC3
- Verify BC3
- Feedback list
- Confirm Tube Destruction**
- Reassign Tube
- Mail list

- My Genomatch
- Home
- Logout

User			
User name	Sample Registrar	Date	12.10.2006
Institution	Test CSR	Role	SAMPLE REGISTRAR

Confirm Tube Destruction

Scan BC1 label

0.098 sec. BACK


Fertig Internet

Patientenlöschung (4-Augen-Prinzip)

GENOMatch - Confirm Tube Destruction - Microsoft Internet Explorer

Datei Bearbeiten Ansicht Favoriten Extras ?

Zurück Suchen Favoriten Adresse <https://www.tembit.de:8443/training/genomatch/bc1dropout.do>



Menu

- Study list
- Assign Patient
- Reassign Patient
- Reassign Trial Site
- Withdraw Patient
- PN/PCI Search
- Assign BC3
- Order BC1
- Verify BC1
- Order BC3
- Verify BC3
- Feedback list
- Confirm Tube Destruction**
- Reassign Tube
- Mail list

- My Genomatch
- Home
- Logout

User			
User name	Sample Registrar	Date	12.10.2006
Institution	Test CSR	Role	SAMPLE REGISTRAR

Confirm Tube Destruction

BC1 dropped. Please destroy the tube.

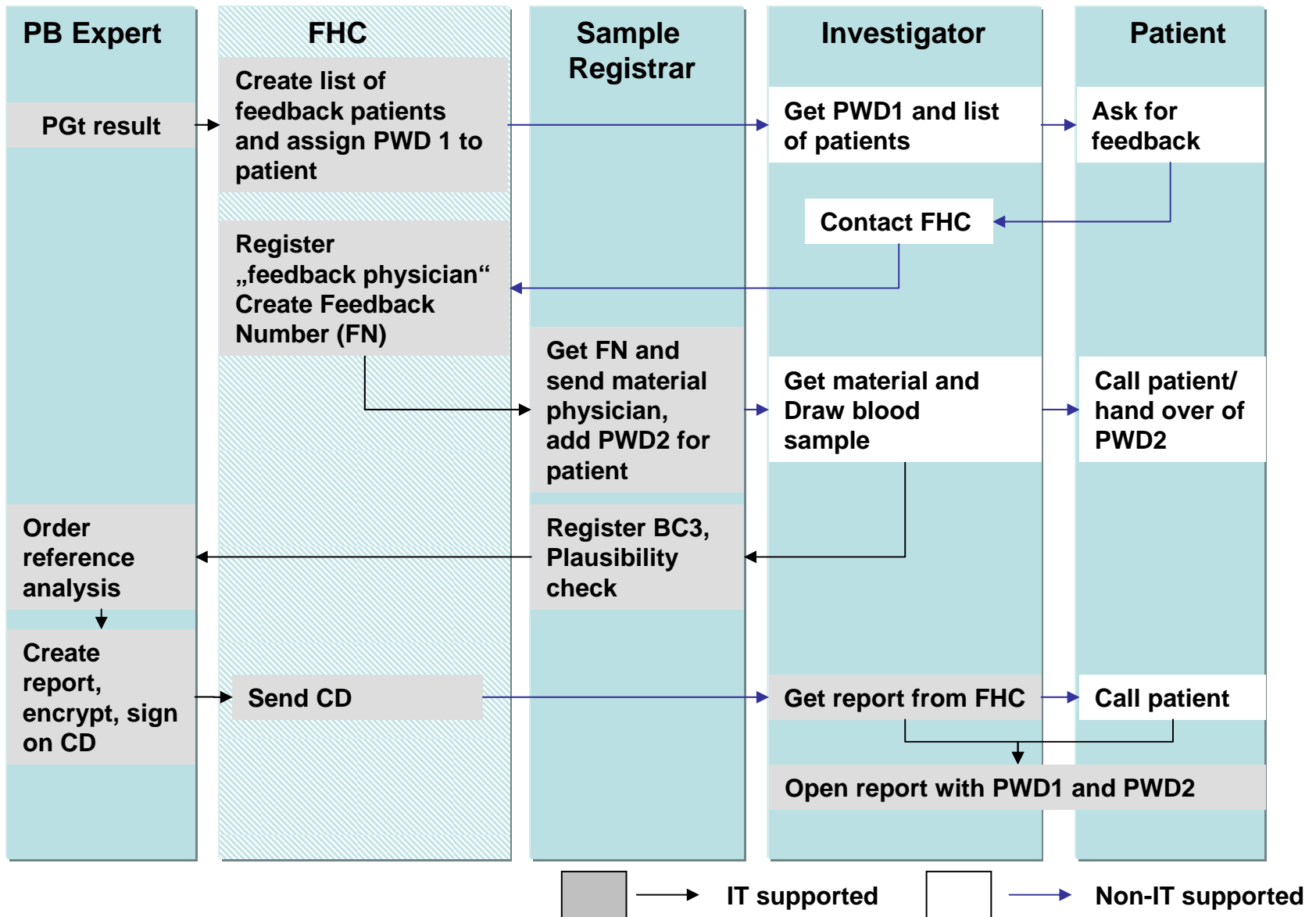
Scan BC1 label

Confirm

0.434 sec. BACK

Fertig Internet

Feedback



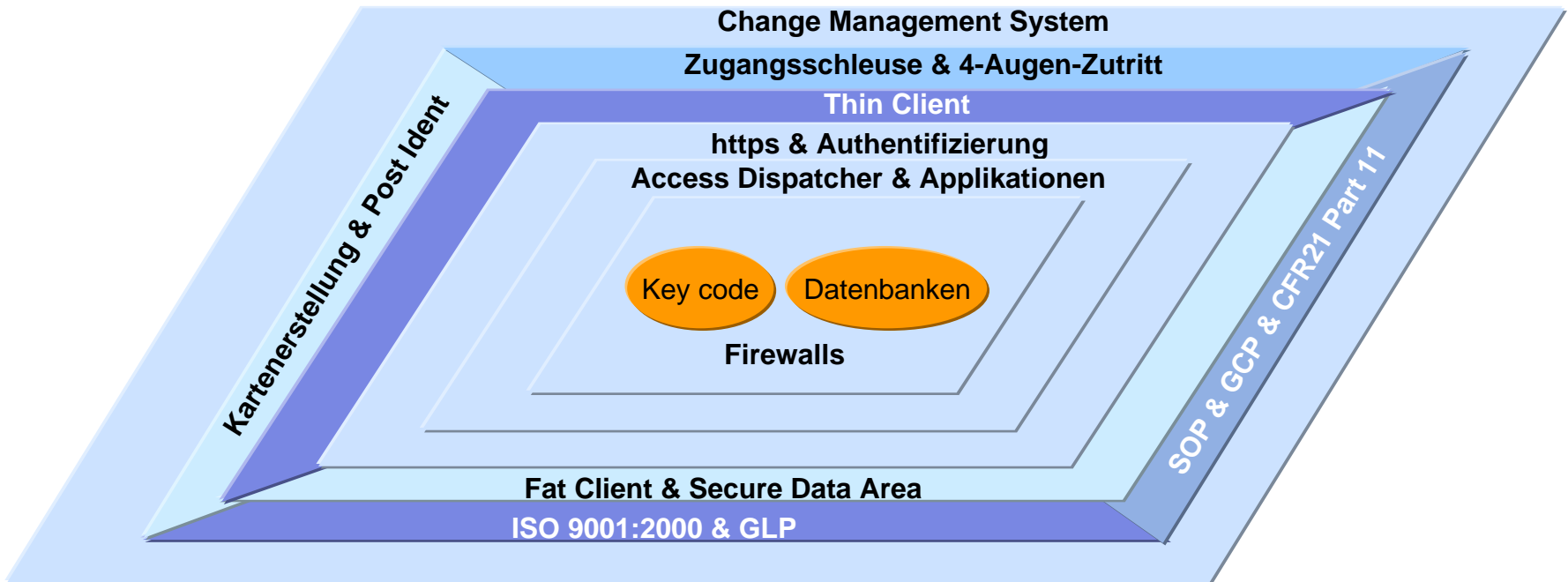


Sicherheitskonzepte für Biobanken am Beispiel von GENOMatch



GENOMatch Sicherheitskonzept

Sicherheitskonzept





Sicherheitskonzepte für Biobanken am Beispiel von GENOMatch



Vertrauen schaffen

Vertrauen schaffen

- Es ist schwer, wenn nicht unmöglich alle möglichen Bedenken von unterschiedlichen Behörden, Verbänden, Organisationen und Patienten/Probanden aus unterschiedlichen Ländern mit unterschiedlichen Kulturen vorherzusehen.

Transparenz – Zuverlässigkeit - Vertrauen

- Systemtransparenz
 - Open Source sorgt für die erforderliche technologische Transparenz
 - SOPs sorgen für die notwendige Prozesstransparenz
- Zuverlässigkeit
 - Open Source “Standards” unterstützen die Systemzuverlässigkeit
 - Automatisierte Testprozeduren bieten einen Beweis für die Zuverlässigkeit
 - Sensible Prozessunterstützung wenn notwendig/erforderlich
 - Einhaltung und geregelte Modifikation von SOPs unterstützen die Prozesszuverlässigkeit
- The more a system is trusted, the better the condition for compliance

Prof. B. Lutterbeck, TU Berlin, FB Recht und Informatik

(Je größer das Vertrauen, desto höher ist die Wahrscheinlichkeit der Zustimmung.)



Sicherheitskonzepte für Biobanken am Beispiel von GENOMatch

Bewertung



- 2004, GENOMatch - *Open Source Best Practice Award*
- Gutachten des ULD-Schleswig-Holstein (2004/2006)
 - Das vorgesehene Pseudonymisierungsverfahren gewährleistet einen Sicherheitsstandard, der über die bisherige Praxis hinausgeht und **setzt** damit **neue Maßstäbe**.
 - Das vorgelegte Datenschutzmanagementsystem stellt die Wahrnehmung des Datenschutzes auch **langfristig sicher**.
 - Das in sich schlüssige und umfassende Konzept ist geeignet, das **Vertrauen** von Probanden in den **langfristigen Schutz** der eigenen personenbezogenen Daten im Rahmen der pharmakogenetischen Arzneimittelforschung **zu stärken**.
- Bisher keine negativen Voten von Ethikkommissionen.



Herzlichen Dank für Ihre Aufmerksamkeit

 *Tembit*