Usage of SAS/IntrNet™ in a global support area

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Schering AG
History

A project called GCD

- A global project was set-up in 1997 to enforce a global clinical development
- Goal of the project was to prepare the processes and the infrastructure
- The IT systems related to
  - Study planning
  - Study tracking
  - Data management

have been replaced

- With the implementation a new support organization was set-up
Usage of SAS/IntrNet in a global support area

Mission of our Support Organization

*Bring the right information to the right people at the right time!*
Analysis of the User community

In our case, three categories of users are existing:

- The standard user, divided in:
  - Frequent users, who need news, FAQ´s and a single point of contact
  - Non-frequent user, who need more personal care in addition to the above

- The super user, who needs more internal product knowledge, enhanced search tools, etc

- The management, who wants to know about implementation status, costs, etc
A fourth user category was found during implementation

- To minimize implementation effort, we to treat ourselves as a user with advanced rights

Other user categories may be found and just access rights have to be adjusted
Analysis of Infrastructure

What infrastructure can we expect in the worst case?

- Slow WAN lines (e.g. routed 64 kbps to South America)
- Different mail systems in newer subsidiaries
- No connection to our Document Management System in smaller subsidiaries
Analysis of the information types

Direct information

- User training
- Post training care
- User group meeting on a regular basis at different levels
  - Global management meetings
  - Global super user meetings
  - Local user meetings
Analysis of the information types (cont.)

Indirect information

- Long term or static information (e.g. user manuals, working procedures)
- Mid term information (e.g. announcement of events)
- Short term information (e.g. alert messages)
- Workflow components (e.g. access forms)
Limitations

Company rules

- Layout restrictions for the Corporate Web (Intranet)
- Current use of Notes for mail and existing applications only (Migration projects need all resources)

Prerequisites

- Project documentation is stored in Document Management System
- A Oracle based user management system was build for our needs
- Designer 2000 for process descriptions
- More than 500 users with different IT skills must be covered
Limitations (cont.)

Our skills

- Excellent Oracle knowledge
- Excellent SAS knowledge
- Limited HTML knowledge
- Very limited Notes knowledge
- No Java knowledge

As always, more work than resources
General

The Corporate Web is the GLUE of all information aspects and therefore THE INFORMATION SYSTEM
Decisions (cont.)

Long term information

- Stored in the Document Management System but linked into the HTML pages

Mid term information

- Directly implemented in HTML

Short term information

- Sent via mail
- Implemented in HTML
Decisions (cont.)

Short term information

- User information have to be stored in databases and automatically presented via tools
- Calculate information on demand instead of hard-coding in HTML
- Put access forms in the Corporate Web where possible
- As a result of a global implementation it is advisable to allow standard users and power users request status information about their accounts
Realization

Usage of tools

- Microsoft Frontpage for HTML editing
- Oracle 7.3.4 for storing user and support information
- SAS/IntrNet™ for the presentation of graphs and lists
- Java for the implementation of the access form
- ASP (Active Server Pages) where SAS 6 is not sufficient due to 200 character limitation (e.g. FAQ’s); this will be changed with SAS 8.
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Realization (cont.)

Windows NT 4
Double Processor
Pentium II
1GB
Internet Information Server

Request of compute services

Send back results

Request of data

Send back data

Windows NT
Single Processor
Pentium II/266
160 MB
Internet Explorer 4/5

Solaris 2.5
Double Processor
UltraSparc 600MHZ
1GB
SAS V6 incl. SAS/IntrNet™

Windows NT 4
Double Processor
Pentium Pro 200
512 MB
Oracle 7.3.4

Global Clinical Systems

Dirk Grosse, April 14, 2000
Our Experience

- Performance is a key issue for acceptance of Internet pages as a visible part of an information system.

- Compared to other tools like e.g. active server pages SAS/IntrNet™ shows a higher scalability.

- Listing of Name, Personal Id and phone for more than 500 users grouped by location needs:
  - 4 seconds before visibility of first user
  - additional 3-4 seconds before all users are listed (this value varies over the different sites)
Realization (cont.)

User Management

- Graphs
  - Increase of users on european servers
  - Number of users per GCD system
  - Number of users per site

- Listings
  - List of users grouped per site
  - List of Workgroup Application Administrators
  - List of Client Administrators
  - Request form for user management tasks per user
Realization (cont.)

Support Information

- Graphs

  - Number of call per area (Internal, Berlin, Europe, Japan, USA)
  - Number of call per system by origin (Hotline, Direct)
  - Number of call per system by type of action

  - Time spent for GCD activities/calls per area
  - Time spent for GCD activities/calls per system
  - Time spent for GCD activities/calls per area and system

- ...to be continued!
Global Clinical Systems

Mission

Business processes in clinical development and in pharmaceutical product safety are analyzed, modeled and implemented via a global information and workflow management process.

The resulting clinical system architecture supports the provision and maintenance of the global information systems for:

- the planning, tracking, data management and archiving of clinical and safety data
- the randomization of clinical studies
- the planning and capture of workflow data for clinical trials
- the process of reporting side-effects
- the SAS production environment in which evaluations of clinical studies are carried out.

We as Global Clinical Systems will:

- help to efficiently design and document the business processes
- configure and implement systems to support these processes and
- maintain the implemented systems.
Realization (cont.)

Our support organization unit provides global information management expertise and operational level support for the business processes and IT systems of the Schering clinical development worldwide.

We take also care for all European subsidiaries on the operational level that do not have respective support themselves.

Berlex and Nihon Schering have their own support structures.
Realization (cont.)

Global Clinical Systems - Microsoft Internet Explorer

Services and Support

User information

We are here to help you with all issues you may have with our Systems. The following section provides resources to make your dealings with us as easy as possible.

If you are having problems with one of our systems, you can call or mail to our helpdesk in Berlin to get information and adequate support to find a solution for your request.
Our helpdesk provides help for all SAG locations in Europe.

Calling Support

Please call +49 30 468 15566
(Monday-Friday 9.00 am - 17.00 pm)
per mail
GlobalApplications, R_D SAG
via electronic form
write now
Realization (cont.)

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Global Clinical Systems
Realization (cont.)
### Realization (cont.)

**List of GCD WAAs**

<table>
<thead>
<tr>
<th>Site</th>
<th>User name</th>
<th>Phone</th>
<th>eMail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>Denturck, Katty</td>
<td>+32 2 712 85 35</td>
<td>Katty.Denturck@MAI/USR/SHG@SCHERINGGROUP</td>
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<tr>
<td>Belgium</td>
<td>Van Wichelen, Karine</td>
<td>+32 2 712 85 70</td>
<td>Karine.VanWichelen@MAI/USR/SHG@SCHERINGGROUP</td>
</tr>
<tr>
<td>Berlin, East</td>
<td>Devencenzi, Barbara</td>
<td>+1 510-669-4619</td>
<td><a href="mailto:barbara_devencenzi@berlex.com">barbara_devencenzi@berlex.com</a></td>
</tr>
<tr>
<td>Berlin, East</td>
<td>Gianitomas, Pat</td>
<td>+1 973-276-2364</td>
<td><a href="mailto:patricia_gianitomas@berlex.com">patricia_gianitomas@berlex.com</a></td>
</tr>
<tr>
<td>Berlin, East</td>
<td>Hanna, Eileen</td>
<td>+1 973-276-2228</td>
<td><a href="mailto:eileen_hanna@berlex.com">eileen_hanna@berlex.com</a></td>
</tr>
<tr>
<td>Berlin, East</td>
<td>Leonardo-Tibbets, Lucille</td>
<td>+1 973-276-2236</td>
<td><a href="mailto:lucille_leonardotibbets@berlex.com">lucille_leonardotibbets@berlex.com</a></td>
</tr>
<tr>
<td>Berlin, East</td>
<td>Marchese, Colleen</td>
<td>+1 973-276-2238</td>
<td><a href="mailto:colleen_marchese@berlex.com">colleen_marchese@berlex.com</a></td>
</tr>
<tr>
<td>Berlin, East</td>
<td>Marcus, David</td>
<td>+1 510-262-5027</td>
<td><a href="mailto:david_marcus@berlex.com">david_marcus@berlex.com</a></td>
</tr>
<tr>
<td>Berlin, East</td>
<td>Mineur, Patricia</td>
<td>+1 973-276-2256</td>
<td><a href="mailto:patricia_mineur@berlex.com">patricia_mineur@berlex.com</a></td>
</tr>
<tr>
<td>Berlin, East</td>
<td>Palma, Louise</td>
<td>+1 973-276-2274</td>
<td><a href="mailto:louise_palma@berlex.com">louise_palma@berlex.com</a></td>
</tr>
<tr>
<td>Berlin, East</td>
<td>Troy, Hannah</td>
<td>+1 973-276-2338</td>
<td><a href="mailto:hannah_troy@berlex.com">hannah_troy@berlex.com</a></td>
</tr>
<tr>
<td>Berlin, East</td>
<td>Wulf, Grexan</td>
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<tr>
<td>Berlin SDG</td>
<td>Fuhrmann, Hans</td>
<td>+49-30-34989350</td>
<td><a href="mailto:Hans.Fuhrmann@schering.de">Hans.Fuhrmann@schering.de</a></td>
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<tr>
<td>Canada</td>
<td>Laplante, Suzanne</td>
<td>+1 514 420 2137</td>
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<tr>
<td>France</td>
<td>Lemaire, Gregoire</td>
<td>+33 320 20 88 98</td>
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<tr>
<td>Italy</td>
<td>Dragoni, Giovanna</td>
<td>+39-0221-65525</td>
<td>Giovanna.Dragoni@SCHERINGGROUP</td>
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<tr>
<td>Jena Pharm</td>
<td>Feig, Ragnar</td>
<td>+49-3641 64 6644</td>
<td>Ragnar.Feig@SCHERINGGROUP</td>
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<tr>
<td>Jena Pharm</td>
<td>Schuet, Dirk-Andreas</td>
<td>+49-3641 64 6648</td>
<td>Dirk-Andreas.Schuet@schering-group</td>
</tr>
<tr>
<td>Leiras Hels</td>
<td>Kuitunen, Risto</td>
<td>+358-9-708 8289</td>
<td>Risto.Kuitunen@schering-group</td>
</tr>
<tr>
<td>Leiras Hels</td>
<td>Kulmala, Mr. Yrjo</td>
<td>+358-9-708 8258</td>
<td>Yrjo.Kulmala@schering-group</td>
</tr>
<tr>
<td>Leiras Hels</td>
<td>Salli, Siru</td>
<td>+358-9-708 8402</td>
<td>Siru.Salli@schering-group</td>
</tr>
<tr>
<td>Leiras Hels</td>
<td>Tapaninen, Mr. Timo</td>
<td>+358-9-708 8230</td>
<td>Timo.Tapaninen@schering-group</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Koning, Els</td>
<td>+31 294 462406</td>
<td><a href="mailto:Els.Koning@schering.de">Els.Koning@schering.de</a></td>
</tr>
<tr>
<td>S&amp;C Berlin</td>
<td>Parkzeit, Jannen</td>
<td>+49 30 80 16712</td>
<td>Jannen.Parkzeit@RGP/LL/SHG</td>
</tr>
</tbody>
</table>
Realization (cont.)

GCD Access Form

- General
  - Create new GCD user account
  - Change existing user account (new Role, additional Projects/Studies, etc.)
  - Delete existing user account

- User Information
  - Surname
  - Firstname
  - Title
  - Personal Id
  - Internal or external staff?
    - Internal

- User is trained (in specific GCD role)

- Site/SBU (e.g. Berlin FCHT)
- Telephone No
- Initials
- Cost Center No
- Cost Center Responsible

Printer Type(s)
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Realization (cont.)

Global Clinical Systems

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Realization (cont.)
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Realization (cont.)

Global Clinical Systems

Services and Support

GCS Team

Statistics and common used lists

The following lists and graphs will be created online and will give you an overview about the current status.

Account Information:
- Request user's status of GCD implementation (please type personal id before submitting)
- Increase of GCD users on european servers
- Number of users per GCD system on european servers
- Number of users per site on european servers
- List of GCD Users grouped by location

Support and Hotline Activities:
- Number of GCD Calls per area, per system, per type of action taken
- Time spent to support GCD calls per area, per system, per area and system

GCD Change Requests:
Frequently Asked Questions

Parameter Form

Please select the GCD application to minimize the data volume or type in the module or an expression of your interest.

Sorry, we haven't realised the usage of logical operators (like AND or OR) and wildcards (like %).

Application

Module

Search for ...

submit
Realization (cont.)

Frequently Asked Questions

Clintrial (4.1) : DESIGN - PAGE SECTION LAYOUT

If you try to delete (at the same time) items with codelists and items without codelists from a page section, you will get an error message while saving; A problem occurred with the database, generating error code 1036 and error message ORA-1036: illegal variable name/number. (Sometimes instead of this you get the message: A problem occurred while attempting to delete a row. The row has been restored.) Save was not successful, but the layout would not be restored. If you reopen the page section layout, the deleted items still there.

Known bug in Clintrial 4.1, will be fixed with 4.2 Workaround. Delete items with codelists seperately, save, delete items without codelists, save again.

Clintrial (4.1) : DESIGN - Delete Page

Delete a page with repeats and at least 1 defined repeat (no patient data, only in Design !). Recreate the page with the same page key with repeats > unique key constraint without repeats > not possible (old repeats are still exist) This problem may also occur, if you delete a study book, which has defined repeats and create/copy the study book again.

If you delete a page the existing repeats are not automatically deleted (delete on cascade), they still exist in the database. So if you recreate the page this will lead you into trouble. Workaround: If you want to delete a page, open the page modify window, delete all existing repeats, save, close and then delete the page.

Clintrial (4.1) : DESIGN - Sequencing in page sections

For a predefined sequence in a studybook an powerbuilder error comes up in Enter during open the page and in Design in page template test mode, telling something with sequences and the page does not open.

The problem is with crossed sequences and no predefined line. Sometimes it is possible to create a sequence with crossed and no predefined line for the crossed part. (Can happen if you copy a page section with crossed sequence, and modify the copy by deleting the defined rows and keep the crossed and modify other parts of the sequence.) Then Clintrial is not able to create the sequence correctly, but no error message comes up, it
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Realization (cont.)

Increase of GCD users

YEAR = 1999

Green area = Total number of new users
Red area = Number of new users per month

Global Clinical Systems
Realization (cont.)

![Graph showing increase of GCD users in 2000]
Realization (cont.)

Number of users per GCD system

- Clinical: 142
- Documetrak: 23
- IMPACT: 433
- Other systems: 1
- Rando: 26
- SWERR: 22
- Study Navigator: 5

Note: Documetrak Users are implemented but "on hold" until validation is completed.
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Realization (cont.)

Number of users per site

Note: Berlex and Nihon users with an account at SAG
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Realization (cont.)