

Development of a Fully Prospective Electronic Submission for Global Dossiers

W.S. Hauck III, Pfizer Central Research

S.D. Schlotzhauer, Schlotzhauer Consulting

S. N. Maniscalco, Pfizer Central Research





Building for Success

- We Learned the 4 T's
- Teams
 - ◆ Just tell them it's not possible
- Technology
 - ◆ Buy the best, use the "coolest" version-1
- Tools
 - ◆ If you do it more than twice, write a tool, define a process, get a resource
- Testing
 - ◆ Live by your product and processes



Results

- Submission on December 30, 1996
- 200 paper volumes
- 30,000 electronic documents
- 1500 SAS datasets
- 120 GB information
- Desktop Unix server and reviewer laptops
- Full electronic archive



Team - Business Goals

- Submit in 1996
 - ◆ (or die trying...)
- All electronic format
 - ◆ Submissions documents
 - ◆ CRFs
 - ◆ Phase II/III data
- The largest submission yet
 - ◆ 12 indications
 - ◆ 14,000 patients
 - ◆ 450,000 CRFs



Technology - Goals

- Fast, faster, fastest in everything
- Buy where possible
- Build / customize at a minimum
- Minimum impact on the desktop
- Global access to the review application and data



Tools - Software Goals

- Web as submission “wrapper”
- PDF for text review & archive
- Documentum for document management
- ClinView and PDF for CRF images
- SAS, PH-Clinical for data
- PDF for patient profiles***
- Excel for PK data***

*** = “Oh yeah, we need some of this too...”

How Did We Do?

Demo #1

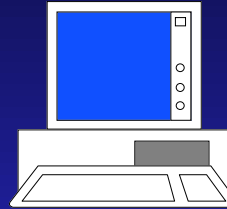
Electronic Submission Navigator





System Architecture

**ESUB
USERS**



PDF Reader
Web Browser
X-Windows

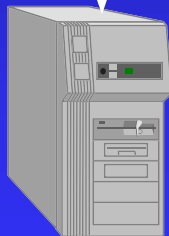
ESUB HOME PAGE

ADMIN

ESUB NAVIGATOR

QUERY

Full Text Search DB



Admin Utilities

CRFs

**SAS
PH**

Text

Profile

Help

QTS



Testing - Success Factors

■ Prototype, prototype, prototype

- ◆ High value features (Export, Multi-Print)

■ Finish the delivery software 2 months before the submission

- ◆ “Yes, version 4.12 is a cool new wonderful technology. Maybe next submission.”

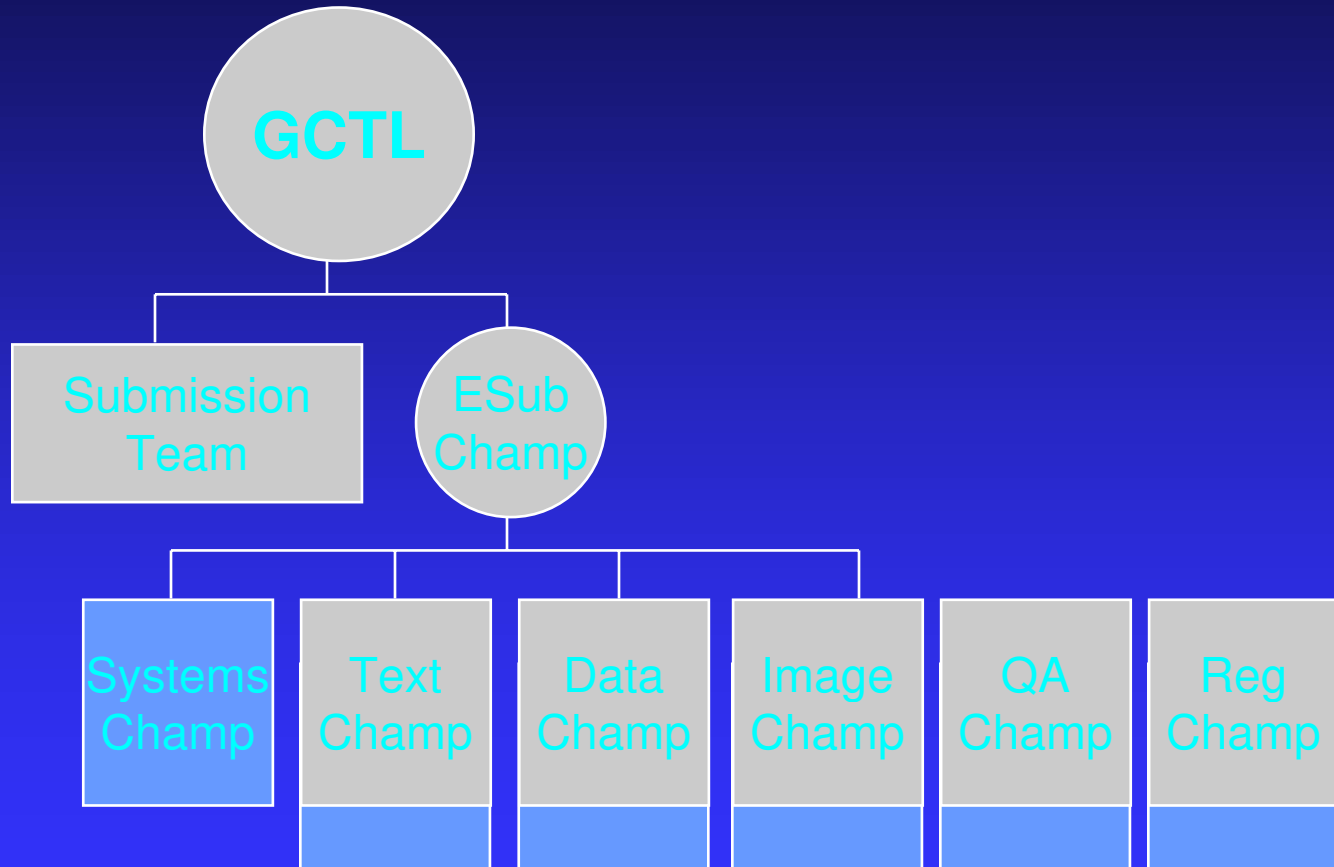
■ Real, committed users

- ◆ “In a ham and egg breakfast, only the pig is committed”
- ◆ 13,000 hours of internal use before delivery
- ◆ The QC/QA tool for submission review

■ Train in 30 minutes, or don't bother

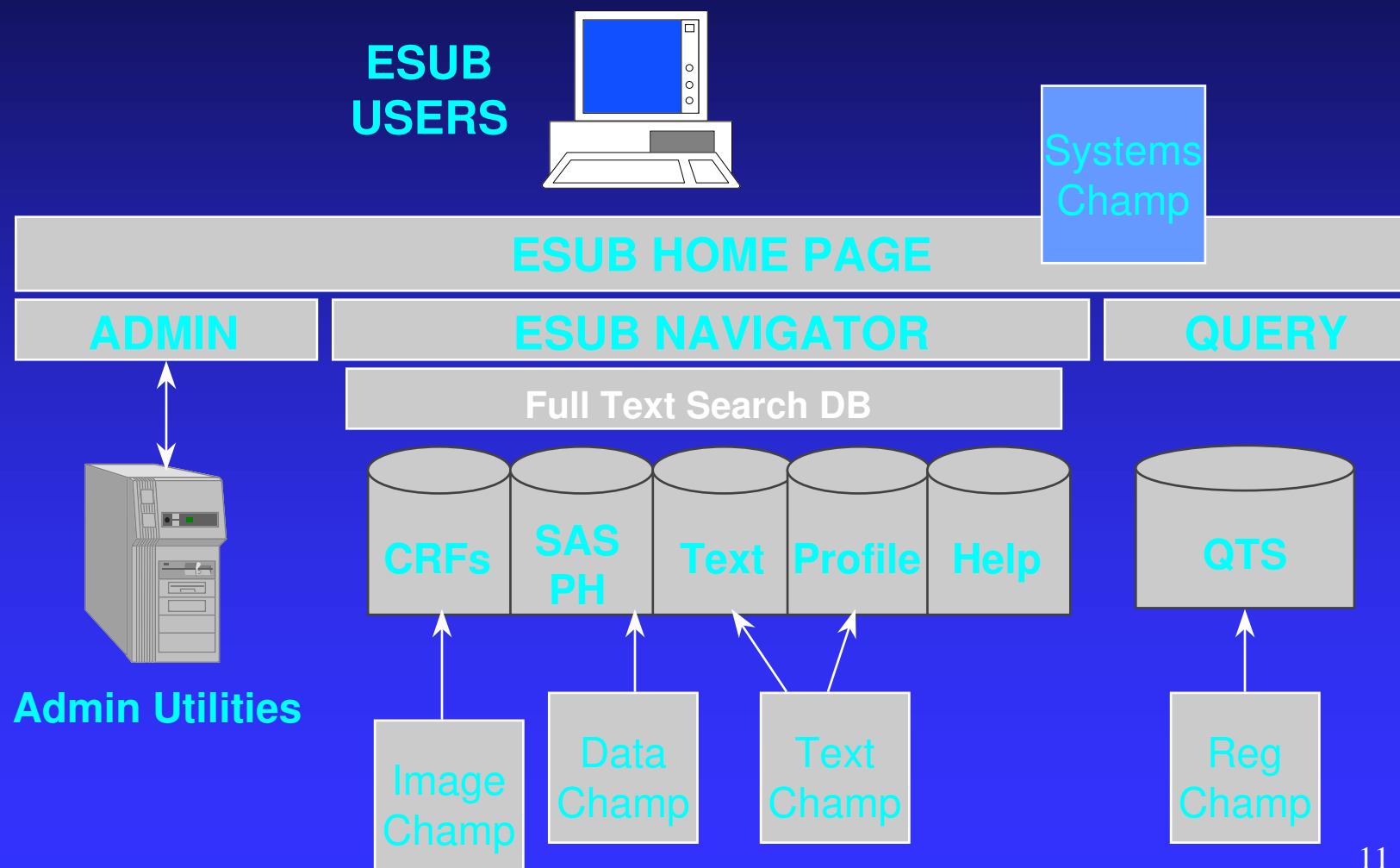


Team - Using Champions





Team - Unambiguous Owners





Teams - Focus on Process

- Common Goal (100% paperless submission)
- LOTS of firsts (only 10% in technology)
- Communicate!
- Can Do or bust
- Well placed IT support
 - ◆ And lots of it...
 - ◆ If you do it more than twice, automate

Communication Tools

Demo #2

The Team Page





Teams - Challenges

- MANY firsts (but which one came first??)
- Process hurdles
- Low level staff readiness and skills
- Content slips
- Fixed Delivery Date



Technology - Submission Scope

- 2200+ volumes
- 450,000 CRFs
- 37 studies + ISE/ISS data
- 9 months from idea to delivery
- 20x growth over original estimates
- From 1 or 2 reviewers to 250+ internal users, globally
- Foundation for NDA, IRD and NDS



Technology - Scalebacks

- One group would not support electronic submission
 - ◆ Developed “Ivory Snow” model (99.44% pure electronic)
 - ◆ See comment on Can Do...
- Automatic hypertext link creation throughout submission
- Large CRF casebooks in PDF



Technology - Additions

(aka “More Stuff We Want”)

- Patient Profiles (>12,000)
- Phase II/III SAS data TOC
- Phase I Excel data
- Online Help TOC
- “Cool Movies”

Help!

Demo #3

If you don't know, ask



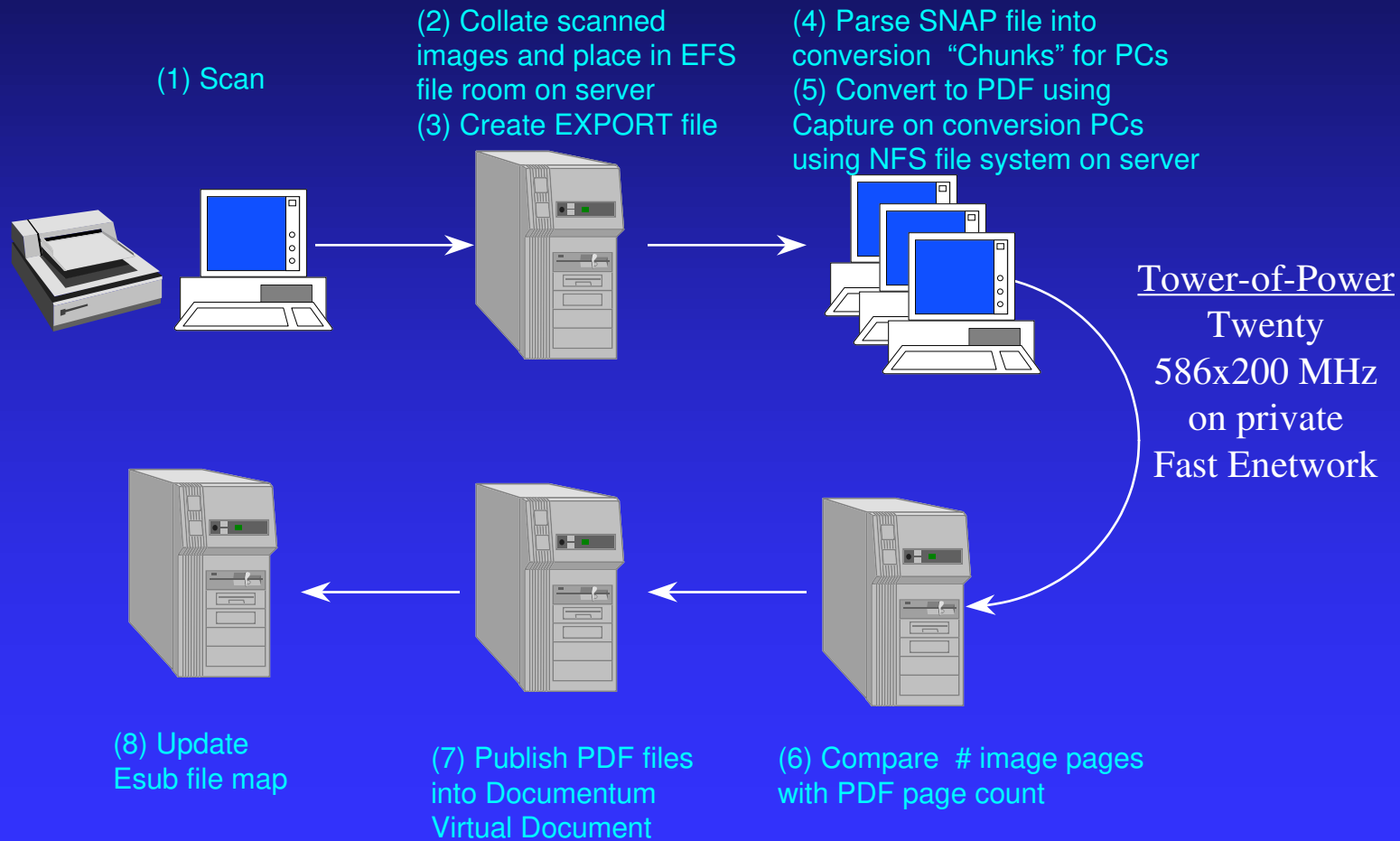


Tools - Support

- Hardware upgrades for users
 - ◆ Old PCs don't support current technology, buy 50.
- Tower of Power
 - ◆ 100,000 pages of legacy paper, no server solution
- Submission hardware
 - ◆ Buy early, buy extra, get management buy-in
- Stabilize software early
 - ◆ Developers providing support needs
- Fight scope creep at the End Game
 - ◆ We'll do this for the next one...



The Tower of Power





Tools - Wrapper Features

- Expand/collapse of TOC
- Title search
 - ◆ Probably single most-used feature
- Full text search
- Print multiple
- Export to PC

Reviewer Features

Demo #4

Export & Full Text Search





Testing - Scope

- Multiple CRO's involved
- Internal cross-department testing
 - ◆ Biometrics read the reports
 - ◆ Clinical worked with data
 - ◆ QA and Systems fix problems
 - ◆ finger pointing as an “unacceptable” behavior
- External testing
- QA early, QA often
- Champion sign off



Testing - Types of Activities

- System testing
- User testing
- Validation of software installs
- Installation testing
- 13,000 hours use before delivery



Results

- Submission on December 30, 1996
- Completed 30 days ahead of internal “gold” standard
- Foundation for NDA, IRD and NDS
- 90% cost reduction in derivative submissions
- 50% reduction in assembly time of next compound
- The Corporate Response: Give Us **MORE**



Lessons Learned

- Anticipate HUGE support need
- Buy even more hardware than seems reasonable
- Plan for training
- Start documentation sooner
- Vendors can be headaches
- Plan more for post-submission support



Lessons to Follow

- Teams work!
- QA vital from the start
- IT wizards needed
- 1st time is always the hardest
- Focus on process
- Vendors can be lifesavers
- Communicate!
- Need combination of teams, tools, technology, testing