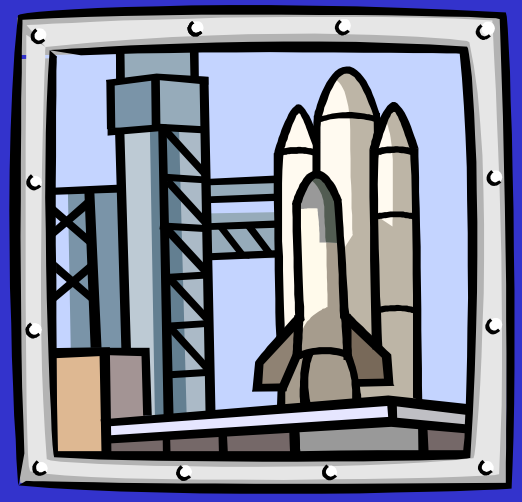
QUINTILES

SAS and the CRO



Peter Stagg

Quintiles Ltd

Discussion

- About Quintiles
- SAS usage in Biostatistics
- Internal challenges
- FDA requirements
- Client requirements
- Data formats
- Reporting standards
- CDISC
- How we have adapted
- Summary

About Quintiles

- Operates in 39 countries
- 18000 employees
- Runs NT server, NT workstation,Unix, Vax
- Server and desktop SAS licences
- Runs Oracle clinical

SAS usage in Biostatistics

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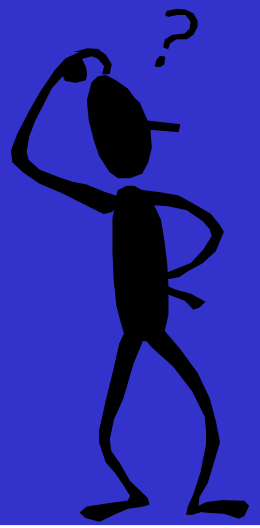
- Extract data from Oracle Clinical
- Transfers files as export files
- Creation of derived datasets
- Output tables, listings and graphs
- Patient narratives
- Statistical analysis

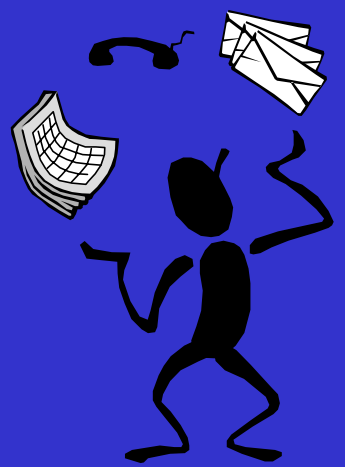
Internal challenges

- New sites have different systems
- Different standards required for each project
- Transferring data/project between sites
- Customers with different SAS versions/operating systems
- Data collection methods
- Output into suitable format
- In text tables for medical writing



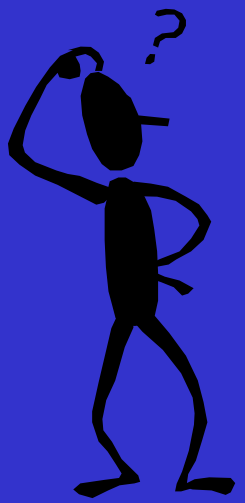
FDA requirements

- 21 CFR Part 11
- Electronic records
- Electronic signatures
- Computer system validation (CSV)
- Audit trails
- Version control
- Electronic submissions



Customer requirements

- Aim of the study
- What is expected from Quintiles
- Data formats
- Report formats
- Turnaround time
- Code delivered for review
- Our system or theirs

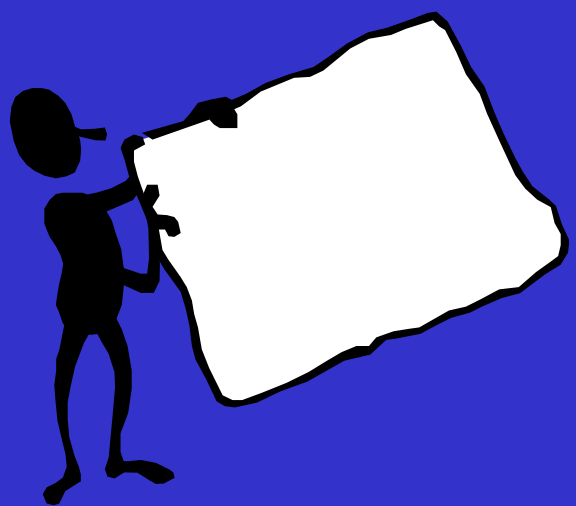


Data formats

- Data from various sources
- Quintiles standard
- Data received from
  - Customer
  - Electronic Diary (minidoc)
  - External labs
  - Fax collect
  - Electronic data collection
  - ECG data

Reporting standards

- Quintiles standard format
- Client standard format
- Client standard template format
- Open standard



CDISC

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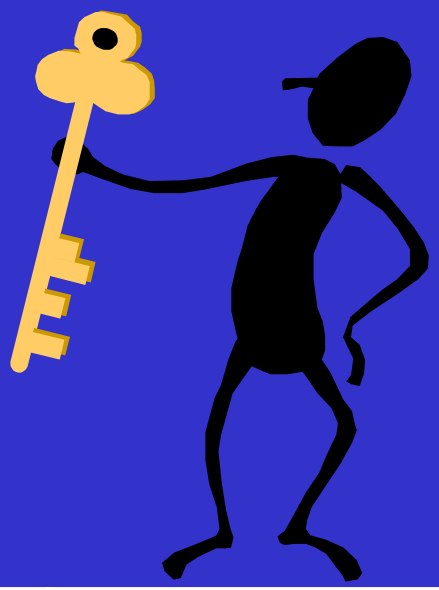
- Clinical Data Interchange Consortium
- Consortium of several organisations
- Vendor neutral platform independent standard
- Primarily uses XML as data standard
- Sets guidelines for dataset standards



Advantages of a data standard

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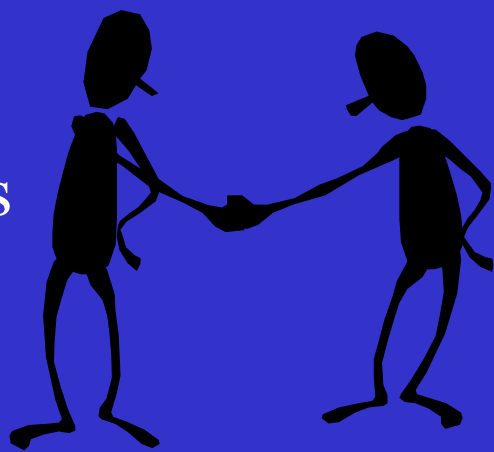
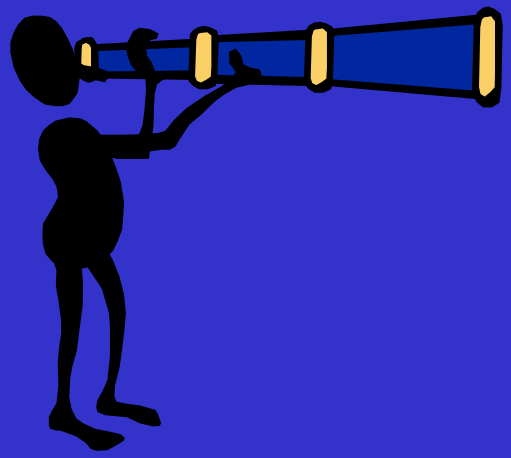
- Uniformity across the study and all studies
- Submission requirements identical
- Data types known (metadata)
- Reduces the need to design new dataset formats
- Reusable code for analysis
- Datasets meet FDA submission standards



How we have adapted

- Developing a common SAS standard
- Audit trail systems
- Maintain a single platform environment
- Develop a working relationship with SAS
- SAS certification
- Investigate new ways of doing business
  - SAS® Enterprise guide
  - SAS® Drug development
  - SAS/Intrnet®
  - CDISC



Summary

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- SAS has the flexibility to fit into our business model
- CDISC model provides industry wide data standard
- The use of SAS is governed by customers needs
- FDA requirements control data submissions
- SAS functionality needed to be demonstrated
- The ability to do more is there, who takes the first step?

References

- www.sas.com
- www.cdisc.com
- CDISC presentation by Graham Bunn Feb 2002
- 21 CFR part 11 Document