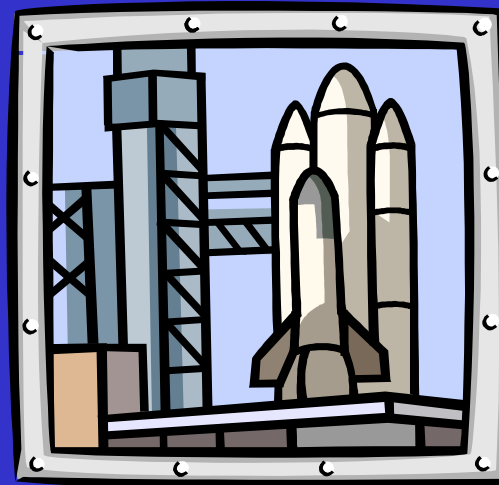


# SAS and the CRO



Peter Stagg

Quintiles Ltd

# Discussion

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

# About Quintiles

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- ◆ 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

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- ◆ 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

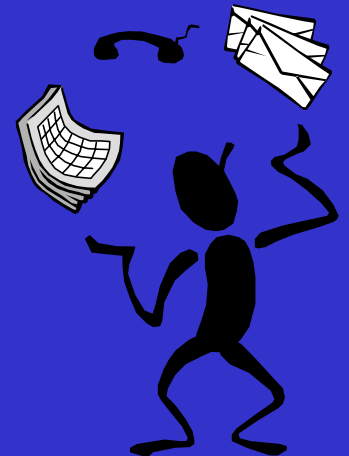


# FDA requirements

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

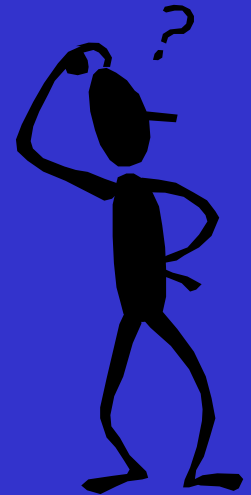


# Customer requirements

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- ◆ 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

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



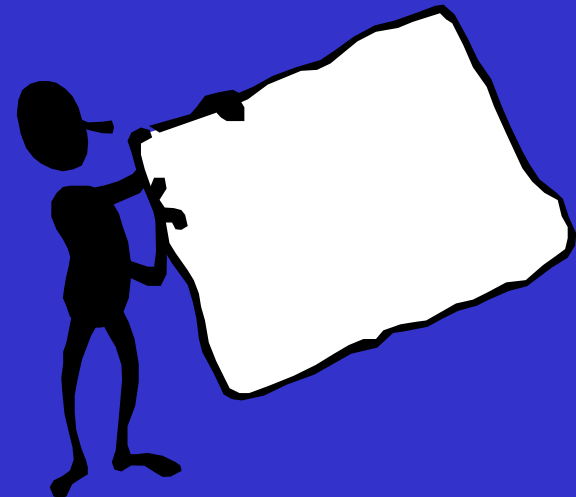


# Reporting standards

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



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

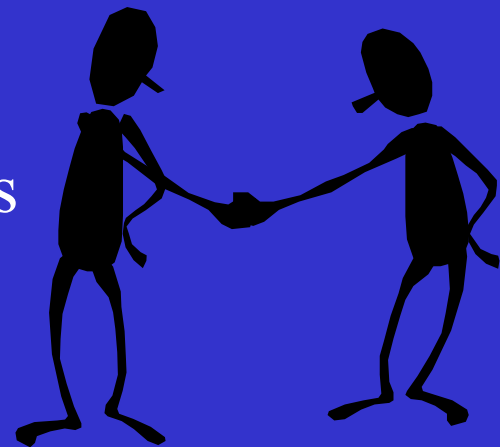


# Advantages of a data standard

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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

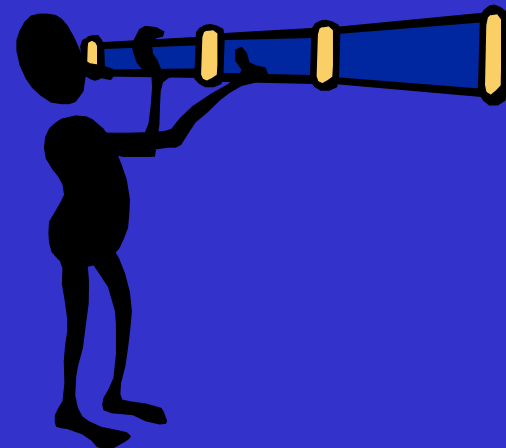


# How we have adapted

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- ◆ 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<sup>®</sup> Enterprise guide
  - SAS<sup>®</sup> Drug development
  - SAS/Intrnet<sup>®</sup>
  - 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

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- ◆ [www.sas.com](http://www.sas.com)
- ◆ [www.cdisc.com](http://www.cdisc.com)
- ◆ **CDISC presentation by Graham Bunn Feb 2002**
- ◆ **21 CFR part 11 Document**