



From CDISC to CSR - Building tools around standards

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Boston, September 28, 2010

biogen idec

Agenda

- History
- Standards Emerge
- Tools Developed
- Conclusion

History

- Biogen - one of the first Biotechs
- Biogen IDEC - “merger of equals”
- PC SAS - individual workstations
- Unix - multiple sites working together
- Global - working across countries.

Standards Emerge

- Adhocracy - no defined standards
- Warehouse - defined data standards
- Tysabri - defining standards across a drug program
- CDISC - using defined standards across all programs.

Tools Developed

- SAS/AF - initial app for extracting data
- Macros - initial attempts at standards
- StarTeam - initial communications / version control package
- Workflow - in-house developed tool
- SMART - standardize safety tables
- Atlas - tool developed around standards.

A day in the life of a stat programmer

2000

- Set up a new study
 - Copy an existing directory
- Update data from warehouse
 - ARTOOL
- Map to SDTM format
 - SDT who?
- Take advantage of standards
 - copy someone else's program
- Send for QC and track modifications
 - Post it note

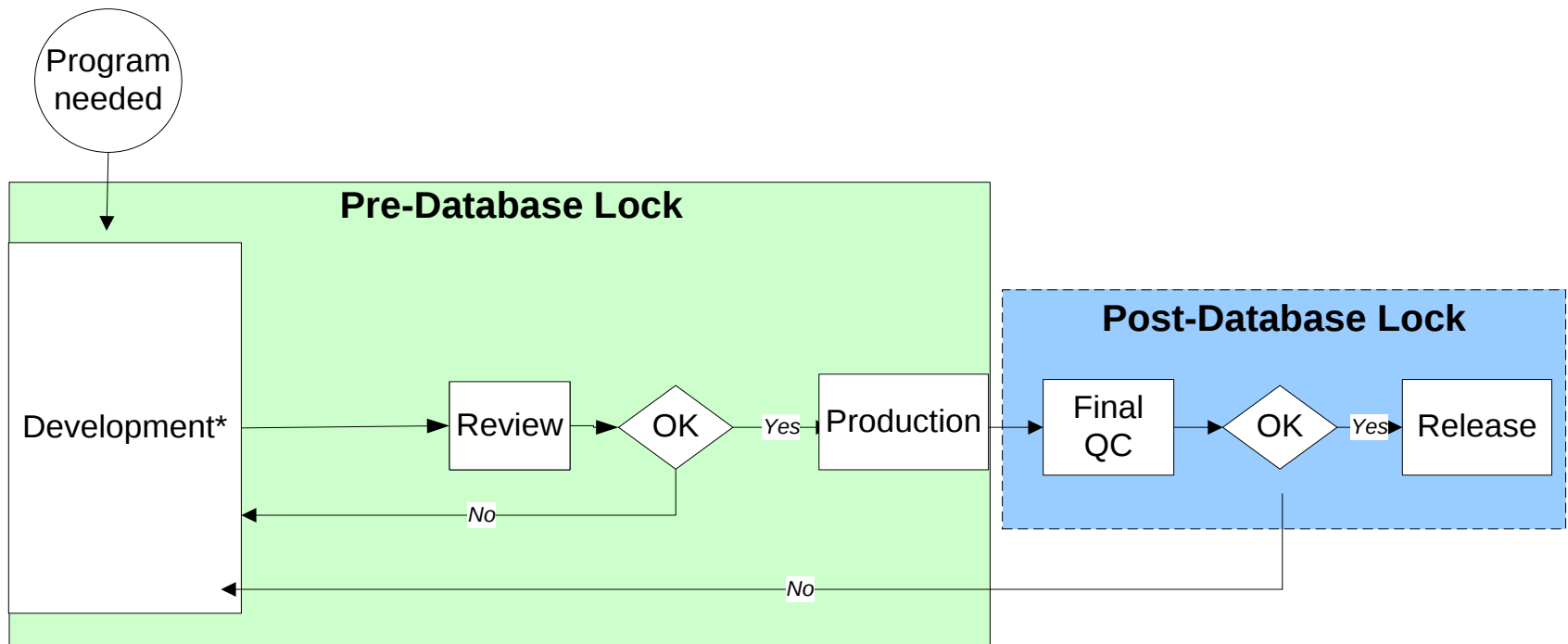
2010

- Set up a new study
 - Simple form via workflow, routed automatically for approval and directory creation
- Update data from OC
 - getdata web based tool
- Map to SDTM format
 - Automatic via Atlas
- Take advantage of standards
 - SMART tables, listings, datasets
- Send for QC and track modifications
 - Workflow

Workflow

- Workflow
 - Based on user needs
 - Able to have in-house development
 - Changeable with needs

Controlling programs through workflow



SMART

- SMART
 - Standard Management Approved Reporting Templates
 - Developed externally
 - Coded in SAS
 - Modified and supported in-house

SMART

- 64 standard tables and listings
- Standards reaching wider acceptance
- Unusual in industry
- Life cycle management: challenging but successful

Atlas

- Custom tool for mapping CDISC domains
- Web based front end
- SAS for data mapping
- Standard or study specific metadata

Atlas

- Atlas
 - Tool based on standards and processes already defined
 - Web based “static” frontend
 - SAS code in back that is validated in-house
 - Extensible with changes to CDISC standards.

Conclusion

- Looked outside
- Built applications where 'appropriate'
- Built in-house standards
- Moved to industry standards
- Smaller and simpler can be better