



43rd
Annual Meeting

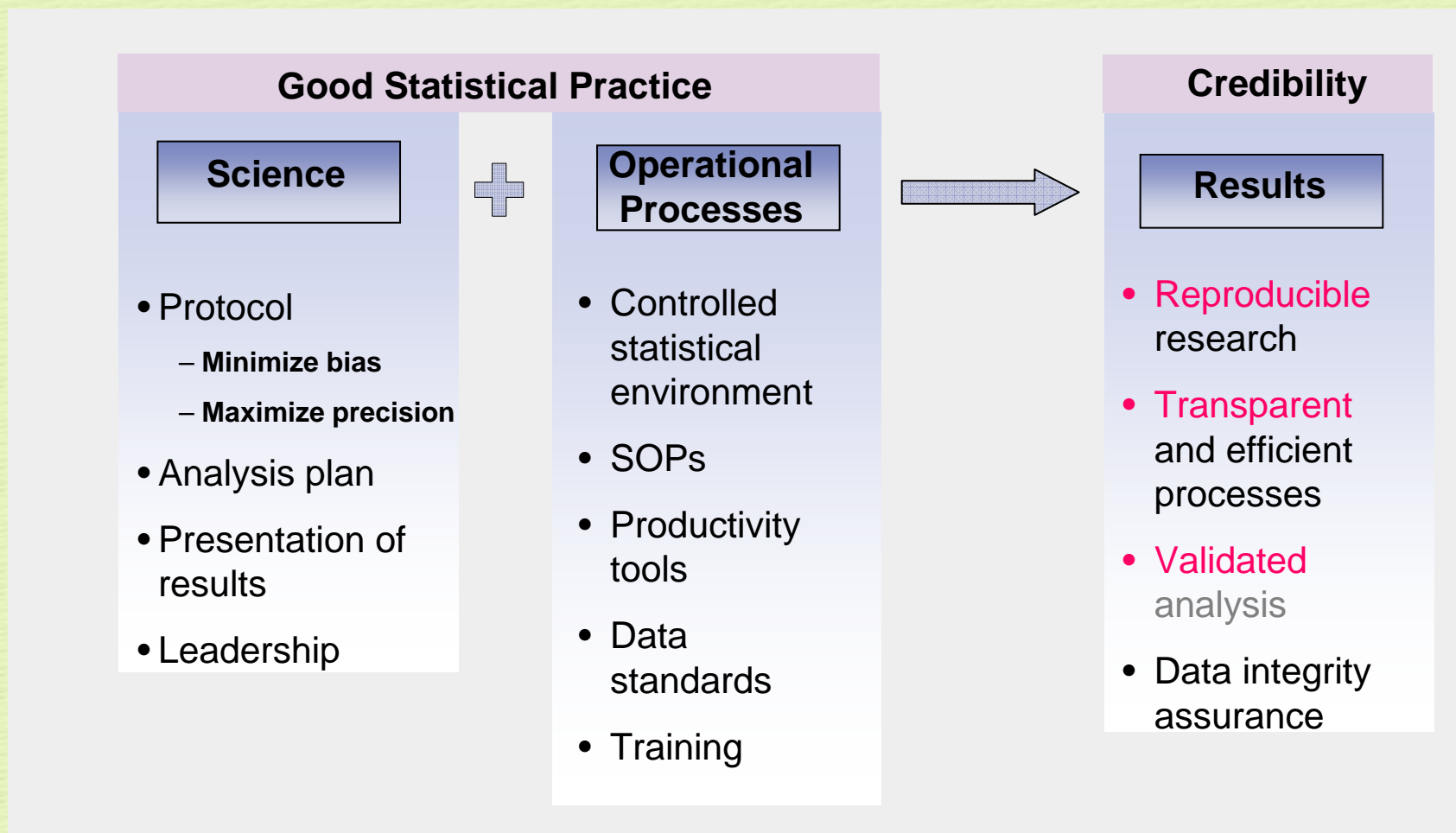


Atlanta - 2007

Future Visions for a Statistical Computing Environment

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Good Statistical Practice leads to credibility of results: reproducible, transparent and validated



What is a Statistical Computing Environment?

A Statistical Computing Environment (SCE) provides a foundation for documenting rigor in the analysis and reporting of clinical trial results while *increasing productivity and quality.*



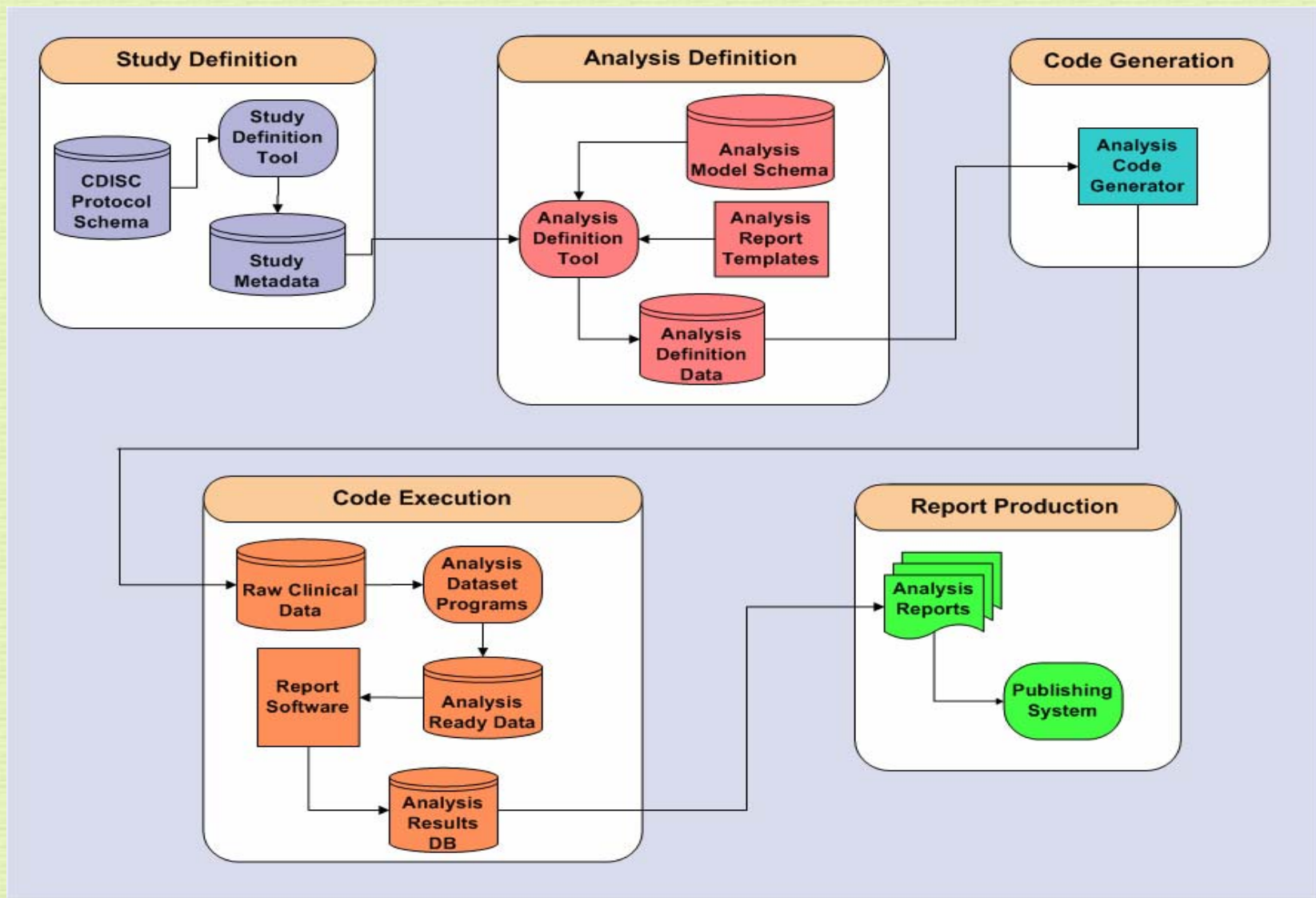
Biostatistics in the pharma industry has made few operational breakthroughs in the last 20 years compared to other disciplines

Current Situation

- Productivity systems are largely missing from statistical operations
- There is little interprocess communication between tasks; much done by hand
- Lack of industry standards and tools – documents, statistical tables and programs
- Lack of efficient systems take away time from the high value work of science



Statistical Operations Activities



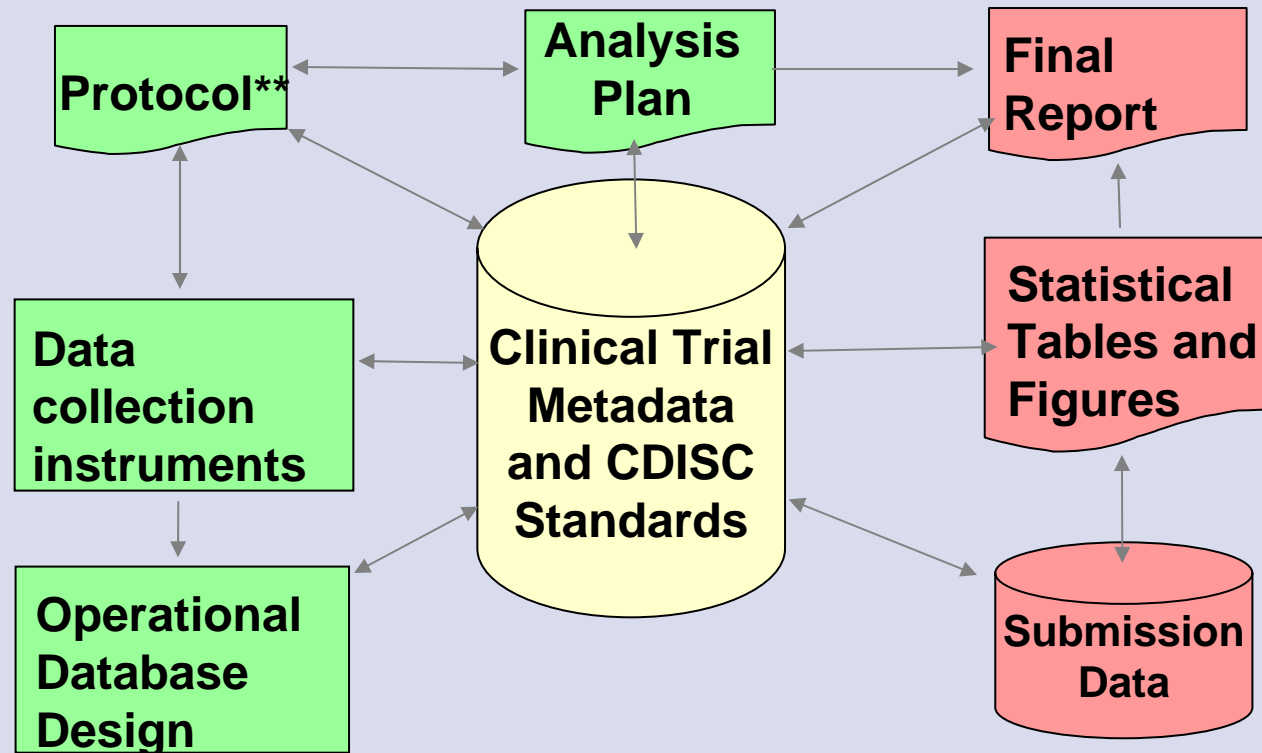
Statisticians need more tools!

Unmet Needs:

- Simple, cheap protocol/study design tool
- Analysis plan authoring tool
 - Define table/figure specs and create of mock tables
 - Automatic creation of programming code
- Metadata manager
 - Study design information
 - ADaM documentation requirements
 - SDTM
- “Smart” define.xml tool



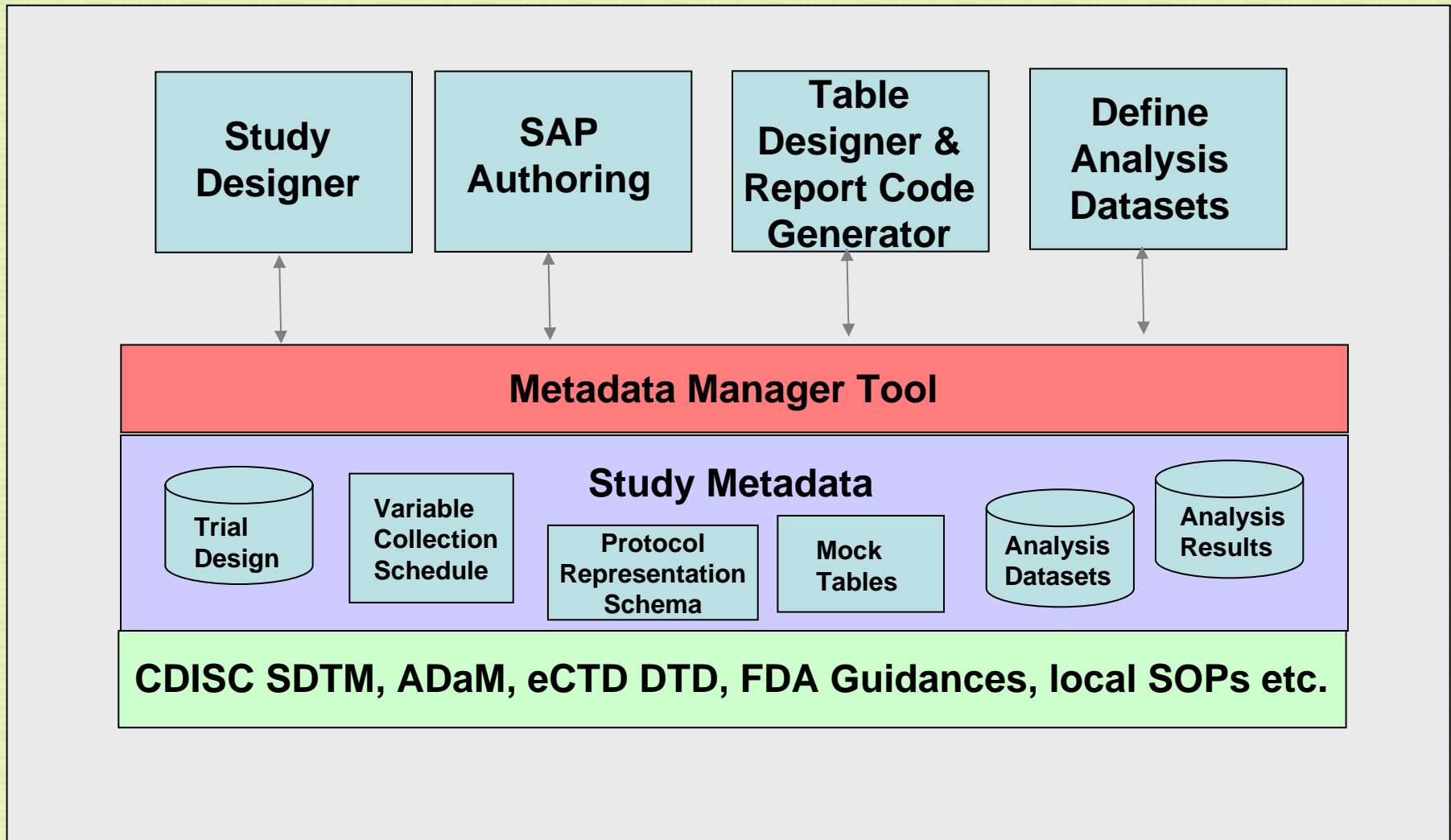
Data Standards Can Drive Statistical Processes



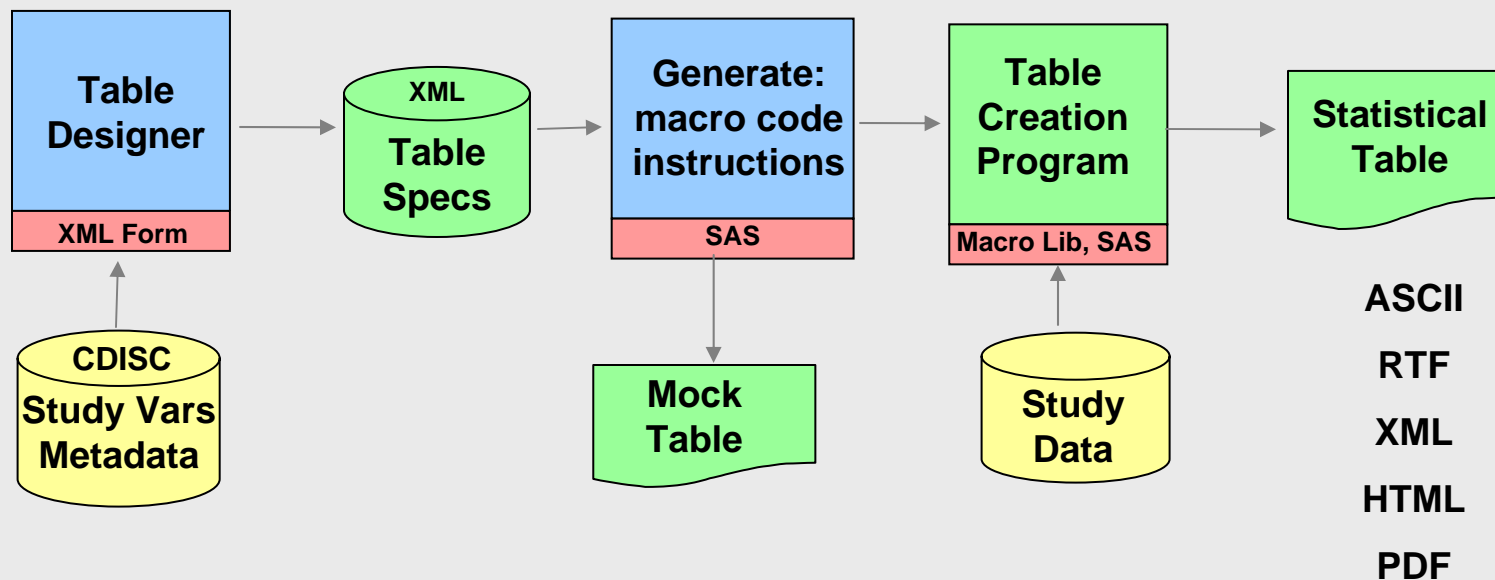
****Publication of a standard, machine-readable model for protocol representation that will facilitate interchange of metadata among systems and stakeholders**

Figure adapted from W. Qubeck (2005), personal communication.

Elements of a Statistical Process Automation



Process Flow Automation for Creation of Statistical Tables



Reference: Hopkins & Collins (2005) "Statistical Table Specification and Automatic Code Generation Using XML". PharmaSUG 2005 Proceedings, <http://www.pharmasug.org/2005/papers/ad16.pdf>.

Questions for Discussion/ Issues for Resolution

- Why has statistical process engineering lagged in this information age?
- How can industry work together to develop specifications for statistical tools?
- How can we stimulate vendors to develop more tools for statisticians?
- Is an open source foundation a possible avenue for industry collaboration?

