

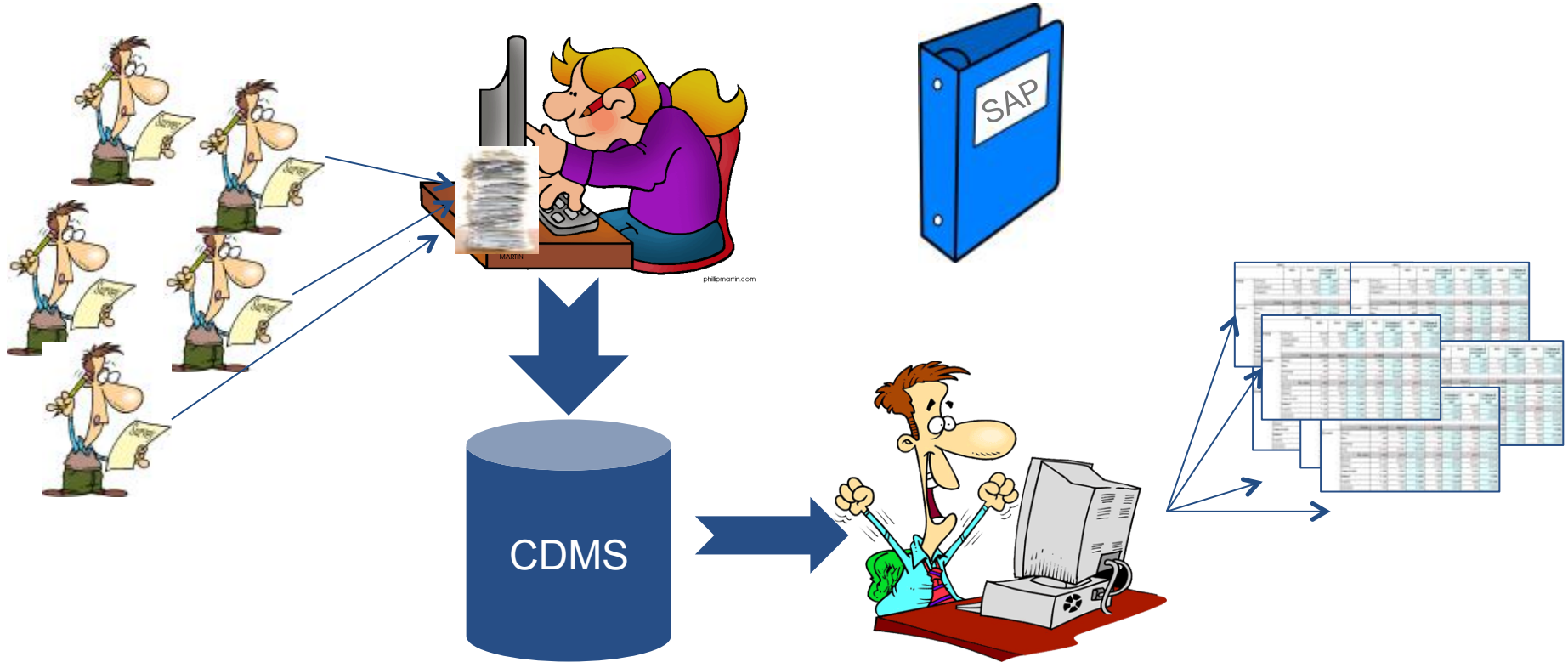


Automating CDISC deliverables through processing Metadata

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Back in the day



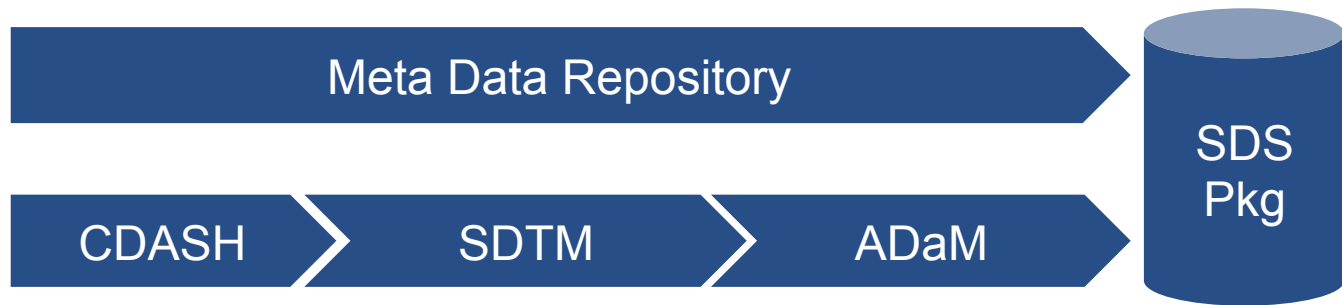
Life was so simple

- Data was collected on paper
- People entered CRFs into a database
- Programmers created SAS programs
- We generated a LOT of reports.

Or was it?

- Each CRF unique
- Delays in entry
- Everything was custom







Challenges to MetaData Driven Approach

- Not Everyone uses CDISC the SAME WAY!
 - Client interpretations of Expected and Permitted
 - Abuse of Extensible CT Lists
 - Internal process extensions
- Retention of Legacy Standards
 - › Internal use of existing standards for portfolio mgmt.
 - › Conversion as necessary
- “They always accepted it in the past”....



Why MDR

- Central Location for Standards
- Governance of Standards
- Repository for Study Specifications
- Starting point for Automation



Getting There - Extending use of Metadata

- Cross Check of Variables Created
 - › Check the specifications against published SDTMIG
- Automated Specification Reviews
 - › Check the specification for completeness against SAS datasets
 - › Check SAS datasets for completeness against the specification
- Define Creation
 - › Use of SAS macros to help create and validate define.xml files both versions 1.0 & 2.0
- SDTM, ADaM, and Display generation.



Getting There - Extending use of Metadata

- Governance of Standards
 - › Tight control:
 - Users request a change in the specifications
 - Librarian needs to approve before use
 - Users can use the updated specification.
 - › Notify and use:
 - Users request a change in the specification
 - Change is available for use as “Provisional”
 - Librarian approves or denies the request.
 - › Aproved – updates user made become active
 - › Denied – user must revert all updates or request new changes.



Getting There - Building Automation

- Map RAW source variables to SDTM domain variables.
 - › Load RAW dataset/variable names in lookup table.
 - › Load SDTM into a lookup table.
 - › Map RAW to SDTM. (Selections from lists, A -> B)
- Map Display output to ADaM.
- Map ADaM variables to SDTM domain variables.
- Custom programming as needed.
 - › Most programming can be standardized.
 - › Since not all studies are “the same”, there will be a need for minimal custom programming.



Getting There - Building Automation

- Validation improvement – Show where everything is.
 - › RAW -> SDTM (RAW map to SDTM)
 - › Displays -> ADaM (Displays map to ADaM)
 - › ADaM -> SDTM (ADaM map to SDTM, plus derivations)
 - › Reports of what has been mapped and what may need to still be mapped.
 - › Programs check the “values” of the specifications for correct spelling and order of variables.
- Automation:
 - › Generation of Controlled Lists
 - › Transformation of Controlled Lists
 - › Define.xml 1.0 & 2.0



Getting There - Building Automation

- Why not everything to SDTM/ADaM all at once?
 - › Some variables within SDTM are too “complex” for 1:1 mapping (RFSTDTC, RFXSTDTC, --BLFL).
 - › Relationships between SDTM domains are challenging. (SUPP--, RELREC, CO, AP--, FA)
 - › Derivation of ADaM variables. (--FL, BASE, CHG)