

# A Day in the Life of a Metadata Table

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# Premise

- No point in collecting metadata if you're not going to use it
- If made easily accessible, metadata can be effectively used throughout the project life cycle
- This use can improve quality of deliverables, reduce code volume, and reduce the time need to get from one "end" to the other "end"
- For metadata to be easily accessible, we need tools. This requires: time and \$ for development and maintenance; organizational commitment to a new paradigm.

# This Presentation

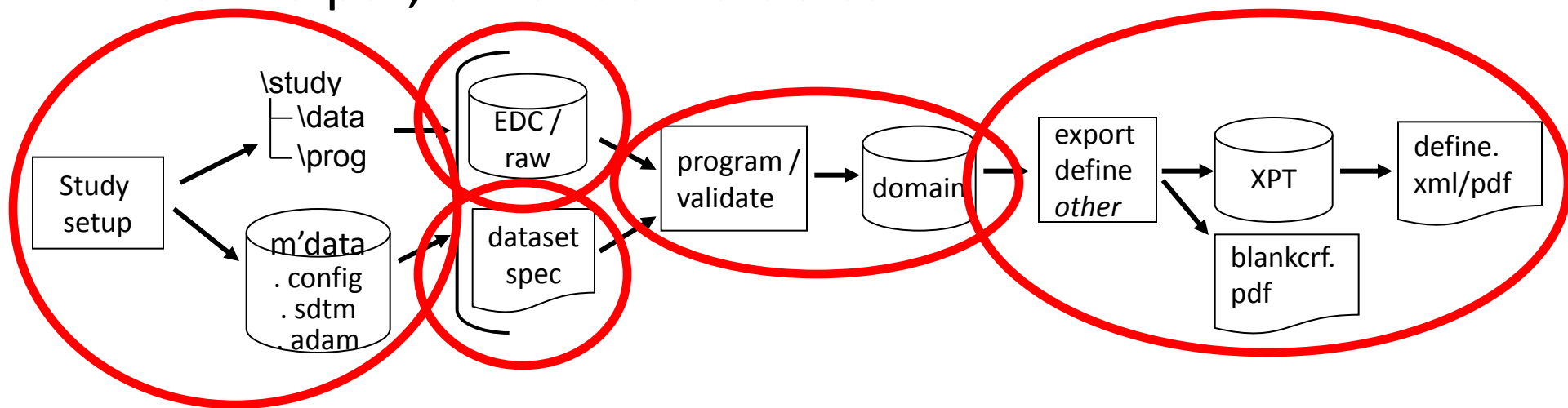
- Rather than simply say “metadata is a good idea” we will look at a table and give real-world examples of its use.
- Goals:
  - Emphasize the benefits of “end-to-end” usage of metadata
  - Be aware of key metadata features (need for and cost of tools, evolution of architecture, etc.)
  - Make the business case for development of validated tools and infrastructure (interface, repository, *et al.*)

# SDTM Workflow Overview



*Highly simplified:*

- Study setup programs create directories, seed m'data
- Client-supplied or internal EDC data
- Dataset specs used for
- Programming and validation of Domains
- Convert to SAS transport format, create define.xml, define.pdf, other deliverables



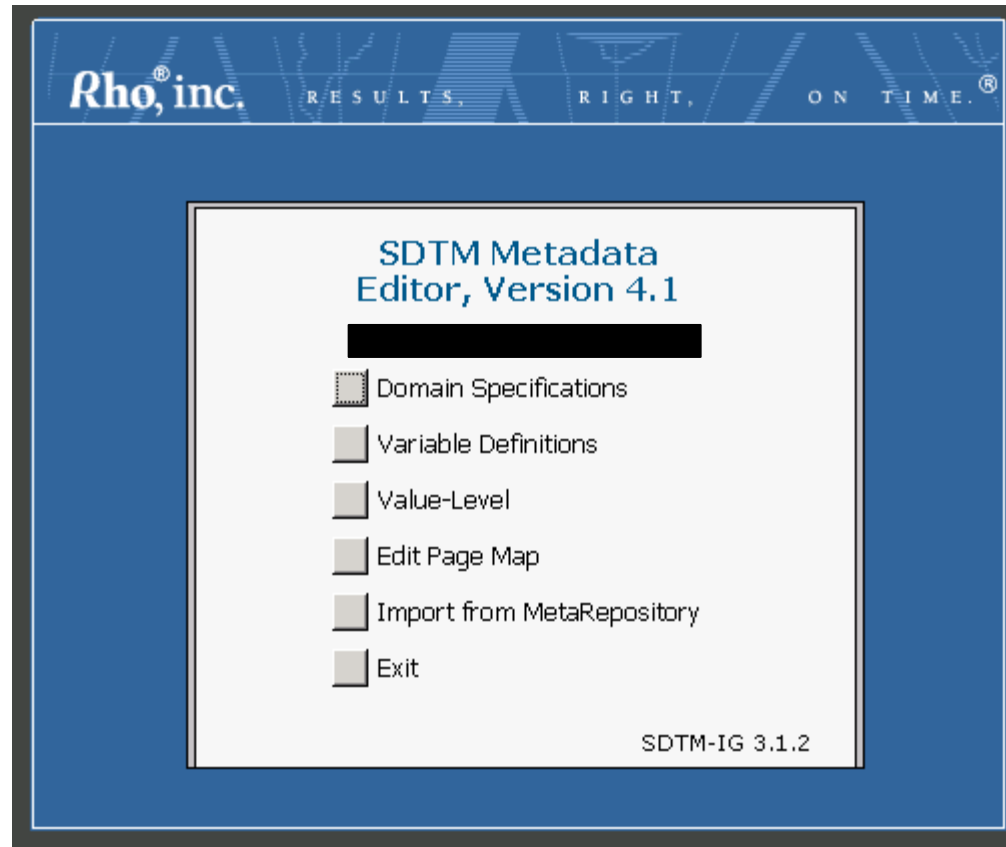
# Metadata Supporting The Process

- Study configuration, Domain, Variable, Value, *others*
- Focus on variable-level. Partial contents:

| Variable       | Content                                     |
|----------------|---------------------------------------------|
| domain         | Domain name (DM, EG, ...)                   |
| variable       | Variable name                               |
| type           | ODM type (text, integer, ...)               |
| length         | Variable length                             |
| label          | Variable label                              |
| order          | Order in dataset (1, 2, ..., n)             |
| definitionProg | Programming definition                      |
| definitionSub  | [optional] Definition to use in define file |
| use            | Include variable in submission? [check box] |
| crflocation    | Page name and number(s) in CRF              |
| core           | Required/expected/permitted?                |

# Interface

Before you can *use* metadata, you have to *create* it.



# Interface - Datasets



SDTM  
Metadata Editor  
Rev. 4.1, 2010-08-24

Domain Specifications for [REDACTED]

[Menu](#)

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[Variables](#)

[Copy Domain](#)

☐ = Standard SDTM-IG 3.1.2 Domain

| Domain             | Description                            | Structure                                                                                       | SubmitDB                            | Keys                                        |         |
|--------------------|----------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------|---------------------------------------------|---------|
| <a href="#">AE</a> | Adverse Events                         | One record per adverse event per subject                                                        | <input checked="" type="checkbox"/> | STUDYID, USUBJID, AETERM, AESTDTC           | Ir      |
| <a href="#">CE</a> | Clinical Events                        | One record per event per subject                                                                | <input type="checkbox"/>            | STUDYID, USUBJID, CETERM, CESTDTC           |         |
| <a href="#">CM</a> | Concomitant Meds                       | One record per recorded medication occurrence per subject                                       | <input checked="" type="checkbox"/> | STUDYID, USUBJID, CMSTDTC, CMTRT            | Ir      |
| <a href="#">CO</a> | Comments                               | One record per comment per subject                                                              | <input checked="" type="checkbox"/> | STUDYID, USUBJID, COVAL                     | Ir<br>R |
| <a href="#">CT</a> | Concomitant Therapies/Procedures       | One record per recorded therapy/procedure occurrence per subject                                | <input checked="" type="checkbox"/> | STUDYID, USUBJID, CTSTDTC, CTRT             | Ir      |
| <a href="#">DA</a> | Drug Accountability                    | One record per drug accountability finding per subject                                          | <input type="checkbox"/>            | STUDYID, USUBJID, DATESTCD, DADTC           |         |
| <a href="#">DM</a> | Demographics                           | One record per subject                                                                          | <input checked="" type="checkbox"/> | STUDYID, USUBJID                            | Ir<br>R |
| <a href="#">DS</a> | Disposition                            | One record per disposition status or protocol milestone per subject                             | <input checked="" type="checkbox"/> | STUDYID, USUBJID, DSSTDTC, DSTERM           | Ir<br>R |
| <a href="#">DV</a> | Protocol Deviations                    | One record per deviation per subject                                                            | <input type="checkbox"/>            | STUDYID, USUBJID, DVTERM, DVSTDTC           |         |
| <a href="#">EG</a> | ECG Test Results                       | One record per ECG observation per time point per visit per subject                             | <input checked="" type="checkbox"/> | STUDYID, USUBJID, EGDTC, VISITNUM, EGTESTCD | Ir<br>R |
| <a href="#">EX</a> | Exposure                               | One record per constant dosing interval per subject                                             | <input checked="" type="checkbox"/> | STUDYID, USUBJID, EXTRT, EXSTDTC            | Ir<br>R |
| <a href="#">FA</a> | Findings About Events or Interventions | One record per finding per object per time point per time point reference per visit per subject | <input checked="" type="checkbox"/> | STUDYID, USUBJID, FATESTCD, FAOBJ, VISITNUM | Ir      |
| <a href="#">IE</a> | Inclusion/Exclusion Criterion Not Met  | One record per inclusion/exclusion criterion not met per subject                                | <input checked="" type="checkbox"/> | STUDYID, USUBJID, IETESTCD                  | Ir<br>R |
| <a href="#">LB</a> | Laboratory Tests results               | One record per analyte per planned time point                                                   | <input checked="" type="checkbox"/> | STUDYID, USUBJID, LBTESTCD, LBDTC,          | Ir      |

Record: 1 of 38    No Filter    Search

# Interface - Variables



SDTM

Metadata Editor

Rev. 4.1, 2010-08-24

Variable Definitions for [REDACTED]

Menu

Print

Domains

[Edit Value-Level](#)

☐ = Required or Expected in SDTM-IG 3.1.2

Domain **All**

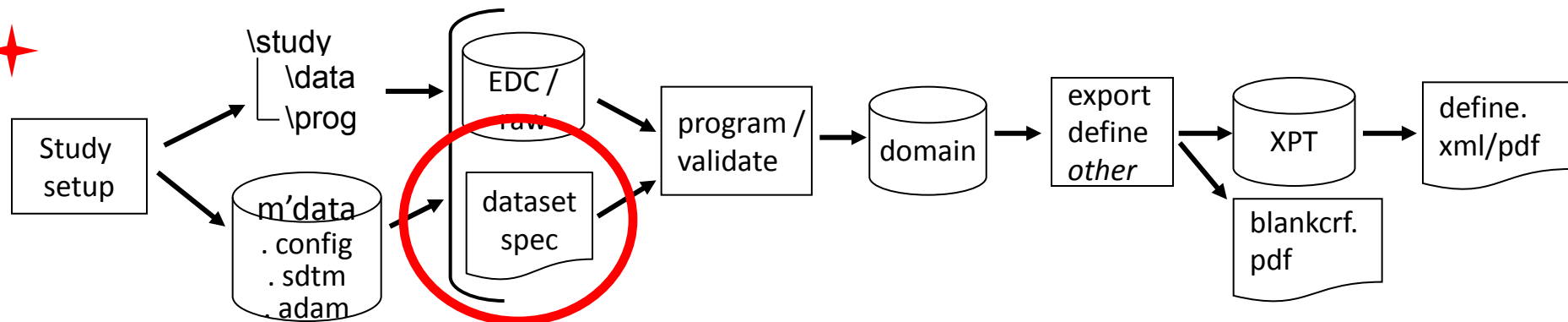
| idDoma | Required | varName | sort | Label                               | Supp                     | Value                    | SubmitDt                            | ODMType | Core | Len | CRFloc            | ProgDef                                                                                                                                    |
|--------|----------|---------|------|-------------------------------------|--------------------------|--------------------------|-------------------------------------|---------|------|-----|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| AE     | Yes      | STUDYID | 1    | Study Identifier                    | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | text    | Req  | 18  | Cover             | [REDACTED]                                                                                                                                 |
| AE     | Yes      | DOMAIN  | 2    | Domain Abbreviation                 | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | text    | Req  | 2   |                   | = 'AE'                                                                                                                                     |
| AE     | Yes      | USUBJID | 3    | Unique Subject Identifier           | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | text    | Req  | 22  |                   | =RAW.AEXPCODE.PROJECT    RAW.AEXPCODE.ID                                                                                                   |
| AE     | Yes      | AESEQ   | 4    | Sequence Number                     | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | integer | Req  | 8   |                   | Sort dataset by keyfields in domain r<br>For each record per subject, assign sequential number from 1 to the numl records for that subiect |
| AE     | No       | AEGRPID | 5    | Group ID                            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | text    | Perm |     |                   |                                                                                                                                            |
| AE     | No       | AEREFID | 6    | Reference ID                        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | text    | Perm |     |                   |                                                                                                                                            |
| AE     | No       | AESPID  | 7    | Sponsor-Defined Identifier          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | text    | Perm |     |                   |                                                                                                                                            |
| AE     | Yes      | AETERM  | 8    | Reported Term for the Adverse Event | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | text    | Req  | 200 | Adverse Events_33 | =RAW.AEXPCODE.AETERM                                                                                                                       |

Record: 5 of 1098

No Filter

Search

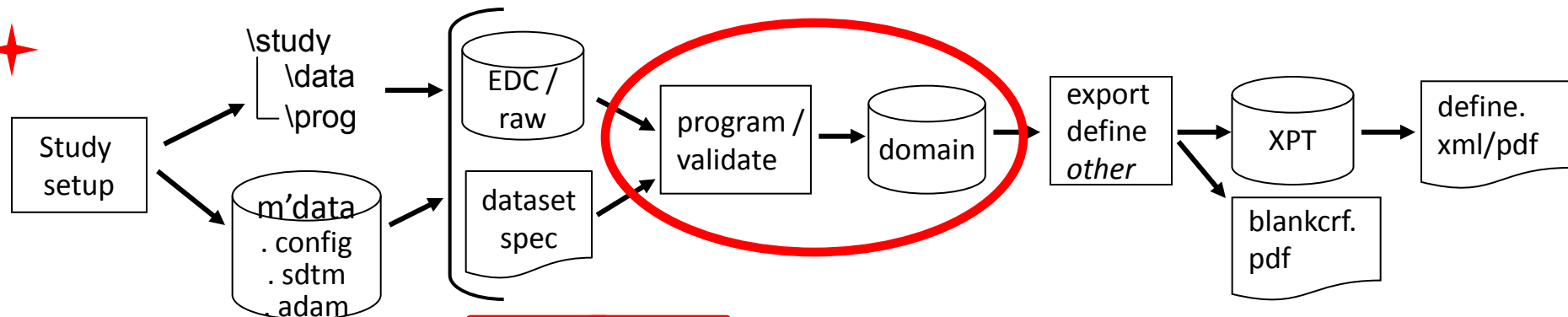
# Tools – Dataset Spec



| Variable       | %create Spec |
|----------------|--------------|
| domain         | ✓            |
| variable       | ✓            |
| type           | ✓            |
| length         | ✓            |
| label          |              |
| order          | ✓            |
| definitionProg | ✓            |
| definitionSub  |              |
| use            | ✓            |
| crflocation    |              |
| core           | ✓            |

| Tool        | Purpose                                                                                                                                                                                                                                      |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| %createSpec | Create programming spec.<br>Among the parameters: <ul style="list-style-type: none"> <li>• Variable order</li> <li>• Domains to include File format (PDF, RTF)</li> <li>• Restrict to variables changed since user-specified date</li> </ul> |

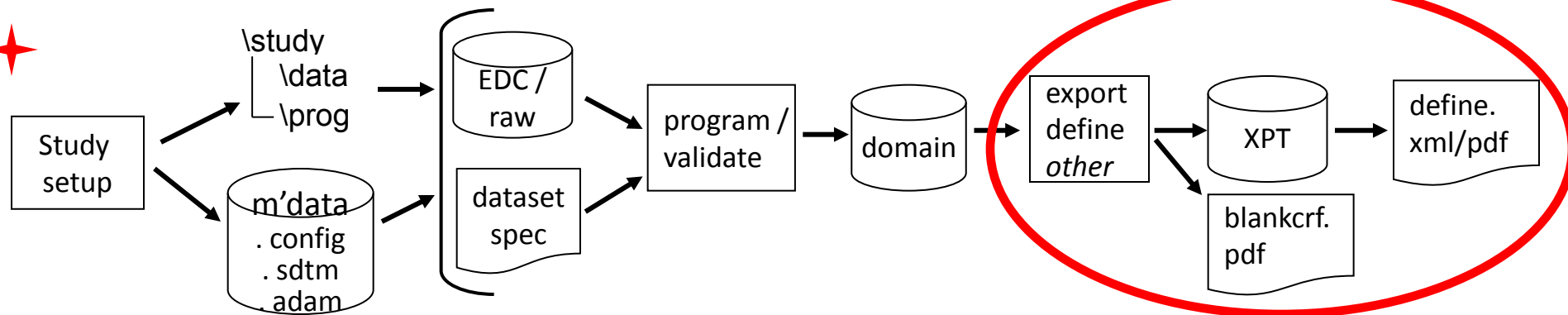
# Tools – Program / Validate



| Variable       | %attrib | %dom Split | %dom Chk |
|----------------|---------|------------|----------|
| domain         | ✓       | ✓          | ✓        |
| variable       | ✓       | ✓          | ✓        |
| type           | ✓       | ✓          | ✓        |
| length         | ✓       |            |          |
| label          | ✓       | ✓          | ✓        |
| order          | ✓       | ✓          | ✓        |
| definitionProg |         |            |          |
| definitionSub  |         |            |          |
| use            | ✓       | ✓          | ✓        |
| crflocation    |         |            |          |
| core           |         | ✓          | ✓        |

| Tool         | Purpose                                                   |
|--------------|-----------------------------------------------------------|
| %attrib      | Build ATTRIB, KEEP statements for a Domain                |
| %domainSplit | Divide a dataset into <i>domain</i> and <i>SUPPdomain</i> |
| %domainCheck | Check for basic SDTM compliance                           |

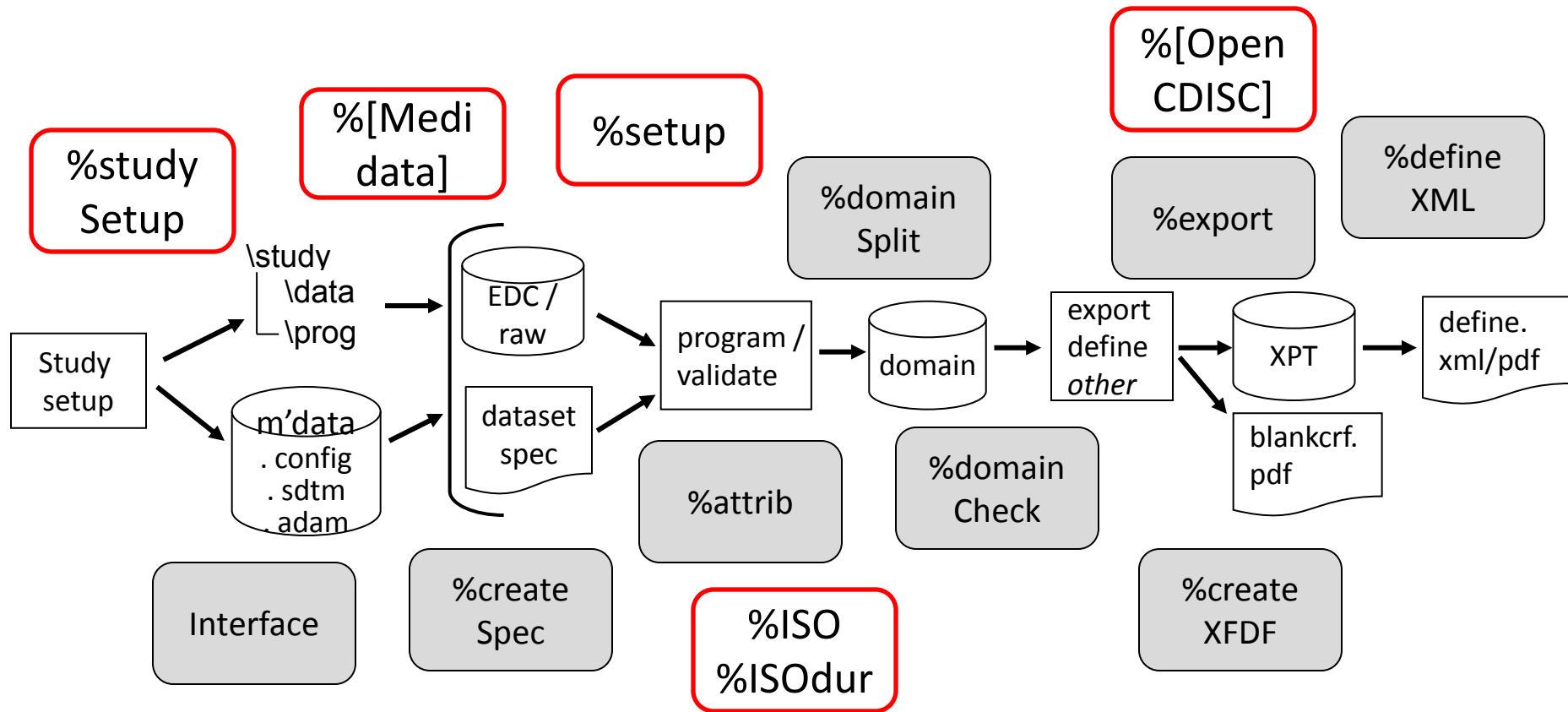
# Tools – Deliverables



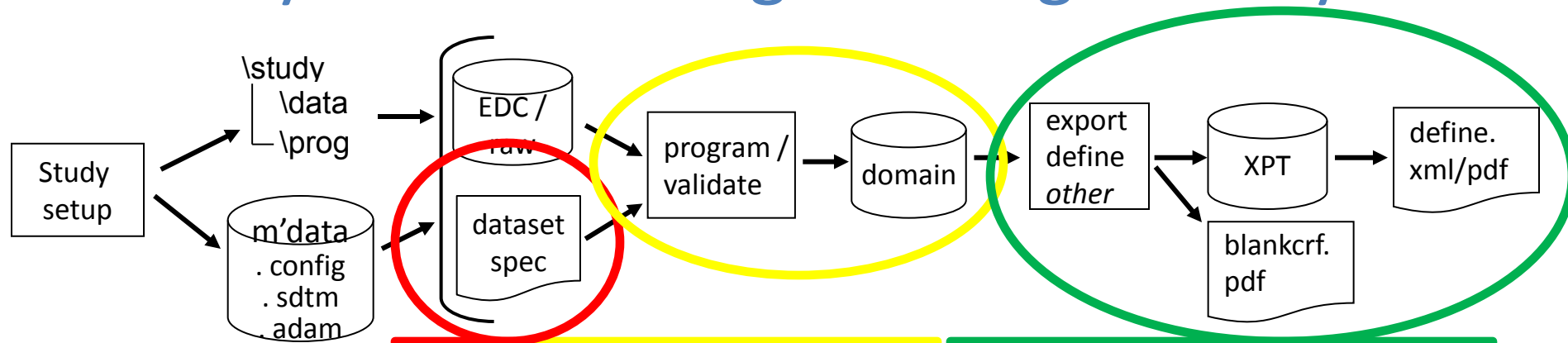
| Variable       | %cr<br>XFDF | %xpt | %def<br>XML | %def<br>PDF |
|----------------|-------------|------|-------------|-------------|
| domain         | ✓           | ✓    | ✓           |             |
| variable       | ✓           | ✓    | ✓           |             |
| type           |             |      | ✓           |             |
| length         |             |      | ✓           |             |
| label          |             |      | ✓           |             |
| order          |             | ✓    | ✓           |             |
| definitionProg |             |      |             |             |
| definitionSub  |             |      | ✓           |             |
| use            | ✓           | ✓    | ✓           |             |
| crflocation    | ✓           |      | ✓           |             |
| core           |             |      | ✓           |             |

| Tool        | Purpose                                                                                                                                                                                                                    |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| %createXFDF | Create annotations for blankCRE.pdf                                                                                                                                                                                        |
| %export     | Create XPT files                                                                                                                                                                                                           |
| %defineXML  | Create define.xml and related/support files<br>Among the parameters: <ul style="list-style-type: none"> <li>• Order of datasets</li> <li>• Rendering of hyperlinks</li> <li>• Display of Controlled Terminology</li> </ul> |
| %definePDF  | PDF version of define.xml reads define.xml, doesn't use any domain/variable m'data                                                                                                                                         |

# Summary: Tools, Interface



# Summary: Variable Usage Through Life Cycle



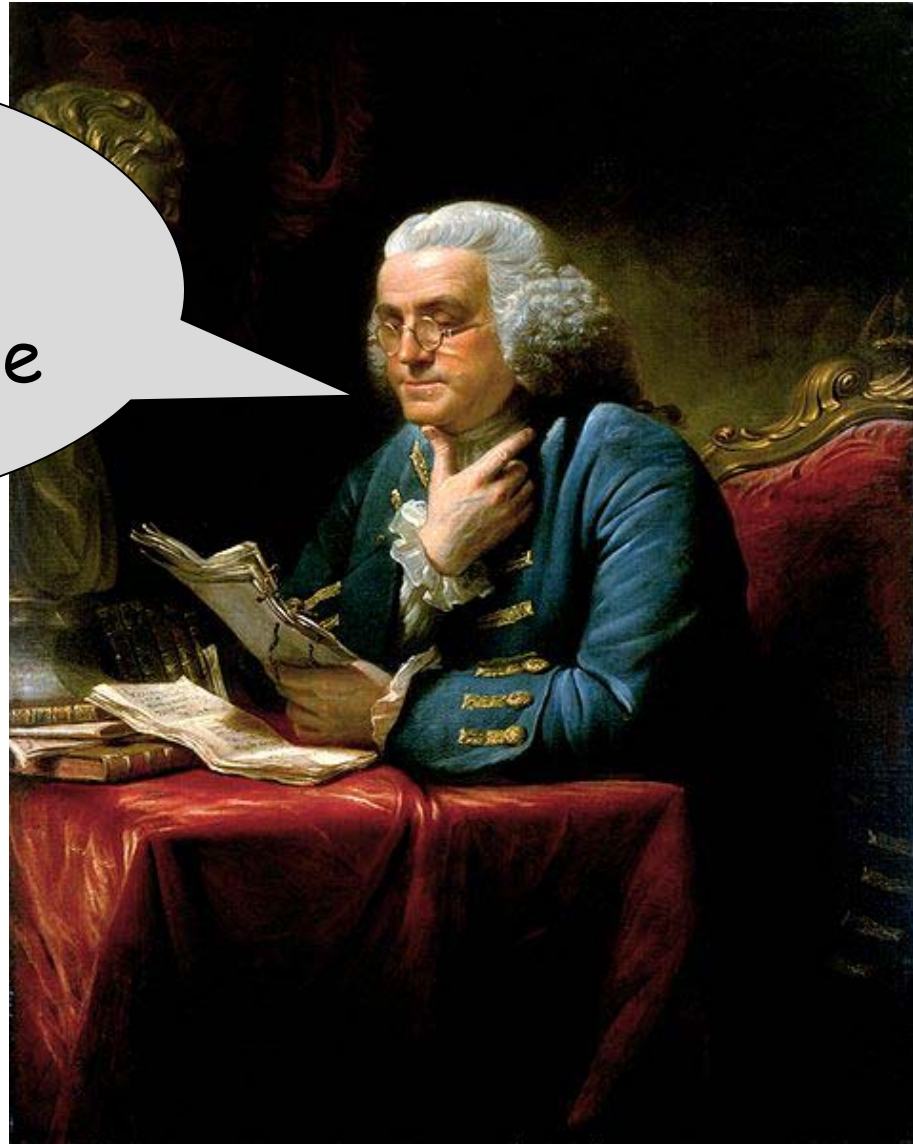
| Variable       | %create Spec | %attrib | %dom Split | %dom Chk | %cr XFDF | %xpt | %def XML | %def PDF |
|----------------|--------------|---------|------------|----------|----------|------|----------|----------|
| domain         | ✓            | ✓       | ✓          | ✓        | ✓        | ✓    | ✓        |          |
| variable       | ✓            | ✓       | ✓          | ✓        | ✓        | ✓    | ✓        |          |
| type           | ✓            | ✓       | ✓          | ✓        |          |      | ✓        |          |
| length         | ✓            | ✓       |            |          |          |      | ✓        |          |
| label          |              | ✓       | ✓          | ✓        |          |      | ✓        |          |
| order          | ✓            | ✓       | ✓          | ✓        |          | ✓    | ✓        |          |
| definitionProg | ✓            |         |            |          |          |      |          |          |
| definitionSub  |              |         |            |          |          |      | ✓        |          |
| use            | ✓            | ✓       | ✓          | ✓        | ✓        | ✓    | ✓        |          |
| crflocation    |              |         |            |          | ✓        |      | ✓        |          |
| core           | ✓            |         | ✓          | ✓        |          |      | ✓        |          |

# Closing Comments

- Metadata can be used throughout life cycle
- Not all variables need to be “in play” at once
- Need to design for new deliverables, processes: this requires adaptable architecture (both tools and metadata)
- Tools
  - improve efficiency and quality and ...
  - require investment (initial, ongoing) and organizational commitment

# And Remember ...

When you're  
finished  
changing, you're  
finished.



# Contact

Your comments are valued and encouraged:

- [Frank@CodeCraftersInc.com](mailto:Frank@CodeCraftersInc.com)
- [www.CodeCraftersInc.com](http://www.CodeCraftersInc.com)