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Document to Content Management: A Paradigm Change

DIA DRM SIAC – Content Re-Use

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Assoc. Director, Regulatory Knowledge & Information Management

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Continuous Improvement

"Do you know that 87.166253% of all statistics claim a precision of results that is not justified by the method employed?"

- Unknown Statistician

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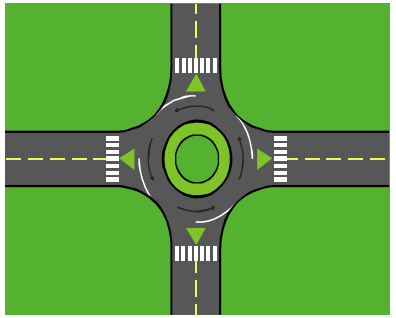
Agenda

- Why Move to Content Management?
- Re-Use & Content Management
- Tracking & Metrics
- Summary



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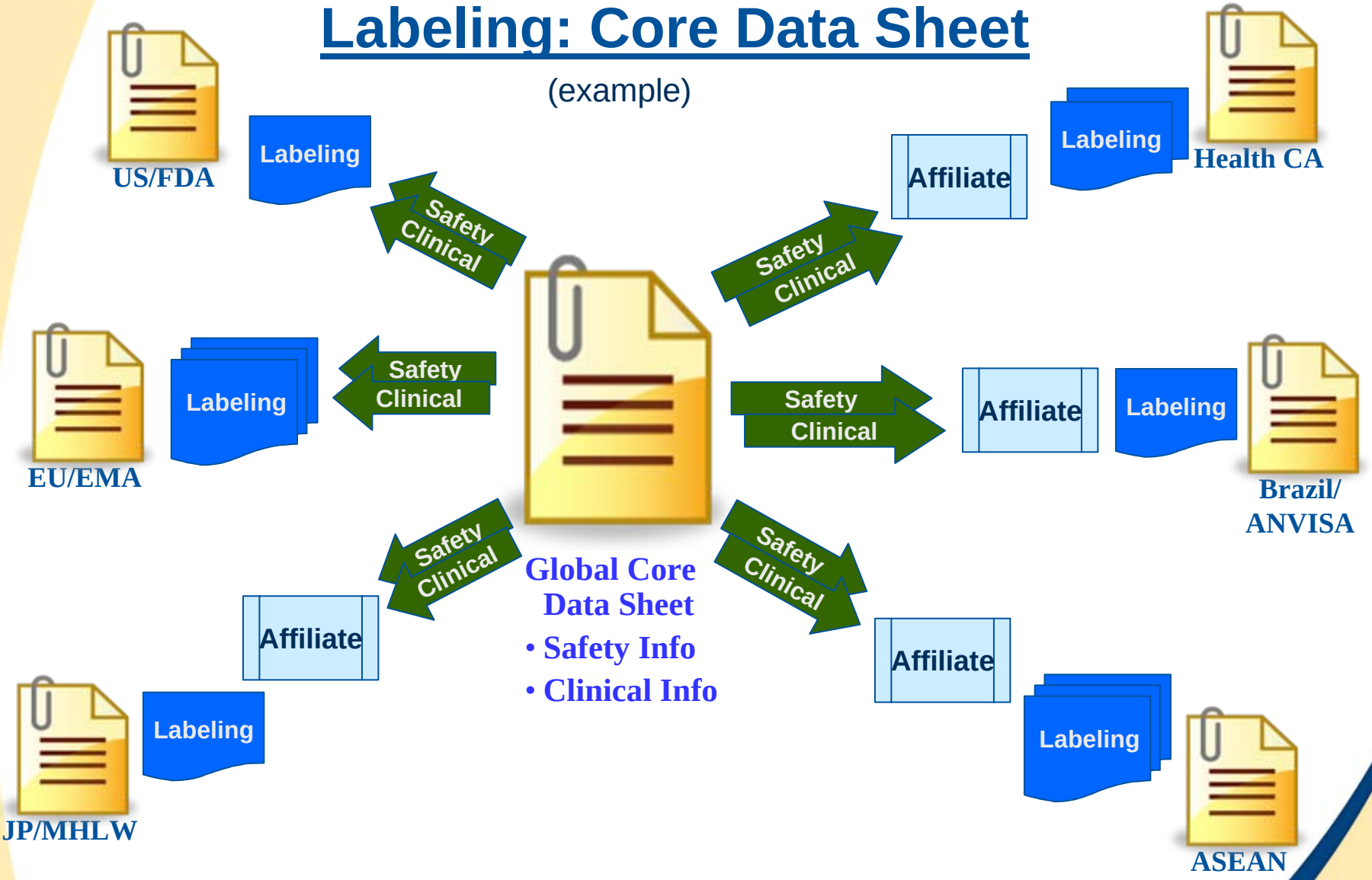
Why Move to Content Mgmt?

- **Labeling**
  - Core Data Sheet mapped to Package Labeling
- **Global Dossier Re-Use**
  - Global Dossier – similar content, different dossiers
- **Module 3 - CMC**
  - Granularity – same content, different sized documents
- **Health Authority Q & A, Correspondence**
  - Track Qs & As by Content
  - Track Qs & As by Health Authority

Consistency of Information

Labeling: Core Data Sheet

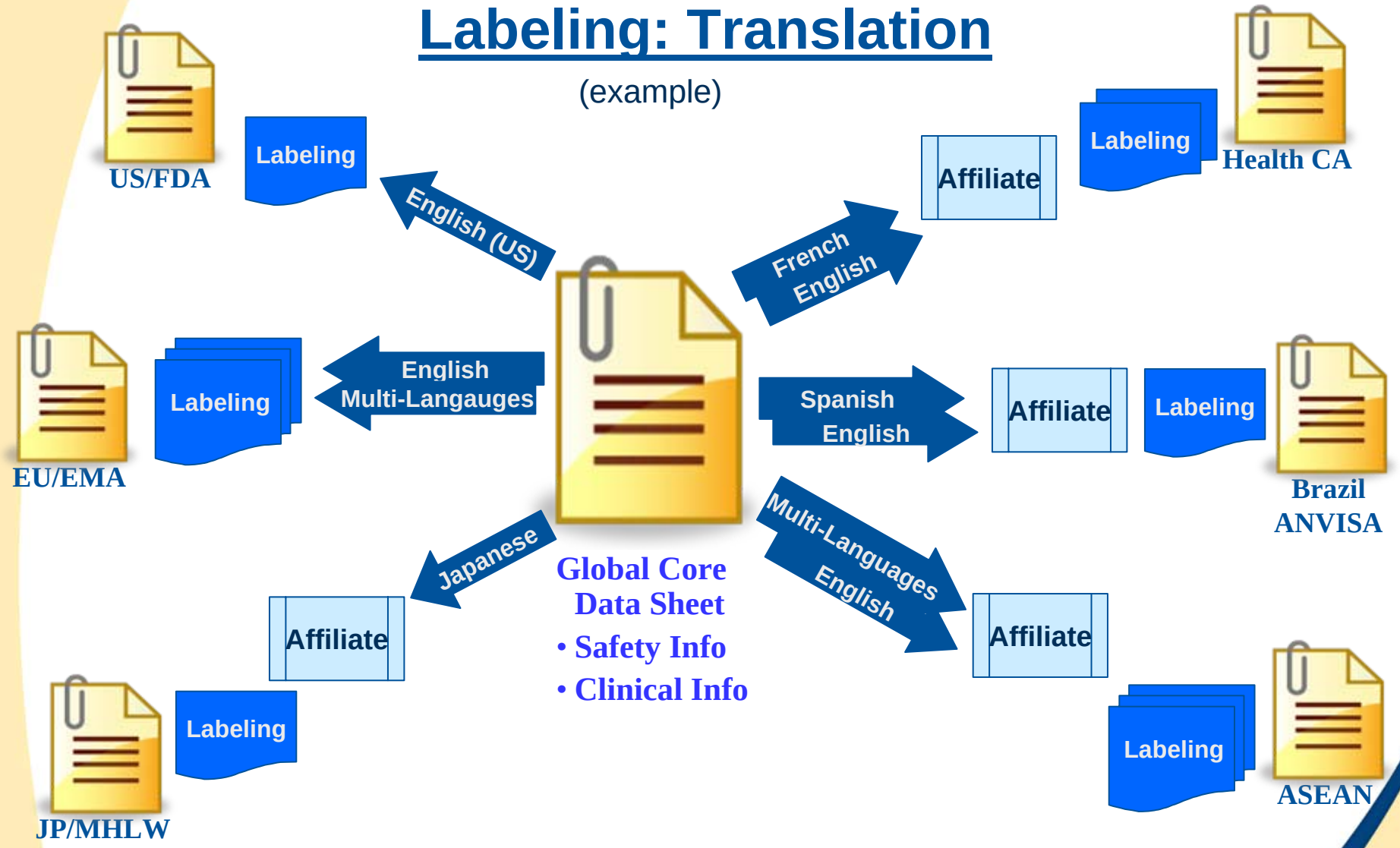
(example)



Consistency of Translation

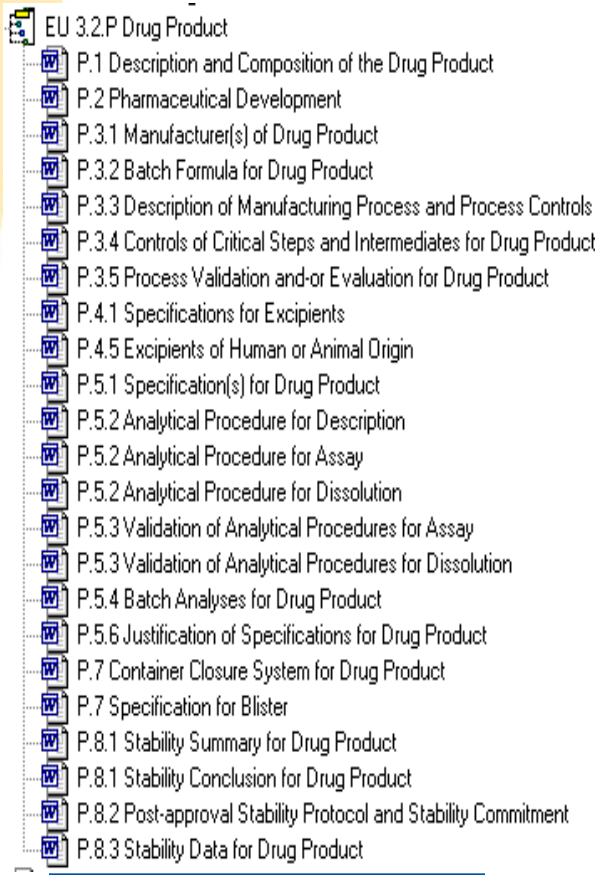
Labeling: Translation

(example)



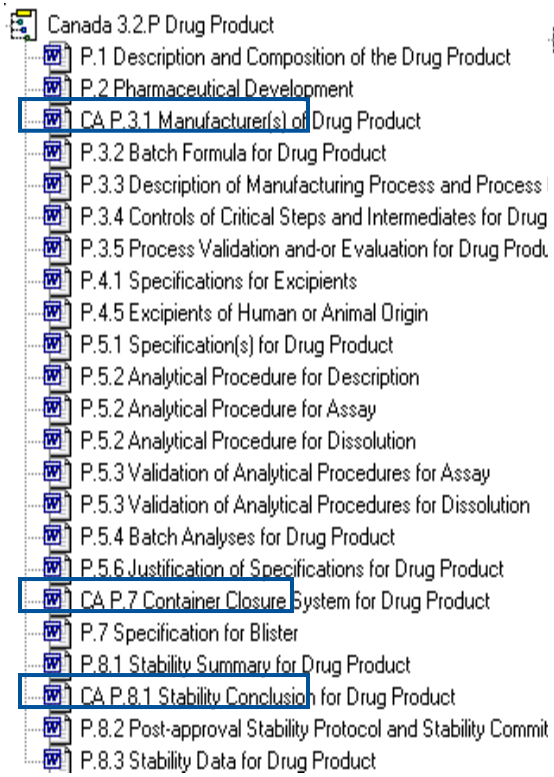
Global Dossier
Marketing application in initial countries
(example Module 3)

Europe



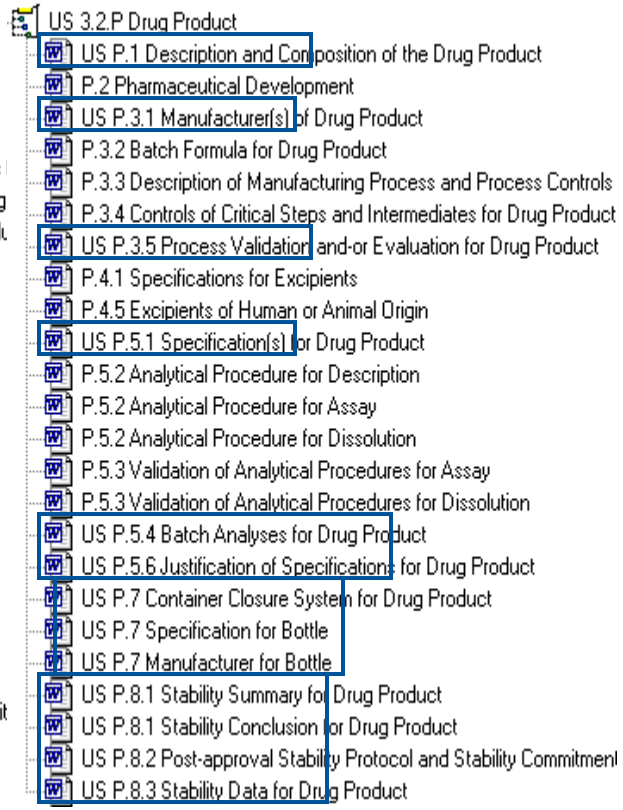
Upload to eCTD

Canada



Upload to eCTD

USA



Upload to eCTD

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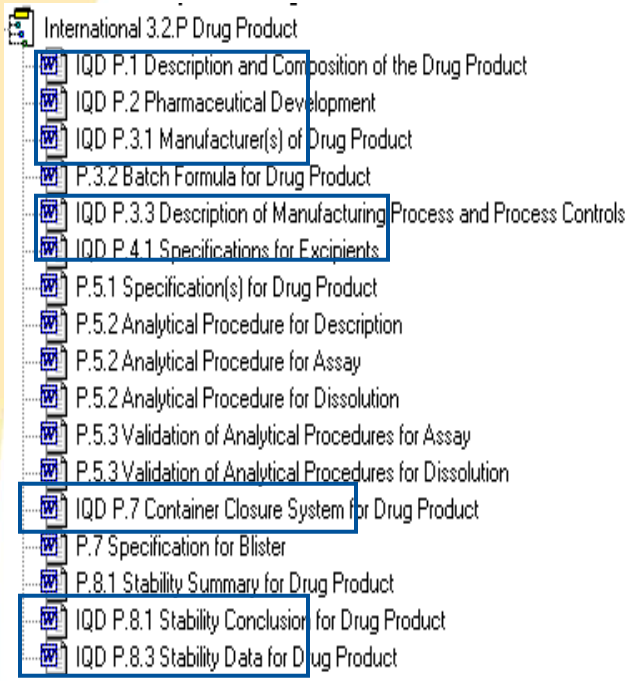
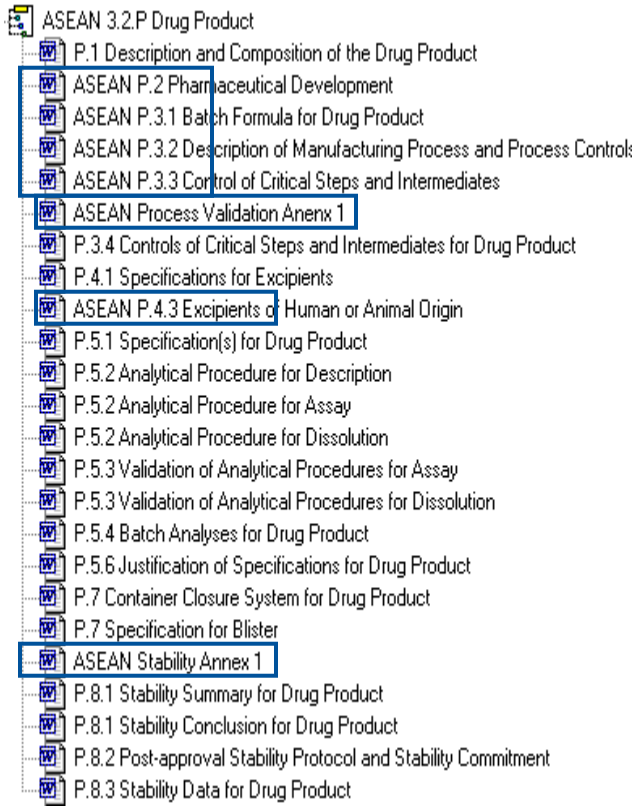
Global Dossier
Marketing application in subsequent countries
(example Module 3)

International



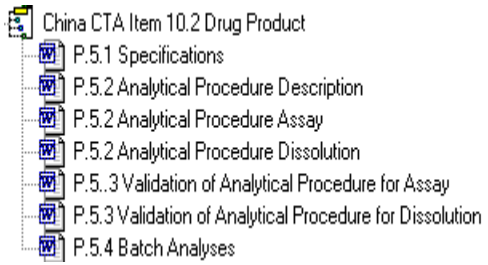
References only to Ph Eur

ASEAN



Different numbering
Additional documents

China



Different organisation (as 'Items')

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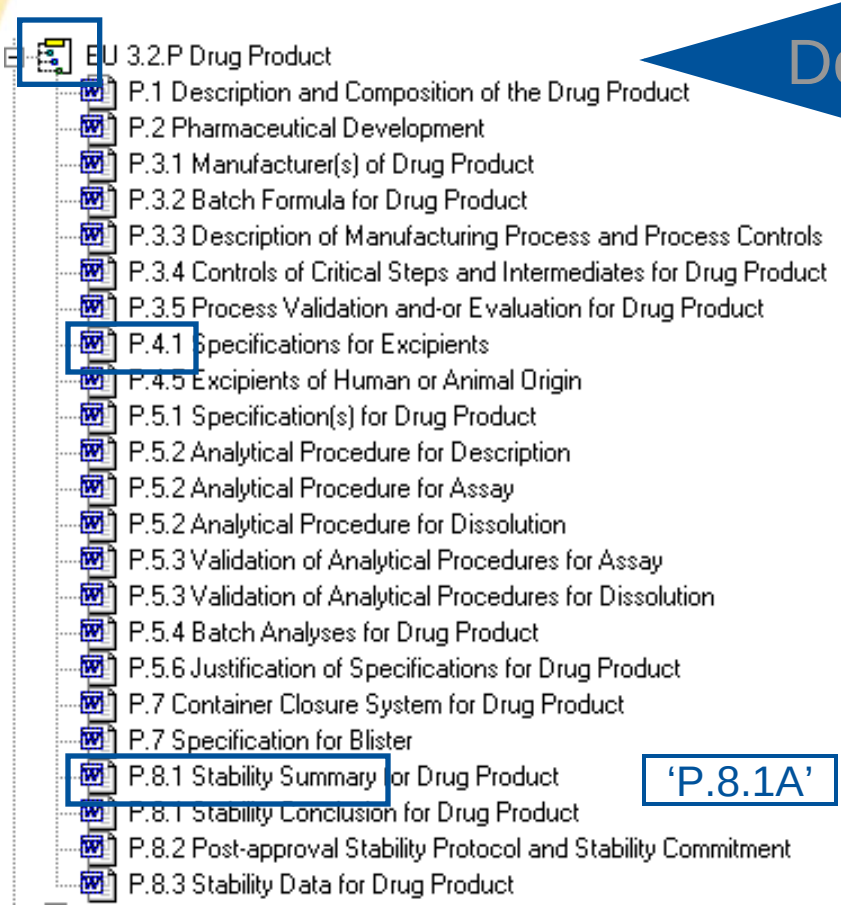
Granularity
Module 3 – CMC



Dossier as a virtual document

Common Technical Document topic

'P.8.1A'

Further granularity*

*** Allowed by ICH M4 "granularity annex"**

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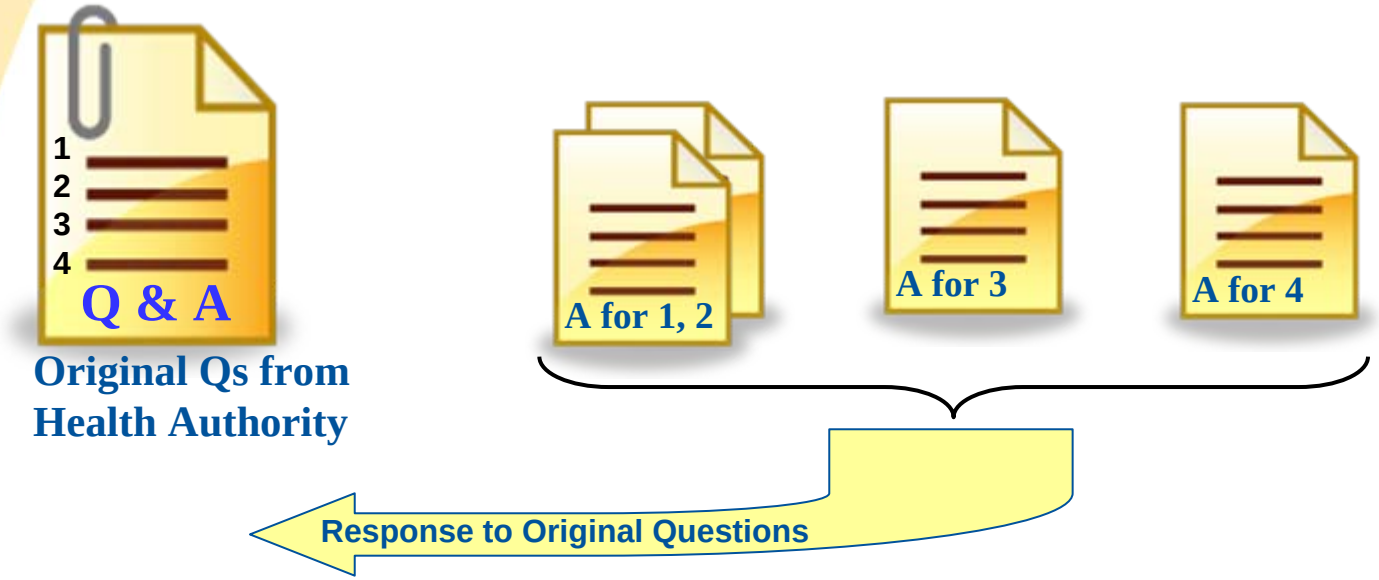
Health Authority Q & A, Correspondence



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Continuous Improvement

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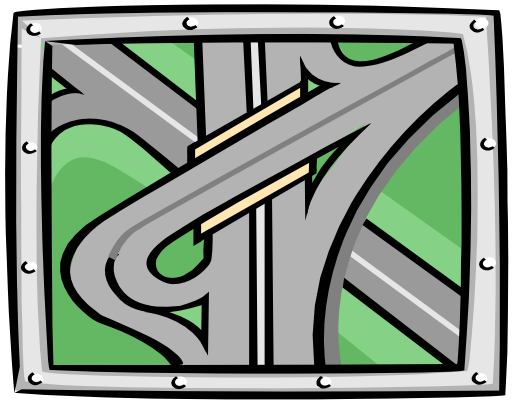
- Re-Use & Content Management
- Tracking & Metrics
- Summary



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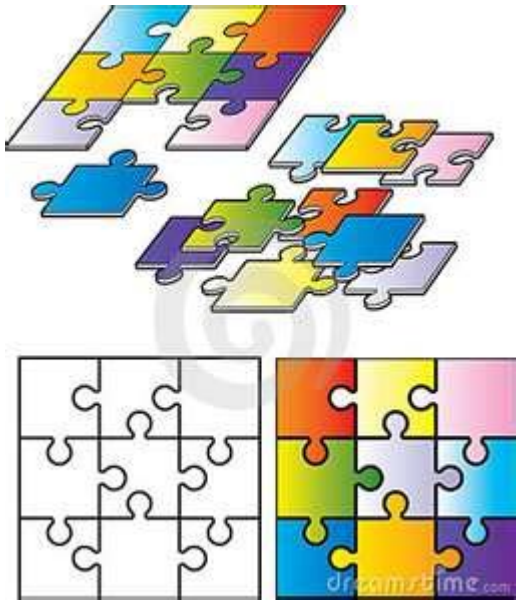
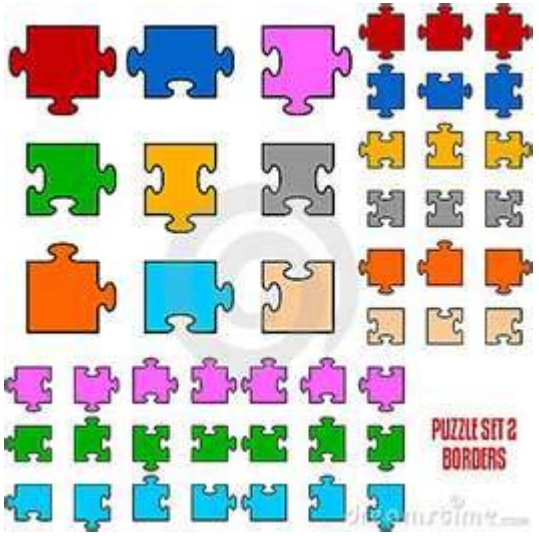
Re-Use & Content Management

- **Technical Manuals vs Submission Documents**
  - Tech Manuals include highly re-useable content
  - Submission Documents less re-useable content

- **Copy&Paste Re-Use vs Tracking Re-Use**
  - Re-Use via Copy&Paste looses tracking From
  - Need Re-Use as traceable content

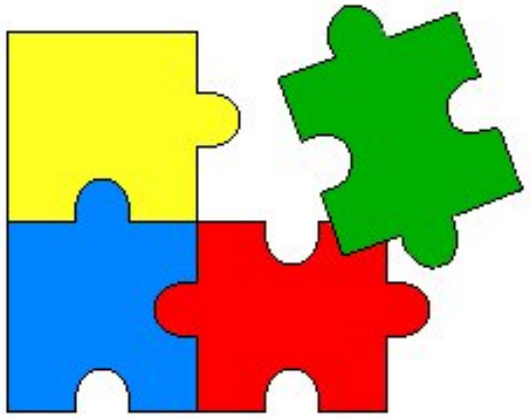
Re-Use:
Tech Manuals vs Submission Docs





- **Technical manuals have high re-use**
  - Many updates to same parts of same documents
  - Hierarchic assemblies allow for scaled re-use (re-use sets of content)

Re-Use:
Tech Manuals vs Submission Docs



- **Submission documents have low re-use**
  - Few updates to same parts (Mod 3 main exception)
  - Content re-use mostly re-use of same sections to different documents, not strictly hierarchic

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Global Dossier
What could using Structured Authoring mean?

- **Re-usability (quality and consistency):**
  - Not caught out by changes that have implications on other documents' content
  - More efficient generation of Module 2.3 Quality Overall Summary
  - Establishment of databases for common information
  - Eliminate transcription errors
- **Potential M3 examples:**
  - 3.2.S and 3.2.P flow diagrams, specifications → Module 2.3
  - Container closure specification → many eCTD applications
  - Manufacturing site addresses → many eCTD applications
  - Facilities and Equipment → many eCTD applications
  - Chemical structures → CTA (IB, IMPD), MAA (M2.3, M3)

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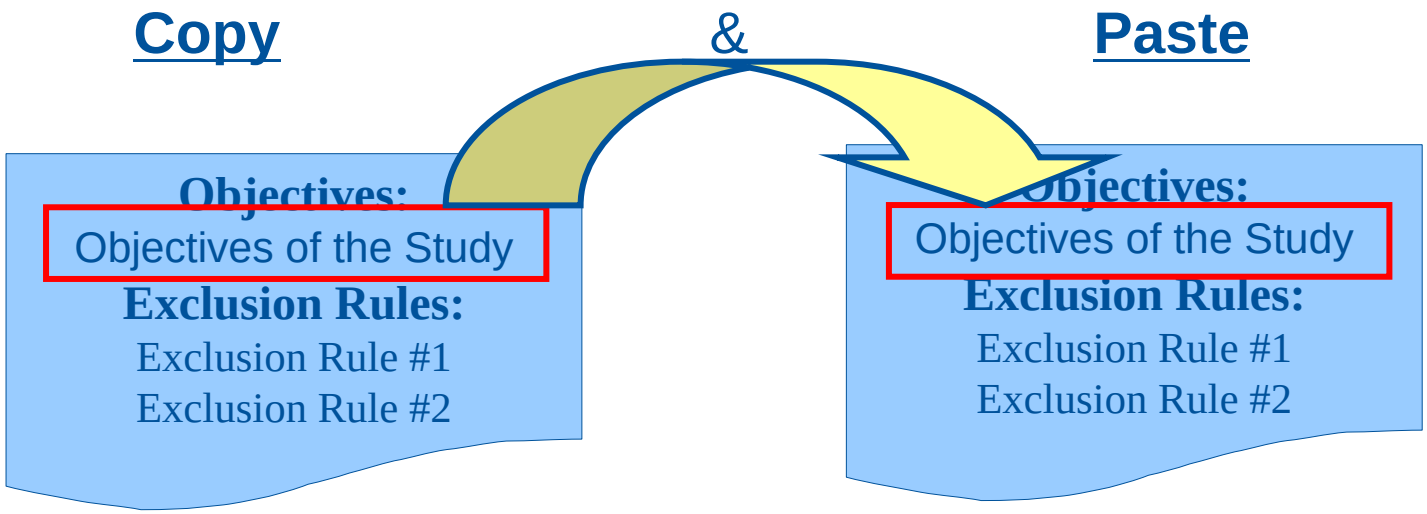
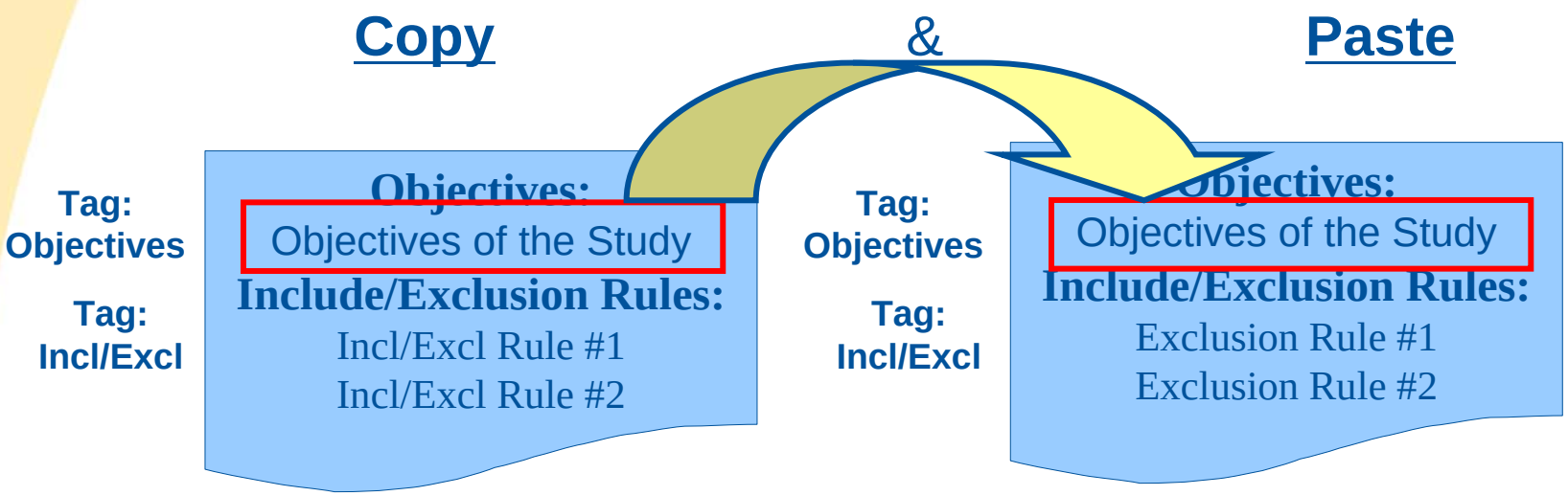
Easy Copy & Paste: No Traceability



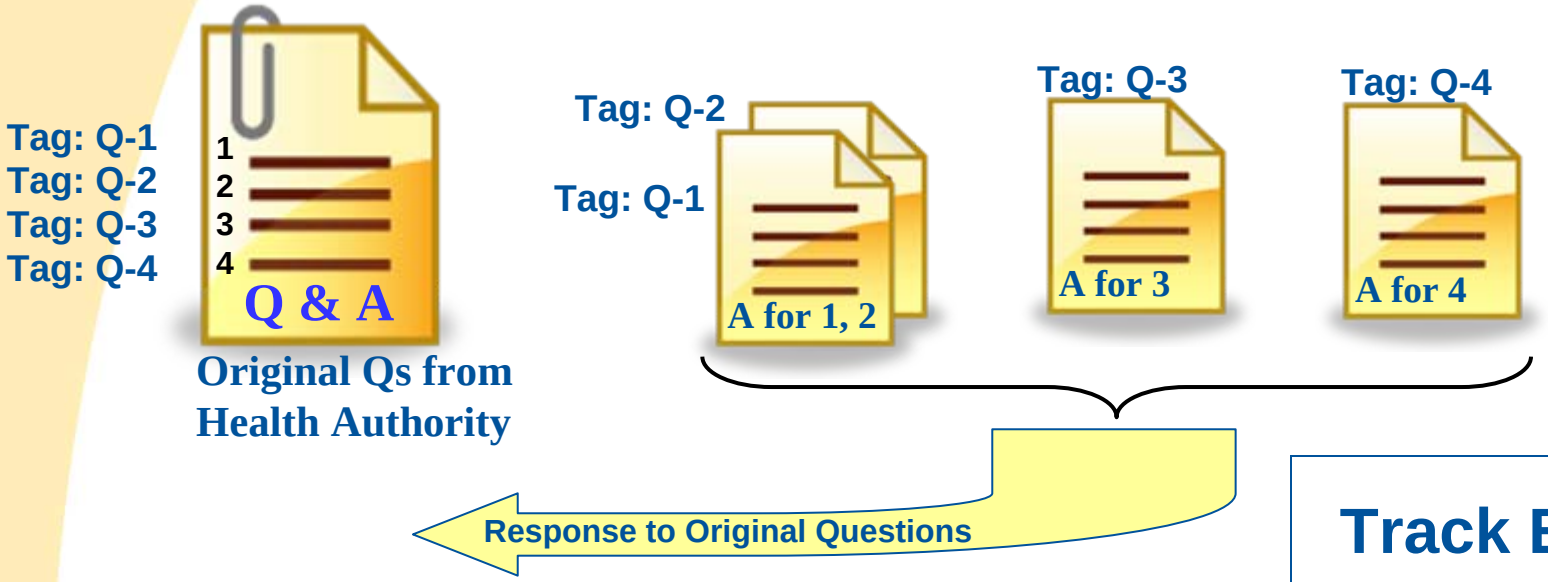
- No Traceability of Content (except in Author's head)
- If changes made to 'Paste' side, no ability to later check if correct except via manual review

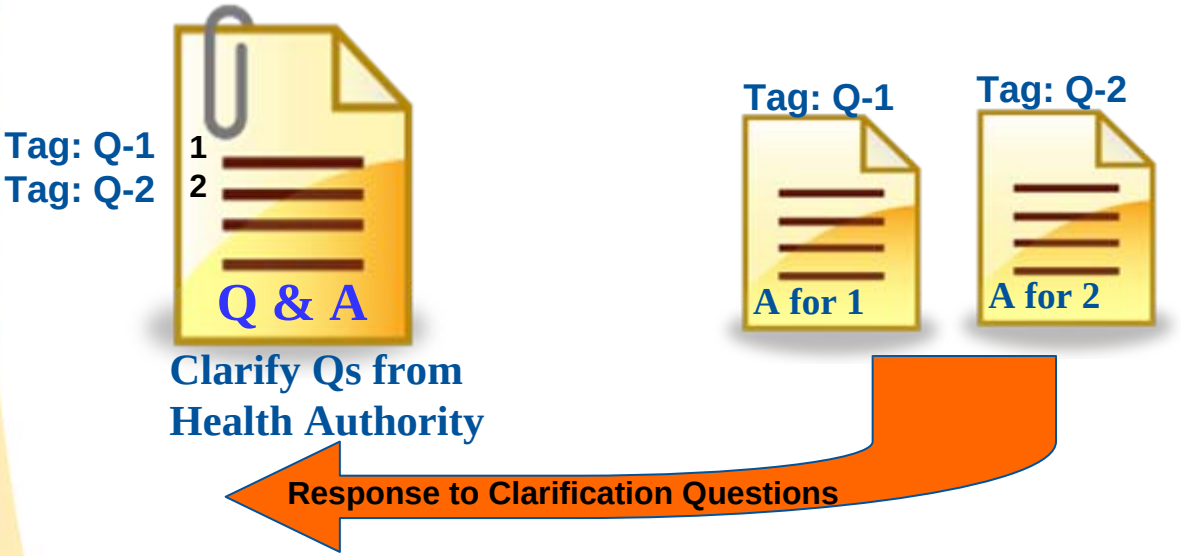
Tagged Copy & Paste: With Traceability



- **Traceability of Content can be determined**
  - Time and Date Stamp
  - Hand-off Metrics
- **Content within tags can be:**
  - Used for regulatory & compliance purposes
  - Used for quality check purposes

Health Authority Q & A, Correspondence





Track Each Q&A Separately

- Time & Date Stamp
- Metrics

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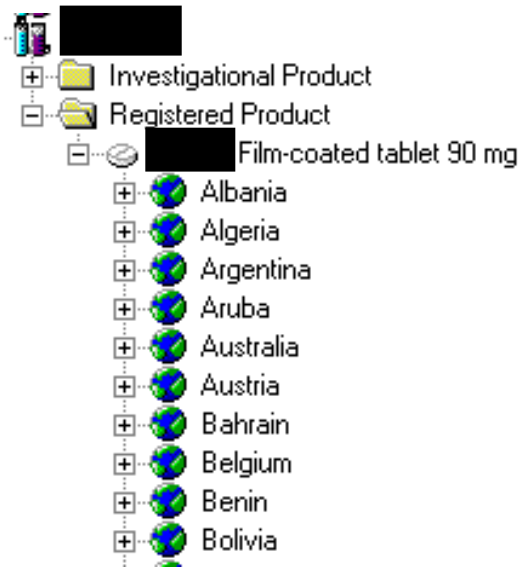
Tracking & Metrics

- Registration (incl. Q&A & Correspondence)
- Labeling
- Global Dossier & Module Re-Use
- Quality Component
- Metrics Component (Improvement)

Ensuring compliance today
Submission Lifecycle Information Management

- **Events** track the outcome of submissions
- **Outgoing package** records which documents were sent to which country
- Monitor if submission has been
  - Dispatched, submitted, approved, withdrawn, divested
- Maintain supply links
- View data from different perspectives



Relies on manual input

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Global Dossier
What might XML offer to applicants?

- **Tracking:**
  - Reference links – update M3 content and flag for M2.3
  - Track at content level instead of document level
    - By approval in 40+ countries, can have territorial variation *
  - Track submissions by country
    - With XML tags can drag and drop a file on an Event to automatically recognize metadata for strength, product, dosage form, manufacturer

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Tracking Changes: Manual Processes

How is Change Tracked?

- Author holds changes and change reasons in head
- Meeting Minutes of discussions?
- What about External / Contract Authors?

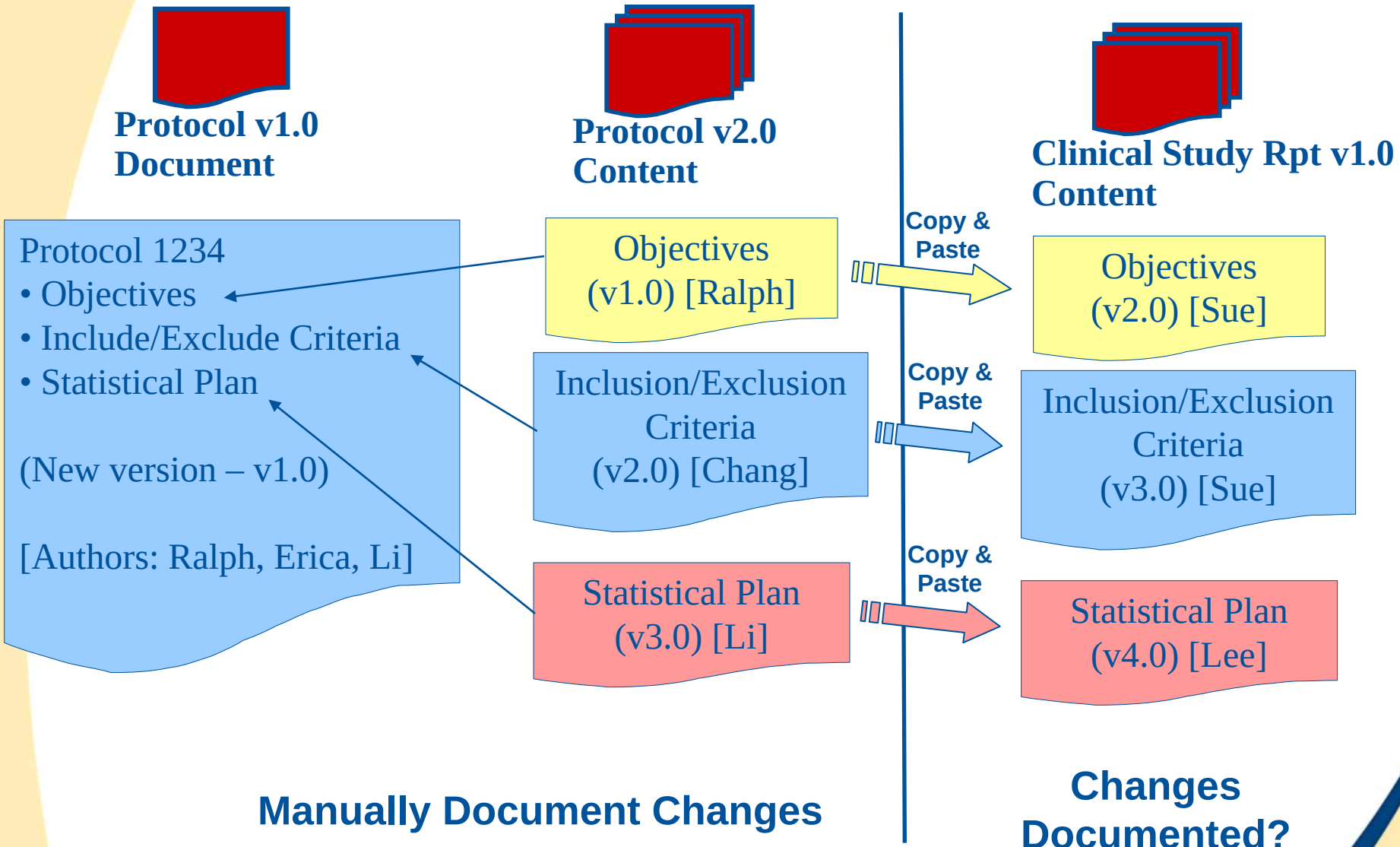
How is Content Re-Use Tracked?

- Author knows where content ‘copied’ from
- How has content been changed when re-used?

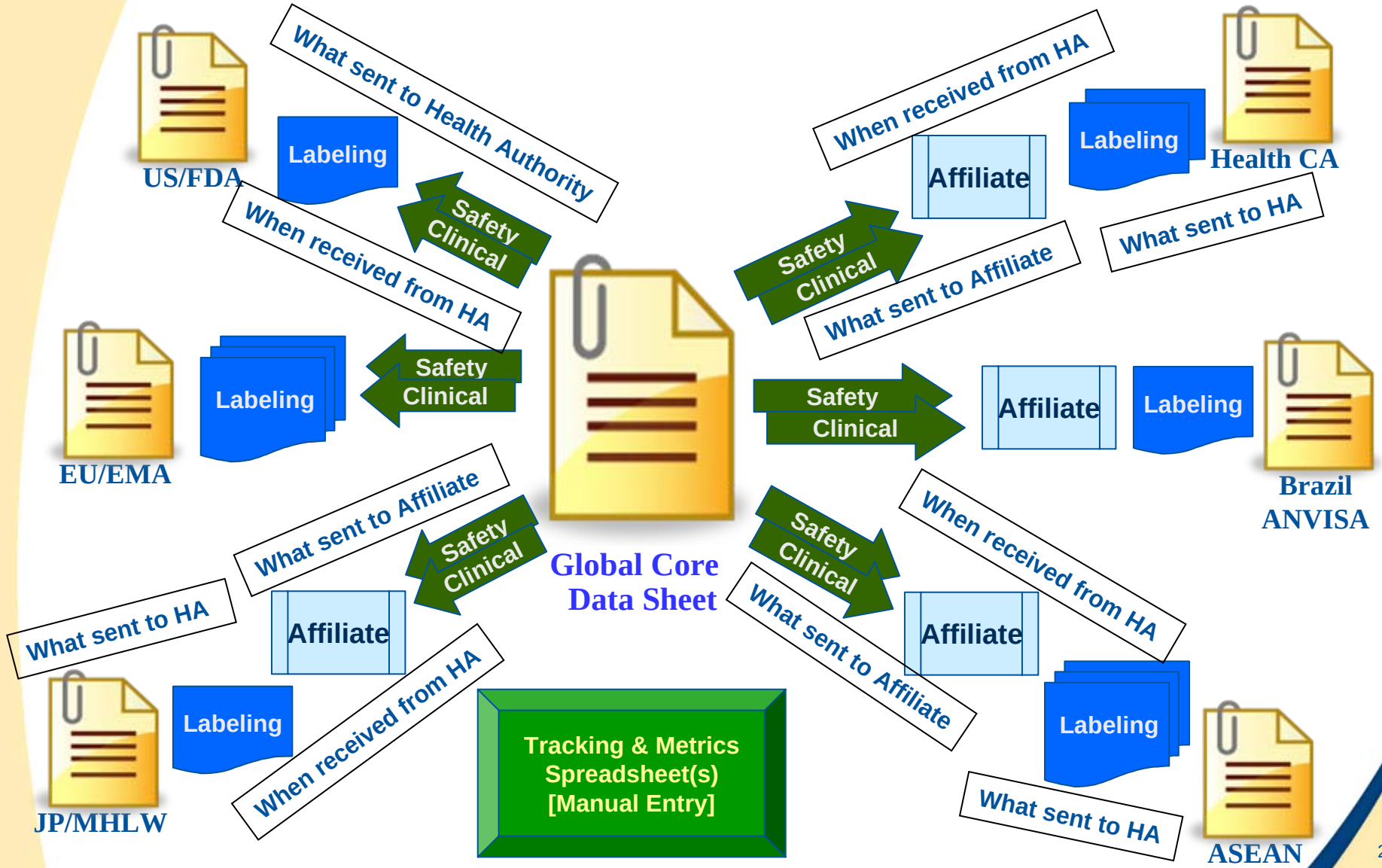
How is Tracking Captured?

- Manual Entry into Spreadsheets
- Manual Entry into Applications (DataBase)

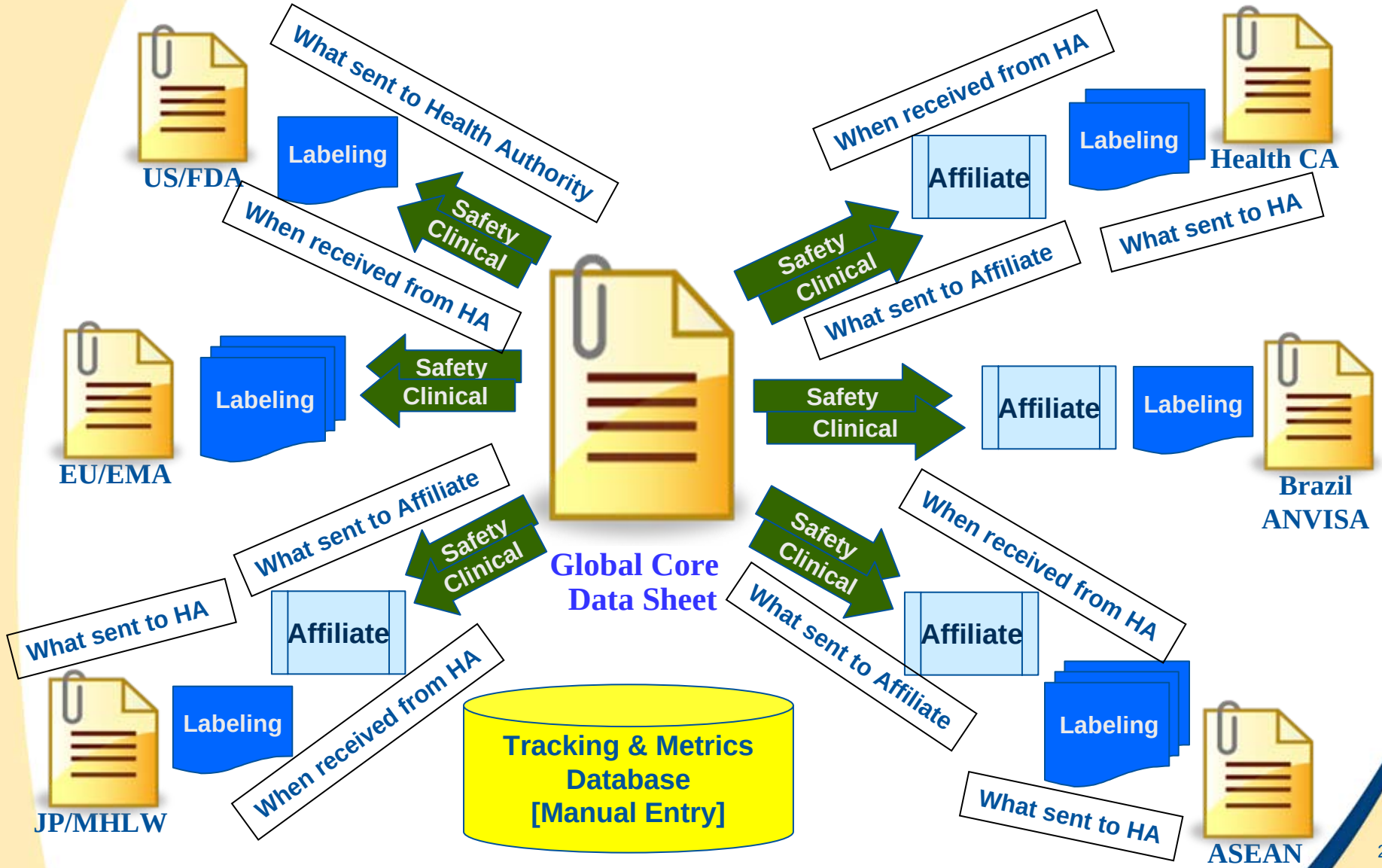
Tracking:
Protocol to Study Report Lifecycle



Tracking & Metrics: Labeling - (Manual Entry)



Tracking & Metrics: Labeling - (Manual Entry)



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Tracking Changes: Automated Processes

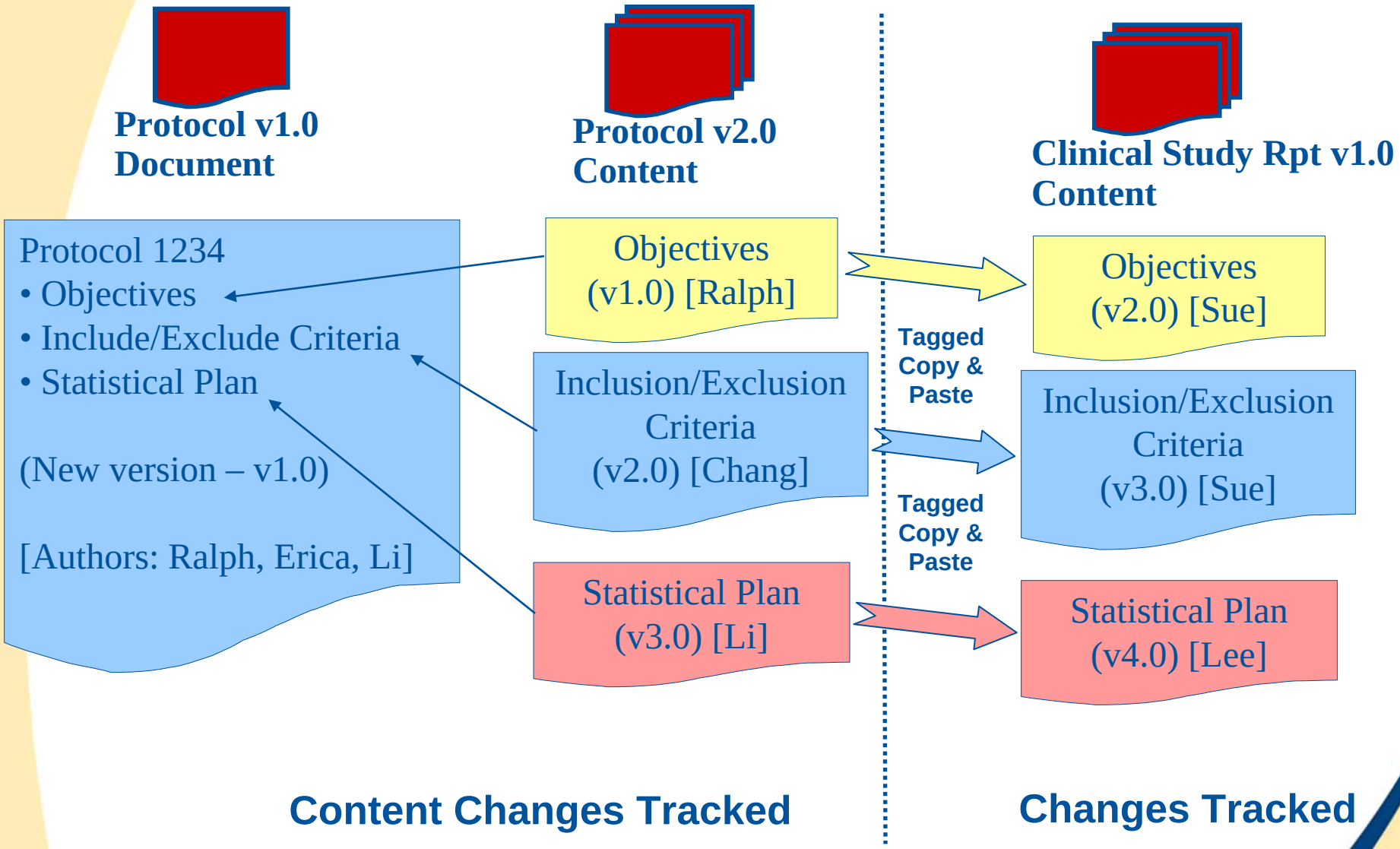
How is Change Tracked?

- Tagged content changes automatically tracked through authoring workflow (internal & external)
- Tagged content, comments & edits, automatically tracked through review workflow (internal & external)

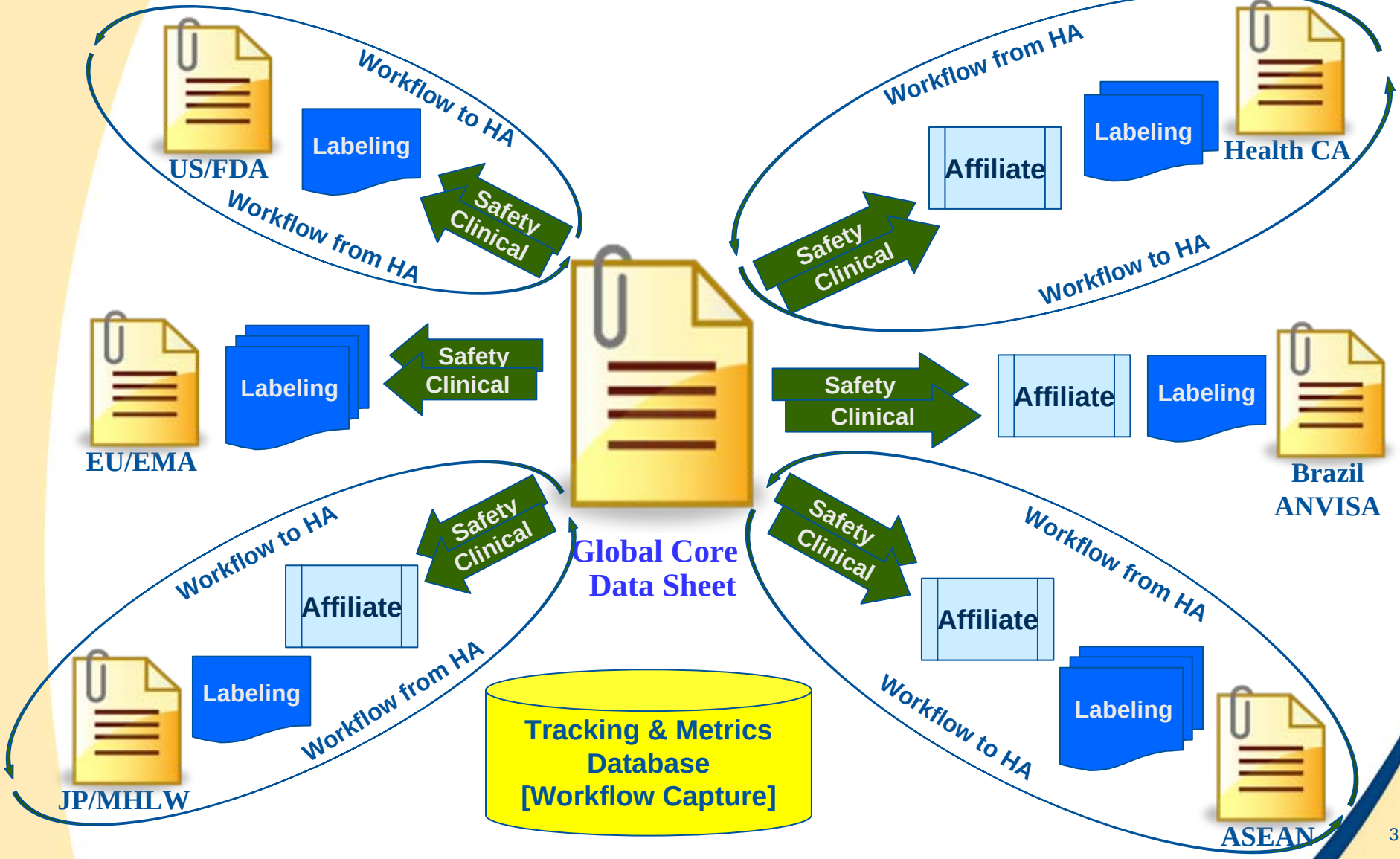
How is Content Re-Use Tracked?

- Re-Use automatically tracked through tagged content and versions
- Changed, Re-Used content automatically tracked via tagging and versions – still needs manual review for changes

Tracking:
Protocol to Study Report Lifecycle



Tracking & Metrics: Labeling - (Automated Entry)



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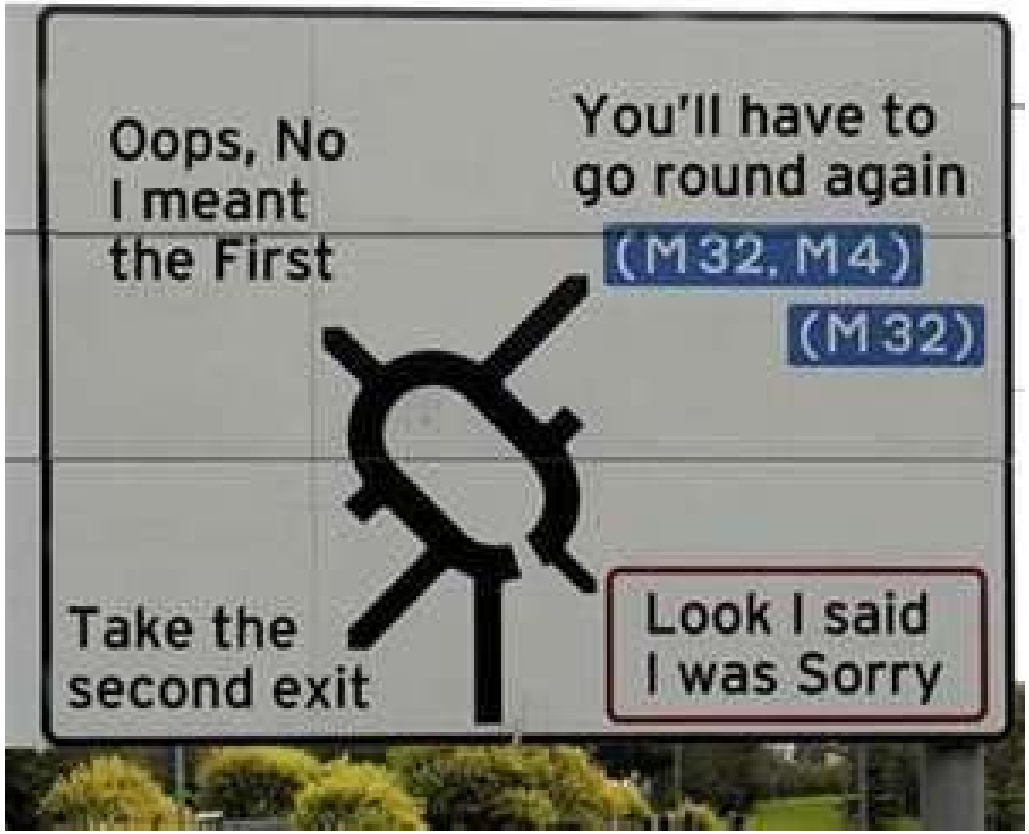
Tracking and Metrics

- **Tracking for Management**
  - Simple Tracking – Content Structured Templates
- **Metrics For Improvement**
  - Manual collection of metrics is time consuming and error-prone
  - Ongoing Metrics gathering requires Automation
- **Workflow Automation**
  - Ongoing Metrics gathering requires Automation
- **Quality Traceability**
  - Traceability required to include Quality Component

Continuous Improvement



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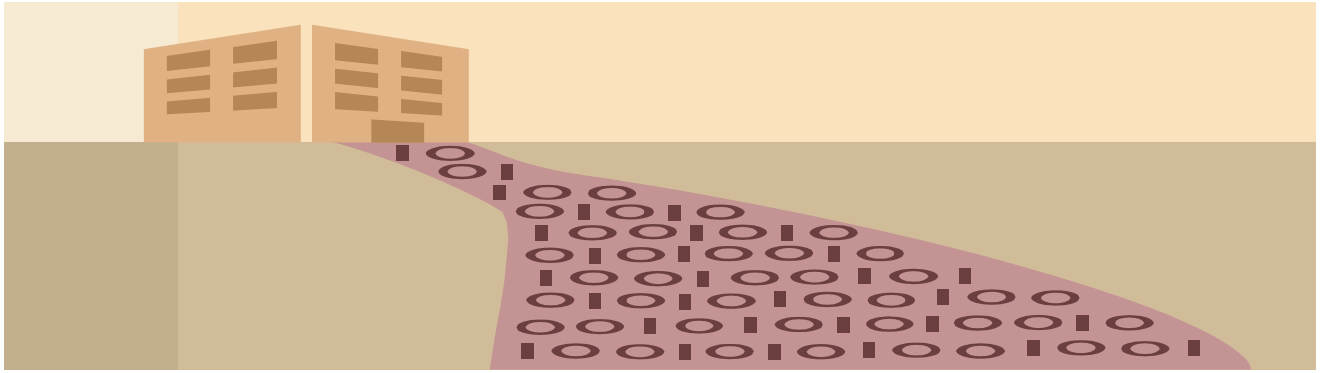
Summary: Moving to Content Management



- Information needs to be managed at the Content level
- Re-Use is helpful – requires Content level management
- Tracking Content & Re-Use is better
- Tracking Content needs to be Automated – Workflows
- Auto-Tracking Content provides Metrics for Continuous Improvement

Continuous Improvement

“There are three kinds of mathematicians; those who can count and those who can't.”
Anonymous