Moving Document to Content Management & Authoring:

Steps for Change

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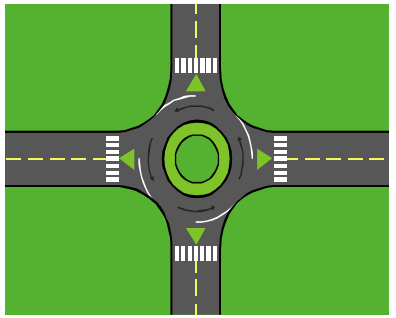
Continuous Improvement

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

Agenda

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



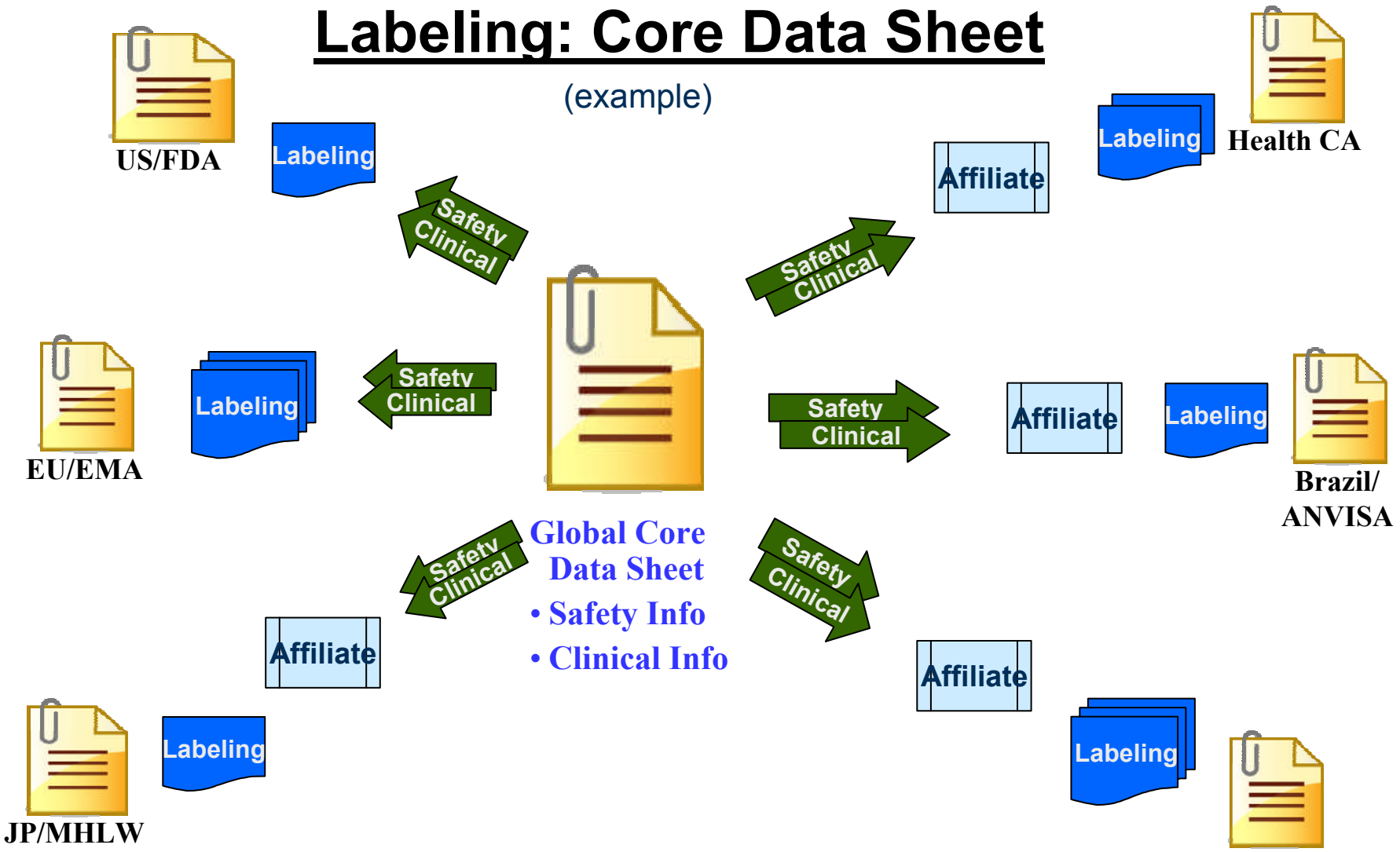
Why Move to Content Management?

- **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

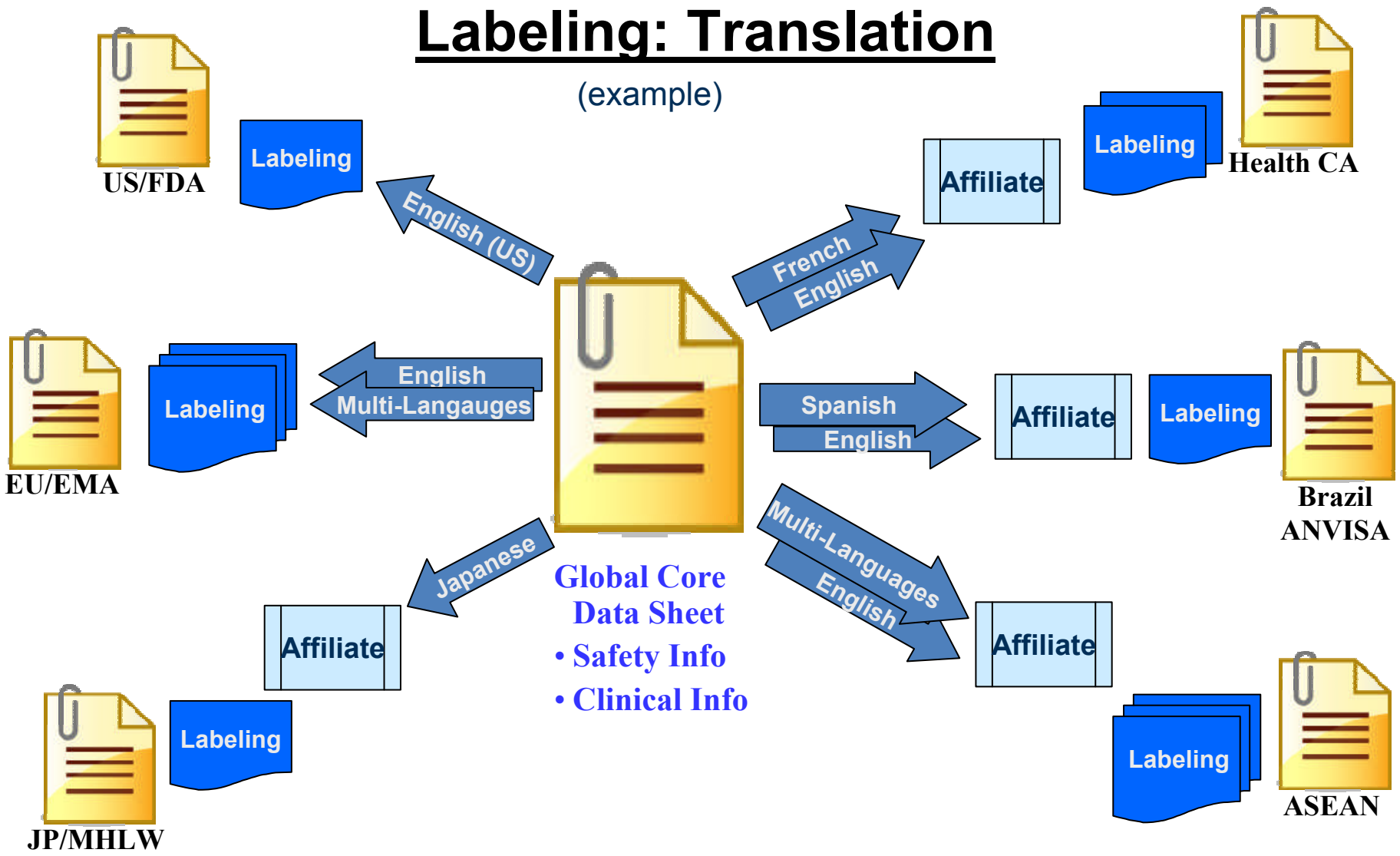
Consistency of Information

Labeling: Core Data Sheet

(example)



Consistency of Translation



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

Europe

- EU 3.2.P Drug Product
  - P.1 Description and Composition of the Drug Product
  - P.2 Pharmaceutical Development
  - P.3.1 Manufacturer(s) of Drug Product
  - P.3.2 Batch Formula for Drug Product
  - P.3.3 Description of Manufacturing Process and Process Controls
  - P.3.4 Controls of Critical Steps and Intermediates for Drug Product
  - P.3.5 Process Validation and-or Evaluation for Drug Product
  - P.4.1 Specifications for Excipients
  - P.4.5 Excipients of Human or Animal Origin
  - P.5.1 Specification(s) for Drug Product
  - P.5.2 Analytical Procedure for Description
  - P.5.2 Analytical Procedure for Assay
  - P.5.2 Analytical Procedure for Dissolution
  - P.5.3 Validation of Analytical Procedures for Assay
  - P.5.3 Validation of Analytical Procedures for Dissolution
  - P.5.4 Batch Analyses for Drug Product
  - P.5.6 Justification of Specifications for Drug Product
  - P.7 Container Closure System for Drug Product
  - P.7 Specification for Blister
  - P.8.1 Stability Summary for Drug Product
  - P.8.1 Stability Conclusion for Drug Product
  - P.8.2 Post-approval Stability Protocol and Stability Commitment
  - P.8.3 Stability Data for Drug Product

Upload to eCTD

Canada

- Canada 3.2.P Drug Product
  - P.1 Description and Composition of the Drug Product
  - P.2 Pharmaceutical Development
  - CA P.3.1 Manufacturer(s) of Drug Product
  - P.3.2 Batch Formula for Drug Product
  - P.3.3 Description of Manufacturing Process and Process
  - P.3.4 Controls of Critical Steps and Intermediates for Drug
  - P.3.5 Process Validation and-or Evaluation for Drug Produ
  - P.4.1 Specifications for Excipients
  - P.4.5 Excipients of Human or Animal Origin
  - P.5.1 Specification(s) for Drug Product
  - P.5.2 Analytical Procedure for Description
  - P.5.2 Analytical Procedure for Assay
  - P.5.2 Analytical Procedure for Dissolution
  - P.5.3 Validation of Analytical Procedures for Assay
  - P.5.3 Validation of Analytical Procedures for Dissolution
  - P.5.4 Batch Analyses for Drug Product
  - P.5.6 Justification of Specifications for Drug Product
  - CA P.7 Container Closure System for Drug Product
  - P.7 Specification for Blister
  - P.8.1 Stability Summary for Drug Product
  - CA P.8.1 Stability Conclusion for Drug Product
  - P.8.2 Post-approval Stability Protocol and Stability Commit
  - P.8.3 Stability Data for Drug Product

Upload to eCTD

USA

- US 3.2.P Drug Product
  - US P.1 Description and Composition of the Drug Product
  - P.2 Pharmaceutical Development
  - US P.3.1 Manufacturer(s) of Drug Product
  - P.3.2 Batch Formula for Drug Product
  - P.3.3 Description of Manufacturing Process and Process Controls
  - P.3.4 Controls of Critical Steps and Intermediates for Drug Product
  - US P.3.5 Process Validation and-or Evaluation for Drug Product
  - P.4.1 Specifications for Excipients
  - P.4.5 Excipients of Human or Animal Origin
  - US P.5.1 Specification(s) for Drug Product
  - P.5.2 Analytical Procedure for Description
  - P.5.2 Analytical Procedure for Assay
  - P.5.2 Analytical Procedure for Dissolution
  - P.5.3 Validation of Analytical Procedures for Assay
  - P.5.3 Validation of Analytical Procedures for Dissolution
  - US P.5.4 Batch Analyses for Drug Product
  - US P.5.6 Justification of Specifications for Drug Product
  - US P.7 Container Closure System for Drug Product
  - US P.7 Specification for Bottle
  - US P.7 Manufacturer for Bottle
  - US P.8.1 Stability Summary for Drug Product
  - US P.8.1 Stability Conclusion for Drug Product
  - US P.8.2 Post-approval Stability Protocol and Stability Commitment
  - US P.8.3 Stability Data for Drug Product

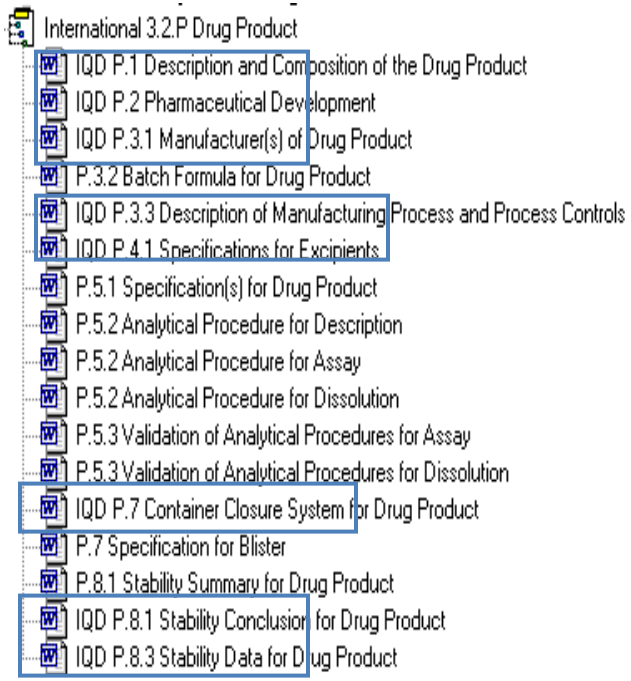
Upload to eCTD

Thank you to Phyllis Thomas for this slide.

Global Dossier (example Module 3)

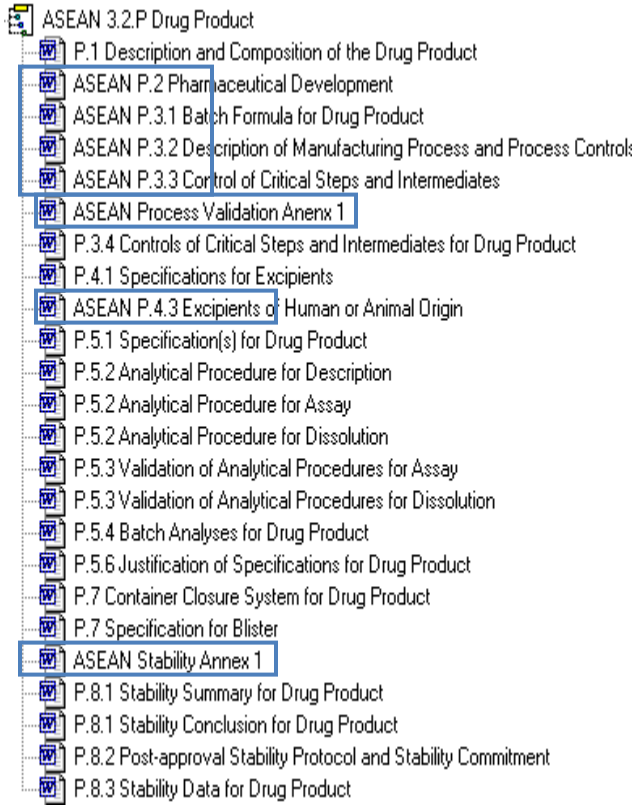
Marketing application in subsequent countries

International



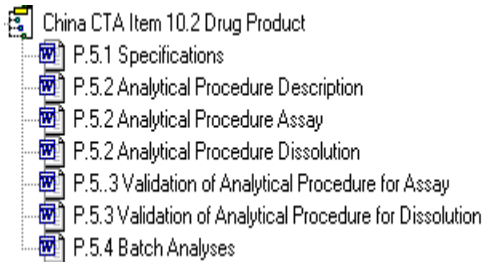
References only to Ph Eur

ASEAN



Different numbering
Additional documents

China



Different organisation (as 'Items')

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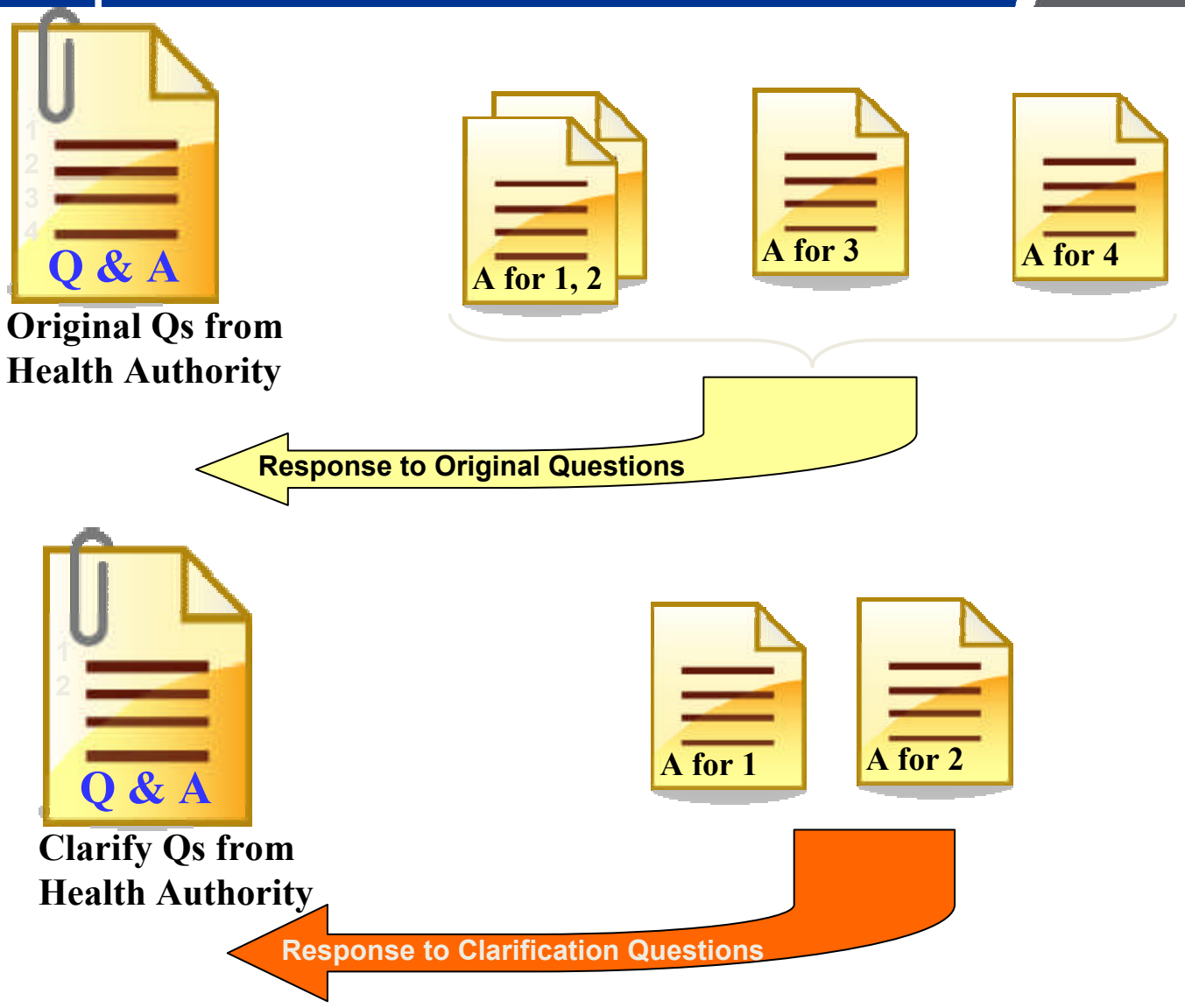
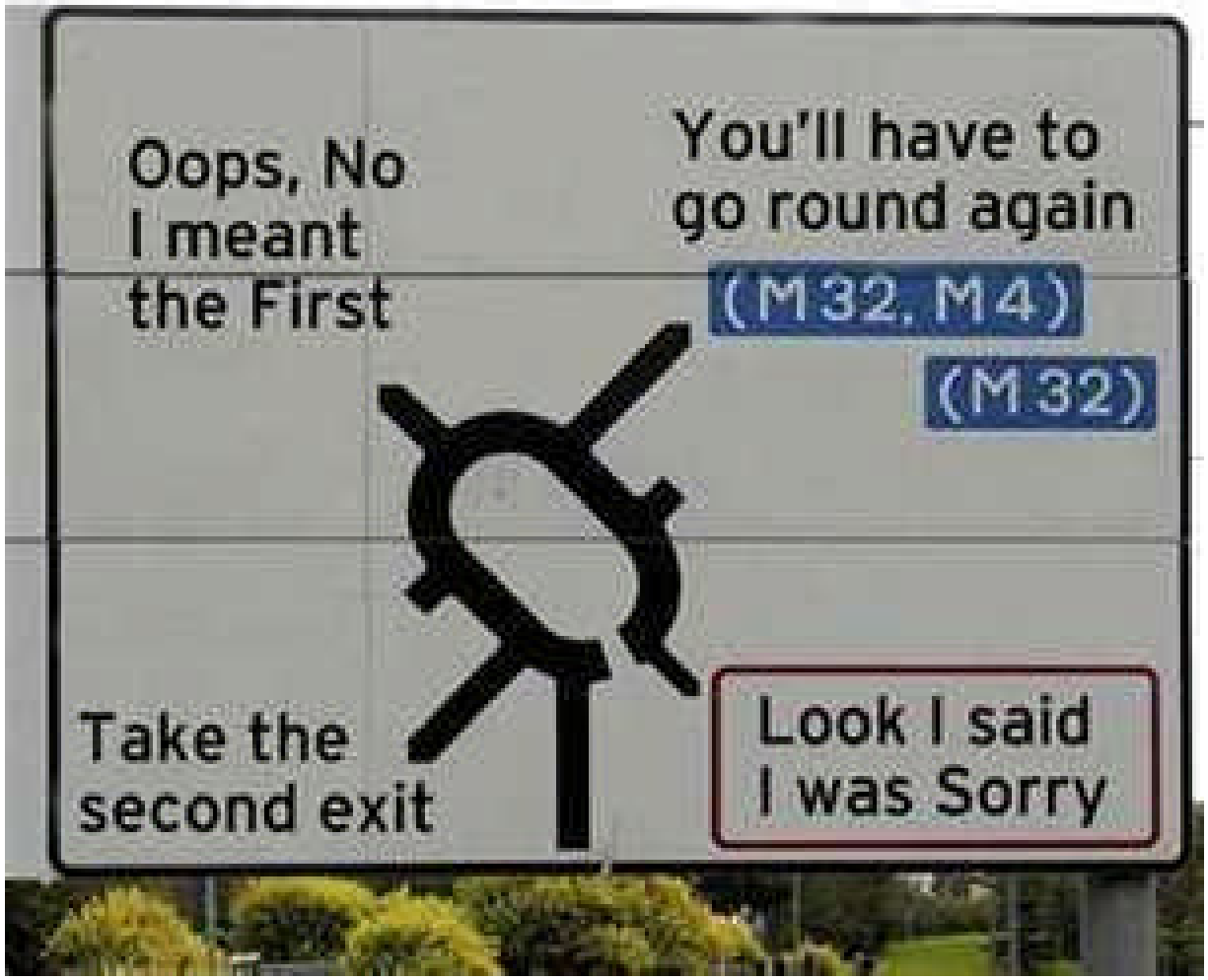
Health Authority Q & A, Correspondence



Continuous Improvement



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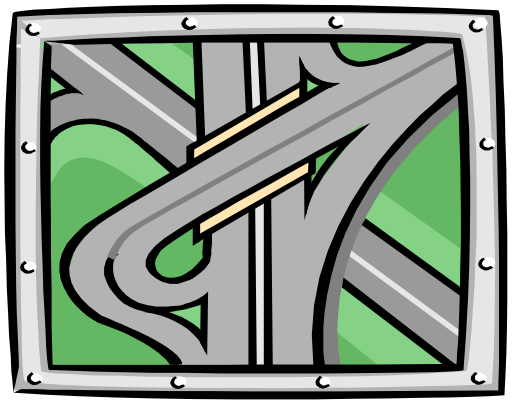
- **Summary**

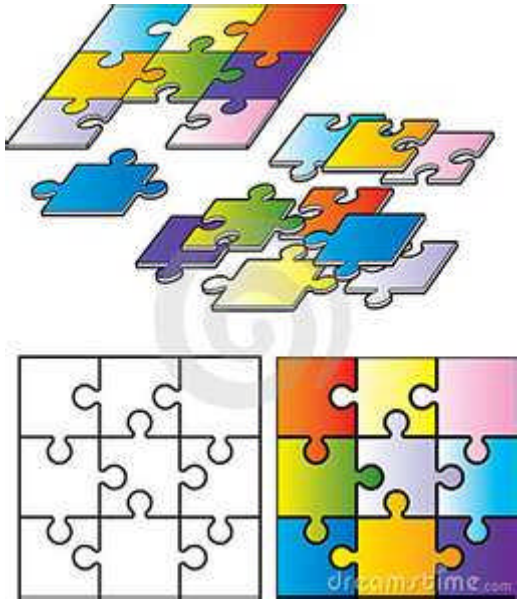


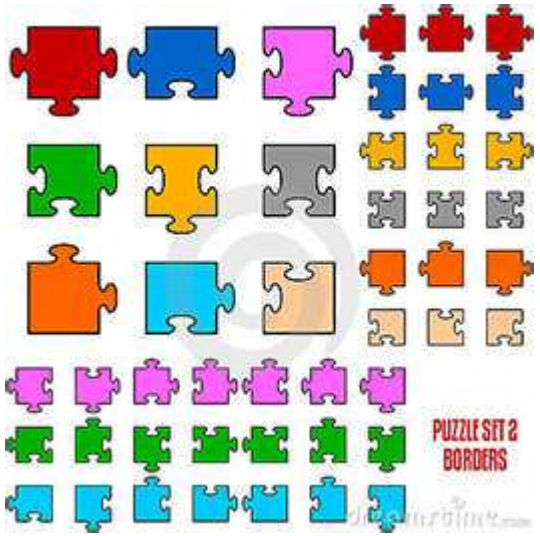
Re-Use & Content Management

- **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

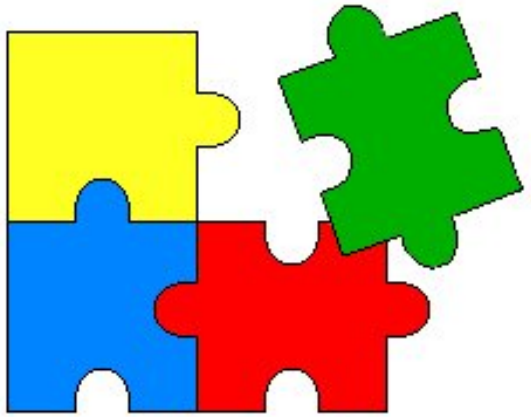
Re-Use:
Tech Manuals vs Submission Docs





- **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

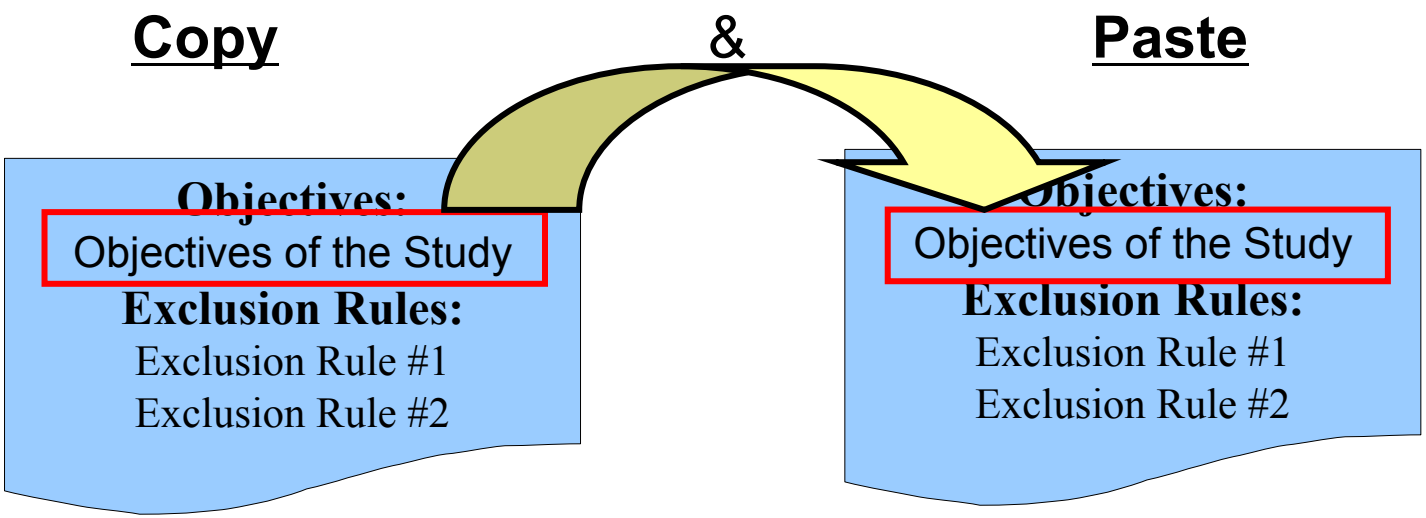


- **Submission documents have low re-use**
  - Few updates to same parts (Mod 3 main exception)
  - Content re-use mostly re-use of same sections to different documents, not strictly hierarchic

Global Dossier
What could using Structured Authoring mean?

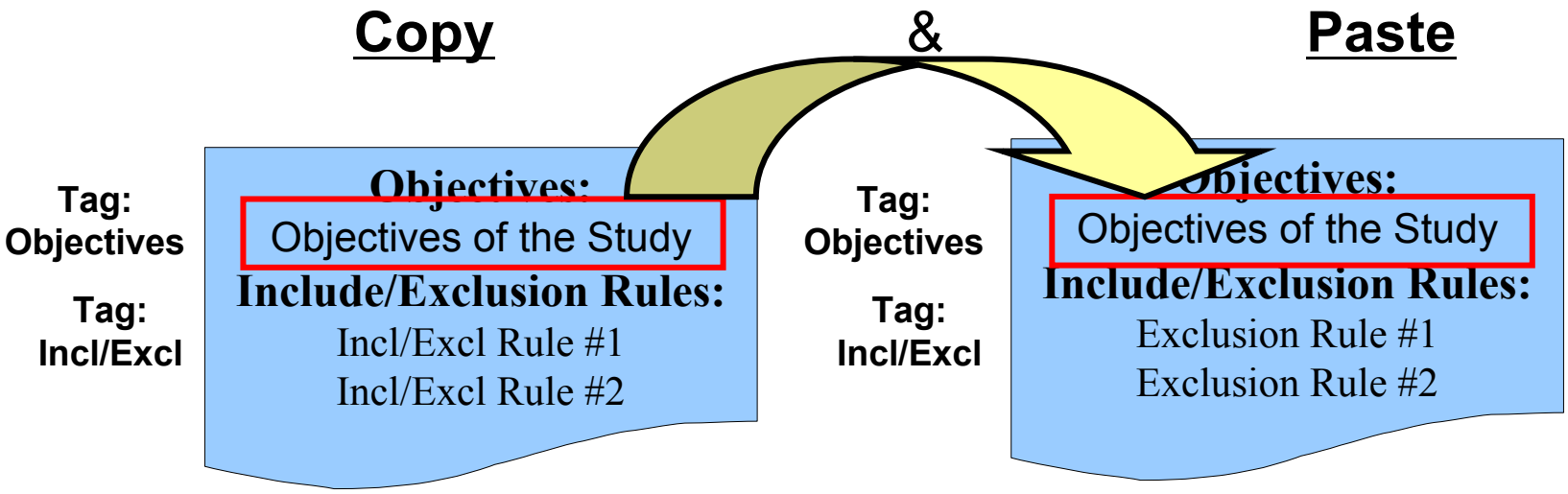
- **Re-usability (quality and consistency):**
  - Not caught out by changes that have implications on other documents' content
  - More efficient generation of Module 2.3 Quality Overall Summary
  - Establishment of databases for common information
  - Eliminate transcription errors
- **Potential M3 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)

Easy Copy & Paste:
No Traceability



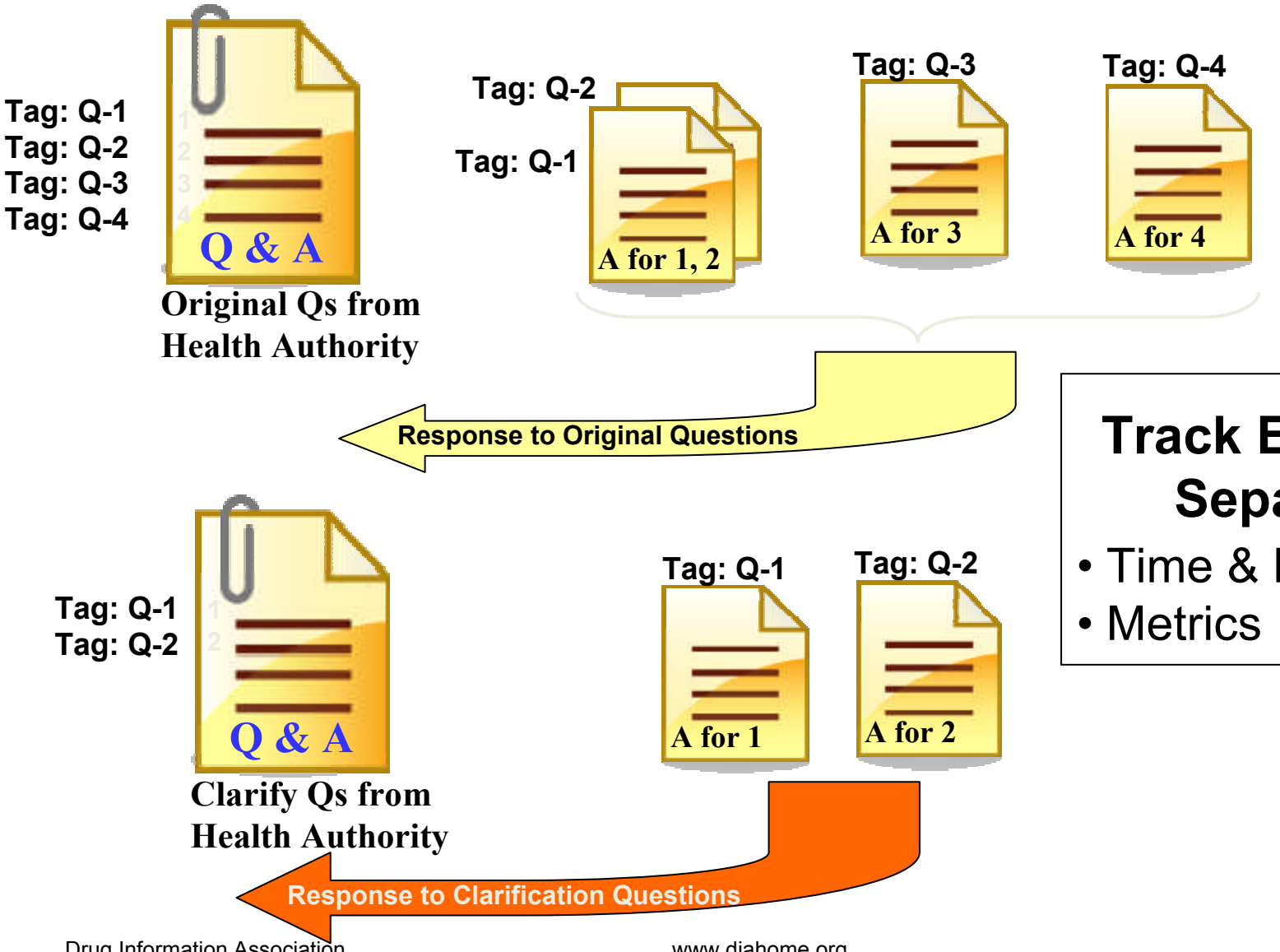
- **No Traceability of Content (except in Author's head)**
- **If changes made to 'Paste' side, no ability to later check if correct except via manual review**

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

Continuous Improvement

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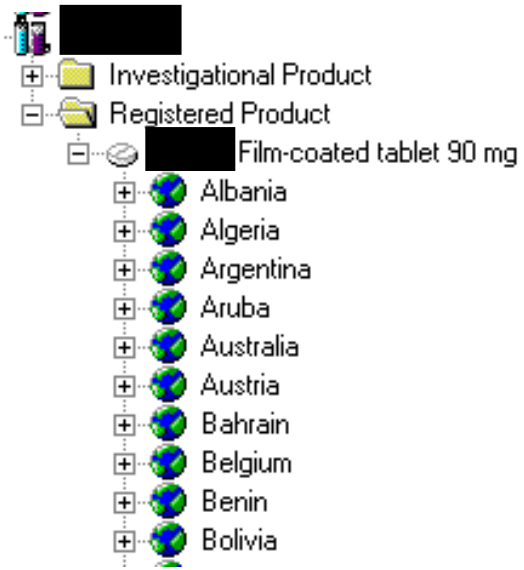
Tracking & Metrics

- **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

Thank you to Phyllis Thomas for this slide.

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

Thank you to Phyllis Thomas for this slide.

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?

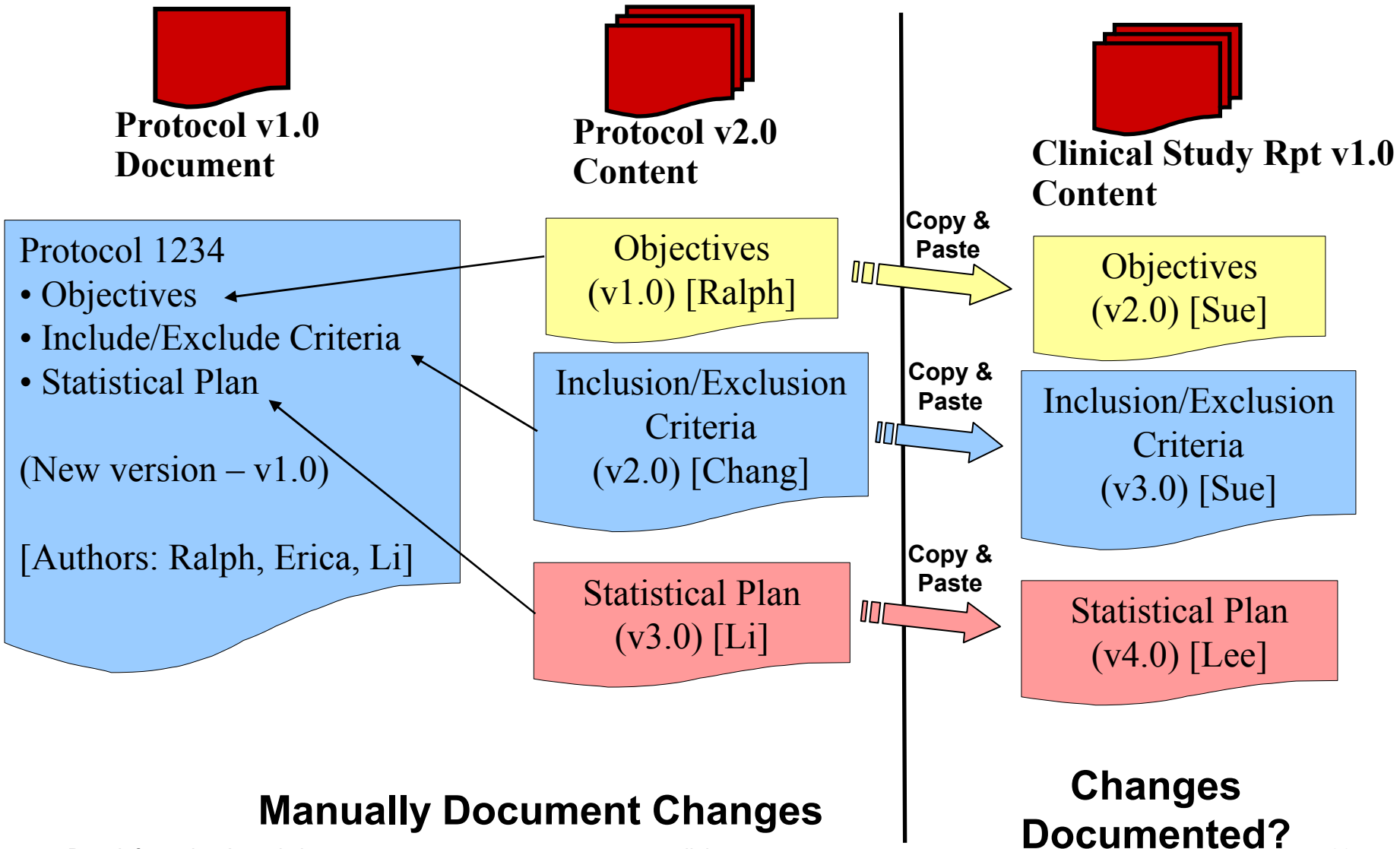
How is Content Re-Use Tracked?

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

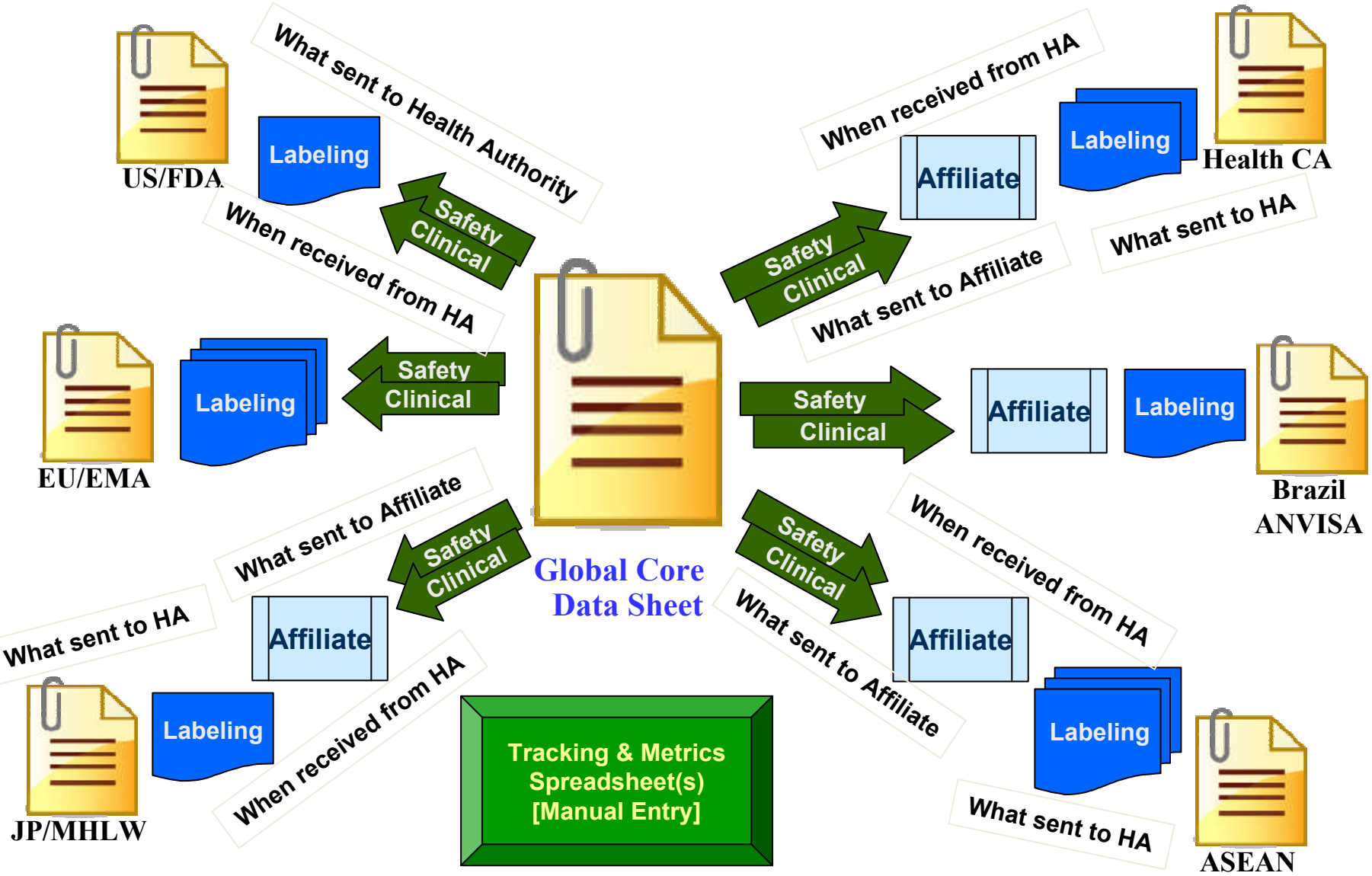
How is Tracking Captured?

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

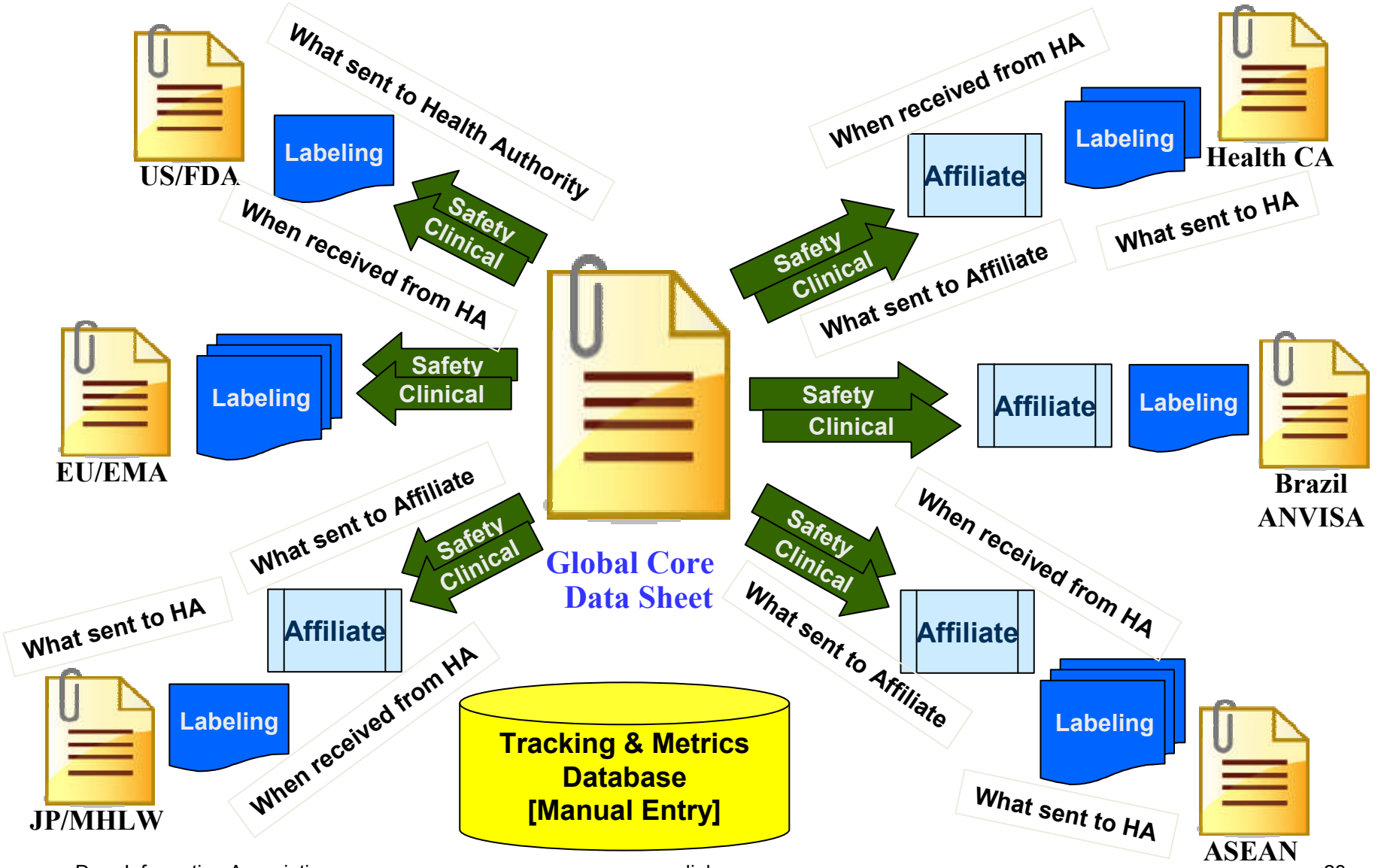
Tracking:
Protocol to Study Report Lifecycle



Tracking & Metrics:
Labeling - (Manual Entry)



Tracking & Metrics:
Labeling - (Manual Entry)



Tracking Changes: Automated Processes

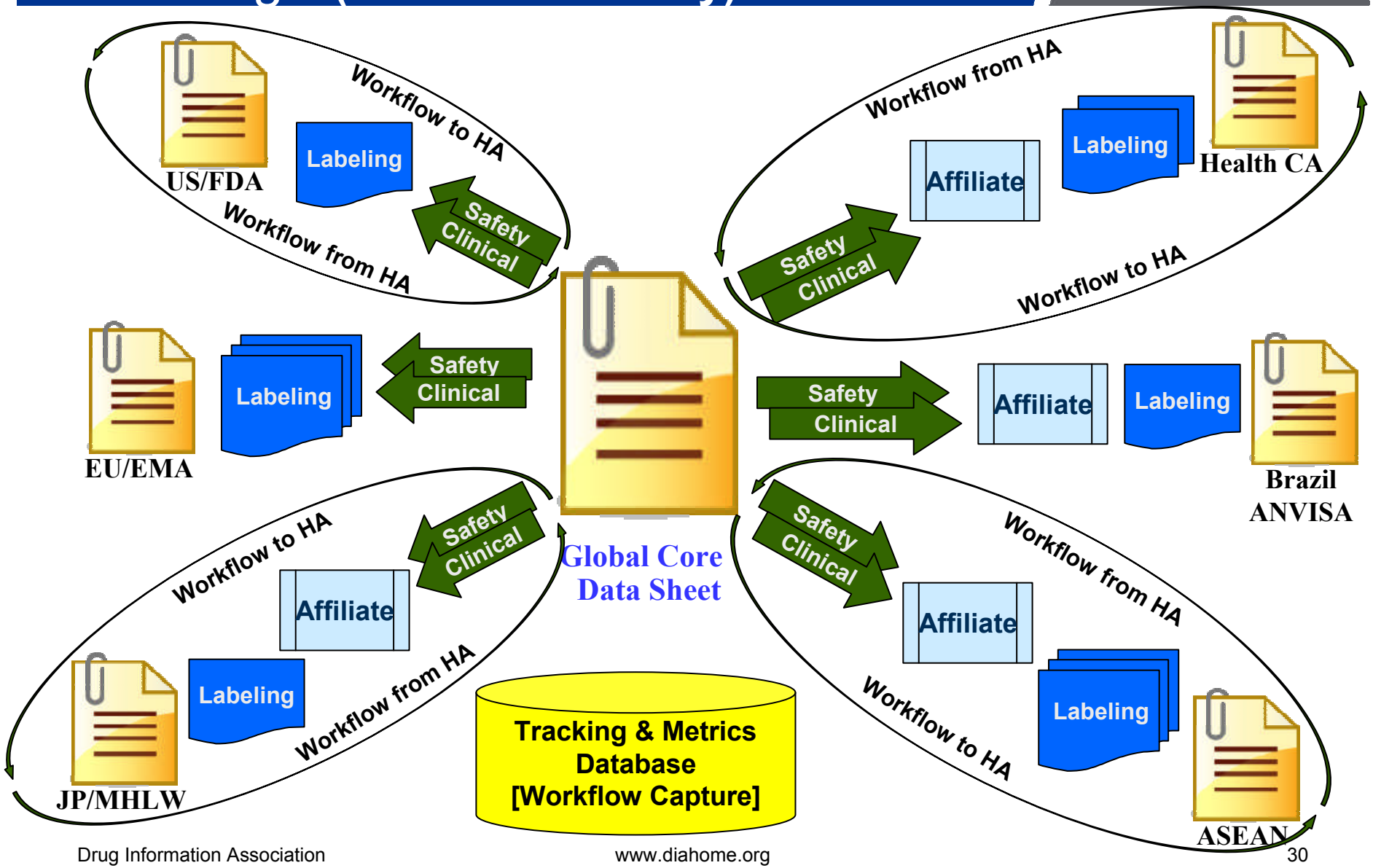
How is Change Tracked?

- 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 & Metrics:
Labeling - (Automated Entry)

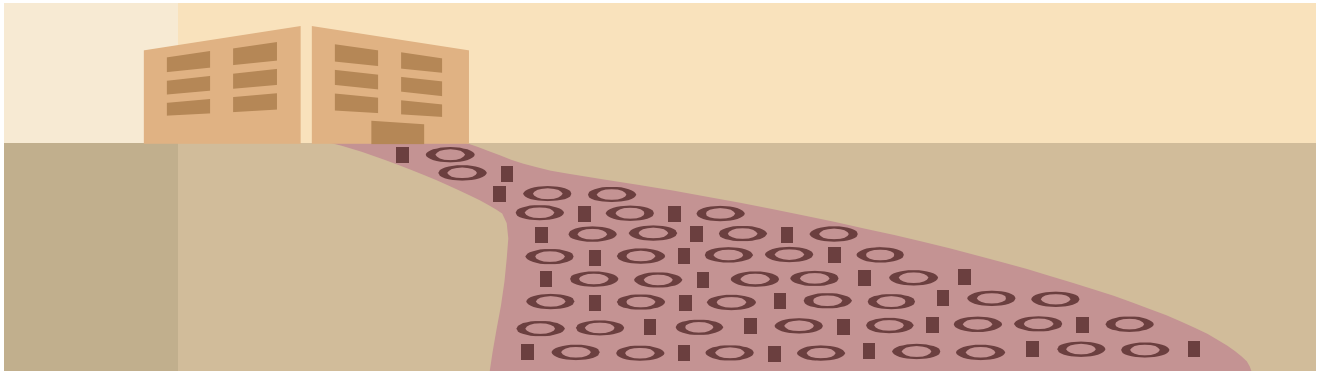


Tracking and Metrics

- **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

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