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Generating Clinical Narratives Using Structured Content Principles

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for

SANOFI

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Contents

- Background
- Key challenges to producing clinical narratives
- What is Structured Content Authoring/Management (SCA/SCM)?
- The Sanofi solution
- How does SCA/SCM help solve these challenges?
- The value statement
- What the future may hold

Background

- Sanofi embarked on Content Reuse program in 2011
- EnCORE platform for established in 2012
- Narrative service established in 2013
- Many new capabilities continue to be added as the service matures
- Narratives constitute a significant portion of clinical content produced

Challenges: Dependencies & Time Constraints

- Narratives cannot be finalized until after DBL ✓
- Limited time available between database lock (DBL) and clinical study report (CSR) finalization ✓
- Narratives written pre-DBL will likely require additional changes and review after DBL ✓
- Authoring time is proportional to the number of narratives to be written ✓

✓ Challenges addressed by SCM/SCA

Challenges: Data Sources & Complexity

- Data come from multiple sources
  - SAS data sets
  - CIOMS / MedWatch safety reports
- Manual copy/paste of data points or tables required ✓
- Data availability may be delayed
- Changes to source data trigger re-review and potential edits to written narratives ✓

✓ Challenges addressed by SCM/SCA

Challenges: Writing & Study Design Needs

- Some data needed as writing aid, but not to be included in the final narratives ✓
  - Need to keep them separate or remove before finalizing
- Some parts of narratives may be reused ✓
  - Events from prior analysis periods or crossover studies
- Narratives may need to be regenerated/revised to include additional events ✓
  - Interim CSRs or agency requests
- Concurrent authoring/review ✓

✓ Challenges addressed by SCM/SCA

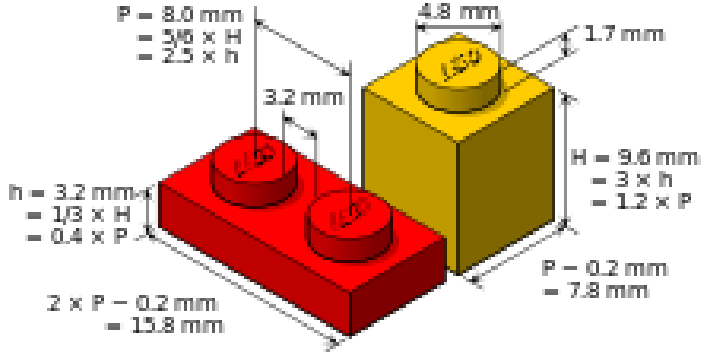
Challenges: Regulatory & Submission Needs

- Subject data may need to be anonymized ✓
- Narratives need to be grouped and ordered in a specific way, which could vary with underlying data changes
- Generating list of subjects requiring narratives
- End-to-end tracking from planning to submission

✓ Challenges CAN be addressed by SCM/SCA

What is Structured Content?

- Unstructured content that has been analyzed and decomposed into smaller “chunks” or components
  - Components can be: documents; sections; paragraphs; sentences; tables; graphics...



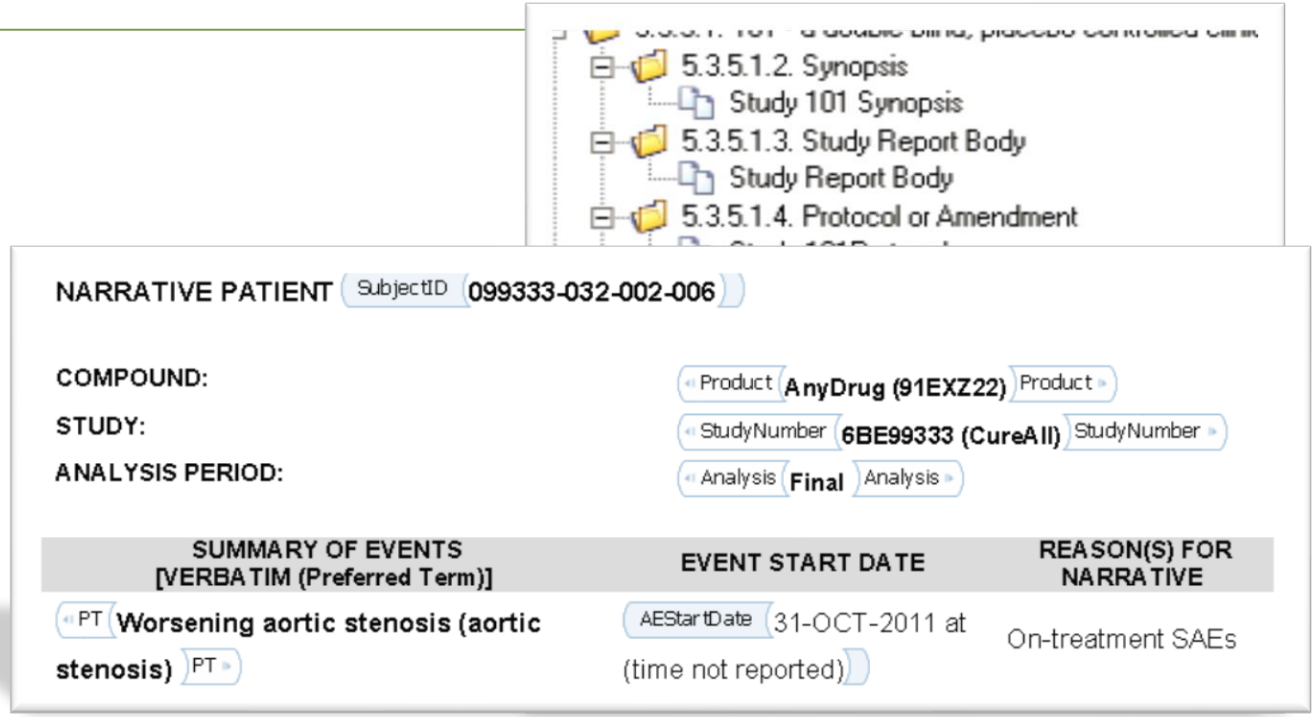
- Components are then classified according to their characteristics and behavior (metadata)

- Components can be created, managed, rearranged, and reused independently
- Document structures are constructed from components, often programmatically

What is Structured Content? (cont.)

When content is structured, you can:

- Define which components are used and in what order within a structure (eg, for a document, or a submission)



- Enable automated or on-demand content reuse from elsewhere and/or allow de novo authoring
- Identify which components are optional and under what circumstances
- Enable editable and/or locked components

Narrative Guidelines Viewed with a Structured Content Lens

Specifically, narratives should include the following:

Read-only Information

Structure

- patient identifier
- age and sex of patient; general clinical condition of patient, if appropriate
- disease being treated (if this is the same for all patients, this information is not required) with duration (of current episode) of illness
- relevant concomitant/previous illnesses with details of occurrence/duration
- relevant concomitant/previous medication with details of dosage
- test drug administered, including dose, if this varied among patients, and length of time administered

Conditional

- the nature, intensity, and outcome of the event
- the clinical course leading to the event
- an indication of timing relevant to study drug administration
- relevant laboratory measures
- action taken with the study drug (and timing) in relation to the event
- treatment or intervention
- post-mortem findings (if applicable)
- Investigator's and Sponsor's (if appropriate) opinion on causality

Components (1 per event)

What is SCA and SCM?

- Structured Content **Authoring** refers to the practice of and tools for writing content to predefined structure in order to promote consistency, reuse, and efficiency
  - Authoring tool can be ubiquitous MS Word or proprietary XML-based products.
- Structure Content **Management** refers to content management capabilities needed to provide an end-to-end feature set from content design, creation, management, and governance
  - Includes traditional content management capabilities such as versioning, audit trail, access control, etc.

SCA/SCM: Key Features

- Component content management
  - Create, manage, and govern components
- Component assembly and authoring
  - Create document structures from components
  - Component-level authoring, review, and approval
- Content reuse
  - Exact, derivative, substitution
- Publishing:
  - Conditional inclusion/exclusion
  - Publish to Word, PDF, etc.
  - Apply business rules (eg, bookmarks)
  - Separation of content and presentation

Sanofi Solution

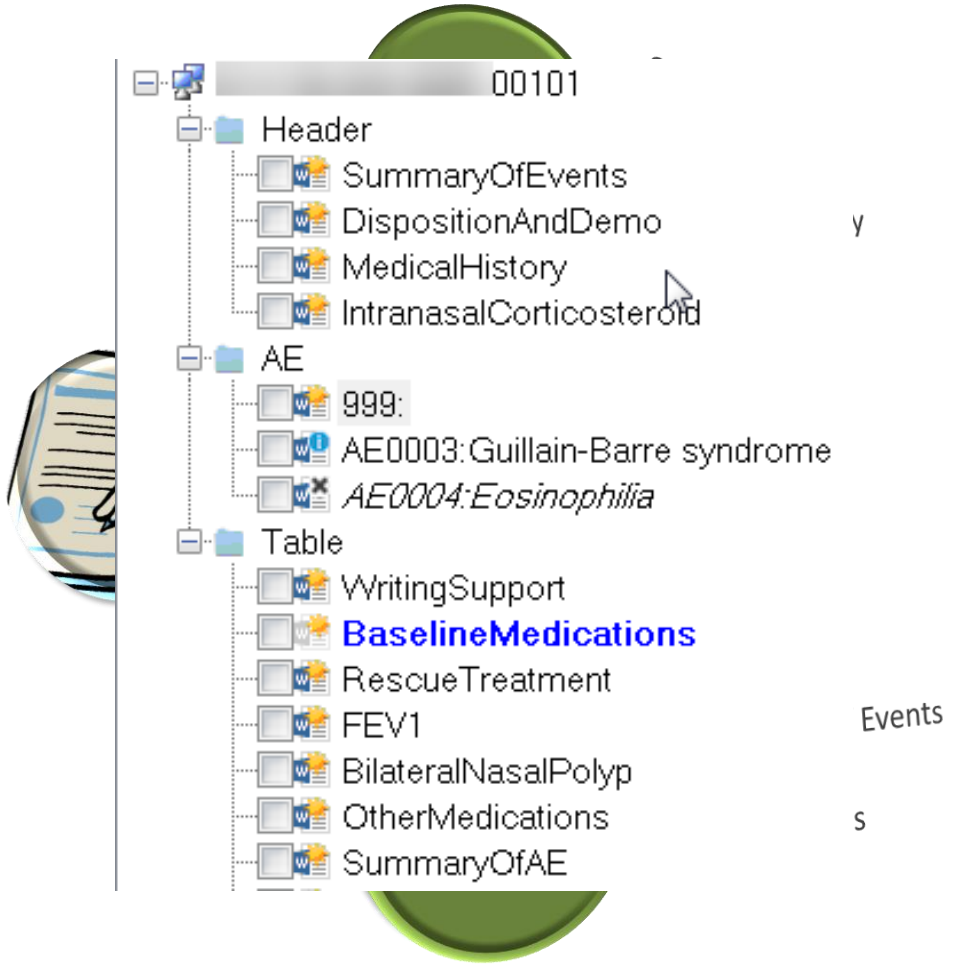
Implemented enterprise-wide SCA/SCM system:

- SharePoint as the Content Management platform
- DITA and DITA Exchange for structured content
  - XML standard for structured content
- SAS and SharePoint automation for creating and managing narrative components
  - Create, import, and assemble components according to business rules
  - Publish in Word format and merge into a single document
  - Provide pre- and post-DBL authoring support

Sanofi Solution (cont.)

High-level business process

- Create and import components into the system
- Assemble components into document structures (“maps”)
- Author and review at the component level
  - Include/exclude components
  - Lock some content for editing
- Reload components, as needed
- Publish as a single Word document for finalization



Challenges Addressed by SCA/SCM

Time Constraints & Data Complexity Challenges

- Allows for staggered import of components as data become available for QC and/or authoring needs
- Allows for reloading of corrected data/content due to QC findings with reduced impact
- Allows for reloading of revised data/content post-DBL
  - Authoring could start pre-DBL
  - Read-only sections are simply overwritten
  - Authored content is reviewed and updated as needed
- Expedited review: read-only content no longer needs to be reviewed

Challenges Addressed by SCA/SCM (cont.)

Writing & Study Design Challenges

- Include tables and other data for authoring aid ONLY
  - Remove from final publication via conditional publishing
- Reuse adverse event/ -of special interest (AESI) content
  - Include components from prior studies (eg, for crossover) or analysis periods
- Add new events with minimal rework
  - Lego brick approach: additional events can be imported as components due to agency requests or revised narrative criteria

Challenges Addressed by SCA/SCM (cont.)

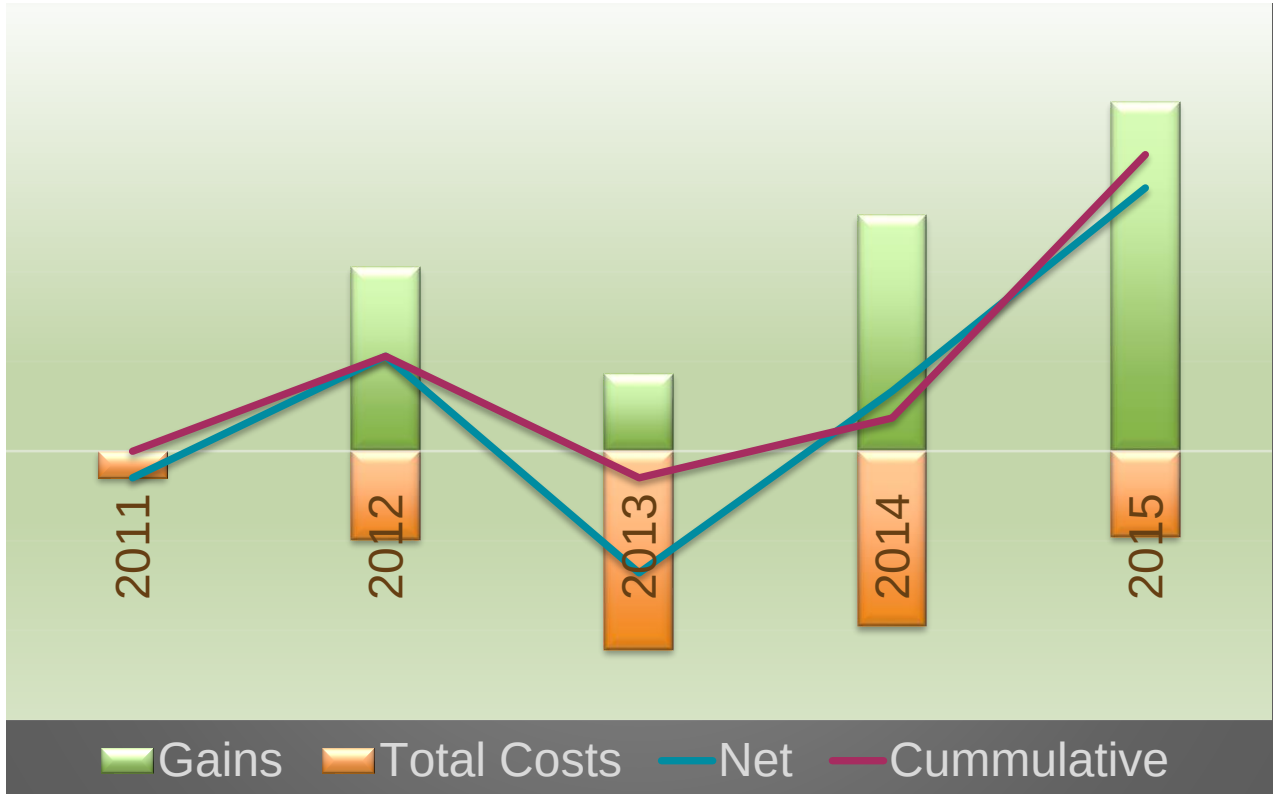
Regulatory & Submissions Challenges

- Apply predefined formatting per business rules
  - Auto-populate header with metadata such as study, product, subject identifier, etc.
  - Auto-apply styles for aiding in narrative compilation for submission
- Content tagging and conditional publishing *(future)*
  - Automatic and user-defined tagging of content
  - Redact/anonymize tagged content upon publishing

The Value Statement: Quantitative

- Estimated time per narrative decreased from 6-8 hours to 2-3 hours; **66% reduction**
- Savings exceed total cost (incl. operations)

Year	# Narratives	% Change
2012	2,000	-
2013	854	**- 58%**
2014	1,788	**109%**
2015	5,108	**186%**
2016	3,841	**-25%**
2017	7,258	**89%**
2018*	12,374	**70%**



- Year-over-year double digit growth
- Producing thousands of narratives; increasingly with more complex and/or study specific needs

* Year to date

The Value Statement: Qualitative

- Established standard narrative processes, templates, and libraries
- Improved quality
  - Eliminated ‘cut and paste’ & formatting errors
  - Consistent structure
  - Read-only content
- Quick turnaround to change requests
- Support multiple submissions a year

The Future/Other Possibilities

- Single document authoring experience in MS Word while retaining the power and benefits of SCA/SCM
- Automated workflows for QC, review and approval
- Shopping cart like approach to narrative template underway
  - Standardize narrative content to make available as libraries
  - Allow users to build their own templates
- End-to-end automation
  - Structured content-enabled narrative template for almost fully automated generation of narratives
  - Machine learning and Artificial Intelligence

Questions?

Thank You

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