DEVELOPING A CONTENT MODEL

INTRODUCTION

Your company, Writers Group, is looking to implement a new structured authoring tool. Initially, the directive is to develop a structured template for the protocol and clinical study report (CSR). Of note, Writers Group has already adopted the basic Word edition of the TransCelerate Common Protocol Template (CPT).

In addition, the trial transparency group has requested that certain data elements required for disclosure purposes get added to the new protocol. This is to enable export of the data elements for eventual upload to CT.gov or EudraCT.

You have been asked to create a content model for the protocol and CSR, including the new data elements for disclosure. This exercise will teach you how to perform the content analysis and design to create a starting content model.

EXERCISE

The following materials have been supplied:

1. Content Model Workbook
2. Common Protocol Template Version 4 (from TransCelerate BioPharma Inc., http://www.transceleratebiopharmainc.com/assets/common-protocol-template/)
3. Clinical Study Report Template (from The Global Health Network, https://www.scribd.com/document/154679434/Clinical-Study-Report-Template-GHT)

PART 1

1. Review the protocol template and mark where the following disclosure elements could be inserted:
    a. Acronym – PROT: title page; CSR: NA
    b. Study phase – PROT: 1.1, synopsis; CSR: title page
    c. EudraCT number – PROT: title page; CSR: NA
2. Review the CSR template and mark where the disclosure elements listed in #1 above could be inserted

    Note: Not all elements may be included in the CSR.

PART 2

In the Content Model workbook, follow these steps:

1. Insert the corresponding document type, section number, and section name (columns B and C) for the following types of content; make sure to populate 1 row for each appearance of the content (within the same document or different documents):
    a. Protocol title – PROT: title page, 1.1 synopsis; CSR: title page, 2 synopsis
    b. Protocol number – PROT: title page; CSR: title page
    c. Compound number – PROT: title page; CSR: title page, 2 synopsis
    d. Short title – PROT: title page, 1.1 synopsis; CSR: NA
    e. Acronym – PROT: title page; CSR: NA
    f. Study phase – PROT: title page; CSR: title page
    g. EudraCT number – PROT: title page; CSR: NA
    h. Objectives and endpoints – PROT: 1.1 synopsis, 3 objectives and endpoints; CSR: 2 synopsis, 8 study objectives
    i. Study rationale – PROT: 1.1 synopsis, 2.1 study rationale; CSR: 7.2 rationale for the study
    j. Inclusion criteria – PROT: 5.1 inclusion criteria; CSR: 9.3.1 inclusion criteria

    Note: If there is no specific section number associated with the content, you can enter a brief description instead (eg, "[Title page]").

    Note: If the content is not included in its own numbered section, include the unnumbered "section name" instead (eg, "Protocol Title")

2. Identify which types of content may be reused *within the same* document (column G)
    a. Indicate where else the content is used within the document (column H)
    b. Indicate the content reuse type as either exact or derivative (column I)

    Note: If content appears multiple times within the same document and therefore has multiple rows, the reuse information can be entered in a single row.

3. Identify which types of content may be reused *across documents* (column J)
    a. Indicate where else the content is used within the document (column K)
    b. Indicate the content reuse type as either exact or derivative (column L)

    Note: The reuse information can be entered in a single row (eg, for the protocol row only).

4. Identify any inconsistencies observed between the protocol and CSR (column F) with respect to section naming or organization (eg, the content is included in 1 section in the protocol, but 2 sections in the CSR)

5. Input the metadata "tag" (column I) – this is used by the tool to enable export/import of the content and association with library and/or instructional text

Note: The "tag" must be the same for content that is being reused within or across documents.

QUESTIONS FOR CONSIDERATION

1. What types of content are best reused as the section level? What about at the paragraph or even sentence level, or even smaller?

2. Think about content typically reused from the protocol to CSR – do you think modification is always necessary? Can you think of a way to minimize or eliminate these modifications?

3. Are there any section name or organizational changes that can be made to the protocol and/or CSR to better enable reuse and/or intuitive understanding of the type of content to be included? Provide examples.

4. What other types of documents include content that may be reused from or into the protocol or CSR? Provide examples.