M11 and USDM Alignment

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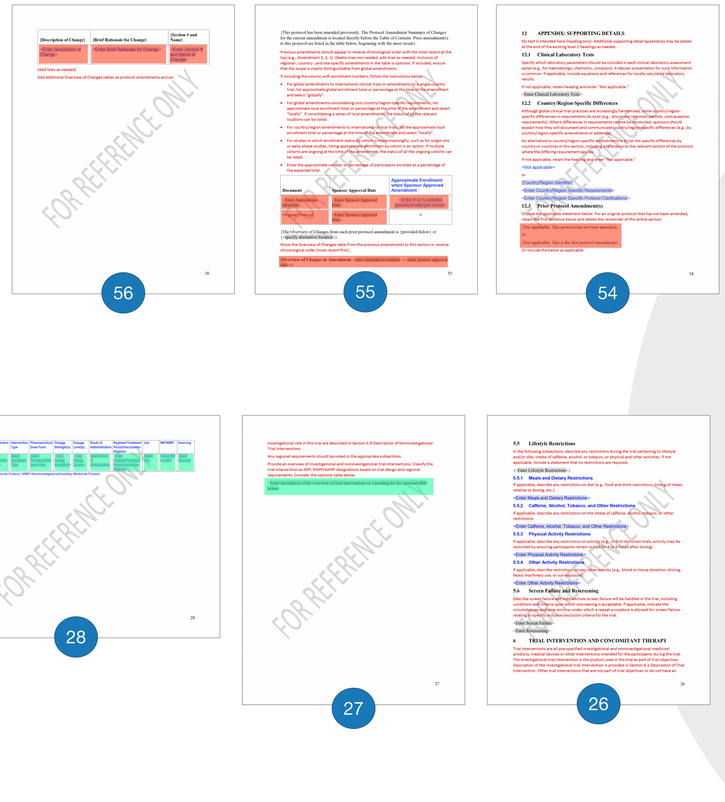
Version 2, 2025-06-09

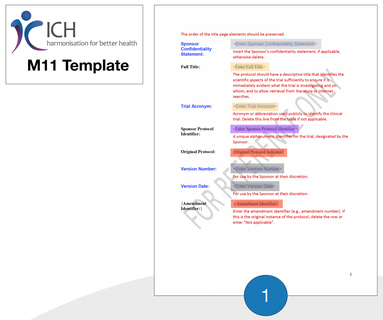
Based On

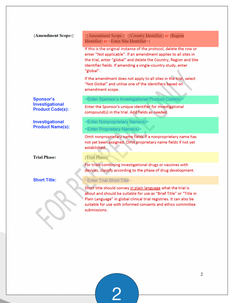
M11: Updated Step 2 Draft *(2025-03-13)*
USDM: Version 4.0.0 *(2025-06-03)*

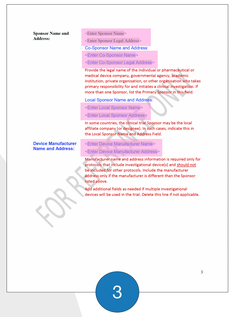
This infographic shows the relationship between the M11 protocol template specification and the structured and unstructured capabilities of the USDM. Each logical area of the M11 protocol template is highlighted along with the associated area within the USDM.

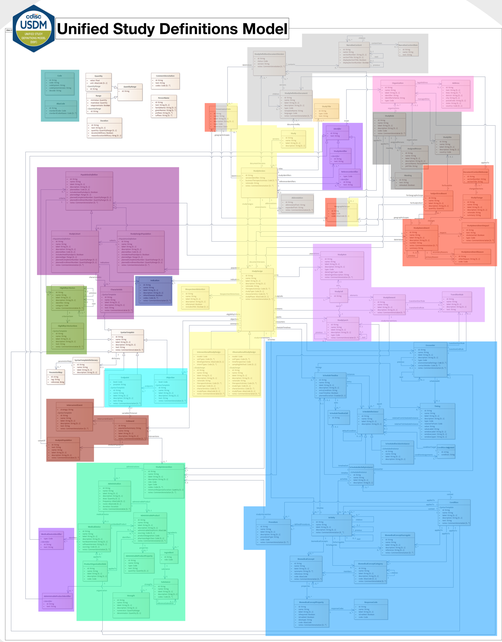
The "mapping" is not precise, it is indicative so as to provide an overview of relationship of am M11 protocol document and the USDM. It endeavours to show how the elements of a protocol document can be stored within the model and how the document can be generated from a populated model

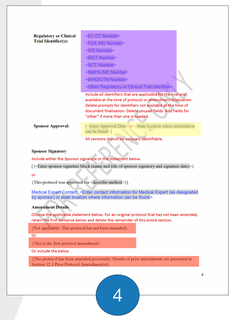


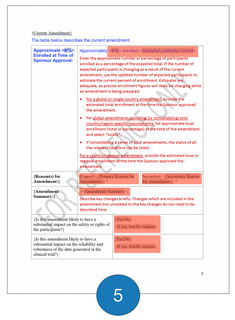


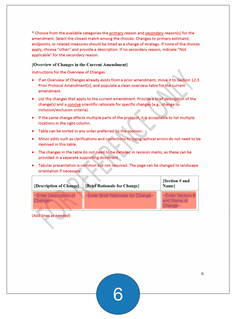


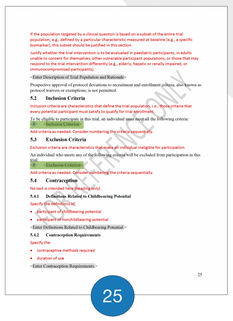


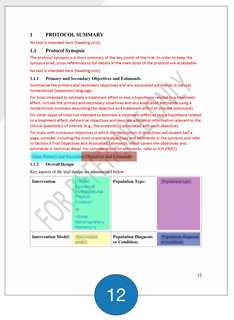


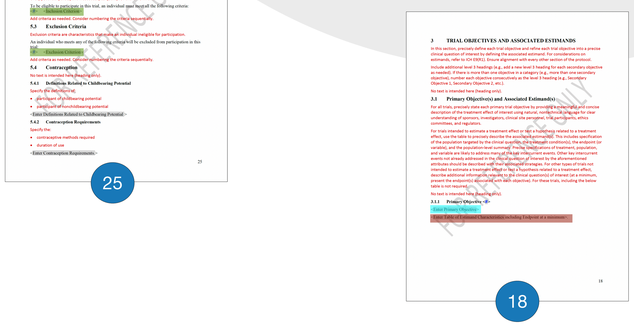


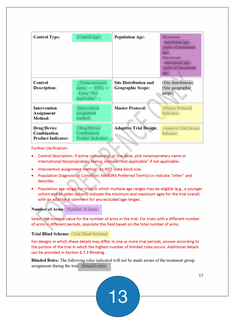


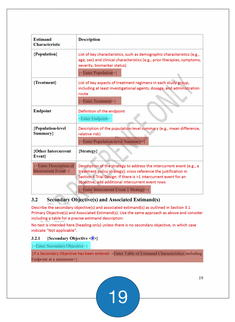


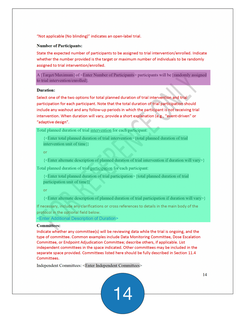


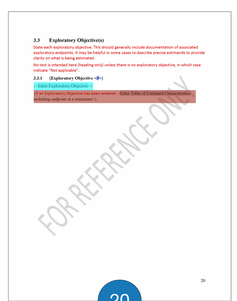


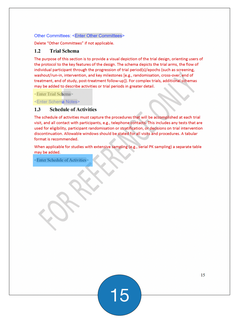


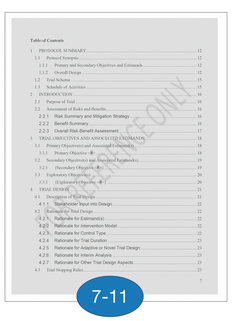


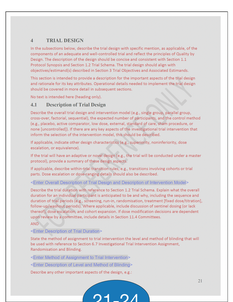












Key

Indicates the page number within the ICH M11 Template Specification

N

- Organizations
- Identifiers
- Amendments
- Titles
- Objectives & Endpoints
- Inclusion & Exclusion
- Population & Cohorts
- Estimands
- Interventions
- Study & Study Design
- High Level Study Design
- Detailed Study Design
- Indications
- Documents and Narrative Content
- Roles
- Controlled Terminology

There is no significance in the choice of colour for a logical area of the USDM

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