

ICH M11 elements: a target to map to

One global identifier per protocol element, linked to its place in the Template, its specification, its term and its USDM attributes

Data

Data in a string

Words

Kerstin Forsberg · the published ICH M11 Technical Specification, Template and Terminology, and the HL7 and CDISC mappings to USDM v4, represented as a knowledge graph

Two standards, one protocol

ICH M11 is the document, USDM is the data



M11 → USDM, as two published mappings state it

HL7 FHIR Clinical Study Protocol IG ballot, May 2026

stated against M11 Step 4 and USDM “v4.0.0 (update pending)”

CDISC DDF-RA v4.0.0, m11_mapping.xlsx

stated against the M11 Step 2 draft and USDM v4.0.0

Protocol content needs a place in both. The question is what exactly one maps to: a Template field, a specification block, a code, or a USDM attribute.

Each mapping is a spreadsheet: a row names an element by code or by name and a USDM class and attribute by name. Data in a string, until it is resolved.

Not yet a target to map to

Data Data in a string Words

One element, several names

The secondary objective:

- {<Secondary Objective>} Specification
- <Enter Secondary Objective> Template
- Secondary Objective Terminology

“Back-up Method for Reporting” in the Specification and Terminology is “Backup Method for Reporting” in the Template and in both mappings. Matched by name, that element gets neither its Template field nor a mapping.

Mapping rows with a code that identifies the element: HL7 134 of 324, CDISC 93 of 323. The rest go by name, or not at all.

A code names a concept, not an element



The element is the pair as the Specification states it: section code list and concept code.

9 codes are elements in two sections: 18 elements.

The place is written as text

“3.2.X where X is a unique number for each Secondary Objective”

Specification, place in the table of contents

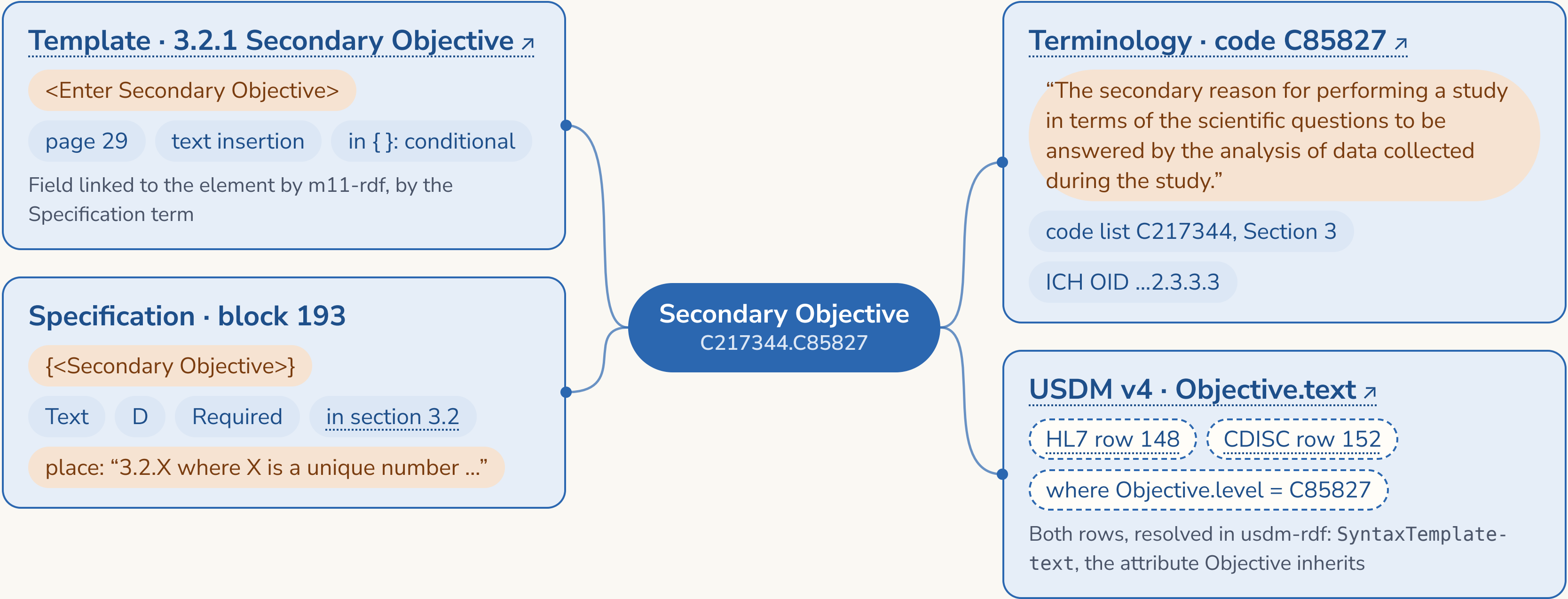
- 3.2.1 the Template, as printed
- 3.2.# the mapping rows

The sections themselves have codes: 160 terms in code list C217272.

Sources: ICH M11 Technical Specification and Template (Step 4, 2025-11-19), ICH M11 Terminology (NCI EVS, 2025-12-19), the HL7 and CDISC mappings; counts from the m11-rdf v0.3.0 build reports.

One element, one global identifier, all its links

Data Data in a string Words



All links on this slide are in m11-rdf v0.3.0. The Template does not state which element a field is; m11-rdf links the field by the Specification term, and each mapping row by its code or name.

Recorded, not repaired

Where the standards don't line up, on the same example

The secondary objective heading

Mapping row, the same in both files (HL7 147, CDISC 151):

Secondary Objective <#>

3.2.#

Objective.label

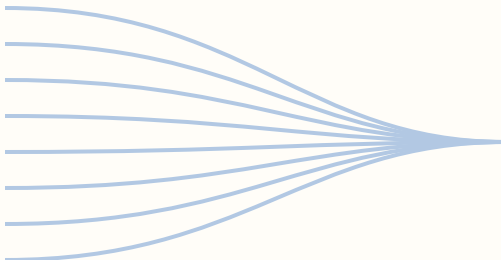
code C85826 · Primary Objective

where Objective.level = C85827

The row contradicts itself: its code is the primary objective, its condition the secondary.

The Specification has a heading here, not an element: {3.2.X Secondary Objective <#>}, H, "Concept: Heading". The exploratory objective heading has the same pattern (HL7 149, CDISC 153).

Narrative elements: one attribute, told apart by a section number



NarrativeContentItem.text

sectionNumber = <desired section>

277 mapping statements, for 140 elements, point at the same USDM attribute. Only the condition tells them apart, and a section number is a string in the study file.

m11-rdf gives each of the 160 sections a global identifier; 108 Template headings are themselves an element.

And for the field on slide 4: in { } in the Template, Required in the Specification. 4 fields linked to an element are like this.

m11-rdf keeps each statement as published, flags it, and lists the rest in its build reports (d2-residue.csv, d5-residue.csv). It does not repair them, and it does not judge which source is right.

What it gives

Map once, to an M11 element

Map your content to https://w3id.org/m11-rdf/C217344.C85827 and you get	
its place	the Template section, heading and field, with page
its specification	term, data type, conformance, cardinality, place in the table of contents
its term	the NCI EVS code and definition, the ICH OID of its code list
its USDM attributes	as the HL7 and the CDISC mapping state them, side by side, as usdm-rdf global identifiers

270

elements, from 284 specification blocks, in 16 section code lists

160

sections; Template headings on their sections

281

Template fields; 271 linked to an element

496

mapping statements; 202 elements mapped by both files, all to the same USDM targets

Not given

a mapping for 55 of the 270 elements; study instances; anything normative. Not an ICH, CDISC or HL7 artifact.

Published sources → [m11-rdf](#) (one graph, rebuilt from pinned files) → USDM attributes in [usdm-rdf](#) · source: github.com/kerfors/m11-rdf

What is left

As good as the published sources allow, for now

SETTLED IN M11-RDF

Identity and place

270 elements, each the pair the Specification states; 160 sections; Template headings on their sections, 108 of them an element.

271 of 281 Template fields linked to an element; 264 of 270 elements reached by a field or a heading.

496 of 647 mapping rows are mapping statements.

NEEDS THE PUBLISHERS

151 mapping rows without a statement

98 with a name that is not a Specification term and no usable code. Rows still marked CNEW: HL7 163, CDISC 212.

34 where the name or code fits more than one element, or code and name disagree.

19 where the element is found but the stated USDM class and attribute are not.

Each listed in `d2-residue.csv`; Template residue in `d5-residue.csv`.

NEEDS A CONVENTION

Content that points at its element

277 statements, for 140 elements, reach USDM only as `NarrativeContentItem.text` plus a section-number string.

A study file needs a way to say: this content is that M11 section or element. Neither USDM v4 nor the mappings have one yet.

m11-rdf applies mechanical, reproducible rules only. Where a rule would need judgement (a near-match of names, a choice between subclasses, a repaired spelling), the row stays in the residue.

USDM v4.1, public review from end of November 2026

Questions to ask of the alignment with ICH M11

Coverage	55 of the 270 elements have no mapping statement. Do they get a place in USDM?
Document content	Can content point at an M11 section or element, rather than at a section number written as text?
Model and mapping	160 rows in each mapping name <code>StudyProtocolDocumentVersion</code> , which USDM v4.0.0 does not have (it has <code>StudyDefinitionDocumentVersion</code>). Is the model changed, or the mapping?
Step 4	The CDISC mapping is stated against the M11 Step 2 draft. For 39 of the 284 section and element-name pairs that both files have, the NCIt code differs.
Codes and names	Where m11-rdf finds a CNEW row by its name (HL7 128, CDISC 154), the element's code is published in the ICH M11 Terminology. Codes in the cells, and names as in the Specification, would make the mapping resolve by code.

When 4.1 is published, m11-rdf is rebuilt against it: the same element identifiers, new USDM and mapping inputs, and the difference per element.