

M11 CT to USDM Analysis

Controlled Terminology with USDM Target Mapping

34 M11 CT elements 32 with USDM target 2 without target 18 with term comparison 16 with differences

All (34)
With Target (32)
Without Target (2)

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
	Original Protocol Indicator	C217046	<code>StudyVersion.amendments</code>	M11 only M11:2 USDM:0 ▶ Show M11 terms	Mapped
	Substantial Impact Safety	C217046	<code>StudyAmendmentImpact.isSubstantial</code>	M11 only M11:2 USDM:0 ▼ Show M11 terms <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;"> <p>M11 CONTROLLED TERMS (NO USDM CT DATA):</p> C49488: Yes C49487: No </div>	Mapped
	Substantial Impact Data	C217046	<code>StudyAmendmentImpact.isSubstantial</code>	M11 only M11:2 USDM:0 ▼ Show M11 terms <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;"> <p>M11 CONTROLLED TERMS (NO USDM CT DATA):</p> </div>	Mapped

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<div style="display: flex; justify-content: space-around;"> C49488: Yes C49487: No </div>	
	Amendment Scope	C217047	<div style="border: 1px solid blue; border-radius: 10px; padding: 2px; display: inline-block;">GeographicScope.type</div>	<div style="display: flex; align-items: center;"> <div style="border: 1px solid orange; border-radius: 10px; padding: 2px; margin-right: 5px;"> ⚠ Diff </div> M11:2 USDM:3 </div> <p style="margin-top: 5px;">▼ Show terms</p> <div style="border: 1px solid gray; border-radius: 10px; padding: 10px; margin-top: 5px;"> <p>✓ MATCHING (BY C-CODE):</p> <div style="border: 1px solid green; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C68846: Global</div> <p>M11 ONLY:</p> <div style="border: 1px solid blue; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C217026: Not Global</div> <p>USDM ONLY:</p> <div style="border: 1px solid red; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C25464: Country</div> <div style="border: 1px solid red; border-radius: 10px; padding: 2px; display: inline-block;">C41129: Region</div> </div>	<div style="border: 1px solid green; border-radius: 10px; padding: 2px; display: inline-block; color: green; font-weight: bold;">Mapped</div>
	Trial Phase	C217045	<div style="border: 1px solid blue; border-radius: 10px; padding: 2px; display: inline-block;">StudyDesign.studyPhase</div>	<div style="display: flex; align-items: center;"> <div style="border: 1px solid orange; border-radius: 10px; padding: 2px; margin-right: 5px;"> ⚠ Diff </div> M11:11 USDM:17 </div> <p style="margin-top: 5px;">▼ Show terms</p> <div style="border: 1px solid gray; border-radius: 10px; padding: 10px; margin-top: 5px;"> <p>✓ MATCHING (BY C-CODE):</p> <div style="border: 1px solid green; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C15600: Phase 1</div> <div style="border: 1px solid green; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C15601: Phase 2</div> <div style="border: 1px solid green; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C15602: Phase 3</div> <div style="border: 1px solid green; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C15603: Phase 4</div> <div style="border: 1px solid green; border-radius: 10px; padding: 2px; display: inline-block;">C15693: Phase 1/Phase 2</div> </div>	<div style="border: 1px solid green; border-radius: 10px; padding: 2px; display: inline-block; color: green; font-weight: bold;">Mapped</div>

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<p>C15694: Phase 2/Phase 3</p> <p>C198366: Phase 1/Phase 2/Phase 3</p> <p>C198367: Phase 1/Phase 3</p> <p>C54721: Early Phase 1</p> <p>M11 ONLY:</p> <p>C217024: Phase 2/Phase 3/Phase 4</p> <p>C217025: Phase 3/Phase 4</p> <p>USDM ONLY:</p> <p>C199989: Phase Ib Trial</p> <p>C199990: Phase Ia Trial</p> <p>C47865: Phase V Trial</p> <p>C48660: Not Applicable</p> <p>C49686: Phase IIa Trial</p> <p>C49687: Phase IIIa Trial</p> <p>C49688: Phase IIb Trial</p> <p>C49689: Phase IIIb Trial</p>	
	Current Amendment Scope Enrollment Definition	C217275	NarrativeContentItem.text	<p>M11 only M11:3 USDM:0</p> <p>▼ Show M11 terms</p>	Mapped

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<p>M11 CONTROLLED TERMS (NO USDM CT DATA):</p> <ul style="list-style-type: none"> C68846: Globally C41065: Locally C218489: By Cohort 	
	<p>Primary Reason for Amendment</p>	<p>C217276</p>	<p><code>StudyAmendmentReason.code</code></p>	<p>⚠ Diff M11:15 USDM:15</p> <p>▼ Show terms</p> <p>✓ MATCHING (BY C-CODE):</p> <ul style="list-style-type: none"> C17649: Other C48660: Not Applicable <p>M11 ONLY:</p> <ul style="list-style-type: none"> C218490: Regulatory Agency Request To Amend C218491: New Regulatory Guidance C218492: IRB/IEC Feedback C218493: New Safety Information Available C218494: Manufacturing Change C218495: IMP Addition C218496: Change In Strategy 	<p>Mapped</p>

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<p>C218497: Change In Standard Of Care</p> <p>C218498: New Data Available (Other Than Safety Data)</p> <p>C218499: Investigator/Site Feedback</p> <p>C218500: Recruitment Difficulty</p> <p>C218501: Inconsistency And/Or Error In The Protocol</p> <p>C218502: Protocol Design Error</p> <p>USDM ONLY:</p> <p>C207600: Change In Standard Of Care</p> <p>C207601: Change In Strategy</p> <p>C207602: IMP Addition</p> <p>C207603: Inconsistency and/or Error In The Protocol</p> <p>C207604: Investigator/Site Feedback</p> <p>C207605: IRB/IEC Feedback</p> <p>C207606: Manufacturing Change</p> <p>C207607: New Data Available (Other Than Safety Data)</p> <p>C207608: New Regulatory Guidance</p> <p>C207609: New Safety Information Available</p>	

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<div style="border: 1px solid #ccc; padding: 5px;"> <div style="border: 1px solid red; border-radius: 10px; padding: 2px; margin-bottom: 5px;">C207610: Protocol Design Error</div> <div style="border: 1px solid red; border-radius: 10px; padding: 2px; margin-bottom: 5px;">C207611: Recruitment Difficulty</div> <div style="border: 1px solid red; border-radius: 10px; padding: 2px;">C207612: Regulatory Agency Request To Amend</div> </div>	
	Secondary Reason for Amendment	C217276	<div style="border: 1px solid #00aaff; border-radius: 10px; padding: 2px; display: inline-block;">StudyAmendmentReason.code</div>	<div style="border: 1px solid #ccc; padding: 5px;"> <div style="border: 1px solid orange; border-radius: 10px; padding: 2px; display: inline-block; margin-right: 5px;">⚠ Diff</div> M11:15 USDM:15 </div> <div style="margin-top: 5px;"> <p>▼ Show terms</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p>✓ MATCHING (BY C-CODE):</p> <div style="border: 1px solid green; border-radius: 10px; padding: 2px; margin-bottom: 5px; display: inline-block;">C17649: Other</div> <div style="border: 1px solid green; border-radius: 10px; padding: 2px; margin-bottom: 5px; display: inline-block;">C48660: Not applicable</div> <p>M11 ONLY:</p> <div style="border: 1px solid #00aaff; border-radius: 10px; padding: 2px; margin-bottom: 5px; display: inline-block;">C218490: Regulatory Agency Request To Amend</div> <div style="border: 1px solid #00aaff; border-radius: 10px; padding: 2px; margin-bottom: 5px; display: inline-block;">C218491: New Regulatory Guidance</div> <div style="border: 1px solid #00aaff; border-radius: 10px; padding: 2px; margin-bottom: 5px; display: inline-block;">C218492: IRB/IEC Feedback</div> <div style="border: 1px solid #00aaff; border-radius: 10px; padding: 2px; margin-bottom: 5px; display: inline-block;">C218493: New Safety Information Available</div> <div style="border: 1px solid #00aaff; border-radius: 10px; padding: 2px; margin-bottom: 5px; display: inline-block;">C218494: Manufacturing Change</div> <div style="border: 1px solid #00aaff; border-radius: 10px; padding: 2px; margin-bottom: 5px; display: inline-block;">C218495: IMP Addition</div> <div style="border: 1px solid #00aaff; border-radius: 10px; padding: 2px; margin-bottom: 5px; display: inline-block;">C218496: Change In Strategy</div> <div style="border: 1px solid #00aaff; border-radius: 10px; padding: 2px;">C218497: Change In Standard Of Care</div> </div> </div>	<div style="border: 1px solid green; border-radius: 10px; padding: 2px; display: inline-block; color: green;">Mapped</div>

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<div data-bbox="1473 188 1868 268">C218498: New Data Available (Other Than Safety Data)</div> <div data-bbox="1473 280 1868 360">C218499: Investigator/Site Feedback</div> <div data-bbox="1473 373 1868 421">C218500: Recruitment Difficulty</div> <div data-bbox="1473 434 1868 513">C218501: Inconsistency And/Or Error In The Protocol</div> <div data-bbox="1473 526 1868 574">C218502: Protocol Design Error</div> <p data-bbox="1473 596 1630 628">USDM ONLY:</p> <div data-bbox="1473 651 1868 730">C207600: Change In Standard Of Care</div> <div data-bbox="1473 743 1868 791">C207601: Change In Strategy</div> <div data-bbox="1473 804 1868 852">C207602: IMP Addition</div> <div data-bbox="1473 865 1868 944">C207603: Inconsistency and/or Error In The Protocol</div> <div data-bbox="1473 957 1868 1037">C207604: Investigator/Site Feedback</div> <div data-bbox="1473 1050 1868 1098">C207605: IRB/IEC Feedback</div> <div data-bbox="1473 1110 1868 1158">C207606: Manufacturing Change</div> <div data-bbox="1473 1171 1868 1251">C207607: New Data Available (Other Than Safety Data)</div> <div data-bbox="1473 1264 1868 1343">C207608: New Regulatory Guidance</div> <div data-bbox="1473 1356 1868 1436">C207609: New Safety Information Available</div> <div data-bbox="1473 1449 1868 1497">C207610: Protocol Design Error</div>	

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<p>C207611: Recruitment Difficulty</p> <p>C207612: Regulatory Agency Request To Amend</p>	
	Section - and Name	C217272	<code>DocumentContentReference.sectionNumber + @sectionTitle</code>	<p>M11 only M11:16 USDM:0</p> <p>▼ Show M11 terms</p> <p>M11 CONTROLLED TERMS (NO USDM CT DATA):</p> <ul style="list-style-type: none">C217342: Section 1C217343: Section 2C217344: Section 3C217345: Section 4C217346: Section 5C217347: Section 6C217348: Section 7C217349: Section 8C217350: Section 9C217351: Section 10C217352: Section 11C217353: Section 12C217354: Section 13C217355: Section 14	Mapped

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<div data-bbox="1473 188 1805 225" data-label="Text">C217356: Section Title Page</div> <div data-bbox="1473 248 1816 312" data-label="Text">C217357: Section Amendment Details</div>	
	Amendment Details	C217274	<div data-bbox="703 443 1046 480" data-label="Text">StudyVersion.amendments</div> <div data-bbox="703 512 1046 549" data-label="Text">StudyAmendment.previous</div> <div data-bbox="703 580 1046 617" data-label="Text">StudyAmendment.previous</div>	<div data-bbox="1451 443 1568 472" data-label="Text">M11 only</div> <div data-bbox="1581 443 1762 472" data-label="Text">M11:3 USDM:0</div> <div data-bbox="1424 504 1673 536" data-label="Text">▼ Show M11 terms</div> <div data-bbox="1447 584 1856 651" data-label="Text">M11 CONTROLLED TERMS (NO USDM CT DATA):</div> <div data-bbox="1469 679 1832 743" data-label="Text">C218485: This protocol has not been amended.</div> <div data-bbox="1469 770 1765 834" data-label="Text">C218486: This is the first protocol amendment.</div> <div data-bbox="1469 861 1848 1023" data-label="Text">C218487: This protocol has been amended previously. Details of prior amendments are presented in Section 12.3 Prior Protocol Amendment(s).</div>	Mapped
1.1.2	Master Protocol Indicator	C217046	<div data-bbox="703 1155 1276 1187" data-label="Text">StudyDefinitionDocumentVersion.children</div>	<div data-bbox="1447 1152 1568 1181" data-label="Text">M11 only</div> <div data-bbox="1581 1152 1762 1181" data-label="Text">M11:2 USDM:0</div> <div data-bbox="1424 1212 1673 1244" data-label="Text">▼ Show M11 terms</div> <div data-bbox="1447 1292 1856 1359" data-label="Text">M11 CONTROLLED TERMS (NO USDM CT DATA):</div> <div data-bbox="1469 1388 1632 1417" data-label="Text">C49488: Yes</div> <div data-bbox="1657 1388 1812 1417" data-label="Text">C49487: No</div>	Mapped

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
1.1.2	Stratification Indicator	C217046	No USDM target	<p>M11 only M11:2 USDM:0</p> <p>▼ Show M11 terms</p> <p>M11 CONTROLLED TERMS (NO USDM CT DATA):</p> <p>C49488: Yes C49487: No</p>	Not Mapped
1.1.2	Drug-Device Combination Product Indicator	C217046	MedicalDevice.embeddedProduct	<p>M11 only M11:2 USDM:0</p> <p>▼ Show M11 terms</p> <p>M11 CONTROLLED TERMS (NO USDM CT DATA):</p> <p>C49488: Yes C49487: No</p>	Mapped
1.1.2	Adaptive Trial Design Indicator	C217046	InterventionalStudyDesign.characteristics	<p>Diff M11:2 USDM:9</p> <p>▼ Show terms</p> <p>M11 ONLY:</p> <p>C49487: No C49488: Yes</p> <p>USDM ONLY:</p> <p>C147145: Stratified Randomization</p> <p>C207613: Extension Study Design</p>	Mapped

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<p>C217004: Single-Center Study</p> <p>C217005: Multicenter Study</p> <p>C217006: Single Country</p> <p>C217007: Multiple Countries</p> <p>C25689: Stratification</p> <p>C46079: Randomized Controlled Clinical Trial</p> <p>C98704: Adaptive Design</p>	
1.1.2	Population Type	C217278	StudyDesignPopulation.includesHealthySubjects	<p>M11 only M11:2 USDM:0</p> <p>▼ Show M11 terms</p> <p>M11 CONTROLLED TERMS (NO USDM CT DATA):</p> <p>C218503: With Disease</p> <p>C218504: Without Disease</p>	Mapped
1.1.2	Intervention Model	C217277	InterventionalStudyDesign.model	<p>Diff M11:6 USDM:5</p> <p>▼ Show terms</p> <p>✓ MATCHING (BY C-CODE):</p> <p>C142568: Sequential</p> <p>C82637: Cross-over</p>	Mapped

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<p>C82638: Factorial</p> <p>C82639: Parallel Group</p> <p>C82640: Single Group</p> <p>M11 ONLY:</p> <p>C17649: Other</p>	
1.1.2	Control Type	C217279	<p>StudyArm.type</p>	<p>⚠ Diff M11:7 USDM:7</p> <p>▼ Show terms</p> <p>M11 ONLY:</p> <p>C120841: Dose Response</p> <p>C184727: Sham Procedure</p> <p>C218505: Different Dose or Regimen</p> <p>C218506: External</p> <p>C28280: No Control</p> <p>C49648: Placebo</p> <p>C49649: Active Comparator</p> <p>USDM ONLY:</p> <p>C15538: Protocol Treatment Arm</p> <p>C174226: Control Arm</p> <p>C174266: Investigational Arm</p>	<p>Mapped</p>

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<div style="border: 1px solid #ccc; padding: 5px;"> <p>C174267: Active Comparator Arm</p> <p>C174268: Placebo Control Arm</p> <p>C174269: Sham Comparator Arm</p> <p>C174270: No Intervention Arm</p> </div>	
1.1.2	Min Age Units	C217048	<div style="border: 1px solid #add8e6; border-radius: 5px; padding: 2px; display: inline-block;">Quantity.unit</div> <div style="border: 1px solid #add8e6; border-radius: 5px; padding: 2px; display: inline-block;">Quantity.unit</div>	<div style="border: 1px solid #add8e6; border-radius: 5px; padding: 2px; display: inline-block;"> ⚠ Diff M11:5 USDM:936 </div> ▶ Show terms	<div style="border: 1px solid #28a745; border-radius: 15px; padding: 5px; display: inline-block; color: #28a745;">Mapped</div>
1.1.2	Max Age Units	C217048	<div style="border: 1px solid #add8e6; border-radius: 5px; padding: 2px; display: inline-block;">Quantity.unit</div> <div style="border: 1px solid #add8e6; border-radius: 5px; padding: 2px; display: inline-block;">Quantity.unit</div>	<div style="border: 1px solid #add8e6; border-radius: 5px; padding: 2px; display: inline-block;"> ⚠ Diff M11:5 USDM:936 </div> ▶ Show terms	<div style="border: 1px solid #28a745; border-radius: 15px; padding: 5px; display: inline-block; color: #28a745;">Mapped</div>
1.1.2	Site Distribution	C217049	<div style="border: 1px solid #add8e6; border-radius: 5px; padding: 2px; display: inline-block;">StudySite.name</div>	<div style="border: 1px solid #add8e6; border-radius: 5px; padding: 2px; display: inline-block;"> M11 only M11:2 USDM:0 </div> ▼ Show M11 terms <div style="border: 1px solid #add8e6; border-radius: 10px; padding: 10px;"> <p>M11 CONTROLLED TERMS (NO USDM CT DATA):</p> <div style="border: 1px solid #add8e6; border-radius: 5px; padding: 2px; display: inline-block; margin-bottom: 5px;">C217004: Single-Centre</div> <div style="border: 1px solid #add8e6; border-radius: 5px; padding: 2px; display: inline-block;">C217005: Multicentre</div> </div>	<div style="border: 1px solid #28a745; border-radius: 15px; padding: 5px; display: inline-block; color: #28a745;">Mapped</div>
1.1.2	Site Geographic Scope	C217050	No USDM target	<div style="border: 1px solid #add8e6; border-radius: 5px; padding: 2px; display: inline-block;"> M11 only M11:2 USDM:0 </div> ▼ Show M11 terms	<div style="border: 1px solid #ffc107; border-radius: 15px; padding: 5px; display: inline-block; color: #ffc107;">Not Mapped</div>

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<p>M11 CONTROLLED TERMS (NO USDM CT DATA):</p> <ul style="list-style-type: none"> C217006: Single Country C217007: Multiple Countries 	
1.1.2	Intervention Assignment Method	C217280	StudyDesign.characteristics	<p>⚠ Diff M11:3 USDM:9</p> <p>▼ Show terms</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p>M11 ONLY:</p> <ul style="list-style-type: none"> C17649: Other C222801: No Intervention Assignment Method C25196: Randomisation <p>USDM ONLY:</p> <ul style="list-style-type: none"> C147145: Stratified Randomization C207613: Extension Study Design C217004: Single-Center Study C217005: Multicenter Study C217006: Single Country C217007: Multiple Countries C25689: Stratification </div>	Mapped

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<div style="border: 1px solid #ccc; padding: 5px;"> <div style="border: 1px solid red; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C46079: Randomized Controlled Clinical Trial</div> <div style="border: 1px solid red; border-radius: 10px; padding: 2px; display: inline-block; margin-top: 5px;">C98704: Adaptive Design</div> </div>	
1.1.2	Trial Blind Schema	C217051	<div style="border: 1px solid #007bff; border-radius: 10px; padding: 2px; display: inline-block;">InterventionalStudyDesign.blindingSchema</div>	<div style="border: 1px solid #ccc; padding: 5px;"> <div style="border: 1px solid orange; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;"> ⚠ Diff M11:4 USDM:5 </div> <div style="margin-bottom: 5px;"> ▼ Show terms </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <p>✓ MATCHING (BY C-CODE):</p> <div style="border: 1px solid #007bff; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C15228: Double Blind</div> <div style="border: 1px solid #007bff; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C187674: Observer Blind</div> <div style="border: 1px solid #007bff; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C28233: Single Blind</div> <div style="border: 1px solid #007bff; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C49659: Open Label</div> </div> <p>USDM ONLY:</p> <div style="border: 1px solid red; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;"> C156592: Open Label for Treatment And Double Blind to Dose </div> </div>	<div style="border: 1px solid #007bff; border-radius: 10px; padding: 2px; display: inline-block; color: #007bff;">Mapped</div>
1.1.2	Blinded Roles	C217281	<div style="border: 1px solid #007bff; border-radius: 10px; padding: 2px; display: inline-block;">StudyRole.code</div>	<div style="border: 1px solid #ccc; padding: 5px;"> <div style="border: 1px solid orange; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;"> ⚠ Diff M11:6 USDM:22 </div> <div style="margin-bottom: 5px;"> ▼ Show terms </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <p>✓ MATCHING (BY C-CODE):</p> <div style="border: 1px solid #007bff; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C17445: Care Provider</div> <div style="border: 1px solid #007bff; border-radius: 10px; padding: 2px; display: inline-block; margin-bottom: 5px;">C207599: Outcomes Assessor</div> </div> </div>	<div style="border: 1px solid #007bff; border-radius: 10px; padding: 2px; display: inline-block; color: #007bff;">Mapped</div>

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<p>C25936: Investigator</p> <p>C70793: Sponsor</p> <p>M11 ONLY:</p> <p>C142710: Participant</p> <p>C48660: Not Applicable</p> <p>USDM ONLY:</p> <p>C142489: Data Monitoring Committee</p> <p>C142578: Independent Data Monitoring Committee</p> <p>C188863: Regulatory Agency</p> <p>C19924: Principal Investigator</p> <p>C215662: Contract Research</p> <p>C215669: Study Co-Sponsor</p> <p>C215670: Local Legal Sponsor</p> <p>C215671: Dose Escalation Committee</p> <p>C215672: Clinical Trial Physician</p> <p>C215673: Pharmacovigilance Group</p> <p>C25392: Manufacturer</p> <p>C37984: Laboratory</p> <p>C41189: Study Subject</p> <p>C51851: Project Coordinator</p>	

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<div style="border: 1px solid #ccc; padding: 5px;"> <p>C51876: Sponsor Medical Expert</p> <p>C51877: Statistician</p> <p>C78726: Adjudication Committee</p> <p>C80403: Study Site</p> </div>	
1.1.2	Independent Committees	C217282	<div style="border: 1px solid #add8e6; border-radius: 10px; padding: 2px 5px; display: inline-block;">StudyRole.label</div>	<p>M11 only M11:5 USDM:0</p> <p>▼ Show M11 terms</p> <div style="border: 1px solid #add8e6; padding: 5px; margin-top: 5px;"> <p>M11 CONTROLLED TERMS (NO USDM CT DATA):</p> <div style="border: 1px solid #add8e6; border-radius: 10px; padding: 2px 5px; display: inline-block; margin-bottom: 5px;">C142578: Independent Data Monitoring Committee</div> <div style="border: 1px solid #add8e6; border-radius: 10px; padding: 2px 5px; display: inline-block; margin-bottom: 5px;">C215671: Dose Escalation Committee</div> <div style="border: 1px solid #add8e6; border-radius: 10px; padding: 2px 5px; display: inline-block; margin-bottom: 5px;">C78726: Endpoint Adjudication Committee</div> <div style="border: 1px solid #add8e6; border-radius: 10px; padding: 2px 5px; display: inline-block; margin-bottom: 5px;">C17649: Other</div> <div style="border: 1px solid #add8e6; border-radius: 10px; padding: 2px 5px; display: inline-block;">C41132: None</div> </div>	<div style="border: 1px solid #38a83d; border-radius: 10px; padding: 2px 5px; display: inline-block; color: #38a83d;">Mapped</div>
12.3	Amendment Scope Enrollment Description	C217275	<div style="border: 1px solid #add8e6; border-radius: 10px; padding: 2px 5px; display: inline-block; margin-bottom: 5px;">GeographicScope.type</div> <div style="border: 1px solid #add8e6; border-radius: 10px; padding: 2px 5px; display: inline-block; margin-bottom: 5px;">GeographicScope.code</div> <div style="border: 1px solid #add8e6; border-radius: 10px; padding: 2px 5px; display: inline-block; margin-bottom: 5px;">StudySite.label</div> <div style="border: 1px solid #add8e6; border-radius: 10px; padding: 2px 5px; display: inline-block;">StudyCohort.label</div>	<p>⚠ Diff M11:3 USDM:3</p> <p>▼ Show terms</p> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 5px;"> <p>✓ MATCHING (BY C-CODE):</p> <div style="border: 1px solid #38a83d; border-radius: 10px; padding: 2px 5px; display: inline-block; margin-bottom: 5px; color: #38a83d;">C68846: Globally</div> <p>M11 ONLY:</p> </div>	<div style="border: 1px solid #38a83d; border-radius: 10px; padding: 2px 5px; display: inline-block; color: #38a83d;">Mapped</div>

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<p>C218489: By Cohort</p> <p>C41065: Locally</p> <p>USDM ONLY:</p> <p>C25464: Country</p> <p>C41129: Region</p>	
12.3	Previous Amendment Overview Section and Name	C217272	DocumentContentReference.sectionTitle	<p>M11 only M11:16 USDM:0</p> <p>▼ Show M11 terms</p> <p>M11 CONTROLLED TERMS (NO USDM CT DATA):</p> <p>C217342: Section 1</p> <p>C217343: Section 2</p> <p>C217344: Section 3</p> <p>C217345: Section 4</p> <p>C217346: Section 5</p> <p>C217347: Section 6</p> <p>C217348: Section 7</p> <p>C217349: Section 8</p> <p>C217350: Section 9</p> <p>C217351: Section 10</p> <p>C217352: Section 11</p> <p>C217353: Section 12</p>	Mapped

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<p>C217354: Section 13</p> <p>C217355: Section 14</p> <p>C217356: Section Title Page</p> <p>C217357: Section Amendment Details</p>	
12.3	Prior Protocol Amendments	C217274	NarrativeContentItem.text	<p>M11 only M11:1 USDM:0</p> <p>▼ Show M11 terms</p> <p>M11 CONTROLLED TERMS (NO USDM CT DATA):</p> <p>C218488: beginning with the most recent.</p>	Mapped
6	Arm Type	C217283	StudyArm.type	<p>⚠ Diff M11:5 USDM:7</p> <p>▼ Show terms</p> <p>✓ MATCHING (BY C-CODE):</p> <p>C174226: Control Arm</p> <p>C174266: Experimental Arm</p> <p>C174267: Active Comparator Arm</p> <p>C174268: Placebo Comparator Arm</p> <p>C174270: No Intervention Arm</p>	Mapped

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				USDM ONLY: <div data-bbox="1467 236 1854 274">C15538: Protocol Treatment Arm</div> <div data-bbox="1467 300 1854 338">C174269: Sham Comparator Arm</div>	
6	Intervention Type	C217284	<div data-bbox="689 450 1048 507">StudyIntervention.type</div>	<div data-bbox="1438 450 1550 497">⚠ Diff</div> M11:12 USDM:13 ▼ Show terms <div data-bbox="1438 577 1899 1353">✓ MATCHING (BY C-CODE): <div data-bbox="1467 657 1796 699">C1505: Dietary Supplement</div><div data-bbox="1467 715 1706 756">C15184: Behavioral</div><div data-bbox="1467 772 1675 813">C15238: Genetic</div><div data-bbox="1467 829 1697 871">C15313: Radiation</div><div data-bbox="1467 887 1680 928">C15329: Surgery</div><div data-bbox="1467 944 1765 986">C16830: Medical Device</div><div data-bbox="1467 1002 1706 1043">C18020: Diagnostic</div><div data-bbox="1467 1059 1635 1101">C1909: Drug</div><div data-bbox="1467 1117 1863 1158">C218507: Non-Surgical Procedure</div><div data-bbox="1467 1174 1653 1216">C307: Biologic</div><div data-bbox="1467 1232 1832 1273">C54696: Combination Product</div><div data-bbox="1467 1289 1657 1331">C923: Vaccine</div> USDM ONLY:</div>	<div data-bbox="1953 450 2087 497">Mapped</div>

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				C98769: Physical Medical Procedure	
6	Use	C217285	StudyIntervention.role	<p>⚠ Diff M11:7 USDM:8</p> <p>▼ Show terms</p> <p>✓ MATCHING (BY C-CODE):</p> <ul style="list-style-type: none"> C158128: Challenge Agent C165822: Background Treatment C165835: Rescue Medicine C18020: Diagnostic C207614: Additional Required Treatment C41161: Experimental Intervention C753: Placebo <p>USDM ONLY:</p> <ul style="list-style-type: none"> C68609: Active Comparator 	Mapped
6	IMP or NIMP	C217286	AdministrableProduct.productDesignation	<p>✓ Match (2) M11:2 USDM:2</p> <p>▼ Show terms</p> <p>✓ MATCHING (BY C-CODE):</p>	Mapped

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;">C156473: NIMP</div> <div style="border: 1px solid #ccc; padding: 5px;">C202579: IMP</div>	
6	Sourcing	C217052	AdministrableProduct.sourcing	<div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> ✓ Match (2) M11:2 USDM:2 </div> <div style="color: blue; font-weight: bold;">▼ Show terms</div> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 5px;"> <div style="color: green; font-weight: bold;">✓ MATCHING (BY C-CODE):</div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 2px; display: inline-block;">C215659: Centrally Sourced</div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 2px; display: inline-block;">C215660: Locally Sourced</div> </div>	Mapped
9.2	Event Type	C217287	NarrativeContentItem.text	<div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> M11 only M11:10 USDM:0 </div> <div style="color: blue; font-weight: bold;">▼ Show M11 terms</div> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 5px;"> <div style="color: gray; font-weight: bold;">M11 CONTROLLED TERMS (NO USDM CT DATA):</div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 2px; display: inline-block; color: blue;">C41331: Adverse Event</div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 2px; display: inline-block; color: blue;">C41335: Serious Adverse Event</div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 2px; display: inline-block; color: blue;">C218508: Trial Intervention Complaint</div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 2px; display: inline-block; color: blue;">C222331: Drug/Device Combination Product Complaint</div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 2px; display: inline-block; color: blue;">C25742: Pregnancy Event</div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 2px; display: inline-block; color: blue;">C218510: Lactation Event</div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 2px; display: inline-block; color: blue;">C218511: Post-Partum Event</div> </div>	Mapped

SECTION	M11 ELEMENT	C-CODE	USDM TARGET(S)	TERM COMPARISON	MAP STATUS
				<p>C218512: Reportable Adverse Event of Special Interest</p> <p>C218513: Not Reportable Adverse Event of Special Interest</p> <p>C17649: Other</p>	