

## The ich-ectd-3-0 Document Type Definition (DTD) in table form

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Although this document has been prepared with the most possible care, it cannot be guaranteed not to contain any errors. The one and ultimate source for checking the validity of XML files in the eCTD is and remains the official Document Type Definition as published by the regulatory authorities.

Unless otherwise specified, subelements **must** be in the order as given in the table

Element	
<b>ectd:ectd</b>	<p><b>Subelements:</b>  <b>m1-administrative-information-and-prescribing-information</b> (0 or 1 occurrences)  <b>m2-common-technical-document-summaries</b> (0 or 1 occurrences)  <b>m3-quality</b> (0 or 1 occurrences)  <b>m4-nonclinical-study-reports</b> (0 or 1 occurrences)  <b>m5-clinical-study-reports</b> (0 or 1 occurrences)</p> <p><b>Attributes:</b>  <b>xmlns:ectd</b> <b>MUST</b> be: "http://www.ich.org/ectd"  <b>xmlns:xlink</b> <b>MUST</b> be: "http://www.w3c.org/1999/xlink"  <b>xml:lang</b> character data, optional (used for language specification of this element and its subelements)  <b>dtd-version</b> <b>MUST</b> be: "3.0"</p>
<b>m1-administrative-information-and-prescribing-information</b>	<p><b>Subelements:</b>  <b>leaf</b> (0 or more occurrences)</p> <p><b>Attributes:</b>  <b>ID</b> is an ID (unique identifier), optional  <b>xml:lang</b> character data, optional (used for language specification of this element and its subelements)</p>
<b>m2-common-technical-document-summaries</b>	<p><b>Subelements:</b>  <b>leaf</b> (0 or more occurrences)  <b>m2-2-introduction</b> (0 or 1 occurrences)  <b>m2-3-quality-overall-summary</b> (0 or 1 occurrences)  <b>m2-4-nonclinical-overview</b> (0 or 1 occurrences)  <b>m2-5-clinical-overview</b> (0 or 1 occurrences)  <b>m2-6-nonclinical-written-and-tabulated-summaries</b> (0 or 1 occurrences)  <b>m2-7-clinical-summary</b> (0 or 1 occurrences)</p>

	<p><b>Attributes:</b>  ID is an ID (unique identifier), optional  <b>xml:lang</b> character data, optional (used for language specification of this element and its subelements)</p>
m2-2-introduction	<p><b>Subelements:</b>  <b>leaf</b> (0 or more occurrences)  <b>node-extension</b> (0 or more occurrences)  P.S. "leaf" and "node-extension" subelements can come in any order</p> <p><b>Attributes:</b>  ID is an ID (unique identifier), optional  <b>xml:lang</b> character data, optional (used for language specification of this element and its subelements)</p>
m2-3-quality-overall-summary	<p><b>Subelements:</b>  <b>leaf</b> (0 or more occurrences)  <b>m2-3-introduction</b> (0 or 1 occurrences)  <b>m2-3-s-drug-substance</b> (0 or or more occurrences)  <b>m2-3-p-drug-product</b> (0 or or more occurrences)  <b>m2-3-a-appendices</b> (0 or 1 occurrences)  <b>m2-3-r-regional-information</b> (0 or 1 occurrences)</p> <p><b>Attributes:</b>  ID is an ID (unique identifier), optional  <b>xml:lang</b> character data, optional (used for language specification of this element and its subelements)</p>
m2-3-introduction	<p><b>Subelements:</b>  <b>leaf</b> (0 or more occurrences)  <b>node-extension</b> (0 or more occurrences)  P.S. "leaf" and "node-extension" subelements can come in any order</p> <p><b>Attributes:</b>  ID is an ID (unique identifier), optional  <b>xml:lang</b> character data, optional (used for language specification of this element and its subelements)</p>
m2-3-s-drug-substance	<p><b>Subelements:</b>  <b>leaf</b> (0 or more occurrences)  <b>node-extension</b> (0 or more occurrences)  P.S. "leaf" and "node-extension" subelements can come in any order</p> <p><b>Attributes:</b>  ID is an ID (unique identifier), optional  <b>xml:lang</b> character data, optional (used for language specification of this element and its subelements)  <b>substance</b> character data, <b>required</b> (must be present)  <b>manufacturer</b> character data, <b>required</b> (must be present)</p>

m2-3-p-drug-product	<p><b>Subelements:</b>  <b>leaf</b> (0 or more occurrences)  <b>node-extension</b> (0 or more occurrences)  P.S. "leaf" and "node-extension" subelements can come in any order</p> <p><b>Attributes:</b>  <b>ID</b> is an ID (unique identifier), optional  <b>xml:lang</b> character data, optional (used for language specification of this element and its subelements)  <b>product-name</b> character data, optional  <b>dosageform</b> character data, optional  <b>manufacturer</b> character data, optional</p>
m2-3-a-appendices  m2-3-r-regional-information	<p><b>Subelements:</b>  <b>leaf</b> (0 or more occurrences)  <b>node-extension</b> (0 or more occurrences)  P.S. "leaf" and "node-extension" subelements can come in any order</p> <p><b>Attributes:</b>  <b>ID</b> is an ID (unique identifier), optional  <b>xml:lang</b> character data, optional (used for language specification of this element and its subelements)</p>
m2-4-nonclinical-overview  m2-5-clinical-overview	<p><b>Subelements:</b>  <b>leaf</b> (0 or more occurrences)  <b>node-extension</b> (0 or more occurrences)  P.S. "leaf" and "node-extension" subelements can come in any order</p> <p><b>Attributes:</b>  <b>ID</b> is an ID (unique identifier), optional  <b>xml:lang</b> character data, optional (used for language specification of this element and its subelements)</p>
m2-6-nonclinical-written-and-tabulated-summaries	<p><b>Subelements:</b>  <b>leaf</b> (0 or more occurrences)  <b>m2-6-1-introduction</b> (0 or 1 occurrences)  <b>m2-6-2-pharmacology-written-summary</b> (0 or 1 occurrences)  <b>m2-6-3-pharmacology-tabulated-summary</b> (0 or 1 occurrences)  <b>m2-6-4-pharmacokinetics-written-summary</b> (0 or 1 occurrences)  <b>m2-6-5-pharmacokinetics-tabulated-summary</b> (0 or 1 occurrences)  <b>m2-6-6-toxicology-written-summary</b> (0 or 1 occurrences)  <b>m2-6-7-toxicology-tabulated-summary</b> (0 or 1 occurrences)</p>