FDA ADMINISTRATION

ECTD SUBMISSION TYPES AND SUB-TYPES

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SUBMISSION TYPES AND SUBMISSION SUB-TYPES

A ***Submission type*** attribute is required for every sequence. An additional attribute of ***submission-sub-type*** is required when utilizing M1 DTD v3.3.
For examples of the correct usage of the ***submission type*** and ***submission-sub-type*** attribute, please refer to the Tables below.
For more information, please access the eCTD Web page at http://www.fda.gov/ectd.

Table 1 - Transitioning from Paper to eCTD using M1 DTD v2.01

When transitioning to eCTD format from paper or a non-eCTD format, the initial eCTD submission should be coded per the current regulatory activity.

Submission Description	Application Type	Submission Transmission	Submission ID	Sequence Number	Submission Type	Sub-Type
Pre-IND Meeting Request/ Briefing Package/Original Application/Labeling Supplement/ Initial safety report Subject- 1234	IND000001	Paper	N/A	N/A	N/A	N/A
New Protocol 1234	IND000001	eCTD	N/A	0000	**Original Application.** All subsequent amendment to the original application should be coded as "amendment" relating to the original application (seq 0000)	N/A
Change in labeling text-1	IND000001	eCTD	N/A	0001	**Labeling Supplement.** All subsequent submission to the Labeling Supplement should be coded as "amendment" relating to Labeling Supplement (seq 0001	N/A
Follow-up 01: Subject 1234	IND000001	eCTD	N/A	0006	**Other** or some sponsors use **Amendment** relating to the Original application (seq 0000)	N/A

Table 2 - Transitioning from Paper to eCTD using M1 DTD v3.3

The initial eCTD submission utilizing M1 DTD v3.3 should be coded per the current regulatory activity. The submission-id should match the sequence number of the transition sequence.

Submission Description	Application Type	Submission Transmission	Submission ID	Sequence Number	Submission Type	Sub-Type
Pre-IND Meeting Request/Briefing Package/Original Application/ Labeling Supplement/Annual Report-2016/Initial Safety Report – Subject 123	IND000002	Paper	N/A	N/A	N/A	N/A
Protocol 1234 - Change in Protocol/New Investigator Files	IND000002	eCTD M1 DTD v3.3	0001	0001	**Original Application.** All subsequent amendment to the original application should have a sub-type of "amendment" and sub-id = 0001	**Application**
Follow-up- Safety Report 1 -Subject 123	IND000002	eCTD M1 DTD v3.3	0002	0002	**IND Safety Report.** All subsequent safety reports (i.e., initial/follow-up) should have a sub-type of "amendment" and sub-id = 0002	**Report**
Change in labeling text	IND000002	eCTD M1 DTD v3.3	0006	0006	**Labeling Supplement** Supplement Effective Date Type = PAS or CBE-0. All subsequent submission to the Labeling Supplement should be coded as "amendment" (sub-id 0006)	**Application**

Table 3 - Transitioning from M1 DTD v2.01 to M1 DTD v3.3

The initial eCTD submission should be coded per the current regulatory activity. If the submission is updating a regulatory activity started in M1 DTD v2.01, the submission-id in M1 DTD v3.3 should match the sequence number of the initial eCTD submission to that regulatory activity. If the submission using M1 DTD v3.3 is creating a new regulatory activity, the submission-id should match the sequence number.

Submission Description	Application Type	Submission Transmission	Submission ID	Sequence Number	Submission Type	Sub-Type
Pre-NDA Meeting Request/ Briefing Package/ Original NDA Application = 0001/ Original application/ Labeling Supplement = 0002/Labeling Supplement	NDA000003	eCTD M1 DTD v2.01	N/A	0000	Presubmission	N/A
Initial Safety Report – subject 123	NDA000003	eCTD M1 DTD v2.01	N/A	0003	**Other** or **amendment** relating to the Original application (seq 0001)	N/A
New Protocol 1234	NDA000003	eCTD M1 DTD v3.3	0001	0004	**Original-application**	**Amendment**
Follow-up 1- Safety Report – subject 123	NDA000003	eCTD M1 DTD v3.3	0003(if sponsor had used "other" as their submission type in v2.01). However, if sponsor had used "amendment" in v2.01, we advise that sponsor start a new Regulatory Activity. If starting a new Regulatory Activity, sponsor should use the current sequence (e.g. 0005) as the sub-id	0005	**IND Safety Report**	**"Amendment"** (if sponsor used 0003 as the sub-id). However, if sponsor starts a new Regulatory Activity, the sub-type will be **"Report"** and the sub-id will be 0005
Change in labeling text	NDA000003	eCTD M1 DTD v3.3	0002	0006	**Labeling Supplement** Supplement Effective Date Type = PAS or CBE-0	**Amendment**

The eCTD Web page can be accessed at http://www.fda.gov/ectd
For additional questions, please contact CBER at esubprep@fda.hhs.gov or CDER at esub@fda.hhs.gov