

CTP ELECTRONIC SUBMISSIONS STANDARDS AND ACTIVITIES

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Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.



- Introduction
- In the Beginning
- CTP Portal
- Technical Considerations
- Expanding on an existing eSubmission Standard, the eCTD
- Conclusion

THE BEGINNING



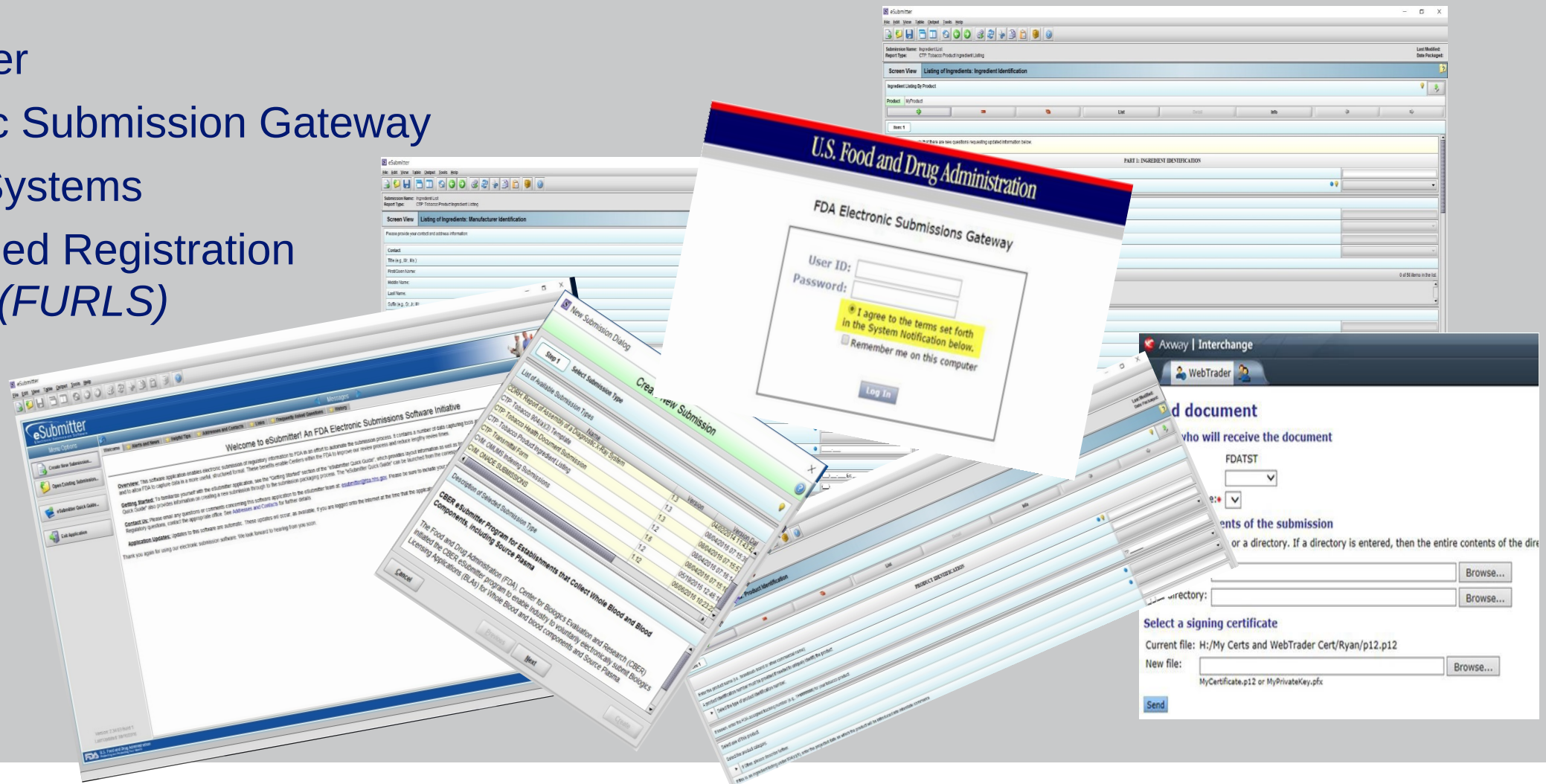
The Tobacco Control Act necessitated capability to receive data and submissions within 6 months, *e.g.*, 904(a)(1), 905(b)

- Registration of Establishments
- Registration of Products
- Report of Ingredients

CTP ADAPTED TOOLS FROM OTHER FDA CENTERS



- eSubmitter
- Electronic Submission Gateway
- Internal Systems
- FDA Unified Registration & Listing (*FURLS*)



CTP PORTAL



- Easy upload of eSubmitter submission files
- Ability to view submission administrative information
- Link to CTP Portal:

<https://ctpportal.fda.gov/ctpportal/login.jsp>

- Account management performed by an Industry Account Manager (IAM)

<https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515185.htm>



PORTAL HOME SCREEN



Key Features: Submission Information, Letter Information, Upload Tool and Secure Messaging

CTP Portal

Home Messages 34 Submissions Admin

Welcome to the CTP Portal

The U.S. Food and Drug Administration (FDA), Center for Tobacco Products (CTP) developed the CTP Portal as part of its initiative to improve submission processing and facilitate interaction with industry stakeholders. The CTP Portal allows industry stakeholders to use the embedded upload feature to transmit eSubmitter-generated submissions; this new transmission method offers industry stakeholders an alternative to the Agency's existing WebTrader Hosted Solution.

The CTP Portal is intended for use by stakeholders in the regulated tobacco industry, including manufacturers, importers, and distributors who make submissions to CTP. The CTP Portal should improve transparency and facilitate communication to speed issue resolution that may otherwise hinder processing and/or access to industry submissions.

The CTP Portal does not replace existing FDA systems and corresponding requirements, including but not limited to Tobacco Registration and eSubmitter, and does not replace submissions made via the FDA Unified Registration Listing Systems (FURLS).

Recent Regulatory Files

Date Issued	File Type	STN
01/11/2016	Decision Letter	SE0021853
10/27/2015	Administrative Extension Response Letter	AS0000618
10/05/2015	Administrative Extension Response Letter	AS0000618
03/06/2015	Acknowledgement Letter	SE0000121
03/05/2015	Acknowledgement Correction Letter	SE0000121

Displaying 5 most recent [View All](#)

Recent Uploads

File Name	User's Name	Status Date	File Count	Status
HD Test_8_9_18.zip	Maiser, Chris	08/09/2018	20	Submission Received
GF_Test.zip	Maiser, Chris	08/09/2018	7	Submission Received
49 GF files.zip	Maiser, Chris	08/08/2018	50	Submission in Progress
1 File 0 cover Letter.zip	Sunga, Diana	08/08/2018	1	Submission Received

Displaying 4 most recent

Recent Notifications

08/09/2018 12:02 PM
The ESG Acknowledgement Regulatory Letter has been posted to the ...

08/01/2018 03:11 AM
A submission is now available for viewing in the CTP Portal [HD0000662](#)

07/16/2018 03:06 AM
A submission is now available for viewing in the CTP Portal [GF1801607](#)

07/12/2018 12:02 PM
The CTP Portal User Admin has changed

Displaying 4 most recent [View All](#)

Let's Get Started

Recent Regulatory Files

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01/11/2016	Decision Letter	SE0021853
10/27/2015	Administrative Extension Response Letter	AS0000618
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Displaying 4 most recent

Let

PORTAL SUBMISSIONS



Key Features:

- Listing of received submissions
- Assigned Submission Tracking Number (STN)
- High-level submission information

CTP Portal

John Doe | Company Logout

Home Messages 68 Submissions Admin Launch Upload Tool

Submissions

Filter By C Search Submissions

STN	Submission Type	Product Name	Date Submitted	Submission POC
RD0000088	RD - Requested/Required Documents	Multiple (12)	04/18/2016	Doe, John
TI0001312	TI - Product Ingredient List (c)(1)	Product 1	04/18/2016	Doe, Jane
TT0000539	TT - Tobacco Constituents	N/A	04/18/2016	Doe, John
RW1600527	SE- Substantial Equivalent Report	N/A	04/18/2016	Doe, Jane
PC0000558	PC - Product Composition	N/A	04/18/2016	Doe, John
PS0000518	PS - Postmarket Surveillance	N/A	04/18/2016	Doe, Jane
NR0000543	NR - Nicotine Reporting	N/A	04/18/2016	Doe, John
TC0000954	TC - General Correspondence	N/A	04/18/2016	Doe, Jane

Test data displayed

PORTAL UPLOAD TOOL



Upload Tool

1

UPLOAD HISTORY

2

UPLOAD FILE

3

CONFIRMATION

Exit

Welcome to the CTP Portal Upload Tool

The Upload Tool allows you to upload and transmit submission packages generated using FDA's eSubmitter software. For additional details regarding the Upload Tool as well as instructions for downloading the FDA eSubmitter software, refer to the Upload Tool section of the CTP Portal Help module.

Please click the icon next to the Status header for a brief explanation of the possible statuses for a given submission.

UPLOAD HISTORY ☐ View Only My Uploads

Search Upload History

File Name	User's Name	Status Date	Package Description	Package ID	File Count	Status
AS 1 cover letter 712 files_002.zip	Pope-Johns , Farah	10/03/2018	Farah's Second upload attempt	I-E-000-00-07C-11	58	<u>Submission In Progress</u>
AS 1 cover letter 712 files_001.zip	Pope-Johns , Farah	10/03/2018	Farah's First Upload Attempt	I-E-000-00-07C-10	655	<u>Submission In Progress</u>
0 cover letter 50 files.zip	Glatstein, Seth	10/03/2018	noletter 50 files	I-E-000-00-07C-0F	50	<u>Submission In Progress</u>
RD 0 cover letter 1 file.zip	Glatstein, Seth	10/03/2018	Test file no coverletter	I-E-000-00-07C-0D	1	<u>Submission In Progress</u>
AP 1 cover letter 1 file.zip	Glatstein, Seth	10/03/2018	Test file1	I-E-000-00-07C-0B	2	<u>Submission Received</u>
AP 1 cover letter 46 files.zip	Glatstein, Seth	10/03/2018	Test file46	I-E-000-00-07C-0C	47	<u>Submission Received</u>
XX 1 cover letter 500 files_002-usedbyhatim.zip	Valiuddin, Hatim	10/02/2018	kk	I-E-000-00-07B-DE	30	<u>Submission In Progress</u>
OM 1 cover letter 1 file-usedbyHatim.zip	Valiuddin, Hatim	10/02/2018	l	I-E-000-00-07B-DD	2	<u>Submission In Progress</u>
OM 0 cover letter 1 file-used by hatim.zip	Valiuddin, Hatim	10/02/2018	hat	I-E-000-00-07B-DC	1	<u>Submission In Progress</u>
Test_Upload_31_Files.zip	Smith, Jeffrey	10/02/2018	Test Upload of zip with 31 attachments	I-E-000-00-07B-D8	30	<u>Submission In Progress</u>
OM regress Test 10 files.zip	Rymaruk, Oksana	10/01/2018	test 10/1/18	I-E-000-00-07B-C9	11	<u>Submission Received</u>
RW 1 cover letter 500 files_002.zip	Rymaruk, Oksana	09/21/2018	nw2	I-E-000-00-07B-A4	30	<u>Submission Received</u>

Key Features:

Listing of uploads including upload date and user who uploaded

Test data displayed

TIPS TO ENSURE SUBMISSION CAN BE... *PROCESSED, REVIEWED AND ARCHIVED*



"We cannot review what we cannot process, open, and read."

File Formats

- ✓ PDF, DOC, DOCX, TXT, XPT, CSV, XLS, XLSX, XML, JPG, GIF
- ✓ Some formats are appropriate for data, others appropriate for images and the narrative
- ✓ Retain extension in the filename to specify the file format type
- ✓ SaS transport file (.xpt) for analysis datasets recommended
<http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards>

File Naming

- ✓ Short, descriptive, unique filenames and file path, e.g., "MainTOC.pdf", "study1.xpt",
- ✓ Special characters and foreign characters cause problems, e.g., #, %, ., &, ><, ç, ü
- ✓ Deep subfolders cause problems, limit path < 180 characters

*Further details available in [Electronic Submission File Formats and Specifications](https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing), listed on the CTP Manufacturer's Page:
<https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing>*

TIPS TO ENSURE SUBMISSION CAN BE... *PROCESSED, REVIEWED AND ARCHIVED*



Legibility/Usability

- ✓ Create PDF files directly from source file
- ✓ For scanned documents, resolution ≥ 300 dpi, optical character recognition (OCR) helps ensure legibility and usability
- ✓ Include table of contents, hypertext links and bookmarks
- ✓ Use existing templates

Integrity and Security

- ✓ Test the submission by installing onto another location and opening
- ✓ Virus scan all files to be submitted to the FDA
- ✓ Avoid use of security settings in files, *e.g., encryption, password protection, printing restrictions*

CTP REFERENCES FOR FILE AND DATA STANDARDS



-  Common Errors and Questions that Delay Submission Processing
Frequently Asked Questions (FAQ) & Common Errors That Delay Submission Processing
-  Electronic Submission File Formats and Specifications
Provides a reference of file formats, data standards useful for submittal and review
-  Overview of the Electronic Submissions Process for Industry
Basic info about the documents and data needed to successfully create and submit an eSubmitter package

*All three available on the CTP Manufacturer's page and CTP's eSubmitter page,
<https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing>
<https://www.fda.gov/ForIndustry/FDAeSubmitter>*

PREPARING FOR YOUR ELECTRONIC SUBMISSION



1. Download the FDA eSubmitter tool to your desktop

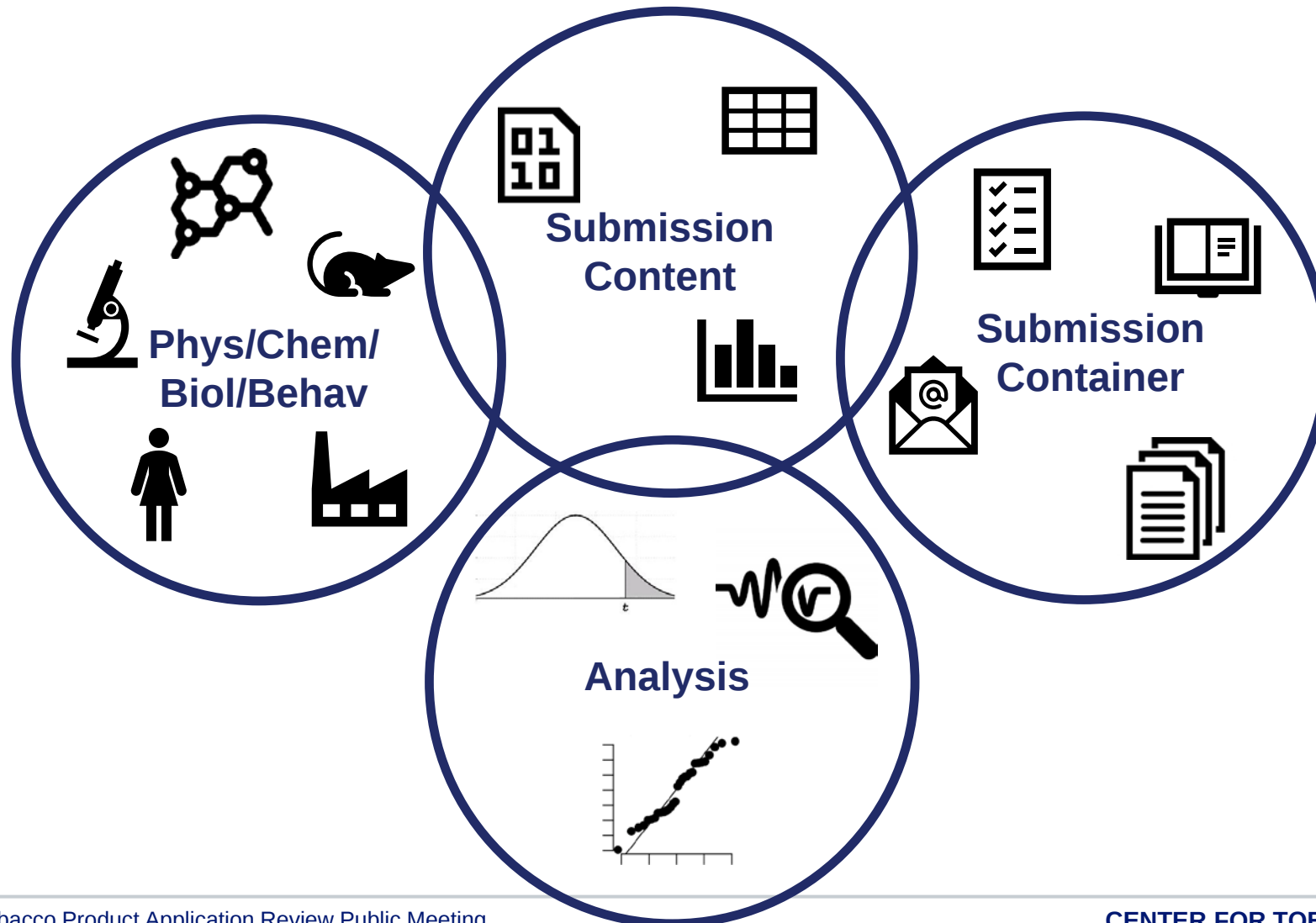
FDA provides instructions, video tutorials and helpdesk assistance
[eSubmitter@fda.hhs.gov or 1-877-CTP-1373]

2. Assemble and package your submission using the FDA eSubmitter tool

3. Create a CTP Portal account for transmitting your eSubmitter package

4. CTP Portal: An Industry Account Manager (*IAM*) is needed to create and maintain user accounts for your company

AREAS OF STANDARDS DEVELOPMENT



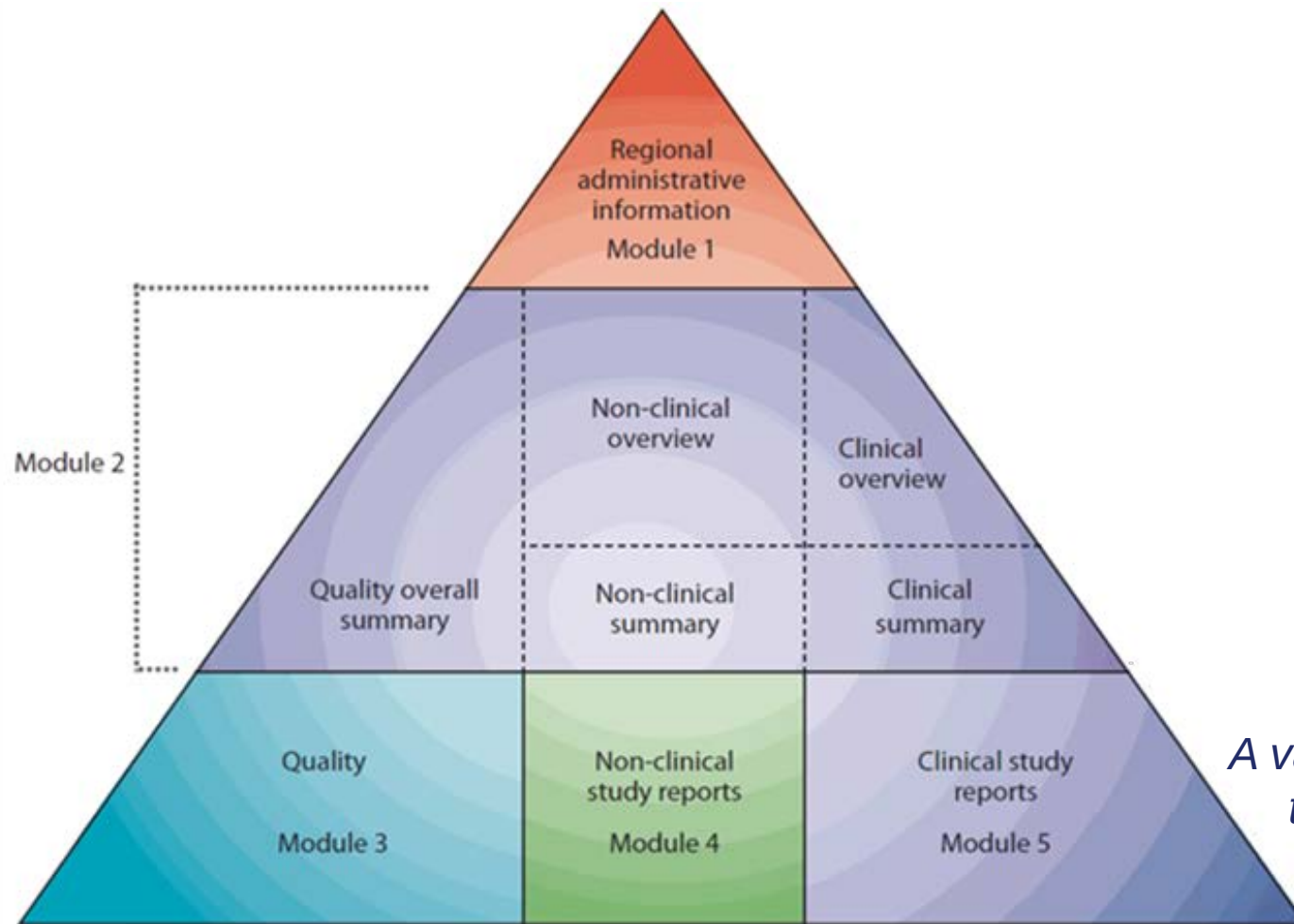
EXPANDING UPON AN EXISTING INTERNATIONAL ELECTRONIC SUBMISSION SPECIFICATION



- FDA makes use of existing standards, *whenever possible*
- FDA uses the eCTD for pharmaceutical products
- FDA pursuing a variation of HL7 **Regulated Product Submission** (RPS) Standard for future submissions; eCTD is the structure and code behind it
- eCTD not suited for Tobacco Products and so CTP is drafting an ...

... **Electronic Tobacco Technical Document, “eTTD”**

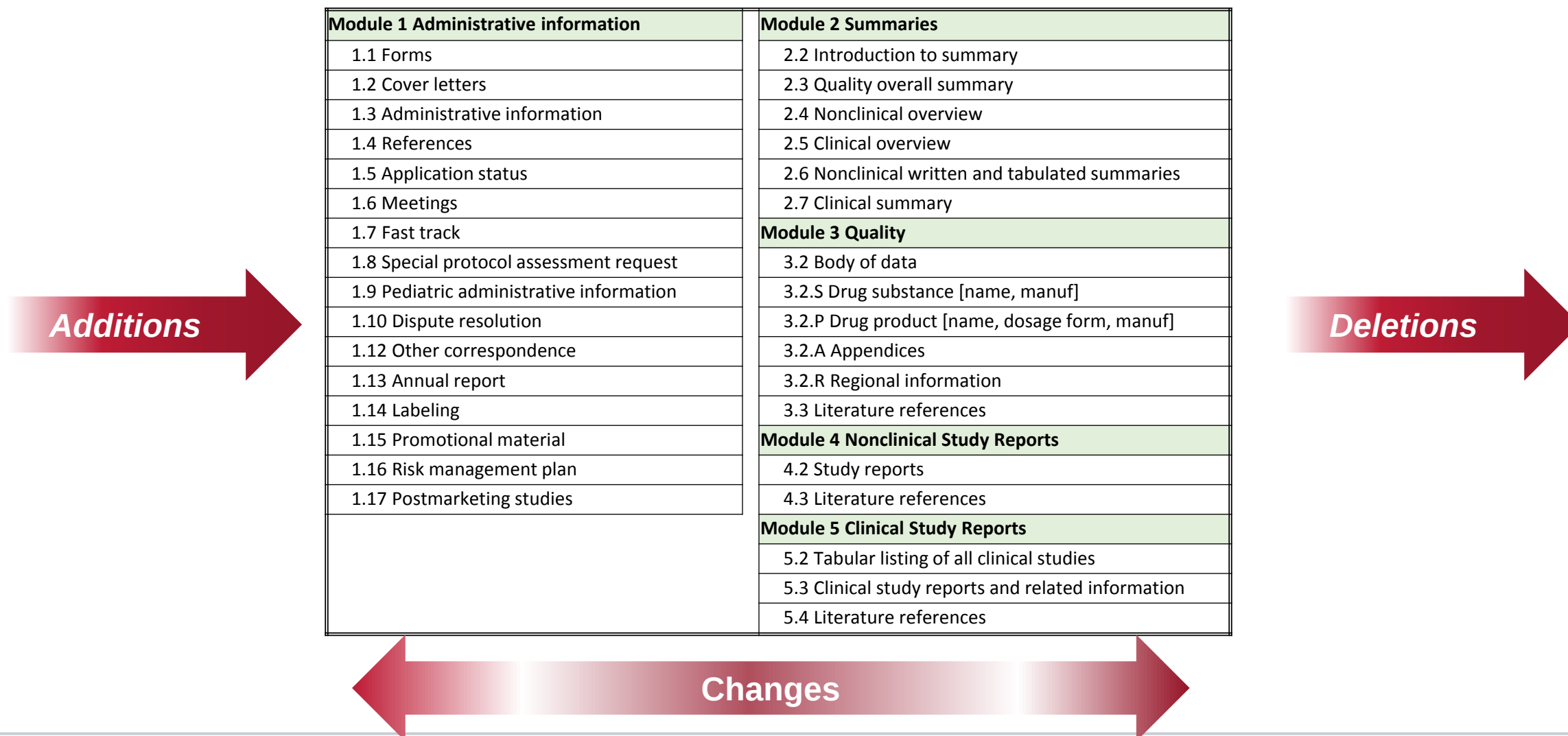
ELECTRONIC COMMON TECHNICAL DOCUMENT (eCTD)



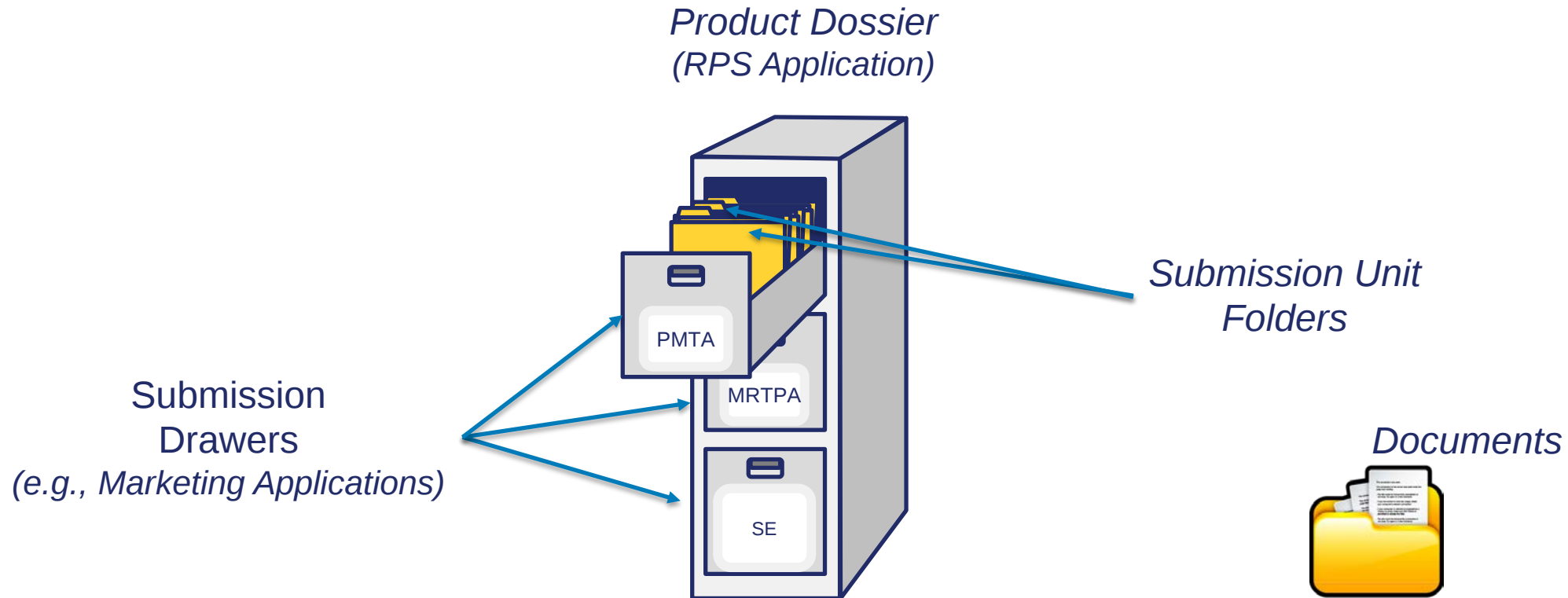
A variation of the eCTD is needed to support tobacco products

<https://www.accessdata.fda.gov/scripts/cder/training/eCTD/menu.htm>

eCTD MODULES- LEVEL 2 OF HIERARCHY



RPS APPLICATION (*PRODUCT DOSSIER*)



POTENTIAL SUBMISSION STANDARD



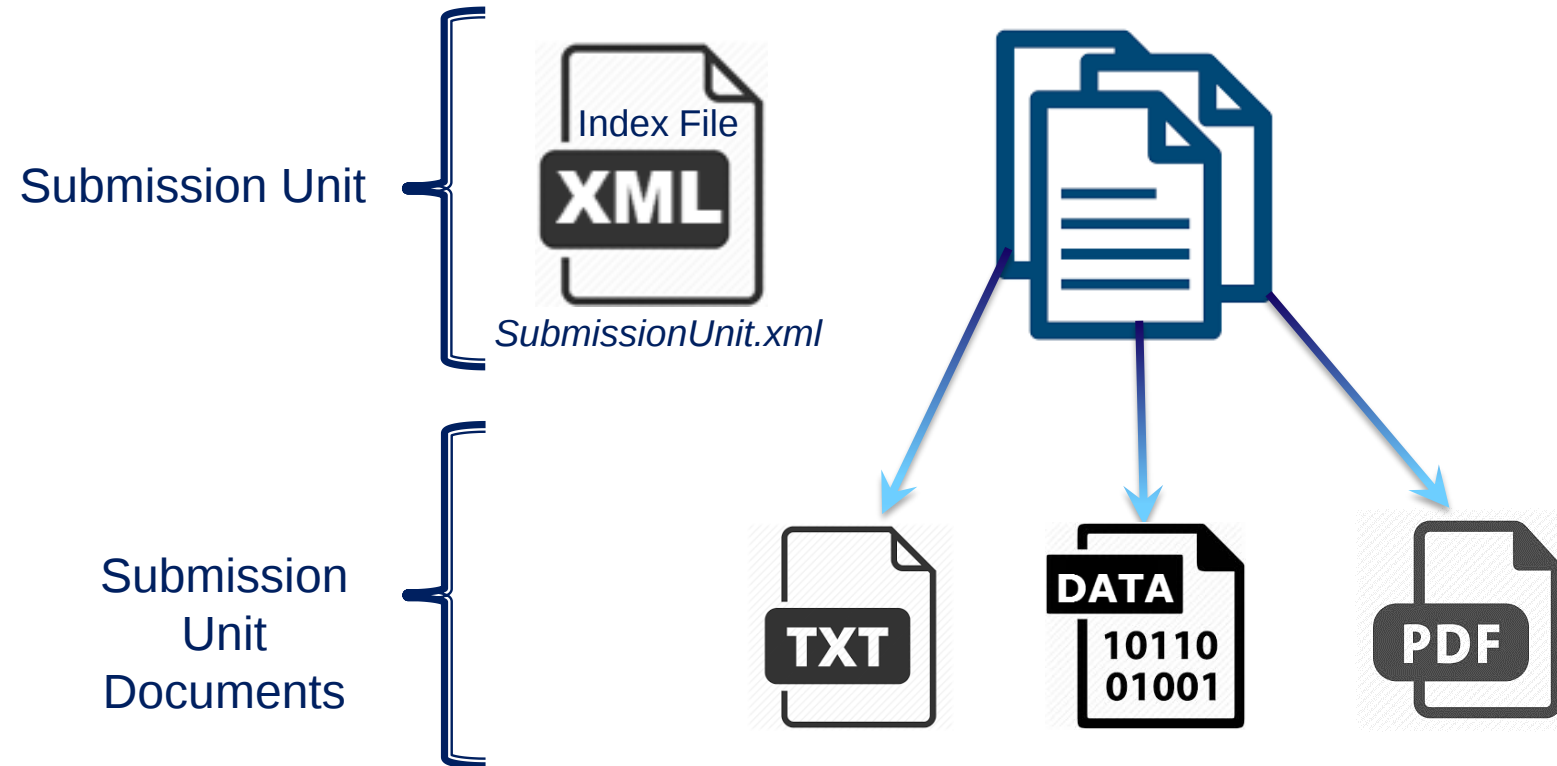
Technical advantages:

- Fully metadata driven – no folder structure to files
- Associates amendments with original information
- Reference previously submitted documents and data
- Supports two-way exchange of information

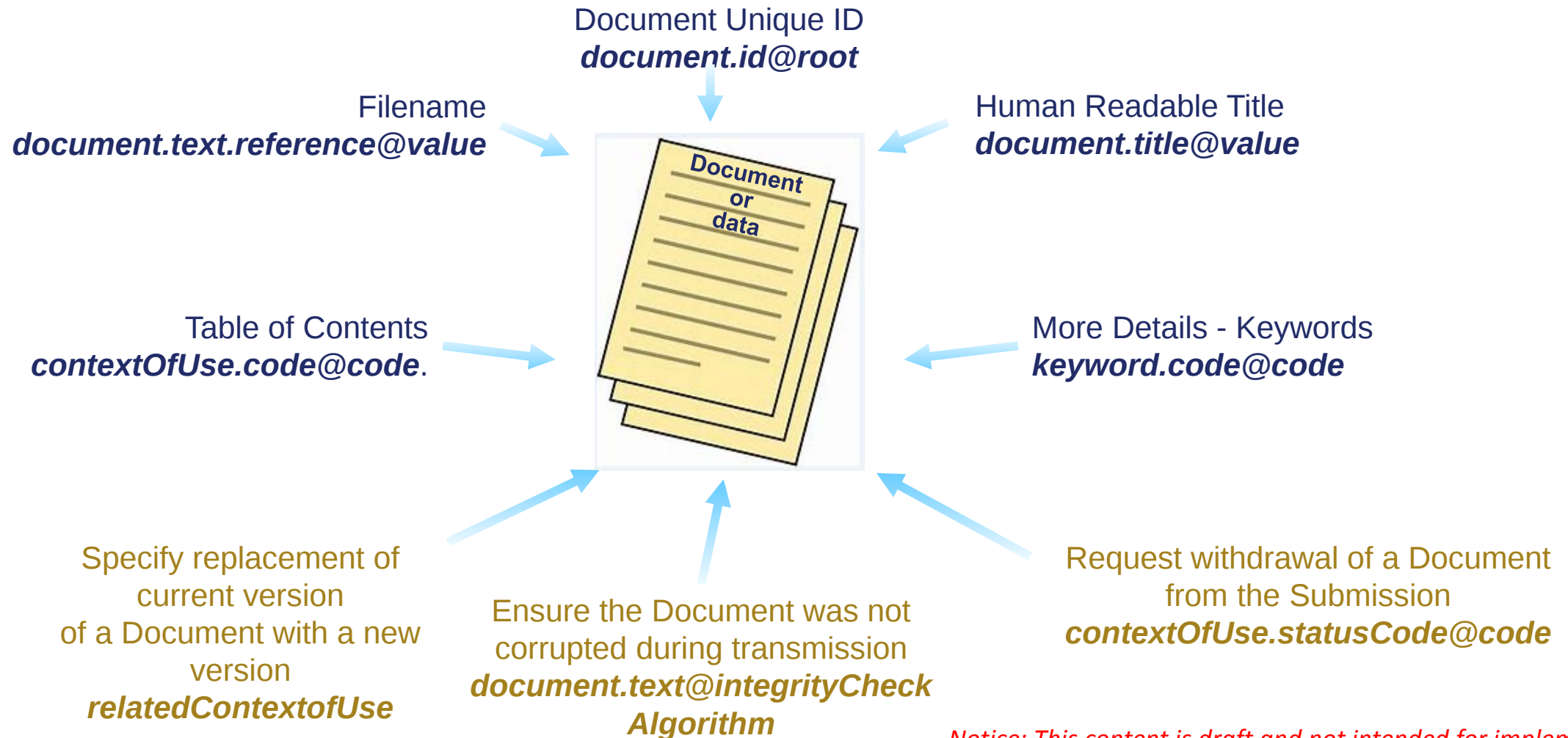
Current eCTD is supported by the commercial marketplace

- Commercial support expected for future standards

TWO MAIN PIECES OF AN eCTD MESSAGE



XML TAGS WITHIN AN eCTD MESSAGE- METADATA ABOUT A SUBMISSION DOCUMENT



Notice: This content is draft and not intended for implementation

EXAMPLE eCTD XML SUBMITTED WITH DOCUMENTS

```
</component>
- <component>
  - <document>
    <!--document ( Section 7.2.17 )-->
    <id root="9eeb0374-86e7-11e8-adc0-fa7ae01bbebc"/>
    <!--BR061,62,63-->
    <title value="ctp_1.6 meeting"/>
    <!--BR064-->
    - <text integrityCheckAlgorithm="SHA256">
      <reference value="meeting.pdf"/>
      <!--BR067-->
      <integrityCheck>45268d0989ab4c403072e9f89376bf9178de1fcfef4ce4468f95c6b3a00f9be1</integrityCheck>
      <!--BR065,66-->
    </text>
  </document>
</component>
- <component>
  - <document>
    <!--document ( Section 7.2.17 )-->
    <id root="9eeb05ae-86e7-11e8-adc0-fa7ae01bbebc"/>
    <!--BR061,62,63-->
    <title value="ctp_1.6.2 industry meeting package"/>
    <!--BR064-->
    - <text integrityCheckAlgorithm="SHA256">
      <reference value="meetingpackage.jpg"/>
      <!--BR067-->
      <integrityCheck>bc8ceab0d289741597683a911e30eddc062f7bfa915743414213243f3df7c43f</integrityCheck>
      <!--BR065,66-->
    </text>
  </document>
</component>
- <component>
  - <document>
    <!--document ( Section 7.2.17 )-->
    <id root="9eeb07de-86e7-11e8-adc0-fa7ae01bbebc"/>
```

TECHNICAL SPECIFICATION IS BEING DRAFTED



- Technical Implementation Guide (TIG)
 - ✓ Details the use of XML tags and structures
 - ✓ Provides validation rules for mandatory and optional items
 - ✓ Identifies which fields require the use of controlled vocabularies
 - ✓ Explains user defined keywords to describe documents
- Controlled vocabulary (CV) to define valid values for certain fields
- Sample Files to illustrate the use of the specification for several common tobacco submission types

... ACTIVITIES CONTINUED



- Building internal technology to accommodate eTTD
- Initial proof-of-concept test with software companies
- *then...* Provide draft documents for public comment

We look forward to working with industry to streamline the submission process and...

- *Improve the Fidelity of Input*
- *Facilitate the Overall Process*
- *Communicate Submission Status More Directly*