



REPRINTS DESK

The Content Workflow Company

The Role of the Information Center in Critical Regulatory Submissions

By Ian Palmer, Head of Marketing @ Reprints Desk

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About Me & My Affiliation



Ian Palmer

- » Head of Marketing at Reprints Desk
- » 13 years experience in information industry & with library technologies
- » Most recent obsession: micro-blogging, specifically Twitter...
<http://twitter.com/reprintsdesk>

Reprints Desk | The Content Workflow Company

- » Rated #1 in 2008 Document Delivery Vendor Scorecard by Outsell, Inc.
- » Only document delivery provider with Rightsphere® rights management integration
- » Named to 'KM World 100,' companies that matter most in knowledge management in February 2009
- » **Advocate for librarians**

About This Presentation



Content

- » Regulatory submissions & one (1) submission trend YOU should know about
- » The opportunity/role for YOU & your Information Center
- » Why YOU should care
- » How YOU can get involved

Format

- » Interactive

Regulatory Submissions are Critical



» There are many types of submissions

- Investigational new drug applications & investigational medicinal product dossiers (INDs/CTA-IMPDs)
- Abbreviated New Drug Applications (ANDAs)
- Marketing applications (e.g. NDAs, BLAs, 510Ks/PMAs)
- Marketing authorization applications (MAAs)

» It is the mechanism for achieving ROI on R&D

» Serving as the primary non-R&D barrier to future sustainability & growth

Regulatory Submission Formats (and Processes!) are Changing



The Old "NDA" Way

- » Paper format
- » Prepared immediately prior to submission



The New 'eCTD' Way

- » Electronic format
- » Prepared continuously from start of clinical trials

eCTD is Becoming the Global Standard



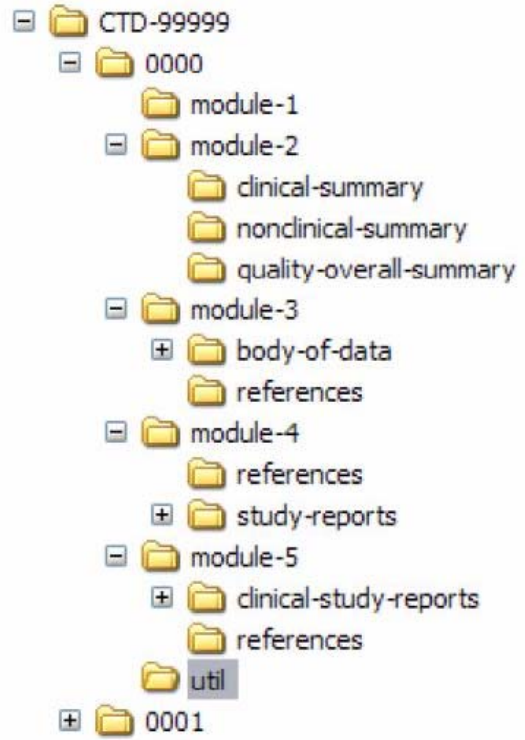
In the U.S.,
the Food and Drug Administration (FDA) has mandated that electronic drug submissions be in eCTD format **since 2008.**



In Europe,
the European Medicines Agency (EMA) has outlined an implementation strategy that requires the use of the eCTD format for all drug & biologic electronic submissions beginning **in 2010.**

Around the world,
countries such as Canada, Australia, Japan, and others are also migrating to eCTD as the standard.

What is the Electronic Common Technical Document (eCTD)?



- » **The specification** designed by the International Conference on Harmonization (ICH)
- » **Represents a common organization structure** for the submission of regulatory information to worldwide health authorities
- » **Comprised of five (5) modules:**
 - *Administrative Information and Prescribing Information*
 - Common Technical Document Summaries
 - Quality
 - Nonclinical Study Reports
 - Clinical Study Reports

[view FDA sample](#)

What Does an eCTD-Formatted Document Actually Look Like Inside?



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The screenshot shows the Adobe Acrobat Professional interface. The main content area displays a table titled "Datasets for Study XXX-XXX". The table has four columns: Dataset, Description, Structure, and Location. The rows list various datasets such as Adverse Events (AE), Protocol Amendment (AMD), Central Laboratory Collection (CLAB), Concomitant Medications (CM), Investigator Comment Log (COM), Inclusion and Exclusion Criteria (CRIT), Demographics (DEMO), Drug Accountability Log (DLOG), 12-Lead Electrocardiogram (ECG), Efficacy (EFF), Fasting (FAST), Hypoglycemic Events (HYPO), Interactive Voice Response System (IVRS), Unmasked Kit Schedule (KIT), Laboratory Results (LABDATA), Medical History (MH), Physical Exam (PE), Pharmacokinetic Data (PKDATA), and Reproductive Status and Urine Pregnancy Test Results (RSTUR). The table also includes a "METHODOLOGY" section describing the study as a multicenter, randomized, double-blind, placebo-controlled study.

Dataset	Description	Structure	Location
AE	Adverse Events	One record per subject per adverse event (keys=PT AETERM AESTDT AEENDT)	AE.spt
AMD	Protocol Amendment	One record per subject (keys=PT)	AMD.spt
CLAB	Central Laboratory Collection	One record per subject per visit (keys=PT CPEVENT LBEDT)	CLAB.spt
CM	Concomitant Medications	One record per subject per concomitant medication (keys=PT CMTERM CMDOSE CMREAS CMSTDT CMENDT)	CM.spt
COM	Investigator Comment Log	One record per subject per visit per comment (keys=PT VST SECTION PAGE COMSEQ REPEATSN)	COM.spt
CRIT	Inclusion and Exclusion Criteria	One record per subject per visit per page (keys=PT VISIT PAGE)	CRIT.spt
DEMO	Demographics	One record per subject (keys=PT)	DEMO.spt
DEMOGALL	Demographics	One record per subject for all subjects appearing on any data set except IVRS and LABDATA because it also contains stream failures (keys=PT)	DEMOGALL.spt
DLOG	Drug Accountability Log	One record per subject per dose (keys=PT VST DSEPR DS2DT RETDT MEDID REPEATSN)	DLOG.spt

What Do Peer-Reviewed Journal Articles Have to do with eCTD?



- » Used as supporting evidence within submissions
- » Included as references within multiple sections
- » Require digital document formatting
- » Compiled in bulk OR individually as needed
- » Compiled in 3 ways:
 - In advance at one time
 - In progression with R&D phases
 - Immediately prior to submission

How Are Most eCTD Submissions Prepared Today?



- » **Directly by the submitting healthcare company**
 - Regulatory Affairs – submission or regulatory affairs specialists, data or dossier managers, program managers
 - Project Managers

<< OR >>

- » **Via a contract research organization (CRO), or outsourced publishing services vendor**

How Libraries Can Help



- » **Assume primary responsibility** for sourcing an eCTD journal article supplier
- » **Centralize eCTD journal article service** within library service offerings
- » **Ensure global accessibility** of eCTD journal article service
- » **Ensure the eCTD journal article service is easy to use** by integrating within document delivery online ordering environments

Why a Role for the Library Makes Sense



- 1. It is where the best domain expertise exists**
 - Managing information services and electronic resources
 - Fulfilling end user needs
 - Understanding copyright laws
- 2. Provides a global view into content procurement and usage**
- 3. Consolidates procurement for increased bargaining power**
- 4. Enables more internal constituents to benefit from library support**

Don't Forget "The Article" BIG Picture



- » The article lifecycle flows through and within the product lifecycle
- » Wherever "the article" flows is an opportunity for the library to be involved



- » Journal Subscriptions
- » Electronic Databases
- » Search Solutions
- » Document Delivery
- » Bibliography Software Tools
- » Publication Planning

- » Medical Information
- » Marketing Materials
- » Promotions & Communications
- » Salesforce Enablement

6 Steps to Get Your Library Involved



- 1) Research eCTD and eCTD article services
- 2) Connect with Regulatory Affairs and IT
- 3) Formalize role for early (Phase 1) involvement
- 4) Source an eCTD article service provider
- 5) Integrate eCTD article service with document delivery
- 6) Promote your services

Commentary On Support for Regulatory Affairs & eCTD Submissions:



Antoinette Azevedo, President

e-Submissions Solutions.com

“Invariably the submission is held up waiting for that last journal article or monograph. It is better to collect them starting at the IND phase rather than waiting for the NDA.”

Commentary On Support for Regulatory Affairs & eCTD Submissions:



Robin Holmes, Information Services & Content Management Consultant

Formerly with Jazz Pharmaceuticals, Johnson & Johnson, and ALZA Corporation

“An eCTD solution should be an information center expertise and deliverable. With this, the center can enhance document delivery by leveraging existing purchases and removing a cause of submission delays.”

Commentary On Support for Regulatory Affairs & eCTD Submissions:



Ginette Larocque, Regulatory Affairs
Manager, eCTD Submissions & Systems

Wyeth Canada



Wyeth Canada is a world leader in the research and development of innovative high quality health care products which spans the range of pharmaceutical, biotechnology, vaccines, consumer-health care and animal health-care products.

“My greatest need is to receive journal articles from the library as 'submission-ready components' to remove any interference with the eCTD validation.

For example, the removal of hyperlinks for e-mail addresses and websites and the presence of bookmarks (when applicable) to facilitate navigation through the article by reviewers.”

Acknowledgements



» **Antoinette Azevedo**, *e-SubmissionSolutions.com*

- Founder e-SubmissionSolutions.com, a world-renowned expert in the tools, techniques, processes and vendors involved in producing eCTDs and the supporting technical infrastructure, including electronic document management systems and submissions publishing outsource services. Her clients range from large, international pharmaceutical companies to small, virtual biotechnology companies.

» **Ginette Larocque**, *Regulatory Affairs Manager, eCTD Submissions & Systems at Wyeth*

- Ginette managed the implementation of the eCTD program at Wyeth Canada in 2005. Ginette manages the entire program which includes publishing submissions to Health Canada, coaching her colleagues on how to create compliant submission-components, and how to approach the management of the lifecycle of documents. Ginette also has an excellent relationship with the eCTD group at Health Canada and has been known to make suggestions on how to evolve with submissions filed in the eCTD format.

Acknowledgements



» **Verna Goodloe**, *Supervisor, Information Technical Services at Allergan*

- Verna is a contributing member of Allergan's Submissions Management and Readiness Team or SMART which is a group name that she coined. This group meets frequently to review best practices in streamlining processes across multiple functional areas with a goal to minimize timeline delays and improve the regulatory publishing process. The SMART group includes member from Regulatory Affairs, Regulatory Publishing, Project Management, Quality/CMC, Clinical, Non-Clinical, Document Management, Medical Writing, Data Management and the Corporate Information Center (CIC). The CIC offers regulatory submission support by delivering FDA quality articles and proprietary reports in preparation for the eCTD.

» **Robin Holmes**, *Information Services & Content Management Consultant*

- Robin Holmes is an information management expert with more than 18 years of experience. She delivers a broad range of consulting services spanning subscription management, rights compliance, and information research.



For Additional Information



- » Discuss eCTD support with your industry colleagues
- » Reach out to Regulatory Affairs
- » Connect with me on Twitter: twitter.com/reprintsdesk
- » Email me: ipalmer @ reprintsdesk.com