

Save Time and Resources –

The electronic Common Technical Document

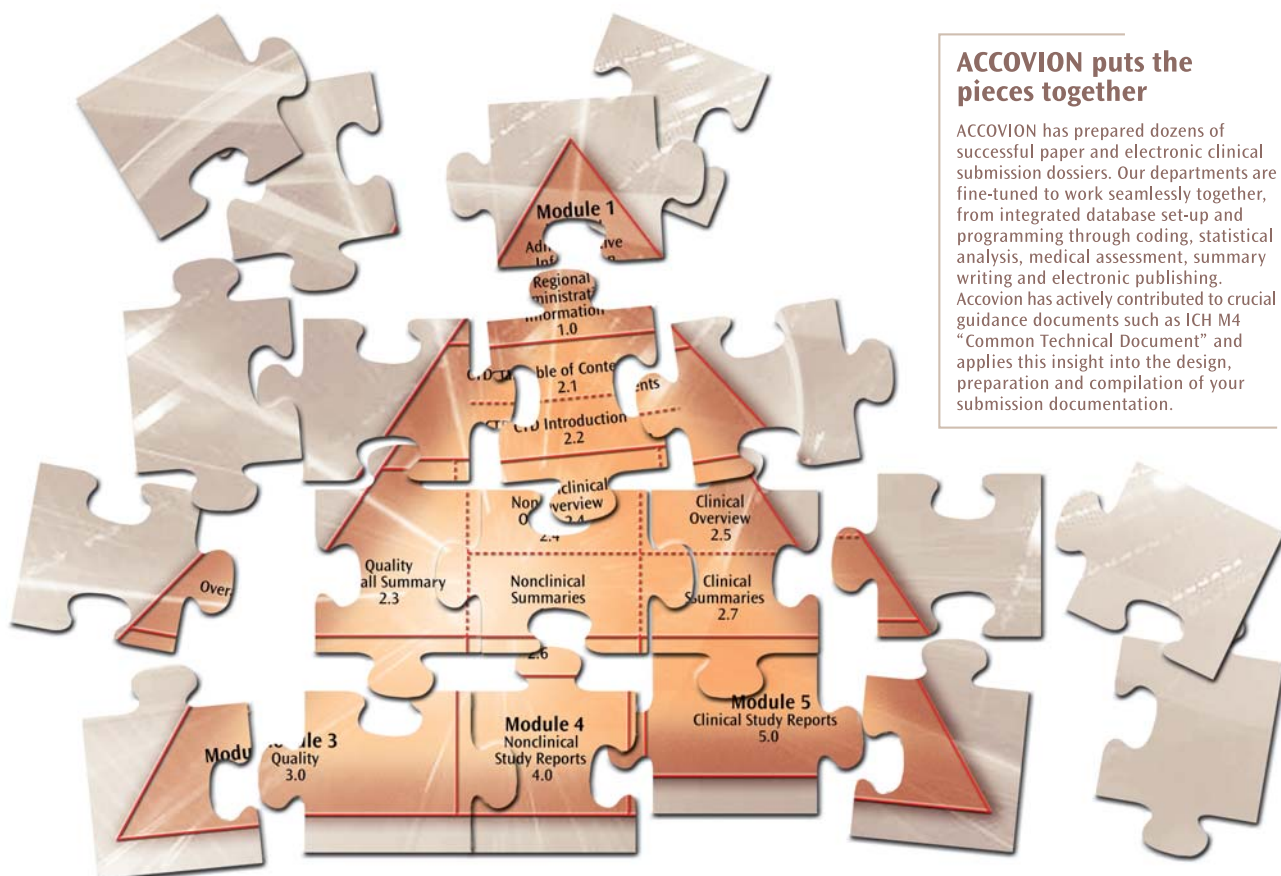
The eCTD is the electronic version of the Common Technical Document (CTD), the internationally agreed format for new medicinal product Marketing Authorization applications to regulatory authorities in the US, EU and Japan. ACCOVION works with you to implement this widely used and increasingly required interface for information transfer – providing advantages for you and your regulatory reviewers.

✓ eCTD Advantages

- ✓ Facilitates faster approvals
- ✓ Saves printing, shipping and resource time and costs
- ✓ Optimizes document management
- ✓ Promotes standardization
- ✓ Includes XML backbone files for easy navigation
- ✓ Facilitates regulatory review
- ✓ Improves communication
- ✓ Covers the entire lifecycle of a product

✓ eCTD Countdown

- ✓ 1 January 2008: US FDA CDER requires all electronic submissions in eCTD format (waivers and paper submissions still possible)
- ✓ 1 July 2009: the EMEA strongly recommends eCTD electronic-only submissions
- ✓ 1 January 2010: the EMEA mandates the use of eCTD format (for all electronic-only submissions and for all applications, new and existing, and all submission types)



ACCOVION puts the pieces together

ACCOVION has prepared dozens of successful paper and electronic clinical submission dossiers. Our departments are fine-tuned to work seamlessly together, from integrated database set-up and programming through coding, statistical analysis, medical assessment, summary writing and electronic publishing. Accovion has actively contributed to crucial guidance documents such as ICH M4 "Common Technical Document" and applies this insight into the design, preparation and compilation of your submission documentation.

for more information visit us at

www.accovion.com

✓ How the eCTD and ACCOVION Benefit You

✓ **Submit fully compliant dossiers**

Current and impending regulatory requirements mandate the eCTD format for all electronic submissions. Ensure your submission fulfills all international requirements with a state-of-the-art, hyperlinked electronic dossier prepared by an expert with a successful track record. **ACCOVION** is your preferred partner for eCTD submissions, combining in-depth knowledge of regulatory requirements with years of clinical development experience, encompassing all major therapeutic areas. You'll receive complete, consistent, correct and compliant documentation electronically published to ICH M2 specifications, including the eCTD XML backbone.

✓ **Enhance your product value**

Standardized clinical data plays a crucial role in the drug approval process and will enhance your product value through proactive life-cycle management. The standards developed by the Clinical Data Interchange Standards Consortium (CDISC) are already in use at the US FDA and ensure a smooth data exchange between the various vendors and the regulatory authorities. Data definition file generation in XML format (define.xml) aids reviewers in navigating through your deliverables. A CDISC corporate sponsor since 2002, **ACCOVION** can integrate the latest CDISC standards into all major steps of your data flow model.

✓ **Reduce time to approval**

Reviewers require a comprehensive understanding of your product. Provide the comparisons and insights they need with fully integrated data displayed in carefully designed tables and figures, analyses of subpopulations, and presentations of findings across studies discussed in the light of current medical opinion. **ACCOVION** prepares integrated summaries of efficacy and safety, overall clinical summaries and overviews that provide an essential framework to support your proposed product labeling and minimize reviewer questions—reducing time between submission and approval.

✓ **Maintain timelines and quality**

Each day matters during the countdown to submission. Meet critical deadlines and maintain quality through tight project management, flexible resource management and rigorous quality control processes. **ACCOVION** streamlines eCTD production with cross-functional, dedicated teams using validated IT systems and SOPs in accordance with international regulations. Key eCTD team members include publishing specialists who expertly prepare and assemble each part of your electronic submission and resolve technical challenges before critical deadlines.

✓ **Accelerate decision-making**

A submission dossier with consistent information across multiple documents requires careful planning, organization, and timely decisions. Achieve continuity and consistency across long-term projects with professionals who know your product. **ACCOVION** project teams plan submission modules while developing other documents for your product, building a dossier that consistently presents the benefit-risk ratio to your target audiences. This forward-looking approach accelerates your decision-making at key points during eCTD development, minimizing delays on the critical path towards dossier finalization.

Put yourself ahead with ACCOVION.

Contact us to learn how you can experience eCTD Power from ACCOVION!

ACCOVION GmbH
Helfmann-Park 10
D-65760 Eschborn
Germany
Phone: + 49 6196 7709-0
Fax: + 49 6196 7709-120

04/2009

ACCOVION. Global reach. Personal touch.

for more information visit us at

www.accovion.com