

### Electronic Publishing – Navigate your way to regulatory success.

*Like any journey through unfamiliar territory, finding a way through a submission dossier is a daunting task for any reviewer. A single clinical report may consist of tens of thousands of pages and hundreds of tables, figures and listings. An entire dossier may contain scores of clinical, non-clinical and quality reports. The reviewer's goal is to provide a sound regulatory assessment of quality, safety and efficacy.*

*Your goal is to enable the reviewer to locate information required as quickly and efficiently as possible, with no wrong turns on the way. Traveling through a strange country requires reliable navigational instruments, a good map and clear signposts. This is where ACCOVION's long experience in the field of electronic publishing will add significant value to your regulatory documentation and speed the journey to regulatory approval.*



#### From the end to the beginning

The final product of the electronic publishing process can be both a paper and an electronic report or dossier. The main navigational tools are multi-level tables of contents, lists of tables, figures, and appendices, and very extensive cross-referencing. In an electronic dossier, these elements will also appear as hyperlinks. The final documentation appears seamless, consistent and complete despite its origins over a wide reach of time and space.

The key to success is that the many thousands of “signposts” will remain accurate throughout revision and compilation of the scores of component documents that are provided in a wide variety of different formats. Any revision cycle may have wide-reaching consequences for page numbering, table and figure numbering, chapter headings and subheadings and overall document organization. Signposts can easily become inaccurate. ACCOVION maintains quality without losing time by building the electronic publishing process into document creation and writing from the beginning. Publishers and medical writers discuss document structure, templates and technical specifications with the client at the outset.

Publishing of draft documents is part of our service and enables quality control and adjustment of navigational elements throughout document development. Automatic generation and updating of these elements saves vital time when compilation and assembly of voluminous documentation is on the critical path to submission, with almost no risk of error.

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[www.accovion.com](http://www.accovion.com)

## Electronic Publishing

### ✓ **The electronic Common Technical Document...**

Regulatory authorities are now implementing the recommendations of the **ICH M2** working group, which foresees standard technical specifications for electronic submission dossiers written to the Common Technical Document (CTD) format. These specifications comprise the eCTD and include the use of PDF format for component documentation with standard naming conventions, linked together using an XML “backbone” for navigation. ACCOVION’s publishers and medical writers are widely experienced in writing and assembling CTD-style dossiers and have the tools and know-how to apply the eCTD specifications to the new electronic standards. We can advise you from the earliest stages in the development of your CTD modules to ensure that your dossiers will be compliant whenever in the future you plan to submit your new drug application.

### ✓ **...and other key documents**

ACCOVION builds electronic publishing not only into reports and submission dossiers but also into all complex documentation that requires accurate and reliable navigation. This can include investigator’s brochures, investigational medicinal product dossiers (IMPDs), INDs, and study protocols. We also have particular experience in applying the publishing process to hyperlink case report forms with data correction log forms, a common requirement during regulatory review as a pre-requisite to assessment of data validity.

### ✓ **ACCOVION can offer you**

- ✓ Publishers and documentation specialists with very wide experience of document publishing
- ✓ Stand-alone publishing of study reports and other clinical and non-clinical documents for subsequent compilation into electronic dossiers (eCTD), either by ACCOVION or another provider
- ✓ A flexible publishing process and toolkit that can be suited to your templates and in-house standards
- ✓ Direct access via secure IT platforms to your inhouse publishing tools, to complement your own publishing resources at peak workload times
- ✓ Seamless integration of medical writing and publishing services for fast, reliable, accurate and efficient clinical document production
- ✓ Consultancy and planning of your clinical trials and regulatory document structure to optimize manpower, budget and timing at all stages

**Put yourself ahead with ACCOVION.**

*Contact us to learn how you can experience Electronic Publishing Power from ACCOVION!*

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**ACCOVION. Global reach. Personal touch.**

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