CTI
Clinical Trial and Consulting Services

November Newsletter

Volume 10, Issue 11

We are recruiting for CRAs in the US, UK, France, Belgium, Sweden and the Netherlands!

Upcoming Medical Meetings CTI will be Attending …

American Society of Hematology
Atlanta, GA
December 8 – 11

Employee Update

Congratulations to the following CTI employee recently promoted:

Robert McRae – Assistant Study Manager

Quick Links…

Our Website

Email

Join Our Mailing List!

Electronic Common Technical Document (eCTD)

CTI has prepared both paper and electronic regulatory submissions for more than a decade since we began clinical trial and consulting work for our biotech and pharmaceutical clients. Now, CTI has expanded our in-house capabilities to include electronic publishing and submission of regulatory documents. Using Quantum™ software from Octagon Research Solutions, **CTI can now prepare regulatory submissions in eCTD (electronic Common Technical Document) format, which is the worldwide standard for electronic submission of regulatory documents.**

An eCTD is comprehensive and includes defined places for clinical study protocols, amendments, and reports; annual reports; preclinical studies; correspondence with regulatory agencies; country-specific forms; chemistry, manufacturing, and control information; and all of the overviews and summaries required for marketing applications. The eCTD structure serves as a backbone for CTI to build drug product dossiers from the foundation in an electronic format. It places every document in a specified section and facilitates efficient review by global regulatory authorities. Electronic links are created throughout the published documents to allow instant navigation from any point to any other point where related information can be found.

CTI can develop, publish, and submit eCTD marketing applications in the United States, Europe, Canada, and some countries in Asia and Latin America. In Europe, eCTD submission of marketing applications is already mandatory, and in other countries will be mandatory soon. In the US, the FDA currently accepts both paper and eCTD submissions for NDAs, but has announced that eCTD submissions will become mandatory 2 years after final guidance is issued. The exact date for the beginning of mandatory electronic submission of NDAs in the US has not been announced, but is likely to be in 2015. Mandatory electronic submission of INDs will follow, possibly in 2016.

Using the eCTD format simplifies life-cycle management for regulatory submissions from the IND to the BLA or NDA in the US and from the

Contact Us

If you are interested in scheduling a meeting with CTI, please contact Nick Schatzman at 513-598-9290 or via email at nschatzman@ctifacts.com

marketing application through all post-approval submissions in Europe. Once a regulatory submission has been created in eCTD format, all of the following submissions for that product can be added to the existing structure, an efficient process which saves time and avoids re-work.

CTI looks forward to continuing to utilize our regulatory expertise with the various agencies to create documents for submission and help our clients navigate the regulatory process throughout the life-cycle of their products. With eCTD publishing and submission capabilities added to our suite of services, we can now offer a seamless process from the earliest stages of drug development consulting through formal submission of documents electronically to the regulatory agencies. **During the current time of transition from paper to electronic regulatory document submission worldwide, CTI has the expertise needed to help our clients understand and comply with the evolving document submission requirements.**

For additional information about eCTD publishing and submission, please contact us.

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About CTI

CTI Clinical Trial and Consulting Services is a repeat winner of "Best Places to Work" in Greater Cincinnati

CTI Clinical Trial and Consulting Services (CTI) is a unique drug and market development company offering a full range of services which encompass the entire lifecycle of drug development. These services include regulatory pathway design, clinical trial management, data analysis, medical writing, CME and training program development, market analysis and development and other consulting services. CTI focuses on the specific disease areas of solid organ transplant, hepatitis, infectious disease, end-stage organ disease and hematology/bone marrow transplant. With its combined expertise of clinical knowledge and market experience, CTI is uniquely positioned to incorporate both clinical and market driven endpoints and interpretations to provide extraordinary results.