CTI Clinical Trial and Consulting Services

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CTI Clinical Trial and Consulting Services named "Best Places to Work" in Greater Cincinnati for Second Consecutive Year

Upcoming Medical Meetings CTI will be Attending ...

CTI will have a significant presence at upcoming medical meetings over the next few months.

American Transplant Congress
Philadelphia, PA
April 30th – May 4th

Digestive Disease Week 2011
Chicago, IL
May 7th – May 10th

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

The Voluntary Harmonization Procedure (VHP)

The national implementation of the EU Clinical Trials Directive (2001/20/EC) has not been very effective in reducing the diversity of the national regulatory requirements across the EU. This results in a time consuming and complex procedure during the start-up phase of any European multinational clinical study.
Therefore, in 2009 and 2010, the EU Clinical Trials Facilitation Group (CTFG) defined the VHP as a voluntary regulatory pathway that harmonizes some of the EU regulatory procedures being mandatory in single member states.
Any VHP starts with an electronic submission of the abbreviated CTA documentation from a sponsor to the central VHP coordinator (VHP-C) who will review the CTA on completeness and forward it to the participating national competent authorities (P-NCAs) within 5 days. The P-NCAs will review and return their assessment back to the VHP-C who informs the sponsor about the single responses within 30 days. In case of a unanimous approval by all reviewing parties, the sponsor has to submit the CTA again within 20 days to each P-NCA, who then have 10 days to return their feedback back to the sponsor.
Although the above example certainly describes a best case scenario, it is likely that the VHP procedure is, in general, significantly less time consuming and complex than the conventional multistate procedure.

In summary:

- VHP represents a one-stop-shop for CTAs
- VHP requires e-submission
- Timelines for sponsors and NCAs are well defined
- Substantial Amendments are within the Scope of VHP

If you are considering which geographies to conduct your upcoming study, please contact us to discuss timelines among other considerations.

Employee Update

Please welcome the newest addition to CTI:

Nrupali Gandhi – Clinical Safety Scientist

Congratulations to the following CTI employees recently promoted:

Shawna Bredek – Associate Director, Clinical Trials

Quick Links...

Our Website

Email

Join Our Mailing List!

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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.