CTI
Clinical Trial and Consulting Services

June Newsletter

Where Life-changing Therapies Turn First

Volume 11, Issue 6

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

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

Employee Update

Congratulations to the following CTI employees recently promoted:

Erin Kraus – Associate Study Manager

Sandy Stagge – Director, Clinical Trials

Nick Schatzman – Senior Business Development Associate

Please welcome the newest additions to CTI:

Dr. Ralph Campaneria – Medical Director

Clinical Trial Considerations – US vs. EU

While clinical trials across the world have many similarities, there are certain considerations to take into account when planning for a trial in the EU. CTI regularly conducts studies in both geographies and can assist in your planning needs.
CTI has offices in North America, Latin America, and throughout Europe, in addition to regional employees that span the globe. Approximately 40% of our active trials include international sites and we are currently managing trials in more than 20 countries.

Below is an overview of the major differences between the US and the EU:

	US	EU
Regulatory Authority	FDA (US)	Competent Authority (per country) EMA (Europe) for marketing authorization (MA)
Regulatory Authority Submission Document(s)	Investigational New Drug (IND) Can use same IND for multiple trials (protocols) of same investigational drug IND results may be developed into a New Drug Application in the Common Technical Document (CTD) format	Clinical Trial Application (CTA) Submit a new CTA for each clinical trial A series of CTAs may contribute to the clinical part of a Common Technical Document (CTD), called Module 5 and potentially also to Marketing Authorization (MA)
IRB/Ethics Committee	IRB (usually only one type of submission) • Central (national) • Local (institution)	Ethics Committee (varies by country and region) • Central (national and regional) • Local (institution)
Insurance	Described in the site contract and Informed Consent (ICF)	Requires a separate "Certificate of Patient Insurance" but is also described briefly in the protocol as well as the ICF

Ed Kouche - Director, International Accounting and Finance

Mark Vogele – Senior Regulatory Specialist

Bonnie Graham – Clinical Safety Scientist

Anna Litowczenko – Senior CRA, Poland

Quick Links…

Our Website

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	US	EU
Legal Representative	N/A	All non EU Sponsors must have a designated Legal Representative established in the EU. This is a natural or legal person established in the EU who, explicitly designated by a non-European manufacturer, takes over on his behalf full responsibility for all activities related to the conduct of a clinical trial in the European Economical Area (EEA)
Payments	Typically pay site only	Typically pay multiple parties at a site depending on number of contracts
Translations	Minimal translation costs except ICF translations if needed	Major translation costs for regulatory submissions, ICFs, site contracts, SAE documentation, etc.
Project Team	Many have cost efficient staffing due to one country and one language	CRAs and regulatory staff needed for each country and language. Staffing may not be as cost efficient.
Responsible Person EudraVigilance (RPEV)	N/A	All trials must have an assigned RPEV who is responsible for SUSAR Reporting (expedited reporting) and e.g. annual reports in the context of clinical trials in the EU. RPEV reports into the Eudravigilance Clinical Trial Module (EVCTM) and **can be located outside the EU.** This role is sometimes confused with the Qualified Person Pharmacovigilance (QPPV) which is specific to marketed medicines and must be located in the EU.
Qualified Person Drug	N/A	This Qualified Person Drug **has to be located in the European Community** and needs the qualification to act as importer (if the IMP is produced outside EEA), and he/she needs a Manufacturer Authorization and a Qualification Certificate by an Authority of a Member State of the European community. This Qualified Person is responsible for Drug Release
Coordinating Investigator	N/A	All multicenter trials need a Coordinating Investigator per country who is assigned the responsibility of other Investigators at different centers

		across a country

As a midsize CRO, **CTI provides the flexibility absent at many large CROs and has the ability to provide a dedicated team to each complex global clinical trial we manage ensuring successful execution.** Due to our therapeutic expertise, we are frequently asked to provide innovative solutions to support global trial needs and have developed effective models to successfully execute trials with sites located throughout the world. **CTI's experience in global project execution has lead to successful results for our Sponsors as evident by a 95% repeat business award rate.**

Keep a look out for more clinical trial highlights about the EU and other regions of the world in future additions of this newsletter!

For more information, please contact:
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About CTI

CTI Clinical Trial and Consulting Services is an innovative, international drug and device development organization that delivers a full spectrum of clinical trial and consulting services from bench to commercialization with a focus on immunology and a passion for helping life-changing therapies succeed in chronically and critically ill patient populations. CTI's focused therapeutic approach provides pharmaceutical, biotechnology and startup firms with clinical and disease area expertise from a unique mix of academic, medical and industry specialists; rich intellectual capital in transplantation, immunology, infectious diseases, hematology, cardiology, nephrology, hepatology, regenerative medicine and rare diseases; flexible study designs that accelerate development programs and deliver high approval ratings that are among the best in the industry; and exceptional global project management and gold standard safety and data management systems that strengthen their program's success potential. Established in 1999 and headquartered in Cincinnati, OH; CTI has offices in North America, Europe and South America.