CTI CLINICAL TRIAL & CONSULTING

Newsletter

Where Life-changing Therapies Turn First®

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Developing Clinical Evaluation Reports

What is a CER?

A Clinical Evaluation Report (CER) summarizes the identification, appraisal, and analysis of relevant clinical data pertaining to a medical device, and establishes whether there is adequate evidence to support device safety and performance when used as intended by the manufacturer.

The CER is part of the regulatory documentation supporting market approval (known as CE-Marking) for medical devices sold in Western Europe and other non-US countries. *Every medical device sold in these areas requires a CER.*

Every medical device sold in the European Economic Area requires a Clinical Evaluation Report.

The clinical evaluation is an ongoing process throughout the lifecycle of the device, beginning with the initial CER and continuing with re-certification of existing CE-marked products as well as those that have undergone significant changes in design, software, labeling, etc.

Imagine if the FDA required renewal of existing PMAs or 510(k)s for every marketed medical devices every two to five years. In fact, this is a "real-world" dilemma affecting clients who develop, manufacture, and market medical devices in Europe. Without securing CER renewal, there can be no sales of existing CE-marked devices within Europe.

Recently, the new European Union Medical Device Regulations were adopted about one year after the CER guidelines (MEDDEV 2.7.1/4) underwent a near-complete revision. They focus, in part, on rigorous requirements for device equivalency as well as higher expectations for the validity of clinical evidence and state of the art therapies.

Depending on the type of medical device and the amount of available data, CER preparation can be a time-consuming and resource-constrained process.

How CTI Can Help

CTI has provided Clinical Evaluation Reports for many medical devices, including new launches, established devices, and periodic follow-up reports on devices for which we previously provided initial CERs. Our CER specialists at CTI meet or exceed the new requirements for education and professional experience set forth by MEDDEV 2.7.1/4, and have the knowledge and experience necessary to deliver high-quality CERs that meet our client's needs.

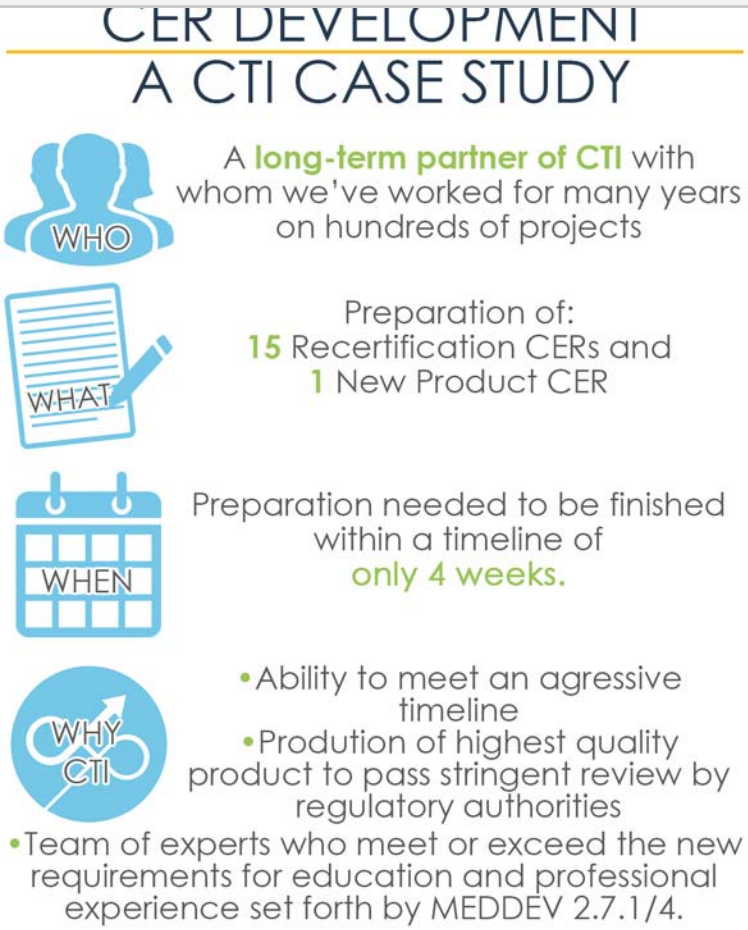
CTI has developed CERs and provided support to our CER clients in several ways - from completing the systematic literature review that produces the data to support the device, to writing specific CER sections, to development and ownership of the full document. Our CTI experts will work efficiently and effectively, in collaboration with the client, to develop a concise yet thorough CER, resulting in acceptance by the governing body.

CTI Cares Spotlight:

down syndrome association of greater cincinnati

The Down Syndrome Association of Greater Cincinnati (DSAGC) was established in 1981 to empower individuals, educate families, enhance communities and together, celebrate the extraordinary lives of people with Down syndrome. The DSAGC serves southwest Ohio, northern Kentucky and southeastern Indiana including Hamilton, Butler, Brown, Clermont, Warren, Highland, Clinton, Adams, Boone, Campbell, Kenton and Dearborn counties. Its constituency is composed of 1,400 individuals with Down syndrome of all ages, 3,000 family members and over 300 local professionals.

Nominated by: Emily Munafo, Human Resources Generalist



We welcome the opportunity to discuss an efficient process that will meet the regulatory requirements and minimize your time and efforts so you can focus on your products and customers.

New Additions & Promotions at CTI

Matt Bobinski promoted to Senior Study Manager

Frank Ernst joins as Executive Director, Health Economics and Outcomes Research

Brian Johnston promoted to Director, Clinical Trials

Michael Minshall joins as Director, Health Economics and Outcomes Research

Allison Schroeder promoted to Senior Manager, Marketing & Corporate Communications

Jim Westerkamp promoted to Vice President, Consulting Operations

John Williams promoted to Associate Director, Clinical Monitoring

Tom Winrod promoted to Director, Clinical Trials

Upcoming Meetings We Will Be Attending

CAR-TCR Summit
Boston, MA
September 11-12

Transplant Administrator Conference
San Diego, CA
September 15-16

Acute Chronic Liver Failure Meeting
Chicago, Illinois
September 5-8

To schedule a meeting with us at one of these, please click here

Join our Team! We're looking for individuals to fill these positions:

Assistant Director, Medical Writing (Greater Cincinnati, OH Area)

Assistant Manager, Study Coordination (Greater Cincinnati, OH Area)

Clinical Research Associate (US, UK, Germany, France, Spain, Australia, Brazil, Korea, Taiwan, Japan, Argentina, Singapore, Thailand, Isreal)

Clinical Quality Assurance Auditor (Greater Cincinnati, OH Area)

Manager, HECOR (Greater Cincinnati, OH Area)

Marketing Associate (Greater Cincinnati, OH Area)

Regulatory Specialist (Greater Cincinnati, OH Area)

(Greater Cincinnati, OH Area)

Senior Director Operations, Regulatory Affairs & Medical Writing (Greater Cincinnati, OH Area)

Study Manager (Greater Cincinnati, OH Area; Raleigh, NC; Philadelphia, PA; San Francisco, CA; London, UK)
Click here for more information and to apply!