maxer CONSULTING

EMA CLINICAL TRIAL INFORMATION SYSTEM (CTIS)

TRAINING PROGRAMME

The application of EU Regulation 536/2014 requires a general understanding of its objectives and an adequate level of information on the components and functionalities of the EMA Clinical Trials Information System (CTIS). Managing the life cycle of Sponsors' clinical trials through CTIS urges making timely decisions. The trials already registered in EudraCT may require transition to CTIS. The ones that will register before January 31, 2023, need an early assessment to decide whether to submit the Clinical Trial Application according to the Directive EC/2001/20 or EU Regulation 536/2014. Lastly, the clinical trials with the "last patient, last visit" date planned after January 31, 2025, will have to comply with the Regulation and be submitted under CTIS.

CTIS MASTER TRAINER PROGRAMME

After obtaining the EMA CTIS Master Trainer certificate, Maxer has developed a training course, available in English or Italian, based on the EMA CTIS Master Trainer Programme. The training course is divided into two sessions of four hours each and deals with the following topics:

1. Background

Historical and regulatory framework of the path that led to the approval of Regulation 536/2014 and the operation of CTIS.

2. New concepts in CTIS

Based on Regulation 536/2014, CTIS has integrated some essential innovations, e.g., low interventional trials, co-sponsorship, etc.

3. Transition from the Directive to the Regulation

Based on the expected date of the LPLV, the trials already registered on EudraCT must be subject to a strategic assessment of whether to remain in EudraCT or to transit to CTIS.

4. Overview of the sponsor workspace

The CTIS environment accessed by the sponsors has functionalities that, to be managed appropriately, require the acquisition of some basic knowledge.

5. Management of users and organisations

CTIS users must register in different ways according to the type of profile; high-level administrators, in particular, are responsible for approving the request for registration of colleagues or third parties (i.e., CROs or vendors) with operational responsibilities.

6. How CTIS Clinical Trial Application process works

The fundamental processes of CTIS show significant differences compared to the ones based on the EC Directive 2001/20. This section describes how to undertake and complete them.

7. Management of RFIs while creating a CTA

One of the most critical aspects of CTIS is the management of response times to the Request For Information sent by EMA or one or more Member State Concerned. EEU/ EEA MS calendars will be uploaded by EMA in CTIS and used to calculate due dates. Task timer calculation is based on specific ground rules.

8. Templates for CTIS applications

EMA has created templates that support the four types of applications foreseen in CTIS: initial application (IN), additional MSC application (AMSC), substantial modification (SM), non-substantial modification (non-SM). The templates provide an overview of the data fields and documents that sponsors need to complete in clinical trials applications to be submitted to CTIS.

9. Data Transparency: how to publish results

CTIS provides methods for publishing the trial results substantially different from EudraCT: no longer structured information but a document in two versions: one in full for the regulatory authorities, one anonymised and written for the public. In addition, the drafting of the layperson summary for each trial becomes mandatory.

10. Questions & answers from the CTIS Master Trainer forum

The group of participants in the EMA Master Trainer has addressed some of the most controversial issues of CTIS. The training programme leverages them to provide concrete answers to the most frequently asked questions.