DIA RESOURCE GUIDE 2014

Clinical Trial Disclosure: Towards a More Transparent World

DIA DEVELOP INNOVATE ADVANCE

Clinical Trial Disclosure: Towards a More Transparent World

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Introduction

Transparency of clinical trial information is taking on new dimensions, including the release of participant-level data. Discussions now focus on the different mechanisms for transparency and their scope, objectives, and audiences. This increased transparency changes the availability and use of information from clinical trials and brings with it new data-use opportunities and operational challenges for industry and academia.

On October 1-2, 2013, DIA held the meeting: Clinical Trial Disclosure: Towards a More Transparent World to take a closer look at these issues. From that meeting, we have compiled this resource guide to walk you through the:

- current clinical trial disclosure requirements in the US and EU;
- interrelationships among medical writing, regulatory affairs, and clinical trials disclosure teams to maintain consistency for protocol registration and results reporting;
- impact of greater transparency in the clinical trial disclosure environment on industry and academia; and
- advantages and implications of the availability of clinical trial disclosure databases.

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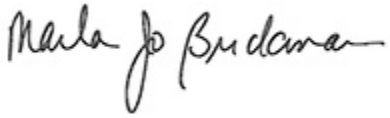

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An Update on Clinical Trial Registries and Results Disclosure in the EU and US

EudraCT V9–Publication of Result-related Information in Europe

EudraCT is a registry of information on all interventional clinical trials of medicinal products with the following characteristics:

- At least one site in an EU or European Economic Area (EEA) country
- At least one site in a non-EU/EEA country if part of a pediatric investigation plan (PIP)
- Started on or after May 1, 2004

EudraCT contains data on more than 7 million participants in 35,000 clinical trials in adults and 3,000 trials in children.

The full EudraCT dataset is accessible only to EU and EEA regulators, but some EudraCT data are available to the public through the EU Clinical Trials Register (EU CTR) and the World Health Organization's (WHO's) International Clinical Trials Registry Platform.

Components of two EU regulations—Article 57(2) of Regulation (EC) No 726/2004 published in 2004 and Article 41 of Regulation (EC) No 1901/2006 published in 2006—called for posting and publishing result-related information on clinical trials. The EU subsequently published guidelines specifying the clinical trial results that must be entered into EudraCT.

The current version of EudraCT, V8, contains only protocol-related information on clinical trials. The EMA is upgrading EudraCT to enable sponsors to enter clinical trial results into EudraCT for publication in the EU CTR. In developing V9, the EMA worked closely with colleagues in the United States (NIH) to ensure consistency with the data model of ClinicalTrials.gov and regarding standardization of the data formats for uploading. In EudraCT V9, clinical trial sponsors, PIP addressees, and ministries of health will be able to post clinical trial results using the EudraCT interface or by uploading an XML file. After the results are submitted, an automated system will complete a technical validation of the data. If the validation findings are positive, the results dataset will be made publicly available on the EU CTR within 15 days for.

- Phases 2–4 trials in adults and Phase 1 trials in adults only if part of a PIP
- Phases 1–4 trials in children

The posting party will be able to add updates later, but earlier versions will continue to be available to the public. The EMA will be able to remove information that is not valid or add a note to this effect.

The deadlines for posting results to EudraCT are listed in Table 1.

Table 1. Deadlines for Posting Clinical Trial Results on EudraCT V9

Clinical trial end date	Type of	Deadline for	Type of information