DIA Trial Master File Reference Model: Overview and Implementation

Event #10234 • June 10, 2010

10:00-11:00 AM EDT | 8:00-9:00 AM MDT | 4:00-5:00 PM CET
9:00-10:00 AM CDT | 7:00-8:00 AM PDT | 3:00-4:00 PM BST

PRESENTERS

KAREN ROY
Global Business Development Director
Phlexglobal Ltd.

LISA MULCAHY
Mulcahy Consulting LLC

FRAN ROSS
Continuous Process Improvement Senior Analyst
Genzyme Corp

CAROL SMITH, MBA, MT (ASCP)
Director, Clinical Documentation
Cephalon, Inc.

IVAN WALRATH
TMF Process Owner
Pfizer, Inc

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

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A collaborative effort of 120 representatives from 87 biopharmaceutical companies, contract research organizations, consultancies, technical vendors, and regulatory agencies has resulted in the definition of the DIA Trial Master File (TMF) Reference Model. This model consists of a standardized taxonomy and metadata and outlines the clear definition and organization of TMF content using standard nomenclature, which can be used and adapted by any company. This webinar will provide an overview of the TMF Reference Model, define its scope and application, and present practical use and views of the model by an industry panel.

FEATURED TOPICS

- Overview of the TMF Reference Model
  - What is TMF Reference Model?
  - Why Is the Model Needed?
  - Genesis of the Model
  - Benefits of the Model?
  - When Will the Model be Finalized and Launched?
  - Who Will Manage the Model?
- Scope and Application
  - Who Should Use the Model?
  - What Artifacts Does the Model Cover?
  - Paper Versus Electronic TMFs
- Practical Use of the Model
  - Industry panel that will present:
    - Why the Model Is Important
    - How the Model Will Be Adopted and Adapted

WHO SHOULD ATTEND

Professionals involved in trial master files, including:

- Clinical project managers
- Clinical research associates
- Records and document managers
- Quality assurance managers
- Regulatory managers
- Archivists
- Computer systems developers

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Technical Requirements for Audience Members

Browser
Microsoft® Internet Explorer 5.2 or higher
Netscape® Navigator 7

Computer
166Mhz Pentium-based PC with Microsoft® Windows® 98, NT, ME, XP or 2000
Sun JVM 1.4* for Microsoft JVM (all versions supported by Microsoft Windows OS shown above)
Sun SPARCstation with Solaris 8 or 9
Audience: 64 MB RAM

**If you need to install Java Virtual Machine (JVM) on your system, please download it from the Sun Microsystems website.*

Internet Connection Speed
56k or faster

Display
800x600 pixel resolution or greater (1024x768 pixels recommended)

Attendees using Macintosh OS
Microsoft IE 5.2
Macintosh OS 10.2X

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LEARNING OBJECTIVES

At the conclusion of this webinar, participants should be able to:

- Outline why essential documents listed in ICH E6 GCP Section 8 are not comprehensive enough for a TMF
- Discuss the purpose and intent of the TMF Reference Model
- Explain how three companies are adopting and adapting the model for the enhancement of their TMF processes

DIA Vision

DIA is the global forum for knowledge exchange that fosters innovation to raise the level of health and well being worldwide.

DIA Mission

DIA fosters innovation to improve health and well being worldwide by:

- Providing invaluable forums to exchange vital information and discuss current issues related to health products, technologies, and services;
- Delivering customized learning experiences;
- Building, maintaining, and facilitating trusted relationships with and among individuals and organizations that drive and share DIA values and mandates; and
- Offering a multidisciplinary neutral environment, respected globally for integrity and relevancy.

WEBINAR

CONTACT INFORMATION: Questions about this Webinar? Contact Wendy Moyer at the DIA office in Horsham, PA by telephone +1.215.293.5810, fax +1.215.442.6199, or email Wendy.Moyer@diahome.org.

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