Transitioning Clinical Trials from Directive 2001/20/EC to Regulation (EU) 536/2014
via the Clinical Trials Information System

15 December 2023
13:30 – 18:00 CET | Virtual Live Training Course

DIA Learning

| FACULTY

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| OVERVIEW

The live virtual training course aims to enhance knowledge in managing transition applications in CTIS. Legal basis, regulatory and operational aspects of transitions will be explained. Practical case studies to manage the transition in CTIS will be demonstrated. Participants will have the opportunity to ask questions in order to gain a comprehensive understanding of the CTIS transition activities required for compliance.

| KEY TOPICS

- Legal base and regulatory aspects
  - Clinical trials in scope for transition
  - Documentation requirements
  - Sources of references and guidance
- Operational aspects
  - Timing of transition and planning considerations
  - Consolidating versus harmonizing dossier components
  - Product cross-reference and "IMPD-Q only" application concept
- Procedural aspects
  - Master EMA database pre-conditions (IAM, OMS, XEVMPD)
  - Expected process (timelines, RFI/responses, substantial modification to complete transition dossier)
- Practical case studies to manage the transition in CTIS
  - Initial transition application
  - Subsequent Substantial Modification (SM)
  - IMPD-Q only application scheme

| LEARNING OBJECTIVES

At the conclusion of this virtual live training course, participants will be able to:

- Recognise the legal and regulatory aspects for transition.
- Develop a robust transition implementation strategy.
- Identify the transition application dossier components.
- Deploy the CTIS transition activities required for compliance.

| TARGET AUDIENCE

This training course is intended for professionals **with knowledge on CTIS functionalities and involved in transitioning clinical trials** such as

- Commercial Sponsors of clinical trials
- Non-commercial Sponsors of clinical trials
- CROs

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AGENDA | 15 DECEMBER 2023 | 13:30 – 18:00 CET

13:30 WELCOME NOTE AND INTRODUCTION

SESSION 1: LEGAL BASE AND REGULATORY ASPECTS

- Clinical trials in scope for transition
- Documentation requirements
- Sources of references and guidance

SESSION 2: OPERATIONAL ASPECTS

- Timing of transition and planning considerations
- Consolidating versus harmonizing dossier components
- Product cross-reference and "IMPD-Q only" application concept

SESSION 3: PROCEDURAL ASPECTS

- Master EMA database pre-conditions (IAM, OMS, XEVMPD)
- Expected process (timelines, RFI/responses, substantial modification to complete transition dossier)

15:00 BREAK

15:30 SESSION 4: PRACTICAL CASE STUDIES TO MANAGE THE TRANSITION IN CTIS

- Initial transition application
- Subsequent Substantial Modification (SM)
- IMPD-Q only application scheme

18:00 END OF THE TRAINING COURSE

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