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**Interactive Training in Applied GCP for Investigators & Site Personnel**

Institute of Oncology

Ljubljana, Slovenia

5 April 2024

INTRODUCTION

Performance of clinical trials according to the Good Clinical Practice (GCP) standard has been introduced as a European regulatory requirement for clinical trials with medicines but as this is a globally agreed best practice standard for clinical research involving human subjects, it is an ethical obligation for clinical researchers to apply this standard to all type of studies to ensure optimal protection of participants and generation of reliable results. It is the basis for enabling funding, acceptance of publications and for patients’ access to new treatments. This standard has implications for all stakeholders and processes in clinical trials. However, despite overall commitment and best intentions to apply to these requirements, monitoring, audits and inspections regularly find deficiencies of different levels of severity.

In this interactive 2 mornings lectures current experience and requirements of GCP-conform set-up and performance of clinical studies will be presented, practical implications and examples discussed and pragmatic solutions for your daily practice elaborated.

FACULTY

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AGENDA

09:00 Welcome and Introduction

09:05 ICH-E6(R2): Good Clinical Practice Principles and Guideline Content Questions & Answers

10:15 The Informed Consent Process from the Investigator Perspective Questions & Answers

11:00 Break

11:20 Responsibilities of the Investigator for the Set-up of a Clinical Trial at the Site Questions & Answers

12:00 Compliance in Document Management Questions & Answers

13:00 Lunch

14:00 Sponsor-Investigator’s Responsibilities for Critical Elements in Conducting Clinical Trials Questions & Answers

15:00 PI’s responsibilities in Safety Reporting in Clinical Trials Questions & Answers

15:30 Risk-adapted Management of Clinical Trials Questions & Answers

16:15 Multiple Choice Test

17:15 End of the Training