Training Certificate

Mauro José Pappaterra

has participated in a 4 h course

Introduction to Good Clinical Practice

MS Teams meeting on

02-JUN-2021

The training was prepared and conducted by a member of AM Quality Department with more than 20 years experience in clinical research

Gavin Robert Wood PhD

Course elements:

- Relevant GCP definitions
- Principles of GCP
- Role of the IEC
- Tasks and duties of the investigator
- Tasks and duties of the Sponsor/the CRO having been delegated trial related functions
- The ethical principles in clinical research Declaration of Helsinki/Taipei/Geneva
- Fundamentals of data integrity requirements
- Trial Master File / essential documents
- Good Documentation Practice
- GCP aspects in imaging studies
- Pseudonymization and General Data Protection Regulation in the context of clinical research

The above element were chosen considering the TransCelerate “Minimum Criteria for ICH E6 (R2) GCP Investigator Site Personnel Training” and the services and tasks of Antaros Medical as a CRO performing imaging reads.

Antaros Medical