

Certificate

We hereby confirm that

Dr. Maria Paula Vazquez Pianzola

has passed the course exam

**Clinical Investigators I: Basic GCP & clinical research
training**

and ECTS 1.0 have been awarded.

Bern, 09. Mär 2023



PD Dr. med. Sven Trelle
Director, CTU Bern

Certificate of Attendance

We hereby confirm that

Dr. Maria Paula Vazquez Pianzola

participated in the course

Clinical Investigators I: Basic GCP & clinical research training

on 28 February 2023, organized by CTU Bern

Course contents: *(2-day course: self-learning 5.5 h & lectures 7.5 h)*

- Ethics and history
- Swiss Human Research Act
- ICH Good Clinical Practice Guideline E6 (R2)
- Basics of clinical research and study designs
- Critical appraisal of a clinical trial
- Clinical Data Management
- Monitoring
- Patient information and consent
- Safety

References:

This course is based on:

- Federal Act on Research involving Human Beings SR 810.30, version of 26.05.2021
- Ordinance on Clinical Trials in Human Research SR 810.305, version of 26.05.2021
- Ordinance on Human Research with the Exception of Clinical Trials SR 810.301, version of 26.05.2021
- ICH Harmonised Tripartite Guideline E6 (R2) Guideline for Good Clinical Practice, version of 10.11.2016

Additional note:

Swissethics confirmed that this training program fulfils the published requirements for Investigator Level courses. Participants finishing this training program fulfil the requirements of Art. 10 HRA and Art.6 ClinO.

The attendance is acknowledged with:

8 credits of the SGKPT, Schweizerische Gesellschaft für Klinische Pharmakologie und Toxikologie

8 credits of the SGPM, Schweizerische Gesellschaft für Pharmazeutische Medizin

Bern, 28 February 2023



PD Dr. med. Sven Trelle
Direktor
CTU Bern