

LIST OF MOST IMPORTANT TRAININGS

- May 2005 (**Utrecht, The Netherlands**): ISO training
- September 2005 (**on-line training**): CRO's (name reserved) SOPs training with final test
- January 24th – 26th, 2006 (**Cambridge, United Kingdom**): database and clinical trial management system training
- Throughout 2005 and 2006 (**on-line training**): several online Novo Nordisk SOPs training
- December 3rd, 2007 (**Milano, Italy**): Quintiles' GCP training with audit simulation
- February 12th - 13th, 2008 (**Uxbridge, United Kingdom**): Electronic Data Capture (EDC) training
- March 4th – 7th, 2008 (**Zermatt, Switzerland**): communication strategy and quality control training
- April 1st – 2nd, 2008 (**Milano, Italy**): EDC training
- January 16th, 2009 (**on-line training**): GCP training successfully performed at PharmaSchool
- March 19th – 22nd, 2009 (**Zermatt, Switzerland**): communication strategy and quality control training
- May 18th, 2009 (**on-line training**): EDC training
- February 9th – 14th, 2010 (**Zermatt, Switzerland**): communication strategy and quality control training
- April 16th, 2010 (**on-line training**): EDC training
- May 21st, 2010 (**on-line training**): escalation of quality issue
- July 19th, 2010 (**on-line training**): escalation of quality issue
- February 2nd – 6th, 2011 (**Zermatt, Switzerland**): communication strategy and quality control training
- From May to September 2011 (**on-line training**): several on-line trainings regarding GCP, aseptic technique, fire safety, privacy, bribery, HIPAA and more
- January 25th – 29th, 2012 (**Zermatt, Switzerland**): communication strategy and quality control training
- March 23rd, 2012 (**on-line training**): IATA training (version 4.0)
- September 22nd, 2012 (**on-line training**): Barnett GCP training
- February 5th, 2013 (**on-line training**): Code of Conduct
- June 6th – 7th, 2013 (**Palermo, Italy**): real life monitoring training
- August 22nd, 2013 (**on-line training**): Roche Transcelerate GCP training
- September 15th, 2013 (**on-line training**): Policy Guidelines on Corporate Communications
- May 15th, 2014 (**on-line training**): anti-corruption training
- June 8th, 2014 (**on-line training**): Barnett GCP training
- November 30th – December 2nd, 2015 (**Barcelona, Spain**): Investigator Meeting with professional training/update
- February 21st – 23rd, 2016 (**Atlanta, USA**): Investigator Meeting with professional training/update
- October 8th, 2016 (**on-line training**): ClinTrak EDC system
- October 9th, 2016 (**on-line training**): The Global Health Network GCP training
- October 4th – 5th, 2017 (**London, United Kingdom**): Professional training/update
- October 25th – 26th, 2017 (**Vienna, Austria**): Investigator Meeting with professional training/update
- March 15th – 16th, 2018 (**Rotterdam, The Netherlands**): Cultural awareness, innovation in Coronary Heart Disease, innovation in structural heart treatment, congenital cardiology and case description, ISO 14155 versus GCP, General Data Protection Regulation, Medical Device Regulation
- September 24th, 2018 (**on-line training**): NIDA GCP training certificate
- September 26th - 27th, 2018 (**London, United Kingdom**): Sponsor's general training
- January 24th - 25th, 2019 (**Miami, USA**): Sponsor's general training

- *March 26th - 27th, 2019 (Köln, Germany)*: Sponsor's general training
- *May 16th, 2019 (Amsterdam, The Netherlands)*: Sponsor's general training
- *June 14th- 15th, 2019 (München, Germany)*: Investigator/CRA Meeting with professional training/update
- *February 3rd, 2020 (on-line training)*: Conducting a Site Evaluation Visit; Conducting a Site Initiation Visit; Conducting a Periodic Site Visit; Conducting a Site Termination Visit; Financial Disclosures by Clinical Investigators; Good Documentation Practice; Incident Management; On-site IMP Accountability; Preparation, Filing, Storage and Transfer of Essential Documents; Project Team Transition; Protocol Deviation Management; Regulatory Agency Site Inspection Preparation Visit; Regulatory Approval for Shipment of IMP to Clinical Sites; SAE Reporting; Serious or Persistent Non-compliance; Suspected Fraud in Bioresearch
- *June 4th, 2020 (on-line training)*: COVID-19 Emergency Business Practice; COVID-19 Remote Monitoring Business Practice
- *August 24th, 2020 (on-line training)*: Good Clinical Laboratory Practice (GCLP) - Sample Management, Conduct of The Work, Data Recording and Data Reporting
- *August 24th, 2020 (on-line training)*: Good Clinical Laboratory Practice (GCLP) – Quality Management
- *October 7th, 2020 (on-line training)*: Research in Global Health Emergencies – Ethical Issues
- *November 23rd, 2020*: 21 CFR Part 11 Compliance Training for Operations
- *November 24th, 2020*: GCP_ICH E6 R2 Advanced Overview Clinical Operations
- *November 25th, 2020*: Global Data Privacy Regulation (GDPR)
- *November 28th, 2020*: Escalation of Significant Noncompliance
- *December 4th, 2020*: Remote SDV according to Communication AIFA dated 17Sep2020, EU commission Guidance and applicable Memos to File
- *November 28th, 2020*: HIPAA Training
- *January 3rd, 2021 (on-line training)*: IQVIA GCP eLearning
- *March 15th, 2021*: Clinical studies CTAs and legal documents for EMEA
- *March 15th, 2021*: Clinical studies CTAs and legal documents for North and South America
- *March 19th, 2021*: Italian regulation overview (Part 2)
- *April 13th, 2021*: Worldwide anti-corruption policy, procedures and compliance certification
- *April 14th, 2021*: Centralised Monitoring & Surveillance Department Overview
- *June 15th, 2021*: GCP section 2 - ICH, harmonization and GCP principles - An introduction to ICH E6
- *July 1st, 2021*: Italian regulation overview (part 2)
- *August 9th, 2021*: Corporate-wide policies code of conduct
- *August 9th, 2021*: The reporting of safety information to regulatory authorities, ECs-IRBs
- *October 11th, 2021*: GMO studies - Submission process and timelines
- *October 18th, 2021*: Metabolism Pharmacocynetics
- *October 27th, 2021*: IMP essentials
- *November 19th, 2021*: Quality Risk Management Applied for Clinical Trial Projects, GCP relevant Processes and Systems
- *November 25th, 2021*: Process of obtaining Consent Form from routine to Clinical Trials
- *November 29th, 2021*: Update on ICH E8
- *November 29th, 2021*: Regulation (EU) #536/2014 – Safety reporting considerations
- *November 29th, 2021*: Audit Trial review – Practical aspects
- *February 2nd, 2022 (on-line training)*: NIDA GCP training
- *February 14th, 2022*: Writing and reviewing Action Items
- *February 14th, 2022*: Notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol
- *February 14th, 2022*: (EU) No. 536/2014 Labelling - New labelling requirements for IMP and AxMP

- *February 25th, 2022*: New CTS and readiness of Italy overview
- *April 4th, 2022*: Central Risk Management
- *May 20th, 2022*: Update about Italian regulation
- *June 30th, 2022*: Trip Report MVR writing
- *November 15th, 2022*: Quarterly Training of Italian Staff: Requirements for electronic source data and electronic patient files and Remote Source data verification
- *March 17th, 2023*: Round table about the recent decrees regarding the Ethic Committees in Italy
- *May 19th, 2023*: The development of the Clinical Research
- *June 7th, 2023*: Internal audit for compliance with MoH Decree - Findings and Actions
- *June 22nd, 2023*: Management of IMP on-site, Site Delegation Log-CV and staff documentation, Site management according to CTIS
- *June 23rd, 2023*: Digital therapies – Challenge and opportunity for the clinical research, the health and the National Sanitary System
- *June 23rd, 2023*: Stability and expiration dates of the clinical trials batches
- *June 24th, 2023*: Statistic calculation
- *September 9th, 2023*: GCP - Annual GxP refresher training
- *March 8th, 2024*: Handling of Safety Information Received By Non-Safety Associates Knowledge Assessment
- *May 17th, 2024*: Essential Documents Quality Review Assessment
- *July 9th, 2024*: Regulatory inspection management
- *July 9th, 2024*: Sponsor audit process
- *November 15th, 2024*: ISO 14155-2020 Good Clinical Practice for Medical Devices
- *November 20th, 2024*: GCP training
- *November 27th, 2024*: GCP refresher
- *February 5th, 2025*: IATA Dangerous Goods Regulations 66th Ed. v. 25
- *February 5th, 2025*: Understanding ISO 14155-2011 for Medical Devices (v. 1.0)
- *June 7th, 2025*: ICH GCP E6(R3) training
- *June 7th, 2025*: Monitoring Knowledge Check
- *July 26th, 2025*: ICH GCP E6(R3) training
- *September 12th and 19th, 2025*: ICH E6(R3) GCP- The new era of Good Clinical Practice has begun. Organised by Assomonitor
- *March 2nd, 2026*: ICH GCP E6 (R3) certification exam
- *March 6th, 2026*: Economics of cybercrime
- *July 3rd, 2026*: Secure browsing