

INTERNATIONAL CLINICAL RESEARCH ACADEMY

405 Ogilvy Avenue, suite #101, Montreal, QC, Canada, H3N 1M3

DIPLOMA

This is to acknowledge that
Safra Fairuz, CCRP

successfully completed the Clinical Research Professionals (CRA/CRC) Certification Program

Duration: 200 academic hours. Course outline:

- ◆ Pharmaceutical Industry Overview
- ◆ History of Clinical Trials Regulations
- ◆ Ethical Principles Clinical Research
- ◆ Medical Terminology and CT Glossary
- ◆ Overview Of Drug Regulatory Process
- ◆ International ICH GCP Guidelines
- ◆ FDA Title 21 CFR and 45 CFR 46
- ◆ Canadian Clinical Trial Regulations
- ◆ Phases of Clinical Trials & requirements
- ◆ Roles of Sponsor, Investigator, CRA, CRC
- ◆ Institutional Review Board IRB/IEC/REB
- ◆ Informed Consent, ICD Design
- ◆ Safety Monitoring, AE/SAE Reporting
- ◆ Study Design, Preparation, Start-up
- ◆ Protocol and Case Report Form Design
- ◆ Clinical Trials Conduct, CRA & CRC Tasks
- ◆ Subjects Recruitment and Retention
- ◆ Site Evaluation and Site Selection Visit
- ◆ Investigator Meeting & Site Initiation Visit
- ◆ Monitoring Efficiency, Site Monitoring Visit
- ◆ Clinical Trial Site Management Activities
- ◆ Study Termination, Site Close-Out Visit
- ◆ Data Management in Clinical Trials
- ◆ Preventing Errors, Fraud and Misconduct
- ◆ Audits and Inspections
- ◆ DSMB Data Safety Monitoring Board
- ◆ HIPAA Compliance Requirements
- ◆ Essential Documents in Clinical Trials
- ◆ EDC and Clinical Trial Management Systems
- ◆ PMN Pre-Market Notification FDA 510(K)
- ◆ PMA Medical Devices Pre-Market Approval
- ◆ IDE Investigational Device Exemptions
- ◆ Time Management and Work Organization

President: _____

Svetomir Krastev, MSc, CCRA



Montreal, 7 March 2023

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