Clinical Research Training Program for the Clinical Research Associates (CRA)/ Clinical Research Coordinators (CRC

This Training program will be a 12-Week Program that will be ninety percent (90%) virtual due to CDC preventive guidance for COVID-19.

There are Twelve (12) modules to be completed by prospective students. There following Modules will be areas of foci:

Week	Modules	Titles	Descriptions indicating pertinent scopes		Remark
1	**Module 1 Billy**	**Introduction to Clinical Trial**	1. an overview of the drug development and clinical trials processes. 2. The discovery of new molecules, how discoveries become drugs or devices, the purpose of clinical and pharmaceutical research and development, the economics of drug development, cost/benefit analyses in clinical development, Phase I-IV clinical trials, and an introduction to the special problems of each phase 3. Elements of an investigational brochure (IB) and/or investigational device use (instructions for use) 4. Elements of and rational for subject eligibility requirements 5. Rationale for complying with a protocol 6. Study design characteristics (e.g. double-blind, crossover, randomized) 7. Study objective(s) and end points/outcomes 8. Use of supplemental/rescue/comparator product in study design	**Billy**	

			9. Treatment assignments (e.g. randomization, open label, registries) 10. Therapeutic area and/or available learning resources (e.g. standard of care versus research		
2	Module 2 **Tayo/Billy**	**Foundation of Good Clinical Practice in Clinical**. ***Using the Online resources***	This course introduces student to: 1. good clinical practice (GCP) in clinical research according to FDA regulations and International Conference on Harmonization (ICH) guidelines. 2. Conducting clinical trials in accordance with GCP; regulations established by state, federal, and international regulatory bodies; 3. and the roles and responsibilities of investigators, sponsors, monitors, and auditors. 4. Elements of an effective root cause analysis and corrective and preventive action (CAPA) plan, 5. Elements of and rationale for monitoring plan(s) Investigator's Brochure (IB) and 6. Monitoring responsibilities and Principals of Risk-Based monitoring 7. Responsibilities of various clinical trial entities/personnel (e.g. CRO, Sponsors, regulatory authority(ies), data manager) 8. Audit and Inspection processes (Preparation, participation, documentation, and follow-up	**Tayo**	

			9. Introduction to important Clinical trial activities (e.g. Pre-study activities, Site selection activities, Site initiation activities, Interim Visit activities, site close-out activities, study completion activities, staff qualifications activities and study team training requirements 10. Essential documents (e.g. Trial Master file (TMF) Investigative Site File)		
3	**Module 3 Tayo**	**Fundamentals of Clinical Research Management.** ***Using Online Resources***	The purpose of this module is to introduce you to the process and procedures of monitoring a clinical trial as a clinical research associate working for a pharmaceutical or device manufacturer (known as the sponsor) in the following outlines: 1. Focuses on trials conducted under U.S. FDA applications (INDs and IDEs). 2. The process of monitoring begins with creating a risk-based monitoring plan and progresses through selecting qualified investigators, executing the assessments defined in the monitoring plan, changing the plan and actions when problems and issues are identified, and closing the sites as their study participation concludes. 3. Sponsors follow Standard Operating Procedures for monitoring clinical trials, which are based on the FDA regulations as found in **21 CFR, Parts 11, 50, 54, 56, 312 and 812 and in guidance**		

			documents, such as the International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP) E6, E8, E9 4. Purpose, processes, and management of protocol compliance /non-compliance 5. Roles of various clinical trial entities/plans (e.g. Medical monitor, Vendors, IRR/IEC, Sponsor, CRO) **as guided by different parts of 21 CRF and GCP E6, E8, E9** 6. Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring. 7. Communication Documentation requirements (e.g. email, phone)		
4	**Module 4 Tayo**	**Clinical Trials and Site Management for** **1. CRC and** **2. CRA**	This course will cover and train the students: 1. the process of coordinating and managing a clinical study from the perspective of day-to-day operations of a clinical research study, from planning site logistics and constructing timelines for the study-initiation visit to closing out a study. 2. The course will focus on the operational, interpersonal, and data-management aspects of the process: Act as the main source of communication between site and sponsor. Evaluate trial sties for participation. Follow study plans (e.g. monitoring plan, communication plan).	**Tayo**	

			Obtain/verify vendor credentials (e.g. lab certification/licensure) 3. Sample/diagnostic collection, shipment verification, reporting and storage requirements. Verify equipment calibration and maintenance. Ensure proper collection, processing, and shipment of specimens (e.g. centrifuge, preparation of slides, freezing, refrigeration) 4. Monitor appropriate staff, facility, and equipment availability throughout the study: Identify issues and recommend investigatory/site corrective actions. Ensure adequacy of investigational product/device and associated supplies and ensure proper storage, dispensing, handling and disposition of investigational equipment and supplies use and maintenance 5. Study timelines 6. Subject responsibilities for study participation 7. Contracts and budgets (e.g. subject compensation, site payment) 8. Subject compliance assessment: Assess subject compliance. Re-evaluate the recruitment strategy as needed. 9. Subject responsibilities for study participation		

			10. Contracts and budgets (e.g. subject compensation, site payment)		
5	Module 5 **Tayo**	Pharmaceutical Law	The Course will discuss: 1. the presents principles and practices of the Federal Food, Drug and Cosmetic Act governing the research and development of pharmaceuticals and biologics for both humans and animals including an analysis of legal and social constructs affecting industry and 2. the academic clinical investigator with emphasis on FDA enforcement actions.	**Tayo**	
6	Module 6 **Billy**	Ethical Issues in Research	This course will discuss: 1. ethical issues to sound clinical research, review the foundations of regulations for clinical investigations, and to 2. better understand the operational imperatives of Good Clinical Practices 3. ensuring site's compliance with IRB/IEC requirements and other ethical considerations (e.g. Declaration of Helsinki, Belmont Report) and Identify the safety and expected therapeutic effects of the investigational product/device. Developing and/or following a recruitment strategy that complies with ethical considerations. And to recognize the importance subject confidential information and privacy regulations (e.g.HIPPA, GDPR)	**Billy**	

			4. Protocol deviation/violation identification, documentation, and reporting processes and Recruitment plan/strategies		
7	Module 7 **Billy**	Contemporary Issues in Human Research Protection	Human subjects are essential to the conduct of research intended to improve human health. As such, the relationship between investigators and human subjects is critical and should be based on **honesty, trust, respect**. The course will discuss: 1. Goals and Principles of Human Subjects Protection • Nazi Medical War Crimes • Syphilis Study at Tuskegee • Timeline of Important Historical Events 2. Privacy and Confidentiality in Protecting the Human subjects	**Billy**	
8	Module 8 **Simbiat/Tayo**	Current Federal Regulatory Issues in Biomedical Research	This course explores: 1. how the rapid pace of scientific discovery and the changing ways in which patients, researchers, policymakers, and the public interact are forcing a never-ending reassessment of how to govern biomedical research. 2. While most core principles remain in place, this course examines 3. where and how innovation requires a new look at existing approaches	**Tayo/ Simbiat**	
9	Module 9	Clinical Data Management	The course will discuss:	**Billy**	

	Billy		1. Data management activities 2. Data privacy principles and access to site/subject records 3. Elements and purposes of data collection tools (e.g. CRF/eCRF, patient reported outcome devices) 4. Elements of and process for data query (e.g. query writing) 5. Source documentation requirements (e.g. ALCOA-CCEA) 6. Record retention and destruction practices and requirements 7. Source data review (SDR) and source data verification (SDV) purpose and process 8. Elements of pharmacovigilance (e.g. CIOMS, IDMC/DSMB, safety databases)		
10	Module 10 Tayo	Clinical Project Management for CRA	This course will explore a strategic approach to pharmaceutical and medical device project management. Project management has been a well-established practice outside the pharmaceutical industry for many decades. However, with ever-increasing pressures of competitors, regulatory requirements, generic drugs and medical device innovations, its utilization is essential. It is more important than ever to use project management techniques to get products to market because, as we all know, "time is money".	**Tayo**/	
11	Module 11 **Billy**	Patient Recruitment and Informed consent CRC/CRA	Clinical trials represent the link between scientific discovery and medical effectiveness.	**Billy**	

			Hundreds of innovative therapies are developed in the laboratories, but few make it past early development, if at all. Clinical trials today can cost hundreds of millions of dollars and take years to research. New clinical research starting for pharmaceuticals and medical devices is on the increase. Investigational New Drugs (IND) submissions have been growing steadily over the past several years. In order to support the increase in research, it becomes more imperative to accelerate patient recruitment and enrollment. However promising new drugs and devices may be, the research cannot move forward without enough subjects who are willing to participate and who will remain for the duration of the study.		
12	Module 12 **Tayo/Billy**	Clinical Trials Research Practicum	Site rotations: shadowing the CRA and CRC on site.	Tayo/ Billy	

References:

1. https://medclinicalresearch.com/
2. https://www.online.drexel.edu/online-degrees/biomedical-degrees/cert-cr/index.aspx
3. https://grahamschool.uchicago.edu/academic-programs/professional-development/clinical-trials
4. https://atriumhealth.org/education/cabarrus-college-of-health-sciences/academic-programs/clinical-research-certificate-program
5. https://acrpnet.org/training/
6. https://acrpnet.org/certifications/