The Roadmap to Navigating Clinical Research: Your Survival Guide to Compliant Study Management: Onboarding clinical research professionals can often be a daunting task. Boot camps and crash courses are expensive, site administrators have little time to develop homegrown programs and most rely on one-way learning platforms with little opportunity to ensure competence before study staff are expected to assume study management responsibilities. This may lead to challenges in study compliance and staff retention due to not feeling adequately trained. Our hope is that by offering what we have learned to others in a train the trainer concept, separated into 6 modules that it will enable sites to utilize this program to effectively onboard new staff across their organization.

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Fees:	*$12,000.00 initial purchase (includes 2 hours of consultation time with the authors)*	
	$2,000.00 annual licensing fee	
Optional Tools for Purchase:	*Pre/Post Knowledge Assessment*	*$1,500.00 one-time fee*
	RedCap Data Dictionary (allows for program management via RedCap)	*$3,500.00 one-time fee*

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Module 1- Introduction to Clinical Research
- Introduction to Clinical Research
- Clinical Research Project Types and Funding Sources
- The Clinical Research Team- It Takes a Village
- Watch-outs in Clinical Research

Module 2- Feasibility, Financials and Agreements
- Establishing and Executing a Feasibility Assessment Process
- Budgeting for Breakeven in Clinical Research
- Clinical Research Agreements and How to Manage Them

Module 3- Study Start-Up
- Study Start-Up Overview
- Protocol Dissection
- Good Documentation
- Creating Source Documents
- Recruitment
- Pulling it All Together

Module 4- Study Management
- Managing Study Data and Research Records
- Reportable Events
- Managing AE's, SAE's Concomitant Medications
- Writing Notes to File
- The Business Side of Study Management
- Participant Retention

Module 5- Informed Consent
- Informed Consent Process
- Writing an Effective Consent Form

Module 6- Essential Document Management, IRB and Compliance
- Essential Document Management
- The Administrative Binder

Working with the IRB
Monitoring and Auditing
Steps to Compliance, Obtaining High Quality Data and Being Audit Ready