CLINICAL TRIALS TRANSFORMATION INITIATIVE

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Key Elements for Site Investigator Success: Infrastructure, Training, Staff Support, and Actionable Solutions

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Processes for Initiating New Clinical Investigators

- **Educational and training programs**
  - Conferences put on by professional organizations
  - Institutional resources at Academic Medical Centers
  - Certification programs in GCP principles
  - Degree programs (Masters Degrees in clinical research)
- **Apprenticeship opportunities with experienced investigators**
  - Serve as a sub-investigator for clinical trials
  - Participate in IRB submissions and reviews
  - Active involvement in financial and budget negotiations
  - Shadow research coordinators in all research activities

COCATS 4:Training in Cardiovascular Research and Scholarly Activity

TABLE 1 Core Competency Components and Curricular Milestones for Training in Cardiovascular Research and Scholarly Activity

	Competency Component	Milestones (Months)			
	MEDICAL KNOWLEDGE	**12**	**24**	**36**	**Add**
1	Know the roles and functions of DNA, RNA, and proteins.			I	
2	Know the principles of genetics, genomics, proteomics, metabolomics, and pharmacogenomics.			I	
3	Know the principles of epidemiological methods.			I	
4	Know the principles of outcomes evaluation.			I	
5	Know the basic principles of biostatistics.			I	
6	Know the principles underlying hypothesis formation, specific goals definition, hypothesis testability, and statistical power achievable.			I	
	EVALUATION TOOLS: global evaluation, in-training examination, and multisource evaluation.				
	PATIENT CARE AND PROCEDURAL SKILLS	**12**	**24**	**36**	**Add**
1	Skill to review published research data and assess the adequacy of research design, data analysis, and logical deduction.			I	
2	Skill to appropriately integrate scientific concepts and research advances in routine clinical encounters.		I		
3	Skill to routinely assess the quality of evidence in clinical decisions.		I		
4	Skill to apply principles of biomedical ethics as they pertain to human subject research in the identification of patients as potential research subjects, presentation of alternatives, obtaining of informed consent, and ensuring the security of clinical data used for research.		I		
	EVALUATION TOOL: multisource evaluation.				

COCATS 4:Training in Cardiovascular Research and Scholarly Activity

SYSTEMS-BASED PRACTICE		12	24	36	Add
1	Effectively access and utilize national registry data for research.		I		
2	Know the role of and how to interact with institutional review boards.		I		
	EVALUATION TOOLS: direct observation and multisource evaluation.				

PRACTICE-BASED LEARNING AND IMPROVEMENT		12	24	36	Add
1	Identify knowledge and performance gaps and engage in opportunities to achieve focused education and performance improvement.		I		
2	Appropriately integrate new or emerging medical evidence.			I	
	EVALUATION TOOLS: multisource evaluation, and reflection and self-assessment.				

PROFESSIONALISM		12	24	36	Add
1	Demonstrate sensitivity to patient autonomy and safety in research.	I			
2	Practice with integrity in the conduct of research, including understanding issues relating to relationships with industry.		I		
3	Interact respectfully with ancillary and support staff.	I			
	EVALUATION TOOLS: conference presentation, direct observation, and reflection and self-assessment.				

INTERPERSONAL AND COMMUNICATION SKILLS		12	24	36	Add
1	Communicate with fellow trainees and faculty about cardiovascular science and how this might impact clinical care (e.g., through journal clubs).		I		
2	Effectively communicate study results during presentations.		I		
	EVALUATION TOOLS: direct observation and multisource evaluation.				

Realities of Training New Clinical Investigators

- **Are trainees encouraged/required to participate in site-based research activities during residency/fellowship training?**
  - What proportion of trainees actually consent patients for trials?
  - What resources are leveraged to support training and involvement?
- **Is emphasis placed upon individual research accomplishments or team-based research activities?**
  - Publications/presentations vs. experiential training
- **Are faculty members at Academic Medical Centers recognized or incentivized to participate in site-based research activities?**

Infrastructure to Support Site Investigators - Institutional

- **Centralization of Clinical Research Support**
  - HR resources to hire and train research staff and ensure they are talented, well-trained, and have prior trial experience
  - Regulatory expertise to review protocols and contracts and prepare for site audits
  - Coordinated GCP training and updates
  - Support for IRB submissions and contract negotiations
  - Financial templates for budget preparations and financial accounting during trial conduct and close out

Infrastructure to Support Site Investigators – Practice-Level

- **Clinical Research Support**
  - National organizations to train and support research team members
  - Limited central support, unless a large group practice or a practice within an integrated health system
  - Financial, regulatory, and GCP expertise is variable and hard to access

Time Requirements

- **Prepare prior to trial implementation**
  - Use knowledge and experience when reviewing protocols to identify and budget for time commitments
  - Likely need to have multiple, ongoing trials to fully occupy research staff and have the flexibility to reassign staff based upon flexing time commitments during the lifespan of trials
- **Reality check**
  - Time commitment for site-based research is rarely accounted for with salary considerations that are heavily weighted for clinical productivity or individual research grants (at academic medical centers)

Actionable Solutions

- Formalize training for site-based research at Academic Medical Centers and advocate for this to be part of the standard requirements for clinical training for any specialty
- Provide formal mentorship and apprenticeship opportunities for trainees and young physicians to learn “on the job”
- Promote and incentivize team-based research at institutions and within practices
  - Leverage institutional resources when available
  - Lead by example – recognize team members, promote a healthy, supportive research environment
- Solidify site-based research as a professional activity, not a hobby

THANK YOU.

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