The Who, What, Why, Where and When of building a competent clinical research workforce

Presented to: EQuaTR Meeting
Presented on: May 4, 2017
Presented by: Terri Hinkley, Workforce Innovation Officer, ACRP
Relevant Disclosure

• I am paid by ACRP.
Learning Objectives and Agenda
Learning Objectives

• Discuss the current clinical research landscape and why workforce development is a critical imperative
• Evaluate the means by which workforce development is being implemented
• Explore the future state of preparation of the clinical research workforce as a means of addressing current gaps and challenges
Agenda

• What is competence?
• Why is competence important?
• When will competence be measured? Who will be impacted?
• How will competence be assessed and measured?
What is Competence?
Competency

A specific range of skill, knowledge, ability to do something successfully, being adequately or well qualified, the condition of being capable of to meet demands, requirements
Competency defined

- Competence is defined in the Oxford dictionary as “the ability to do something successfully or efficiently”
- In the workplace, definitions of competence include “the ability to perform tasks and roles to the expected standard” and “the skills and ability needed to practice safely and effectively without the need for direct supervision”

Agenda

COMPETENCY

<table>
<thead>
<tr>
<th>KNOWLEDGE</th>
<th>SKILLS</th>
<th>ATTRIBUTE</th>
<th>Outstanding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relates to information</td>
<td>Relates to the ability to do</td>
<td>Relates to qualitative aspects</td>
<td>Performance of task or activities</td>
</tr>
<tr>
<td>Cognitive domain</td>
<td>Physical Domain</td>
<td>Personal characteristic or traits</td>
<td></td>
</tr>
</tbody>
</table>
Competence

• Competence focuses on performance: what someone does rather than their knowledge or personal characteristics\(^1\)

• Employers have been complaining that university prepared students are not entering the workforce with the ability to do the tasks required in their roles\(^2\)


Current Measures of Competence

• GCP training
• Certification
• University or college degree
• Medical license
• Nursing license
• Some other license
Why Focus on Competence?
Why Competence?

- Current clinical trial landscape
- Current regulatory environment
- Future trends
“There are going to be major changes. The system we have right now is not sustainable.”

Janet Woodcock, MD, Director of CDER, FDA
Study Enrollment Realities

Doubling Planned Timelines

<table>
<thead>
<tr>
<th>Increase in Planned Study Duration to Reach Target Enrollment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall</strong></td>
<td>94%</td>
</tr>
<tr>
<td><strong>Cardiovascular</strong></td>
<td>99%</td>
</tr>
<tr>
<td><strong>CNS</strong></td>
<td>116%</td>
</tr>
<tr>
<td><strong>Endocrine/Metabolic</strong></td>
<td>113%</td>
</tr>
<tr>
<td><strong>Oncology</strong></td>
<td>71%</td>
</tr>
<tr>
<td><strong>Respiratory</strong></td>
<td>95%</td>
</tr>
</tbody>
</table>

Enrollment Achievement Rates

- **Well Exceed Enrollment Targets**: 13%
- **Meet Enrollment Targets**: 39%
- **Under Enroll**: 37%
- **Fail to Enroll a Single Patient**: 11%
## Protocol Complexity

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Scientific</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Number of Endpoints</td>
<td>7</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Total Number of Unique Procedures</td>
<td>21</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td>Total Number of Procedures</td>
<td>97</td>
<td>163</td>
<td></td>
</tr>
<tr>
<td>Proportion of Procedures that are ‘Non Core’</td>
<td>18%</td>
<td>31%</td>
<td></td>
</tr>
<tr>
<td>Total Number of Eligibility Criteria</td>
<td>31</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Operating</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median Number of Countries*</td>
<td>4.7</td>
<td>9.5</td>
<td></td>
</tr>
<tr>
<td>Median Number of Investigative sites</td>
<td>124</td>
<td>196</td>
<td></td>
</tr>
<tr>
<td>Median Number of Patients Randomized</td>
<td>729</td>
<td>597</td>
<td></td>
</tr>
<tr>
<td>Total number of data points collected**</td>
<td>494,236</td>
<td>929,203</td>
<td></td>
</tr>
</tbody>
</table>
Capitalized Cost to Develop an Approved New Drug

($US millions expressed in 2013 dollars)

- 2003: $1,044
- 2013: $2,558
Overall Success Rates

1980s: 21.3%
1990s: 19.1%
2000s: 16.4%
2010s to date: 11.3%
Drug Development Durations

(Cycle Time in Years from IND Filing to NDA Approval)

Source: Tufts, CSDD
Amendments and Change Orders

Mean Number of Amendments per Protocol

- Phase I: 1.8
- Phase II: 2.2
- Phase III: 2.3
- Phase IIIb/IV: 1.9

Mean Number of Change Orders per Study

- Phase I: 1.1
- Phase II: 2.5
- Phase III: 4.6
- Phase IV: 2.3
Perpetual Fragmentation

Unique 1572 filers

<table>
<thead>
<tr>
<th>Year</th>
<th>Annual Clinical Trial Volume</th>
<th>Proportion of Total</th>
<th>Percent who have not filed again since 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>18,608</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2001</td>
<td>28,246</td>
<td>52%</td>
<td>57.2%</td>
</tr>
<tr>
<td>2005</td>
<td>29,883</td>
<td>26%</td>
<td>29.0%</td>
</tr>
<tr>
<td>2009</td>
<td>34,959</td>
<td>14%</td>
<td>8.3%</td>
</tr>
<tr>
<td>2013</td>
<td>39,791</td>
<td>8%</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

Above 100% indicates the sum of all categories.
Most Common CI Deficiencies

• Failure to follow the investigational plan and/or regulations
• Protocol deviations
• Inadequate recordkeeping
• Inadequate accountability for the investigational product
• Inadequate communication with the IRB
• Inadequate subject protection – failure to report AEs and informed consent issues
FDA Inspection Findings 2014

Most Common CI Deficiencies

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NIH Standards and Requirements

• Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials
  - “This policy establishes the expectation that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2)”

• Enhancing Clinical Research Professionals’ Training & Qualifications (ECRPTQ)
  - Competency development for study staff and PIs in CTSA
  - Including social and behavioral research

The Present: Technological Innovations

- Internet of Things
- Wearables, apps
- Raspberry Pi
- Telemedicine
- IBM Watson

Nearly universal use of smart phones, simplicity of apps, and increasing numbers of wearable data collection, monitoring, and transmission devices provide opportunities to both expand research, while bringing the cost down simultaneously.

John Neal, PCRS Network LLC. Presented at the Executive Summit on Site Strategies April 16, 2016. ACRP Meeting & Expo
Real-Time Monitoring

• EDC and EHR have increased our ability to monitor data quickly
• QbD focuses on the absence of errors that matter and only collecting data relevant to the research question
• RBM focuses on analyzing data for outliers that may indicate issues with data and allow for focused monitoring
• IoT has increased the ability to monitor data from a number of sources real time
Monitoring Dashboard
Monitoring Dashboard

What Will Drive Change?

- Cost of drugs continues to increase, without commensurate improvements in outcomes
- Cost and time to develop new drugs continues to increase
- Protocols have become increasingly more complex
  - Too much non-core data is being collected\(^1\)
  - The cost burden has shifted to sites
- New technologies will facilitate better, lower cost data collection
- More players entering the space looking for opportunities to disrupt and innovate

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Adapted from: John Neal, PCRS Network LLC. Presented at the Executive Summit on Site Strategies April 16, 2016. ACRP Meeting & Expo
End of the Clinical Research Site?
Advent of New Roles

Lead, Internet of Things (IoT) Technology Leader for Medical Devices

is recruiting for a Lead, Internet of Things (IoT) leader for Medical Devices (R&D Innovation). This position can be located at any Business Technology Leader of the R&D Innovation product line. Up to 20% travel, domestic and international is required.

Medical Devices represents more than 60 manufacturing sites and 26,000 employees who plan, source, manufacture and deliver high-quality and cost-effective medical products to our customers around the globe each day. Work of the MD organization supports a multitude of product platforms, new products and delivery systems that are used in a wide range of procedures throughout the healthcare industry, including interventional cardiology, electrophysiology, minimally invasive surgery, hospital sterilization, clinical laboratory testing, diabetes management, joint replacement surgery and vision care.

The Lead, Internet of Things (IoT) Technology Leader for Medical Devices will:

Be responsible for global vision, strategies, and roadmap execution for Medical Devices’ IoT platform(s).
What Does the Future Hold?

- Less focus on disease and increased focus on prevention
- Increased focus on leveraging registries and big data
- Precision medicine will lead to smaller trials; n of 1 trials
- Research sites will amalgamate and drastically reduce in number with increasing use of telemedicine, trial visits conducted at participant’s home or PCP office
- Virtual trials; IoT will allow for remote monitoring of protocol adherence and study data
What Does the Future Hold?

- Increased centralization and amalgamation of technology providers, CROs and sponsors
- Sponsors will insource all clinical activities and integrate with their technology platforms
- Reduced use of AMCs
- Increased IITs
- Completely centralized IRB review; institutional review boards will become extinct
While suppliers and leading organizations like TransCelerate BioPharma and the Clinical Trials Transformation Initiative focus efforts on improving clinical trial quality and efficiency through innovation in **process and technology**, we need to be recognized as *leading the development of grassroots professionals (people)* conducting clinical trials.
When Will Competence be Measured? Who Will be Impacted?
When Will Competence be Measured?

- Initiatives are already underway, but formal competence measurement will likely gain ground in 2017 and 2018
- Competence measurement should be an ongoing process
- Use the tools and reports available
  - Monitoring reports
  - Audit reports
  - Inspection reports
  - QC findings
Who Will be Impacted?

• All clinical research professionals!
• Students
• Those entering the profession
• Those looking for new roles
How Will Competence be Measured, Assessed?
The Joint Task Force for Clinical Trial Competency

• Organized under sponsorship of MRCT, ACRES at Harvard
• Supported by ACRP, MAGI, DIA
• Included representatives from industry, academy and nonprofit organizations
• Agreed to work toward aligning and harmonizing the many more focused statements relating to core competencies for clinical research professionals into a single, high-level set of standards which could be adopted globally
• Serves as a framework for defining professional competence throughout the clinical research enterprise
Joint Task Force for Clinical Trial Competence

**FIGURE 1. Competency Domains for the Clinical Research Professional**

1. **Scientific Concepts and Research Design**
   Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials.

2. **Ethical and Participant Safety Considerations**
   Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial.

3. **Medicines Development and Regulation**
   Encompasses knowledge of how drugs, devices, and biologics are developed and regulated.

4. **Clinical Trials Operations (GCPs)**
   Encompasses study management and GCP compliance; safety management; adverse event identification and reporting; postmarket surveillance; and pharmacovigilance, and handling of investigational product.

5. **Study and Site Management**
   Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCP).

6. **Data Management and Informatics**
   Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database.

7. **Leadership and Professionalism**
   Encompasses the principles and practice of leadership and professionalism in clinical research.

8. **Communication and Teamwork**
   Encompasses all elements of communication within the site and between the site and sponsor, CRO, and regulators. Understanding of teamwork skills necessary for conducting a clinical trial.

*Source: Joint Task Force for Clinical Trial Competency*
Use of Competencies

- Competency profiles
- Competency-based training
- Job profiles – linked – person profiles
- Level of competency vs level of job
- Self-assessment & competence

- Competence, Career Development
- Gap Analysis
- Training to Fill Gaps
- Continuous Process (competence not static, jobs change, gaps appear); Life-long Learning
## 8 Competency Domains

<table>
<thead>
<tr>
<th>Competency Domain</th>
<th>Description</th>
</tr>
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Competence Initiatives

- Consortium of Academic Programs in Clinical Research
  - Committee on Accreditation
- ACRES site accreditation initiative
- Entry level assessment through ACRP
- Certification offerings
- Micro-credentials and digital badging
The New DCO – What’s the Difference?

2010 – 2016 Exams
- Investigational Product Management
- Protocol
- Safety
- Trial Management
- Trial Oversight

2017 Exams
- Scientific Concepts and Research Design
- Ethical and Participant Safety Considerations
- Product Development and Regulation
- Clinical Trial Operations (GCPs)
- Study and Site Management
- Data Management and Informatics
Courses by Competency
ACRP 2017 Meeting & Expo: Competence Tracks

Tracks by Competencies
ACRP invites you to submit a winning proposal!

Competency-based tracks...
Practical and solutions-focused content...
In-depth exploration of issues and challenges...
Intermediate- and advanced level education and training...

Be among the hundreds of industry experts delivering high-quality education and training in Seattle. The newly-designed 2017 program aligns to the eight core competencies common to all clinical research professionals, as defined by the Joint Task Force for Clinical Trial Competency. High priority will be given to proposals that offer intermediate-to-advanced-level content that is solutions-focused and explores issues in depth, as opposed to general overviews. Additional consideration will be given to proposals addressing specially-targeted audiences, including principal investigators, executives, data managers, project managers, and Academic Medical Centers.

Please review the following information carefully to increase your chances of selection.

<table>
<thead>
<tr>
<th>Tracks by Competencies</th>
<th>Partial List of Areas Within Each Competency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Concepts &amp; Research Design</td>
<td>• Design of clinical trials</td>
</tr>
<tr>
<td></td>
<td>• Elements of internal and translational study design</td>
</tr>
</tbody>
</table>
Driving Adoption
How Will Competence be Measured, Assessed?
CRA Competency Development: Driving Adoption

COMPETENCIES AS A PROPOSED SOLUTION

Any new set of standards and SOPs must be based on real-world data and contributions from the widest possible array of experts and stakeholders. The foundation of decision-driving data must include a close and careful analysis of the skills CRAs truly need and utilize on a daily basis.

The search for answers could begin with ongoing work being carried out by the Joint Task Force (JTF) for Clinical Trial Competency. This consortium of leading voices in the industry was formed to integrate efforts to identify high-level competency domains for clinical research professionals at large, and to then harmonize those requirements. The team is drawn from experts at Harvard’s Multi-Regional Clinical Trial Center, Amgen, the Alliance for Clinical Research Excellence and Safety, the Consortium of Academic Programs in Clinical Research, FHI360, Deloitte Consulting, and the Association of Clinical Research Professionals, among others.

ACRP believes the time has come to build on the JTF’s work by establishing role-specific competencies, starting with those of the CRA, and for the clinical research enterprise at large to embrace hiring practices that favor professional competence over arbitrary experience requirements.

• CRA shortage
• Arbitrary 2 year experience requirement from sponsor for CRAs to be ‘billable’
• CROs require new hires to have 2 years of monitoring experience
• How can one get experience when they can’t get a job??
Questions?
Thank You
Terri Hinkley
Workforce Innovation Officer, ACRP