CTSA Regulatory Knowledge Key Function Committee Meeting

Making Collaborative Regulatory Support a Success
January 11-12, 2011

Critical Needs for Clinical Research Coordinator Training Support and Career Development

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CTSA Research Coordinator Taskforce

Mission
To support the professional development of Clinical Research Coordinators (CRCs) and help guide institutions how to organize and network their CRC workforce.

• Initiatives:
  o Develop standardized job descriptions to promote career paths
  o Develop approaches to support the retention of CRCs
  o Develop recommendations for education & training
  o Promote the formal certification of CRCs
  o Develop models for Academic Health Centers to organize and network their CRC workforce
Research Coordinator Taskforce

• Two national surveys created & distributed
  – Focus on research coordinator retention and professional development.
  – One geared toward the institution and the other toward study coordinators.
  – The information collected and analyzed from these surveys will allow this taskforce to address and meet the initiatives outlined.
  – Poster presented June 2009
  – Currently a white paper is being prepared for publication.
Why CRC Societies are necessities and not “nice to haves”

• Clinical research at AHIs is broken
• How do we fix it?
• Society of Coordinators
• Setting paradigm
• Comparison to companies (Jim Collins)
• CHOP & Upenn societies
• Challenges to audience - streamline CRC definition
All arches are but temporary features and all will eventually succumb to the forces of gravity and erosion.
Clinical Research Maze

Enter at your own Risk

1. Data Analyses
2. SAE REPORTS
3. FEASIBILITY
4. SCIENTIFIC REVIEW
5. CRFs
6. G
7. P
8. IRB
9. CTRC
10. PATIENT BILLS
11. FUNDING
12. B
13. U
14. G
15. C
16. T
17. A
18. M
19. T
20. A
21. BAA
22. BOLD
23. PPA
24. HOSTATS
25. Grants
26. Drug Accountability
27. BIOINFORMATICS
28. Study Coordinator Support
29. CITI
30. Training
31. Grants
32. Bioinformatics
33. Feasibility
34. Scientific Review
35. Data Analyses
36. SAE Reports
CRC, Are you ready???

PI takes the challenge

Pushing PI over the edge

PI Responsibilities
CRC Navigating the Clinical Research Rapids.....

CRCs need:

A helmet
Training
Support
Knowledge
Skills
Courage
Accountability
Responsibility
Patience
A guide

...You’re either a bit crazy or you gotta love what you do
The CRC

Is navigating for:

The Subjects
The PIs
The Institution
Each other
Who (where) is the weakest link?

Human Subject Protection

Proper Informed consent
- Properly signed, dated, documented
- Title 45 Part 46.405 & 406
- Current IRB approved ICF/assent

Protocol Adherence
- Verbal consent
- Confirm all eligibility requirements are met
- Labs outside protocol specified window
- Any missed tests, labs, visits

Regulatory Binders
- Proper documentation of missed tests
- Labs outside protocol specified window
- 1572, CV, Investigators brochure
- Signed protocol & amendments
- Lab certs, normal ranges +...

Adverse Event Reporting
- IRB approval letters & correspondence
- Know submission requirements
- Understand AE and SAE Definition

Drug Studies
- External IND Safety reports
- Proper SAE reporting
- Proper dose given

Clinical Samples
- Appropriate person administering drug
- Proper storage/destruction/return
- Properly signed, dated, documented
- Processed, stored, shipped properly

Documentation
The CRC is navigating for:

The Subjects
The PIs
The Institution
Each other

Now multiply this by the number of studies one CRC supports.
How does an Institution help the CRC maintain a calm, manageable work environment?
CSTA Clinical Research Coordinator Taskforce:  
CRC Institutional & Individual Surveys  
Summary of Results

Surveys launched: June 10, 2008  
Surveys closed: August 28, 2008

No. of Institutional Respondents: 22  
No. of Individual coordinator respondents: 1590

• Twenty two (22) of the current 24 CTSA institutions responded to the survey.  

• Responses to the individual survey were anonymous and as such, the study was deemed exempt from IRB review in accordance with 45 CFR 46.101 (B) (2).  

• Results of the survey questions were categorized by topic area
CRC Survey Results: Demography

- **CRC workforce ranging from 13-1500 CRCs, with a mean and a median number of 385 and 350 coordinators, respectively.**

- **Years experience of CRCs:**
  - \(~16\% \leq 1\) year\//\ ~37\% < 3 years \// \ ~50\% >5 years

- **Percentage of CRCs with RN degree**
  - **Institutions report:** 39\% of the CRC work force holds an RN (50\% of those RN’s holding a Master’s level degree or higher)
  - Data from the **individual survey** suggests \(~33\%\) of CRCs hold an RN degree (37\% of the RNs with a Masters or doctoral degree)
  - Data from 1995 ACRP survey (357 responders) report 60\% of CRCs w/RN and data from a 2007 survey (205 respondents) report \(~50\%\) of CRCs w/RN.
  - Appears to be a trend toward more non RNs filling the CRC role: possibly due to increased responsibilities of the CRC over the years and fewer of those related directly to patient care.
These data show the conventional assumption that CRCs mainly leave academia for more lucrative positions in the pharmaceutical industry is an oversimplification:

- 21% leave for industry positions
- 10% actually come from industry.
- ~ 31% of CRCs either go back to clinical care or return to school.
Job Descriptions & Career Ladder

- 14 of the 22 institutions responding to the CRC Survey (64%) have standardized CRC job titles

- The two most common job titles: Clinical Research Coordinator and Clinical Research Nurse,

- Remainder of titles exhibited a wide variation.

  - Clinical Research Project Manager
  - Clinical Research Associate
  - Research Program Coordinator
  - Research Nurse
  - Social Clinical Research Specialist
  - Health Project Coordinator
  - Clinical Trials Associate
  - Clinical Patient Coordinator
  - Study Coordinator
  - Data Manager
  - Research Program Manager, Director
  - Research Coordinator I, II, III
  - Clinical Research Specialist
  - Technical Associate
  - Research Assistant

- These data suggest the need for standardized job descriptions within clinical research so that, across institutions, we can differentiate and delineate roles and expectations of clinical research personnel.
CRC Job Responsibilities

- 80% of coordinators surveyed scheduled to work 40-hour weeks
  - ~54% noted they did work a 40 hr week.
  - ~42% reported working in excess 40 hours per week,
    - 21%: 40-45 hours/week
    - 16%: 46-50 hours/week
    - 5%: > 50 hours/week

- 1574 respondents support 9842 studies and 5262 investigators
  - 1 to 85 studies/coordinator (mean of 7.6)
  - 1 to 50 investigators per coordinator (mean 3.7)
    - 46% report difficulty supporting multiple PIs
    - 62% report PIs expect more time spent on study than allotted
CRC Job Responsibilities

• 68% of coordinators felt that tasks were assigned to them appropriately.

• Tasks reported as being out of the CRC scope:
  - Informed consent
  - Budget preparation
  - Adverse event
  - Regulatory submission
  - IND/IDE submission
  - Drug administration
  - Toxicity Assessment
  - Writing chemo orders
  - Billing
  - Contract negotiation
  - Recruitment
  - Grant preparation
  - Protocol writing
  - Blood sample collection/processing
  - Data Entry
  - Maintaining study drugs

• The three most common tasks CRCs reported being least experienced/trained to do:
  - billing,
  - budget preparation
  - contract negotiation
100% of the 22 responding CTSA academic centers report that training is provided for the new CRC.

90% provide continuing education for the CRC.

The type, length and frequency of training, both orientation and continuing education, vary widely from one institution to another (other i.e. informal mentoring program, “brown bag” seminars, educational classes).

Based on survey results, 45% of CRCs indicated they received appropriate training for all the tasks they were required to do.
CRC Self Reported Responsibilities

- Budget preparation
- Billing resolution
- Facilitate contract/budget negotiations
- Preparing for external audits (FDA, NIH, Sponsor)
- IRB submission
- Standard Operating Procedure Development
- Other, please specify
- Study close out activities
- Study document development
- Adverse event reporting
- Managing study files/regulatory files
- Hosting monitoring visits
- Sample processing
- Informed consent
- Recruitment
- Test article accountability
- Responding to data queries
- Study training
- Sample collection
- Patient schedule
- Clinical care (related to the study)
- CRF completion
- Conducting study visits
- Managing subject visits

% Proper Training Not Provided
CRC Satisfaction

• >75% of CRCs reported that their work was both professionally and personally fulfilling.

• 85% believe their job is an important aspect of the overall mission of their institution.

• 41% of CRCs report that there is no opportunity for career advancement or development.

• 51% report that they do not receive a fair salary for what they do.

• 62% of CRCs reported that their investigators expect them to spend more time on their studies than the CRCs are allotted.

Being overworked was reported as one of the top negative aspects about their job and 15% of respondents listed burnout as a reason for leaving their job.

CRC Job Satisfaction Findings (% responses)

<table>
<thead>
<tr>
<th>Top positives about the CRC job</th>
<th></th>
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<tbody>
<tr>
<td>Patient/Subject interaction</td>
<td>29%</td>
</tr>
<tr>
<td>Multitasking/diversity/variety</td>
<td>18%</td>
</tr>
<tr>
<td>Contribution to medical advancement</td>
<td>16%</td>
</tr>
<tr>
<td>Flexibility &amp; autonomy</td>
<td>15%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Top negatives about the CRC job</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Overworked &amp; inadequate pay</td>
<td>20%</td>
</tr>
<tr>
<td>Paperwork, budgets, billing</td>
<td>14%</td>
</tr>
</tbody>
</table>

<table>
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<th>Top motivations for leaving the job</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Better salary</td>
<td>23%</td>
</tr>
<tr>
<td>Career advancement</td>
<td>17%</td>
</tr>
<tr>
<td>Burnout</td>
<td>15%</td>
</tr>
</tbody>
</table>
CRC (Dis)Satisfaction: Quotes from CRCs

• “I would leave b/c management knows how busy of a caseload I have and yet they fail to provide permanent solutions, they only are able to put a band-aid on the issue and that will relieve the immediate stress, but will not prevent it from recurring.
• “Not enough pay for the amount of work I do”.
• “Unfairness and not being compensated for going the extra mile or not having support when needed”.
• “Too many therapeutic areas; too many PIs; too many studies at one time”
• “TOO much overload to the point I feel I cannot do an excellent job of the studies assigned to me. or Better Offer!”
• “Stress due to lack of help and way too many responsibilities for a normal work week”
• “Job demand/long unpaid hours.”
• “Unfair and inconsistent standards between different investigators”
• “Lack of ability to professionally grow”
• “Burn-out from being a one-man show and feeling like you never get enough done”
• “The fact that nothing seems to change, year after year. I’ll discuss projected needs and issues with a study that will be ignored until it is a crisis. The burn out is extreme. No access to my PI, poor communication with PI, amount on my plate, job has not allowed me to have a life in 4 years. Too much time spend dealing with administrative issues with HR, finance...
Institutional Organization of CRCs

• Historically CRCs work for individual investigators and typically lack an institutional identity or institutional recognition that they are part of an important research profession.

• In order to further develop CRCs in their profession and give them an identity and voice in evolving and enhancing clinical research management practices, some academic centers have developed an institutional approach to networking and organizing their CRCs.

• Through a research coordinator society or network, an institution can enhance the quality of clinical research programs by enriching the training and education of clinical research personnel.
Institutional Organization of CRCs

Two CTSA institutions participating on the CTSA CRC Taskforce, reported implementing an institutional model to organize, recognize, and develop their CRCs. Both models use a blend of centralized and decentralized approaches to organizing and networking research coordinators.

- The first model provides automatic membership for all CRCs in the institution’s Society for Clinical Research Coordination and Management.
- The second model implemented at another large CTSA institution combines decentralized and centralized approaches in providing resources and support for clinical research staff and oversight for clinical research studies.
- The Site Based Research (SBR) model is based on the concept that therapeutic alignment of clinical research allows the greatest understanding of subject populations, as well as a local source of knowledge and support with tools tailored to the types of research conducted within the therapeutic area.
Why CRC Societies are necessities and not “nice to haves”

• Clinical research at AHIs is broken
• How do we fix it?
• Society of Coordinators
• Setting paradigm
• Comparison to companies (Jim Collins)
• Challenges to audience - streamline CRC definition
Social Innovation

Makes most first-order innovation and human productivity possible in the first place.

The greatest of all inventions is human organization and society—the ultimate tool for achieving human objectives.

The next wave of enduring great companies (AHIs) will be built not by technical or product visionaries but by social visionaries—those who see their company and how it operates as their ultimate creation and who invent entirely new ways of organizing human effort and creativity.

Great companies (AHIs) are early adopters, if not outright inventors, of progressive management methods. They are among the first to try the outlandish, the different, the radical

The Most Creative Product Ever
by Jim Collins  May 1997
http://www.jimcollins.com
Social Innovation

Networking & Collaborations
Mentor programs
Education & Training programs
Improving Clinical Research processes
Operational and Regulatory Excellence and Compliance

Human Subject Protection
CRC Networks/Societies Evoke a Paradigm Shift at AHIs

“...and that government of the people, by the people, for the people, shall not perish from the earth.”

The Gettysburg Address by President Abraham Lincoln
Gettysburg, Pennsylvania November 19, 1863

“...and that society of the Clinical Research Personnel (CRP), by the CRP, for the CRP, shall form the foundation for Clinical Research at AHIs.”

Clinical Research Address Circa 2009
PROSPER & SCRCM

Professional Society for Pediatric Clinical Research

• Provide orientation support & training materials for all clinical research staff entering the CHOP research environment.
• Act as a central information exchange between Research personnel & the CHOP community.
• Promote & support the standardization of job descriptions and the creation of a career ladder for clinical research personnel.
• Will enhance the quality of clinical research programs by supporting the professional development and enriching the training and education of all clinical research personnel.
PROSPER & SCRCM

• Represent a clear advancement in the institutional recognition of the importance of the CRC profession

• First of its kind

• Allow for direct contribution to ongoing enhancement of our respective clinical research enterprises.

• Working collaboratively/synergistically with CHOP/Penn operational offices to co-develop & integrate ideas/recommendations/aspirations into the institutional priorities and plans
Challenges to CTSA Institutions

1. Prevent the Clinical Research Arch from eroding

2. Implement a new “system” with optimal clinical research organizational dynamics as the foundation.
Where do we start?

The Timeless Physics of Great Companies by Jim Collins

The immutable laws of management physics include some simple yet important concepts:
- Do only those things that you can be the best in the world at;
- those things you can be passionate about;
- things that make simple economic sense.
- Take the axiom that you need to “put the right people on the bus.”

The best executives have always focused first on getting people who share their values and standards. They understood that vision and strategy cannot compensate for having the wrong people. Once you have the right folks in place, it's much easier to steer the bus as conditions change.
Initial role of CRC centered on clinical management of the patient/subject

Expectations of CRC now more sophisticated: Expertise in compliance, research administration, marketing, fiscal & legal activities
Core CRC Responsibilities

- Adherence to an IRB approved protocol
- Participation in the proper consenting of study subjects
- Support of the safety of clinical research subjects
- Coordination of clinical treatment, study visits, and follow-up care
- Subject screening, recruitment, and enrollment
- Education of subjects and family on protocol, study intervention, study drug, etc.
- Maintenance of study source documents
- Proper reporting of adverse events
Additional CRC Responsibilities

- Submissions to regulatory authorities (e.g. IRB, FDA, etc.)
- Regulatory documentation development and management
- Informed Consent Document Development
- Development & Completion of case report forms
- Protocol Feasibility Assessments
- Coordination of pre study, initiation & monitoring visits
- Collection, processing and shipping of laboratory specimens
- Maintenance of drug accountability documentation
- Study budget and/or contract preparation/negotiation
- Management of study finances including resolving study subject billing issues, sponsor invoicing
- ClinicalTrial.gov registration/maintenance
- Acting as liaison for research subject, investigator, IRB, sponsor, and healthcare professionals
- Auditing & Monitoring responsibilities
- Coordination of multi-center studies
Creating a great company requires immense amounts of doing. Yet all that doing diverts us from an equally important and powerful aspect of making progress: deciding what to stop doing.

• The power of removal can be immense.

• Before company owners (AHIs) embark on a blind fury of new initiatives (new tasks given to CRCs), they ought to figure out what to stop doing (delegating to the CRC).

• Let's unplug it (the additional task added to the CRC role) and move on to something else, thus continually freeing resources for the most promising new opportunities.
What tasks should we unplug?

- "Which of your current tasks would you not agree to if you were making a blank-page decision about it today?" Those you identify should be TVs/tasks to unplug.
- Extend this logic to every aspect of your company’s activities—people, products, systems, structures, and even how you spend your time.
- You should create a “stop doing” list to complement your “to do” list. Set aside time to explicitly discuss with your managers what to stop doing.
Our Challenge

• Without adding new resources, how do we redesign the structure of clinical research at our institutions to enhance efficiency?
• 1 person/role cannot do it all.
• The CRC role has expanded to the point of explosion.
• Is it realistic to expect one position to be responsible for so many facets of clinical research?
Consider: Reclassification of the CRC Role

• => Create new positions to take on excess roles being delegated to the traditional CRC.
• A number of these “titles” exist today:
  – Regulatory coordinator
  – Clinical research financial specialist
  – Billing Resolution specialist
  – Protocol development office
  – Data Manager
  – Recruitment Specialist
  – Lab technician (for sample processing)
You’re invited!

And welcome to join the CTSA Research Coordinator Taskforce
Thank You