Clinical Research SWOT Analysis
Drafted by SOM Clinical Research Coordinators

Strengths:

- Clinical Research Coordinators
    - Vested in patients' positive outcome
    - Vested in subjects' safety
    - Vested in conducting clinical research in compliance with all applicable rules, regulations, and current Good Clinical Practices (GCP) for research
    - Dedicated, willing to do what it takes to get the job done
    - Educational background
        - Institutional CRC hiring policy supports and requires (in most cases) minimum of a college degree or an RN license
    - High percentage of certified Clinical Research Coordinators
        - Institution supports and encourages certification
    - High number of CRCs at UVa have many years of clinical research knowledge/experience

- New Clinical Research Unit (CRU) on Barringer 3
    - Beautiful, comfortable space for clinical research subjects
    - Efficient, well-equipped space for clinical research staff to conduct their trials
    - Accommodating, CRU staff who are available to conduct research study visits
    - "PRN" pool of staff available to assist with studies conducted on the CRU
    - Lab processing facilities in Barringer 3 (as well as in the Medical Center) available to all research staff

- SOM Clinical Trials Office (CTO)
    - Advocates for clinical research staff
    - Provides critical services for the clinical research process
    - Excellent resource for clinical research staff

- Institutional Review Board (IRB)
    - Generally responsive not reactive
    - Full board protocol approval times have decreased over the years
    - Full board protocol approval times less than IRBs at some other academic medical centers (and with fewer IRBs)
    - Combines HIPAA process with informed consent process so they don't have to be done separately
    - Multiple training efforts (e.g. IRB 101, IRB 201, learning shots)

- Cancer Center

- Investigational Drug Services
    - Responsive and accurate service

- Diverse education/background of Clinical Research Coordinators (licensed and non-licensed)
    - Independent thinkers able to work independently

- Multiple organizational structures for Clinical Research Coordinators

- o Team structure (a team of CRCs working for a team of investigators)
    - ▪ Allows for back-up when needed
    - ▪ Allows for team approach to problem-solving, etc.
    - ▪ Provides possibility for career growth within the team
- o One-to-one structure (one CRC working with one Principal Investigator (PI)
    - ▪ Provides opportunity to become highly specialized in a medical specialty
    - ▪ Allows for independence
    - ▪ Provides opportunity to learn entire research process

- New clinical career ladder for Clinical Research Coordinators

- Post Approval Monitoring reviews
    - o Provides non-threatening feedback to research teams
        - ▪ Identifies study-conduct related issues and provides opportunity to correct them
    - o Provides educational opportunity to research teams

- Epic
    - o Increasingly providing more features that may improve safety of subjects enrolled in clinical trials
    - o Increasingly providing more features that may improve efficiency of conducting trials
    - o Ability to provide monitors the capability of remote monitoring

- Clinical Research website
    - o Finally there is one site for a clinical researcher to go to find answers to research-related questions

Weaknesses

- Funding issues
    - o Lack of funding or frequent losses of funding gives CRCs a lack of job security, a feeling of instability
    - o No/little bridge funding
        - ▪ Leads to 'job hopping'
        - ▪ Leaves PIs without a CRC when next study starts

- Barriers created between Medical Center and University
    - o Human Resources policies differ which makes it difficult to attract Medical Center employees to academic positions, makes it difficult for them to work in a dual capacity, etc.
    - o Medical Center staff not being willing/able (most times due to being already overloaded with patient care responsibilities) to contribute to the research process (i.e., no time to perform study-related activities such as vital signs, administer study meds, draw blood during night shift, etc.)
        - ▪ This increases the cost of doing studies, many of which (government funded or investigator initiated) cannot bear the costs

- ▪ No infrastructure in place to help alleviate this problem (even when attempts were made to compensate someone from the Medical Center to perform such tasks, the HR policies prevented it from moving forward)
  - o Unspoken message from many Medical Center employees that research has a negative impact
    - ▪ Research can impact the core measures on which units are being evaluated
  - o Less than perfect communication at times between Medical Center and clinical research teams

- • Multiple organizational structures for Clinical Research Coordinators
  - o Team structure (a team of CRCs working for a team of investigators)
    - ▪ Decreases feeling of independence
    - ▪ Increases possibility of losing sight of the big picture, only being able to focus on specific delegated tasks
  - o One-to-one structure (one CRC working with one Principal Investigator (PI)
    - ▪ Presents greater chance of inefficiencies and/or inconsistencies
    - ▪ Presents greater chance of CRC feeling isolated

- • CRC retention issues
  - o Despite new career ladder, there are limited opportunities for advancement for CRCs
  - o Hard to compete with industry – we many times train new CRCs, only to have them leave for industry positions

- • Lack of clinical trial management system (CTMS) that could facilitate the entire clinical research process, from pre-award to post-award.

- • Limited required education for new clinical research staff

- • Institutional Review Board
  - o Expedited protocol pre-review time unacceptably long and arduous
  - o IRB website can be hard to navigate, no search engine on site
  - o Protocol Builder questions can be hard to interpret, despite 'help' provided
    - ▪ Incorrect interpretation can lead to significant time delays and/or rework
  - o Inconsistency in responses from different IRB staff members when presented with questions
  - o Electronic IRB submission process not available

- • Office of Sponsored Programs
  - o Turnover rate seems high
  - o Process takes too much time
  - o No electronic web-based process to support the pre-award and post-award process
  - o Lack of consistent set of processes
  - o Website can be difficult to navigate

- No (or limited) training for Principal Investigators is available

- No centralized support for first time, or one-time PIs (in some cases basic researchers starting a simple study where all they need is blood or tissue samples). In many instances, these PIs are not familiar with the study start-up process and have no support personnel to assist with the process. Therefore, they become frustrated and struggle with the process.

- PIs not always aware of everything that is involved with coordinating a clinical research study. They many times under estimate the amount of effort it requires.

- Lack of understanding on the part of some research team members of the difference between research and practice, which can lead to protocol non-compliance, have regulatory implications, and impact data integrity.

- Limited internal infrastructure
  - No central support for protocol writing/development is available to research staff outside the Cancer Center
  - Limited central support available for IRB submission support
  - No central support for managing multi-center studies

- Lack of billing system that integrates easily with Epic makes clinical trial billing cumbersome

- Hours of the Biorepository and Tissue Research Facility (BTRF) do not accommodate many clinical trial visits which many times are completed after normal working hours

- Human Resources
  - Hiring process for CRCs sometimes prevents the hiring of the best candidate in a timely manner
    - Process requires that the hiring department post a position for a certain CRC level. There are times that the candidate pool at that level is sparse so the hiring department decides that it would be in their best interest to hire a different level. However, to do so requires a fairly lengthy HR process, which means the hiring department either waits out the process or hires a candidate who may not be their first choice.

Opportunities

- Assuming the role of the coordinating center for multi-site trials

- Collaboration with other academic institutions on clinical research projects

- Collaboration with other health care facilities on clinical research projects

- Creation of new relationships across grounds, providing opportunities for translational research projects

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- Partnering with industry on new drug and/or device development projects

- Listing UVa clinical trialists on the top national registries used by Pharma to identify study sites

- Additional central support for administrative aspects of clinical research, such as (not an all-inclusive list):
  - Protocol writing
  - IRB submission
  - Budget development
  - Regulatory document completion/management, e.g.,
    - 1572 completion
    - CV management
    - Financial disclosure forms
  - Sponsor invoicing

- Implementation of a clinical trial management system (CTMS) that spans pre-study to close-out activities of a study; a system that decreases redundancies in the current process. (A simple example: entering the title (and other information) of the protocol into the CTMS would enable populate the information to all forms required for the study (e.g., IRB protocol, 1572, goldenrod).
  - CTMS should be fully integrated with the systems of all applicable committees, office and services, such as (not an all-inclusive list):
    - IRB
    - Grants and Contracts (and Office of Sponsored Programs)
    - Protocol Review Committee
    - SOM CTO
    - Radiation Safety Committee
    - Cancer Center Data Safety Monitoring Committee
    - Patient Financial Services
    - University Physicians Group
    - Epic

- Implementation of an electronic IRB submission process

- Development of a 'launch pad' within the SOM Clinical Trials Office for the training of new Clinical Research Coordinators (CRCs).
  - Concept is to provide new investigators with trained CRCs

- Creation of a "pool" of Clinical Research Coordinators that could be used on a temporary basis by clinical research staff

- Development of a 'research assistant' position that could perform specific tasks of a research project under the supervision of the primary CRC

- Create a bridge between the University Human Resource office and the Medical Center Human Resource office

- Bridge the relationship between Medical Center staff and research staff

- Improvement of clinical care and clinical research coordination

- Introduction and implementation of Epic billing and registration system to allow for time of ordering clinical research billing

- More top down support of clinical research

- Creation of a clinical trial "track" for clinical staff, providing them with the necessary clinical research training and education as well as providing an opportunity to increase their involvement in clinical research

- Addition of "research beds" in the Emily Couric Cancer Center, staffed by trained and qualified oncology nurses.

Threats

- Lack of (or limited and reduced) funding
  - Threatens CRC positions and prevents advancement (no money to pay)
  - Threatens number of clinical research protocols that can be done
  - Potentially threatens the quality of research conducted

- Disconnect between the promise of clinical research support by Medical Center administration and reality at the 'grass roots' level. The MC employees providing patient care are too busy to provide any additional patient services required by a clinical trial.
  - Limits the studies that can be done at UVa
  - Potentially threatens data integrity

- Opening trials for the "sake of having available trials"
  - Increases administrative burden
  - Decreases time of research staff to enroll into other trials
  - Potentially threatens our reputation with sponsors

- Opening trials that are impossible to conduct (e.g., I/E criteria too restrictive, we don't have a large enough patient population, study procedures not conducive to recruiting/retaining subjects)
  - Increases administrative burden
  - Decreases time of research staff to enroll into other trials
  - Potentially threatens our reputation with sponsors

- Inability to compete for pharma trials with other larger, more metropolitan academic centers