Research Program Operations: Running an Effective Clinical Trial Program

Introduction and Overview

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Kelly Willenberg & Associates

Agenda

- Selecting the right trials – ideal and sustainable studies, financial viability, accrual feasibility
- Strategies to manage trial portfolio – consider industry- vs federally-funded trials, site selection/partnerships, operations, infrastructure, performance
- Fiscal accountability and legal considerations and strategies – budgeting; funding; contracting; costs; insurance coverage (coverage analyses, reimbursement, denials); consistency checklist
- Good business practice for clinical trials (CTMS, EMRs, E-regulatory systems and integration)
Evaluate Current State

- Assess personnel and workload within operations
- Analyze the research portfolio
- Validate regulatory processes
- Document business functions

Clinical Trial Selection and Lifecycle

1. Knowing portfolio and competing trials
2. Proper budgeting of all trials so you can sustain operations
3. Identifying subjects centrally for all study visits to be documented and followed
4. Sponsor invoicing and collection of all payments
5. Understanding study maintenance so you know when a trial is not accruing
6. Knowing when to not open a study or when to close it is vital to your financial success closeout

Site Selection, Partnerships, and Infrastructure

- Understanding how your site performs impacts studies you are offered
- Analyzing partnerships to secure higher recruitment and accrual
- Be proficient in regulatory documentation for monitor visits
- Provide a seamless integration with your EDC, EMR and IRB
- Supply financial and progress reports effortlessly to PIs
- Be transparent in federal reporting

Clinical Trial Infrastructure

- Because research is a complex enterprise, consider starting the effort with a simple question:
  - Who does what now?
  - Identify roles and responsibilities
- From “who does what” comes:
  - Who should do what?
  - This involves numerous business/operations decisions, but they should be memorialized in policies and procedures
  - Train when you need to
Manage Portfolio - The Business Function

- Understand Business Function
  - Coverage Analysis
  - Budget
  - Contract
  - Invoicing
  - Reconciliation
  - Payer Management

IT Systems Roundup and GCP

- Inventory all systems
  - IRB system
  - Grants accounting and financials systems
  - Payroll
  - Clinical Trial Management System (CTMS) used for patient and administrative tracking
  - Professional billing system
  - Facility billing system

Know What Tools You Currently Have

Understanding legacy systems and how they can help or hurt

- CTMS
  - Use a CTMS to better enhance your patient management, financial management and billing compliance management

- Claim Scrubber
  - Verify process of eligibility data prior to submitting claims to payors for clinical trials

- EMR
  - EPIC, Cerner, Meditech, GE Centricity, Athena, ARIA, MOSAIQ, NextGen, Allscripts, EClinicalWorks, McKesson

How to Build an Effective Research Team

Marge Good, RN, MPH, OCN
Nurse Consultant, Division of Cancer Prevention
National Cancer Institute
Objectives

- Team perspectives
- Potential staffing models
- Impact of turnover
- Reasons for decision to leave
- Engagement & retention strategies
  - Competencies
  - Career ladders
- Training & monitoring
  - Assessing Workload

What is a team?

- People with complementary skills who are committed to a common purpose, set of performance goals, and approach for which they hold themselves accountable. (HBR – Katzenbach, 2013)

If you want to go fast, go alone, but if you want to go far, go together – African proverb

Research Program Team: A Team of Teams

- Core research staff
  - Manager/Administrator
  - Research Nurse(s)
  - Clinical Research Coordinators (CRCs)
  - Clinical Research Associates (CRAs)
  - Data Managers
  - Regulatory
- Extended members
  - Infusion nurses/clinic staff
  - Pharmacist
  - Laboratory/Radiology/Radiation Oncology
  - Billing & Contracting
  - Other specialties: Surgery, Primary Care, GYN, GU, etc.

Model for Team Effectiveness

- Mutual trust among members
- Sense of group identity
  - Feeling they belong to a unique and worthwhile group
- Sense of group efficacy
  - Belief team can perform well
  - Members are more effective working together than apart (HBR – Druskat & Wolff, 2001)
Top Required Skills

- Manager
  - Effective communication (4)
  - Interpersonal skills
  - Experience and organization
  - Proactive (Schulz, 2017)
- CRA
  - Attention to detail
  - Organizational skills and process understanding
  - Confidence (Kee, 2011)

Value of Core Research Staff

- Physicians dedicated to clinical research are key to success
  - Many express interest but only ~20% actually accrue (Unger, 2016)
  - Reasons physicians do not act as clinical investigator (Taylor, 2004)
    - Time commitment involved (32%)
    - Lack of personal support (30%)
    - Insufficient resources to run trial (26%)
    - Paperwork burden (24%)
  - Above barriers can be reduced with research staff support
- Proper staffing is key to an investigator’s reputation and overall success of program (Baer, 2010; Kee, 2011)
- Staff serve as liaisons between investigators, subjects, care providers, regulatory bodies, sponsors and other involved in research process (Speicher, 2012)

Research-Related Tasks & Potential Staffing Model

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Manager/Coordinator</th>
<th>Regulatory Specialist</th>
<th>Research Nurse</th>
<th>Non-Nurse CRA</th>
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<td>Initiation of study</td>
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<td>Enrollment/randomization</td>
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<td>Adverse event reporting</td>
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<td>Data management (new enrollments &amp; FU)</td>
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<td>Internal auditing/QA</td>
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20 Enrollments/Year

200 Enrollments/Year
Turnover Rates and Associated Costs

- Turnover rate data
  - Worldwide CRA turnover rate > 25% through 2015 (Bishop & Camblos, Applied CT, 2017)
  - U.S. CROs 2016 average turnover rate 21% (Bishop & Camblos, Applied CT, 2017)
  - CRA clinical monitor turnover rate 25.8% (Henderson, Applied CT, 2018)
  - During organizational change process can be as high as 39% (Aarons, 2009)

- Associated costs
  - Negatively impacts staff morale
  - Loss of continuity
  - Loss of knowledge
  - Lower productivity
  - Recruitment - Onboarding
    - Increased workload on remaining staff
    - Likelihood of delayed data submission; increased queries
    - Strong performers burnout as more positions go unfilled
  - Negative reflection to sponsors
  - Signifies internal management problems

Competency timeline estimates

- 6 – 12 months (Baer, 2010)
- 5.5 months (Cooperative Group) (Smith, 2010)
- 1 – 3 months (industry) (SCORR/Applied CT, 2017)

Why are they leaving?

- Job dissatisfaction
  - Lack of career development, advancement and/or promotional opportunities
  - Inadequate resources - do not receive fair salary for effort
  - Need for formal training
  - Most experience on-the-job or “learn by your mistakes”
  - Poor allocation of workload
  - Imbalance of work & non-work life
  - Burnout

- Why are they leaving?
  - Company culture mentality
    - The needs of the business come first - individual's needs come second
    - The business extracts what it needs from the people - “Work is for the boss”
    - When people feel taken advantage of they leave
  - Balance of power
    - Has shifted from employer to employee
  - The Millennials Quandary
    - They do not work to serve authority, they work to serve their own needs
    - “I have a choice. I want more than this. I don’t know what it is but am going to keep looking until I find it.”
    - 70% want to be creative at work
    - Believe it is management’s job to provide them with accelerated development opportunities in order for them to stay.
    - Have to offer something they can’t get on their own - something to help them become a better vision of themselves

Building Engagement

- Employee engagement = the emotional commitment an employee has to the organization and its goals (Bersin, 2015)
- No single factor has more impact than: Clearly defined goals that are written down and shared freely...
- Goals create alignment, clarity, and job satisfaction (Bersin, 2015)
- Hard goals drive performance more effectively than easy goals
  - “Specific” hard goals produce higher level of output than “vaguely” worded ones (Doerr, 2018)
Retention Strategies

- Self assessment/team assessment – continuous improvement feedback programs
  - Query and listen to staff – don’t assume everything is okay
  - What do they like to do?
  - Why do they like what they do?
  - Do they feel part of the planning/decision making process? Is their voice being heard?
  - What can be done to improve job satisfaction?
  - Consider what to stop doing (Suomi, “Pulling the Plug”, 1997)
  - Do away with tasks that do not add value
  - Streamline or off-load tasks that divert staff from primary role (Speicher, et al, CTS Journal, 2012)

- Gap analysis of knowledge base/training needed (find weaknesses; additional needs)
  - Match individuals with suitable tasks

- Balance work & non-work life
  - Flexible work hours – work remotely (top 2 non-financial incentives used by industry) (SCORR/Applied CT, 2017)
  - Cross coverage – task sharing between roles -> flexibility
  - Team building events
  - Regularly acknowledge value of each person

Making an Impact

- “The health of a culture is equal to the collective ability of people who work there to feel the impact of their actions on others.”
  - The most important thing leaders can do is to help people see their impacts on each other.

Retention Strategies

- Establish competencies – opportunities for growth
  - Uses:
    - Position descriptions
    - Orientation guide – content for orientation
    - Identify learning needs
    - Performance appraisal
    - Clinical ladder criteria – evaluation for promotion
  - Competency statements
    - ONS – 2016 Oncology Clinical Trials Nurse Competencies: https://www.ons.org/sites/default/files/OCTN_Competencies_FINAL.pdf
    - Joint Task Force for Clinical Trial Competency (2017 - Clinical Research Professionals): https://www.clinicaltrialcompetency.org/resources-1

Oncology Nursing Society (ONS) – 2016 Oncology Clinical Trials Nurse Competencies

Note: Reused courtesy of the Oncology Nursing Society from 2016 Oncology Clinical Trials Nurse Competencies. Copyright © 2016 ONS. All rights reserved.
Retention Strategies

- Career Ladders
  - Benefit employee and institution
    - Employee:
      - Encourages, recognizes and rewards qualified employees -> enhances retention and attracts quality employees
      - Optimizes clinical performance and professional development
      - Incentivizes accepting additional responsibilities -> drives development of new skills, knowledge and proficiencies
      - Improves job satisfaction and longevity
      - Promotes staff engagement in problem solving & quality improvement
      - Potential pay increase
    - Institution:
      - Experiences less turnover, recruitment and training expenses (= reduced costs) -> improved patient satisfaction scores -> reflected as a quality organization

- Challenges:
  - Acquiring institutional and management support
  - Pay increase for each tier?
  - Professional development (certification, conference fees, professional org. membership, etc.)
  - Purchase of books, educational materials
  - Educational days off
  - Added vacation days
  - Establishing criteria, implementation and follow through process
  - Establish committee - include staff as well as administration and HR
  - Number of tiers/levels - vertical and lateral levels at each step?
  - Qualifications for each level, incorporate competencies - performance-based criteria - points system?
  - Time requirements at each level / self nomination for advancement
  - Annual review/assessment process - who makes determinations?
  - Reward system (Kofman, 2016)
  - Time commitment required

Team Training & Monitoring

- Training
  - Imprinting concept – early exposure/experience may impact future performance; predictor of progression and competence
  - Develop training checklist - use competency statements
  - Cross training
  - Address knowledge gaps - Send to educational meetings (NCTN Groups, NCI-RBs, ONS, SOCRA, etc.)
    - Opportunity for networking
    - Hear results of completed trials and new trial development discussions
  - Collaborative learning opportunities
  - Promote professionalism -> Certification – Pros & Cons
    - Successful certification requires ensuring knowledge
    - Recognize/Reimburse for certification
    - More marketable to outside?
Team Training & Monitoring

- Quality Assurance
- Workload assessment

Workload Tools Literature

<table>
<thead>
<tr>
<th>Name</th>
<th>Pub Year</th>
<th>Model/Focus/Metric</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fowler &amp; Thomas Acuity Rating Tool</td>
<td>2003</td>
<td>Points assigned to protocol tasks. Time in hrs/protocol task X # points = score</td>
<td>500 – 750 points/coordinator</td>
</tr>
<tr>
<td>NCI Trial Complexity Elements &amp; Scoring Model</td>
<td>2009</td>
<td>Points assigned for each of 10 elements: Mod complexity = 1 pt, High complexity = 2 pts</td>
<td>None reported</td>
</tr>
<tr>
<td>US Oncology Research Study Clinical Coordination</td>
<td>2009</td>
<td>Points assigned to each of 21 scoring criteria, complexity based on number of points</td>
<td>None reported</td>
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<tr>
<td>Complexity = 1 pt</td>
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<td></td>
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<tr>
<td>Ontario Protocol Assessment Level (OPAL)</td>
<td>2011</td>
<td>Points assigned, based on number of contact points &amp; type of trial</td>
<td>None reported</td>
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<tr>
<td>University of Michigan - Research Effort Tracking</td>
<td>2011</td>
<td>Staff time/day average per protocol tasks: Staff time=23-35% + trial-related tasks</td>
<td>Data collected over 15 years</td>
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<tr>
<td>Application (RETA)</td>
<td></td>
<td>25-30% = non-trial (vacation, etc.)</td>
<td>* Yrly average Acuity Score per nurse: T=30.6</td>
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<tr>
<td>Wichita CCOP Protocol Acuity Tool (WPAT)</td>
<td>2013</td>
<td>Trial ranked 1-4 based on 6 complexity elements</td>
<td>ASCO Clinical Trial Workload</td>
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<tr>
<td>(Good, et al: JOP 12(8):2171-2190. 2013)</td>
<td></td>
<td>Data collected over 6 month period from 51 community-based research program</td>
<td>Assessment Tool</td>
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<tr>
<td>ASCO Clinical Trial Workload Assessment Tool</td>
<td>2016</td>
<td>Trial ranked 1-4 based on 6 complexity elements</td>
<td>Data collected over 6 month period from 51 community-based research programs</td>
</tr>
<tr>
<td>(Good, et al: JOP 12(8):e536-547. 2016)</td>
<td></td>
<td>Acuity calculated based on FTE and protocol complexity</td>
<td>Results reported based on size of research program</td>
</tr>
</tbody>
</table>

Another Workload Assessment Formula

- P Butera – Atrium Health (2/27/18 presentation)
  - Protocol complexity
    - Range 1 - 4 (low to high complexity)
    - Phase 1 = 4; specimen/registry trials 0.05, 0.25, 0.5; FU = 0, 0.5, 0.25
  - Developed theoretical Work Unit (WU) capacity for each FTE
  - Formula: Per trial -> number of pts (active & FU) x complexity score (active & FU). Add together scores for all trials per individual = WU
  - Expected WU capacity based on experience
    - 0 - 6 months = 12 WU’s
    - 6 - 12 months = 24 WU’s
    - >18 months = 36 WU’s
  - Experience updated monthly
  - Allows for 20% protected time for non-pt. management activities

Tool Available on ASCO Website

ASCO Clinical Trial Workload Assessment Tool is available [www.workload.asco.org](http://www.workload.asco.org).

It’s free but you need to register to use it.
Discussion

Protocol Management & Participant Coordination

Nancy Burns, RN, BSN, OCN
Manager, Oncology Research, UNC, REX Cancer Center

Clinical Trial Operational Strategies for Community-Based Research

Protocol Management & Participant Coordination

- Research Team Awareness & Engagement
- Team Communication Strategies
- Screening, Consenting and Enrollment
- Regulatory Compliance - Lessons Learned
  - Amendment Management
  - Key Personnel Management
- Contracting - Strategies for success
- Sponsored Research Considerations - Public versus Private
- Data and Bio-specimen Management
Research Team Awareness & Engagement

What Does it Take?

- Hiring the right staff
- Providing orientation to the role
- Weekly team huddles
- Weekly research spreadsheet
- Daily case conference attendance
- Organized shared drive and email management
- Communication

A solid orientation experience is key to adding an engaged coworker to your team.

Research Team Awareness & Engagement: Orientation

Weekly Team Huddle
Weekly Research Spreadsheet

Research Team Awareness & Engagement: Connect weekly!

Patient Name | Protocol | MR # | Cycle | Day | Drug(s) | Doses mg/m2 | Comments
---|---|---|---|---|---|---|---

Weekly Team Huddle
Weekly Research Spreadsheet

*All frames and information included are anonymous (no actual PII)

Research Team Awareness & Engagement: Connect daily!

Daily Case conferences
Physician investigators
Nurse Navigators
Email reminders

ASCO Research Community Forum Annual Meeting 2018 Annual Meeting
Research Team Awareness & Engagement:  
Network Shared Drive & Email Files

- Study 001
- Correlatives
- Correspondence
- Financial Info
- Meetings
- Pharmacy
- Regulatory
- Response Evaluations

Screening, Consenting and Enrollment

- Respect for Persons
- Beneficence
- Justice

Screening, Consenting and Enrollment

Physician: this study is worth your consideration!  
Coordinator: helps patient understand the potential benefits in light of the potential risks

Screening, Consenting and Enrollment

Eligibility Confirmation must be a collaborative process between the investigator and the research coordinator, with enrollment status updates provided to the patient as often as necessary
Regulatory Compliance – Lessons Learned

Opening a Study

Project Management Skills
- Sponsor & PI communication
- Operations Review
- Scientific Review
- Billing Coverage Analysis & Budget
- The IRB application
- The Informed Consent preparation

Regulatory Compliance – Lessons Learned

Amendment Management
Every Study Amendment must have evidence of site staff training. The NCI now requires that amendments are implemented within 30 days (no longer a 90 day window)

Regulatory Compliance – Lessons Learned

Key Personnel Training

Adding Key Personnel is a multi-step process to include protocol specific training, EDC training, COI disclosure, add’t to DOA log & 1572, and IRB approval

Regulatory Compliance – Lessons Learned

Contracts Management: Strategies for Success

- Clear email communication between site and sponsor
- pick up the phone!
- Your financial analyst and lead coordinator review is valuable
- The research manager engages both the PI and legal counsel

Clinical Trial Agreements... in successful negotiations both sides achieve their goals

ASCO Research Community Forum
2018 Annual Meeting
**Sponsored Research Considerations - Public versus Private**

- Industry sponsored trials
- Investigator initiated trials (IITs)
- Federally sponsored trials

**Sponsored Research Considerations - Key Components**

- engaged physicians
- capable research staff
- patient volumes
- the right selection of trials
- an administration committed to research

**Data Management - Quality of Source Documentation**

- Structured Research Progress Notes
- Adverse Events
- Concomitant Medications
- Oral study drug adherence
- Response assessment documentation (PR, SD, PD in stg IV solid tumor studies)
- Investigator reviews, edits and signs off in real time
- Informed Consent Documentation

**Data Management Quality**

Data Quality is dependent on

- Source documentation quality
- Timeliness of data entry
- Accuracy of data entry
- Query responsiveness
- Good problem solving skills and attention to details!
- Remember ALLOCA!
  - 
  - In attributable, legible, contemporaneous, original, accurate and complete
- Institutions are shifting to ‘less paper’ binders, relying on source from the EMR
**Data Management Tracking: Go After the Red!**

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*All names and information included are anonymized (no actual PHI)*

**Bio-Specimen Management**

Bio-Specimen Management and Quality is dependent on:

- Following Good Clinical Practice and Good Laboratory Practice
- Ensuring that research staff are trained per 49CFR 172.700 IATA 1.5/Part 6
- Attentiveness to lab manual/protocol bio-specimens directives
- Advanced preparation for every patient
- Close collaboration with Histopathology on tissue blocks and tracking tool
- Good communication between the Research and Laboratory Staff
Research Quality and Effectiveness
Practical Strategies

Kandie Dempsey, DBA, MS, RN, OCN
Director, Cancer Research
Christiana Care Health Services

Auditing for Quality Improvement and Oncology Patient Advocates for Clinical Trials (OPACT)

Objectives

- Christiana Care’s Research Quality Effectiveness Foundation
  - ASCO – Minimal Standards and Exemplary Attributes of Clinical Trial Sites (Zon, 2008)
  - National Cancer Institute Community Cancer Centers Programs (NCCCP) – Clinical Trial Best Practice Matrix Tool
- Best Practice Strategies
  - Auditing Process and Tool Example
  - Oncology Patient Advocates for Clinical Trials
Foundation

American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites

R. Zon, et al., JCO, 2008; JOP, 2011; A. Baer et al., JOP, 2010

NCI Community Cancer Centers Program (NCCCP)

- 3 year Pilot Program started July, 2007
- Ten Community Based Health Care Systems
- 16 Hospitals
- Goals:
  - Accrue More Patients to Clinical Trials in Community Based Settings and Increase Minority Accrual
  - Reduce Cancer Healthcare Disparities
  - Standardize Biospecimen Collection
  - Link Sites to CA Biomedical Informatics Grid (caBIG)

NCI Community Cancer Centers Program (NCCCP)

CT AIM Beginnings

- Created the "Clinical Trials Best Practice Matrix" tool
- To operationally define the minimum standards and exemplary attributes described by Zon et al
**What is the CT AIM Tool?**

- **A self-assessment** and benchmarking tool to facilitate research program improvements
- Consists of 11 attributes
  - 3 progressive levels
    - From less (Level 1) to more (Level 3) exemplary CT infrastructure
- Community cancer research sites “self-assess” their program
- Moves beyond the minimal standards of Good Clinical Practice (GCPs)

**ASCO Exemplary CT Site Attributes**

- Clinical Trial Portfolio Diversification
- High Accrual (> 10%)
- Participation in Clinical Trial Process
- Formal Maintenance of High Education Standards
- **Quality Assurance**
- Multidisciplinary Care
- **Clinical Trials Awareness**

(2bn R., et al., JCO 5/20/08)

**NCCCP Tool Attributes**

- Underserved community outreach and accrual
- Quality assurance
- CT portfolio diversity and management
- Physician engagement in CTs
- Participation in the CT process (e.g., attending sponsor meetings, active on national committees)
- Multidisciplinary team involvement
- Education standards
- Accrual
- CT communication and awareness (e.g., within oncology, beyond oncology, in lay community)

**Attribute “CT Portfolio Diversity” 2014 V.3.0**

- Radio buttons allow only one answer per indicator
Sites wishing to implement exemplary attributes should review and implement them in the context of their demographics, resources, and goals.

Zon, et al.

Delaware/Christiana Care’s Self-Assessment

- Attribute Opportunities Included:
  - Quality Assurance/Improvement
  - Clinical Trial Awareness/Communication

Quality Assurance

- Research sites that internally implement quality assurance programs ensure adherence to GCP guidelines and generation of high quality data
- Conduct routine self audits
- Review and modify SOPs; implement new SOPs
- Record major and minor violations and undertake corrective action
- Periodic external audits will document and enhance quality of the research enterprise
- EMRs and standardized forms, such as CRFs, will improve quality and timeliness of data

Auditing Committee Objectives

- Purpose: Learning experience to ensure data quality, timeliness of reporting, protocol adherence, investigational pharmacy practices. Not intended to be punitive.
- Peer Review: QA Community comprised of colleagues. Reviews conducted in tandem with research nurse/CRA present.
- Frequency: At least monthly.
- Expectations: Charts to be “audit ready” at all times.
- Followup: Provided within 2-weeks. Corrective action plans if necessary. Information may be provided at team meetings for educational purposes.
Quality Assurance Audit Checklist

- Consent
- Eligibility
- Protocol Treatment
- Deviations
- Disease Outcome/Response
- Research Database Documentation
  - CREDIT
  - OPEN
  - RAVE
- Investigational Pharmacy (DARFs)
- Radiation Oncology

### QUALITY ASSURANCE AUDIT CHECKLIST

**Study Number:**

**Case Number:**

**Patient Name:**

**Nurse/CRA Responsible:**

**Date Completed:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the chart audited within 24 hours of Nurse/CRA notification of audit?</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**CONSENT**

- Was the consent the current IRB-approved version? Y N N/A
- Was the patient fully informed? Y N N/A
- Are there copies on the chart? Y N N/A
- Was the informed consent signed and dated by the patient? Y N N/A
- Was consent signed prior to protocol entry? Y N N/A
- Are all of the blindees filled in? Y N N/A
- Was consent signed prior to protocol treatment? Y N N/A
- Is the consent data & time documented? Y N N/A
- Are all required signatures present? Y N N/A
- Is the consent process documented? Y N N/A
- Is the Informed Consent Form completed & with the consent? Y N N/A

**ELIGIBILITY**

- Eligibility checklist completed? Y N N/A
- Was the 2 Nurse Verification sheet signed & dated? Y N N/A
- All required patient info & charts? Y N N/A
- Are all of the elements of eligibility have primary source documentation? Y N N/A
- Have they completed within the required time frames? Y N N/A
- Lab results? Y N N/A
- Radiographic reports? Y N N/A
- Pathology results? Y N N/A
- Is the Patient Registration Form on the chart? Y N N/A

**PROTOCOL TREATMENT**

- Is the current version of the protocol on the chart? Y N N/A
- Was treatment provided as per protocol? Y N N/A
- Were any dose modifications done? Y N N/A
- Were any dose modifications done? Y N N/A
- Were any modifications done? Y N N/A
- Did the prescription and treatment record on the chart? Y N N/A
- Are there drug administration records? Y N N/A
- Were the patient's Height, Weight and BSA recorded? Y N N/A
- Were there any mandatory testings? Y N N/A
- Are there any required lab tests or radiographic scans? Y N N/A
- Were the patient's Height, Weight and BSA recorded? Y N N/A
- Were there any required testings? Y N N/A
- Were there any mandatory testings? Y N N/A
- Did the patient consent to have the optional Correlative Specimens collected? Y N N/A
- Were they collected in the appropriate timeframe? Y N N/A
- Were they stored properly and appropriately? Y N N/A
- Were the patient consent to complete the optional QOL tests? Y N N/A
- Were they completed in the appropriate timeframe? Y N N/A
- Were the patient consent to complete the optional QOL tests? Y N N/A
- Was any new protocol treatment given? Y N N/A
- Is the information correctly documented? Y N N/A

**DEVATIONS**

- Are there any deviations? Y N N/A
- Are there any deviations? Y N N/A
- Are there any deviations? Y N N/A
- Is the report on the chart? Y N N/A
### Disease Outcome/Response

<table>
<thead>
<tr>
<th>Question</th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the Follow-Up process followed?</td>
<td></td>
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<tr>
<td>Is the Follow-Up Transfer Form completed and Up-To-Date?</td>
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<tr>
<td>Is a copy on the chart?</td>
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<tr>
<td>Is the Follow-Up current?</td>
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<tr>
<td>Is there source documentation that corresponds with the dates of Follow-Up reports?</td>
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<tr>
<td>Were the required exams, labs, radiographic reports, QOL &amp; specimens completed in a timely fashion?</td>
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<tr>
<td><em>For CRA's only:</em> check with manager for Queries/Overdue Forms for studies not on RAVE*</td>
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</tbody>
</table>

### Credit

<table>
<thead>
<tr>
<th>Question</th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>Auxiliary Doctor noted?</td>
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<tr>
<td>Credit Checks completed?</td>
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<td>Financial milestones checked?</td>
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<tr>
<td>Was there a Re-Consent needed?</td>
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<tr>
<td>Was it uploaded?</td>
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<tr>
<td>Is there an A - Arm assigned?</td>
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<td>Is the completion date entered?</td>
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### OPEN: Funding

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<thead>
<tr>
<th>Question</th>
<th>Y</th>
<th>N</th>
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<tbody>
<tr>
<td>Are the specimens or QOL submission data entered or comments if not submitted?</td>
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</table>

### RAVE/DAP

<table>
<thead>
<tr>
<th>Question</th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
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<tbody>
<tr>
<td>Any overdue forms?</td>
<td></td>
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<tr>
<td>Any active queries?</td>
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</table>

### DARE'S

<table>
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<tr>
<th>Question</th>
<th>Y</th>
<th>N</th>
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<tbody>
<tr>
<td>Are the chart records agree with the DARE?</td>
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### Radiation Oncology

<table>
<thead>
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<th>Y</th>
<th>N</th>
<th>N/A</th>
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<tbody>
<tr>
<td>If there was a Radiation component, was the Radiation Communication Procedure Followed?</td>
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<tr>
<td>Was the Radiation Therapy Alert form completed appropriately?</td>
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### Comments:

- **Clinical Trial Awareness/Communication**
  - Survey data suggest the public in general, and cancer patients in particular, have a low awareness about clinical trials.
  - Only 3-5% of eligible cancer patients take part in a clinical trial.
  - Clinical trial results are not being routinely provided to research participants once trial is complete/published.
  - Local voice of protocol participants regarding clinic trial engagement was not included.

- **OBJECTIVES**
  - Enhance ways to increase awareness of clinical trials by educating patients and our community members regarding what a clinical trial is and the importance of clinical trial participation. Also, to dispel myths concerning clinical trial participation.
  - Limiting/Reducing the overwhelming feelings in the decision making process by connecting prospective clinical trial participants with survivors who have participated in clinical trials so patients can make informed decisions regarding participation.
  - Develop outreach projects to provide education within the community.
  - Involve patients advocates proactively in clinical trial process, including involvement in protocol development, protocol review, ideas for enhancing clinical trial enrollment and providing the patient perspective to researchers designing clinical trials.
  - Gain feedback for how to provide clinical trial results to former clinical trial participants once studies are complete.
  - Gather ideas for the recognition of clinical trial participants, such as through an annual celebration.

- **INTRODUCTION**
  The American Society of Clinical Oncology (ASCO) issued a "Statement of the Characteristics and Attributes of Exemplary Clinical Trial Sites." An organizational assessment of the standards indicated that "Clinical Trial Awareness" was a value-added attribute that, if enhanced, may contribute to improved accrual and success in maintaining the opportunities for patients and research staff to participate in the clinical trial process. As a result of these findings, "The Oncology Patient Advocate for Clinical Trials Committee" (OPACT) was organized. The committee is integral for enhancing awareness and support for clinical trials. Members include individuals who have participated in the oncology clinical trial process and those that are involved in patient advocacy within our community. The Helen F. Graham Cancer Center (HFGCC), Cancer Research Department has spearheaded this program under the leadership of Stephen Grubbs, M.D., Principal Investigator of the National Cancer Institute designated HFGCC Community Clinical Oncology Program.
Accomplishments

- Reviewed clinical trial consent forms for readability.
- Participated in clinical trial computerized survey testing for ease of use.
- Developed clinical trial educational brochure.
- Serve as advocates for those considering clinical trial participation.
- Enhance awareness by providing educational programs to local High Schools, STEM Programs, Colleges and Universities.
- Represent our community at national venues
  - The Alliance for Clinical Trials in Oncology Cooperative Group
  - American Association for Cancer Research’s Scientist-Survivor Program
  - NCI

Accomplishments

- Attend Community Events: Health Fairs, Relay for Life, local Farmer’s Market, Community Support Groups, Health Care Screening Events, etc.
- Collaborate to develop lay language clinical trial results provided to participants once studies are complete.
- Participate in Annual Clinical Trials Recognition/Celebration Program.
- Bring joy and support to the clinical trial team!

OBJECTIVES

Oncology Patient Advocates for Clinical Trials (OPACT) is a group of cancer survivors who have participated in clinical trials and seek to help other individuals who may be considering clinical trial participation. OPACT serves to enhance awareness of clinical trials, to guide the process and help patients informed decisions and to provide outreach and education to the community.

The OPACT committee was convened and held its inaugural meeting in August 2011. To date, the committee has:

- Provided clinical trial results to study participants whom results have been published in a peer-reviewed journal.
- Developed a logo for the OPACT committee.
- Created an organizational assessment of cancer survivors who have participated in clinical trials so patients can make informed decisions regarding participation.
- Convened an annual “Hero’s Ceremony” recognizing clinical trial participants and physician clinical trial champions.
- Providing outreach and education to the community.
- Proactively engaging in the clinical trial development process.
- Composed a Patient Advocacy brochure, "OPACT: Oncology Patient Advocates for Clinical Trials"
- Serving as advocates for those considering clinical trial participation.
- Enhance awareness by providing educational programs to local High Schools, STEM Programs, Colleges and Universities.
- Represent our community at national venues
  - The Alliance for Clinical Trials in Oncology Cooperative Group
  - American Association for Cancer Research’s Scientist-Survivor Program
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The OPACT committee is concerned and held its inaugural meeting in August 2011. To date, the committee has:

- Become ambassadors for reviewing and approving clinical trial results published in peer-reviewed journals.
- Participated in educational programs regarding the clinical trial process and Institutional Review Board requirements to increase their knowledge about the clinical trial process.
- Highlighted the importance of clinical trials.
- Provided clinical trial results to study participants whom results have been published in a peer-reviewed journal.
- Developed a logo for the OPACT committee.
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Delaware Cancer Clinical Trials Benefit

- Contributions to Cancer Care Advancements
  - Quality Improvement
    - Promotes Education/Best Practices
    - Promotes quality in clinical research
    - Improves Billing/Reimbursement
    - Raises Standards of Care
  - Inclusion of Advocates in Clinical Trial Process
    - Improves Patient Engagement
    - Provides Timely Research Result Summaries to Participants
    - Promotes Clinical Trial Participation in our Communities

Discussion