Tackling the Tribulations of Clinical Trials with Research Technology

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Faculty Disclosure

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I do not have financial or other relationships with the manufacturer(s) of any commercial services(s) discussed in this educational activity.

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Introductions

• Krissy Bouchard, Clinical Trial Manager
  • Raleigh Neurology Associates, Department of Research
    • BS, University of Southern Maine in Business Administration
    • With Raleigh Neurology for 5 years with 1 ½ years dedicated to Clinical Research
    • Raleigh Neurology is a large private practice with a dedicated research center
    • Oversee the daily clinical trial operations in a unique setting of 13 research staff with over 80 active studies

• Kyle Byron
  • Senior Account Manager, Clinical Conductor CTMS
    • BA, State University of New York at Geneseo
    • With Bio-Optronics in research for 3 years
    • Has experience deploying research sites, site networks, AMC’s and Health networks
    • Analyzes current state workflows and map to future states
    • Worked with multiple system integrations
Why Technology?

• Clinical Research has a recently had a changing landscape by adopting technology recently... Why?
  • Increasing efficiencies
  • Cloud based technology allows for access anywhere
  • Managing milestones
  • Instant notifications
  • Tablet and phone access

• Complexity of trials
  • With complex trials and visit windows, future projected dates can become automatic.
    • Coordinator can instantly see future appointments
    • Site Managers anticipating future staff workloads
    • Financial Projections
    • Phone screening with instant answers/analytics
Why Technology?

• Risks of security
  • Using technology has benefits of electronic saving and backups. What happens if you lose your binder?

• Greater Efficiency
• Improvement in Data Collection Management and Analysis
• Improved communication with sponsors and CRO’s
• Reduction of rework and risk due to lost documents
• Stand up studies faster and more efficiently
• Ability to determine reporting needs and sources of data
What’s Out There?

- CTMS
- Patient Payments Systems
- EDC
- EHR
- eTMF
- Webinars/Trainings
- eSource
- RBM
- ePRO/Electronic Diaries

Trends
- Mobile-smart phones, wearable health monitors
- Social-trying to find a way to control this medium while keeping the best interest of the patients, trials and clinical research system in check.
- Cloud
- Big Data
What We Use at RNA

• EMR System
  • Patient Database
  • Provider Scheduling
  • Electronic Source Document Storage

• Document Management
  • Departmental Documents
  • Study Document

• Clinical Trial Management System
  • Study Operations
  • Financial Management
  • Patient/Coordinator Scheduling
  • ...and a lot more!
How Technology Impacts Sites
Financial Management

• Billing
  • Instant reporting across multiple trials, i.e.:
    • What is currently outstanding?
    • How much money are we owed?
    • If it’s CRF payments, are they actually paying us what we are owed?
    • Removing double data entry. Entering into Excel or QB?

• Compliance
• Cost tracking
  • Keeping a true understanding of true costs
  • Allows for time & effort reporting
  • Leverage this into budget negotiations.
  • True break even. Don’t settle for less

• Future Projections
  • Utilizing tools already entered to get financial outlooks for months to come
Study Enrollment

• Maximizing recruitment budgets
  • What recruitment source is providing the most ROI?
  • Do we need to change the ways we recruit?

• Enhancing budget negotiations
  • Easily track prior payments
  • Tracking sponsor payments

• Finding the right patients fast
  • Enter in screening criteria and quickly figure out how many subjects are eligible for a study
Study Enrollment

- Leveraging your website for patient self-service (web recruitment)
  - Have that screening criteria on your website, craigslist, etc.
  - Let them know quickly if they qualify and are interested.

- Tracking deadlines and progress
  - Milestone management
  - Where is the bottleneck in our processes? Do we need additional resources?

- Detailed call center functionality that makes it easy to pre screen, qualify and track patients
  - Quick and easy screening abilities
  - Technology allows for immediate results on screening criteria
  - Have that data transfer through immediately to reporting
  - Know and learn which advertisement mechanisms are most cost effective
Patient Satisfaction

- Visit scheduling
- Consenting
  - Who needs to reconsent?
- Constant communication
  - Email
  - Text
  - Etc.
- Storing patient info for future contact
- Patient payments
  - Debit card simplification
Internal Process Efficiency

• Document management
• Project management
• Decreased duplicate data entry
  • Duplicate data entry is a waste of time
  • Technology allows for data to be entered 1x and have the same information pull through an integration
• Training
  • The process and systems put in place are only as good as the staff is trained.
Internal Process Efficiency

• Coordinator efficiency
  • Falls in line with duplicate data entry
  • Especially patient payment systems
  • No wait or hassle for the patient
  • No time wasted for requesting checks/having checks issued

• Documented and standardized staff workflows
  • Workflow management maximizes productivity
  • Utilizing a system that keeps consistencies for all workers
  • Consistent workflows allow for consistent reporting
  • Is there a process that is taking longer than expected?
  • Can technology help out this process?
Quality and Consistency

• Data quality
  • Reduces errors because of manual entries.
  • Certain systems can facilitate
  • Essential to maintaining the integrity of research
  • Financial component – sites receiving payment

• Patient care
  • Top priority is the care and safety of our patients
  • Tracking patient care through technology
  • Easily review patients prior history
  • Integrations with EHR systems to reduce redundancies
  • Quickly and easily tell if someone qualifies for a trial
    • Or if they qualify for any trial at the site
Communication and Collaboration

• Partner management
• Internal collaboration
  • Easily assign people to do tasks and track their efficiencies
  • Understanding where each part of the process stands without reaching out to people (saves time on both sides)
• Sponsor communication
  • Manage departments of each Sponsor
  • Keep electronic records for instant communication with Sponsors
  • Pushing all information electronically
Reporting

- Business intelligence
- Profitability data
  - Getting a true understanding of internal costs and comparing that with what the sponsor is going to pay. Going through budget negotiations to know what the bottom line is to reach a break even point.
  - Understanding what the Sponsor paid for similar trials previously instantly.
- Recruitment data
  - Easily track where patients are coming from.
  - What’s our best ROI
  - Are certain phone screeners most productive?
- Leveraging past performance for forecasting and negotiations
  - Utilizing entered budgets and visit windows. Having future projections to know whether FTE’s are needed or understand payroll projections.
Reporting

• Site Management
  • Site budgets and investigator payments
  • Subject enrollment and progression, visits, and status
  • IP, ancillary supplies, Protocol Deviations, site visits, and monitor f/u’s

• Financial Tracking
  • Monitoring expenses across a project
  • Tracking investigator payments based on milestones
  • Tracking pass through expenses at site or study level
Workshop Activity

• The Plan:
  • Common research problems (SCRS Will advise on selecting a number of problems below):
    • Ease of reporting/metrics?
    • Financial negotiations?
    • Server based storage vs. cloud/web based
    • Overcoming the “disruptions” of changing to a new system/process-positive and negative of change
    • SIF Process from site to sponsor
    • EDC vs eSource
    • Metrics reporting
  • Ensure there’s tools (white boards, paper, etc.) for users to divide into groups
  • Each group is assigned a common research problem
  • Each group can brainstorm how technology can be used to solve this common site issue
  • Speakers will regroup and each station will present their findings. Speakers will comment, elaborate and facilitate an open discussion for each problem.
Workshop Discussion
Technology: Where to Start?

- Understanding current strengths
- Identifying current weaknesses
- Where does your business want to go in the future?
- What are you already using?
- Seek out best practices before starting your evaluation
Best Practices When Choosing Technology

• What is the main objective of the system? What are the nice-to-have items?
  • Base your decision on the main objectives, but keep in mind the nice-to-have items as
• Ask questions!!
• Do your research
  • Sample the systems
• Understand how the implementation process will happen
  • Are you only getting a user manual and learning on your own?
  • What happens when you are having trouble? Is there support available?
• Is it worth the price?
  • Internally manage resources to make sure the system will be thoroughly learned and used
  • Don’t purchase something if there’s not enough time to make a change
• Implement with a phased approach in mind
  • Don’t overwhelm staff/users with a new system and take on the entire project at once
How to Find the Technology Your Site Needs?

• What questions should your site ask to vendors?
• Who should be involved in the decision?
• What things should you not forget to think about:
  • User-centric design of software (good UI/UX – not common in healthcare)
  • A projected timeline for implementation
  • Using a phased approach (core components first then the “nice to have’s” after)
  • Have an internal “super user” if possible
  • Reducing redundancies
    • Are there current systems that are being used that can be eliminated?
• What to expect from vendors
• INTEGRATIONS!!! Ask!
• Where to go to get info?
  • Web
  • Trade shows/conferences (Like this one!)
  • Other sites!
Conclusion

• Improving site quality by enabling sites to run trials faster, less expensive, and with greater efficiency
• Improved data collection and management
• Improved communication with sponsors and CROs
• Budget Negotiation
• Patient recruitment avenues
• Centralized study information
• Getting the drug approved and available quicker
Questions?
Thank You!!

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