Leveraging Technology to Conduct Oncology Clinical Trials More Effectively

Speakers

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Introduction

Dax Kurbegov, MD
Sarah Cannon

Session Focus

- How might research sites leverage technology to:
  - Improve efficiencies
  - Improve quality
  - Expand access
  - Engage stakeholders
- Understand how industry partners are using technology to accelerate and improve the research endeavor
  - Opportunities to enhance sponsor-site partnership
- Recognize the active role of the FDA in modernizing the clinical trial landscape

Tele-Oncology and Clinical Pathways

Ramya Thota, MBBS
Intermountain Healthcare

Typical medical oncologist level of IT sophistication…

I changed all my passwords to “incorrect”.

So whenever I forget, it will tell me “Your password is incorrect.”
“Rural and urban patients with uniform access to cancer care through participation in a clinical trial had similar outcomes.”

Improving access to uniform treatment strategies for patients with cancer may help resolve the disparity in cancer outcomes between rural and urban patients.

Unger et al. JAMA Oncology 2018

Tele-Health for Oncology

- Ability to provide oncology care anywhere
- Standardized treatment, flow and services
- Increase access to subspecialty services
- Patient convenience, engagement and satisfaction (care closer to home with minimal disruption in their lives)
- Opportunity for cost savings to all stakeholders

Case Study

- Rural Community “Richfield, UT” (~20,000 population, 120 miles away from nearest oncology clinic)
- Cancer cases not getting care
- Many not pursuing treatment due to effort and distance

Patient savings:
- Average lost wages (mean) @ $144.01
- Federal mileage reimbursement @ $180.94
- Travel hours saved @ 4 hours 40 min to nearest oncology clinic
- Mileage @ 332 miles

Professional Fees:
- NPV $340
- ROV $170
- Site origination fee @ $220: onsite telehealth fee/hospital clinic

Implementation of Tele-Oncology in Clinical Trials

- Novel way to obtain informed consent
- Minimize number of non-study visits
- Instead of traveling for an initial pre-screen visit, patients at remote sites can be seen by telehealth
- Physicians bill for their time like a normal visit with a telehealth billing modifier
- Only eligible patients travel to tertiary site for clinical trial participation
- Improve access, efficiency and patient convenience (reduce the time and cost)
- Wearables, health apps, implantables, remote symptom monitoring etc.

Challenges with Tele-Oncology

- Reimbursement
- Operational changes requires (staffing and technology requirement)
- Capital required to invest in technology
- Provider reluctance
Clinical Trial Alerts

Clinical Trial Alert and Clinical Pathway Programs

- Physician awareness and appropriate patient identification are key
- Integration of clinical pathway decision support tools to electronic health record
- Deliver standardized treatment across the system
- Improve clinical trial enrollment

Shamah CJ, et al. Journal of Clinical Oncology 34, no. 7_suppl (March 1 2016) 167-167


https://intermountain-viaoncology.com/

Challenges with Clinical Pathways

- Physician/Research staff engagement (click fatigue, time/effort)
- Effect may wane over long term use
- Time consuming
- Integration to electronic health record
Site Pain Points and Solutions
Fran Palmieri, MSN
Sarah Cannon

Presentation Key Topics
- Conceptual framework
- Investigative site pain points, priorities
  - Are there solutions?
- Research management across teams within one central system
  - Sarah Cannon Study Central Highlight
- Expanding trial options for targeted patients
  - Sarah Cannon Genospace Highlight: Identify and bring patients with molecular profiles onto trials more effectively

Framework for Implementing Change with Technology
Why are some organizations more successful in implementing new technology?
- Complex and multi-faceted
- Vision to implemented system requires active participation and engagement
- Active Facilitation
  - Project management, quality improvement, team and group process skills, influence and negotiation skill, expert at embedding and sustaining change
- Key elements have been categorized within Implementation Science Models* and Integrated Technology Innovation Adoption Models (ITIM)**

Lifecycle Approach
Ten Key Considerations
1. Clarify what problem(s) the technology is designed to help tackle
2. Build consensus
3. Consider your options
4. Choose systems that meet clinical needs and are affordable
5. Plan appropriately
6. Don’t forget the infrastructure
7. Have a plan to train staff
8. Continuously evaluate progress
9. Maintain the system
10. Stay the course*

Investment in Systems
Sarah Cannon invested heavily in systems to aid in execution of increasingly complex trials...

Sarah Cannon Study Central Solution
Enabling The Convergence Of Clinical Research And Clinical Care

- Personalized Genomic Data Interpretation
  - Functional characterization of molecular variants within the context of existing clinical trial menu and agnostic to laboratory provider.

- Automated Clinical Trial Matching
  - Highly-specific trial matching to enable efficient patient screening and management, clinical trial workload management, and menu browsing.

- Clinical Decision Support and Collaboration
  - Facilitates virtual collaboration between clinicians and personalized medicine thought leaders to support care across the patient journey.

- Population Cohort Exploration
  - Hypothesis-driven analyses of aggregated clinical and genomic population data to facilitate cohort identification, feasibility analyses, and study selection.

Leveraging Technology

Joanne Dourado, BSN, MBA
Eli Lilly and Company

Site Identification Tools

- Utilize historical performance data
  - Enrollment metrics
  - Quality metrics
  - Blood and tissue collection metrics
- Focused discussion for study feasibility
  - Patient population volume within practice
  - Standard of care
  - Study procedures (including device requirements)
- Move seamlessly into Site Selection

Site Selection and Study Start-Up Tools

- Technologies Supporting Shared Investigator Information
  - Cross-pharma platform
  - Study site workspaces
  - Electronic data and document exchange
  - Single-sign on
- Updated Training Methodology
  - On-Demand training
  - Virtual training sessions
  - Task-Based training for support staff

Additional Technology Opportunities

- Digital/On-line Patient recruitment
  - Digital pre-screening and patient flow management
  - Online/social patient outreach
  - Trial registries and patient education
- Patient trial apps
  - Patient reimbursement
  - Travel assistance/concierge
  - Trial activity management
  - Site communications
- Site productivity apps
  - Site/Sponsor communication tools
  - Site/Sponsor document management and workflow
Leveraging Technology to Conduct Oncology Clinical Trials More Effectively  
- FDA Perspective -

Laleh Amiri-Kordestani, MD  
Office of Hematology and Oncology Products, FDA

Modernizing Clinical Trials Agency’s Priority

- Precision guided medicines can demonstrate strong efficacy signals in early small biomarker selected trials
- The agency is committed to develop a regulatory framework that generates robust evidence of product safety and efficacy as efficiently as possible

FDA Modernizing Efforts

- Collaborated with multiple stakeholders
  - Digital Health Technologies
  - Identified acceptable innovative trial designs
    - Enriched Trials
    - Master protocols

Digital Health Technologies (DHTs)

- Electronic tools that use computing platforms, connectivity, software and/or sensors for health care uses
- DHTs may be used as wearable, implantable, or ingestible sensors, or environmental sensors placed in the subject’s home or immediate environment

DHTs Examples

- Hand-held electronics
- Mobile platforms such as tablet computers and mobile telephones
- Mobile applications that use general purpose and/or specialized hardware

Wearable Sensors

- Small electronic tools containing one or more sensors that are integrated into clothing or worn on the body
  - Examples: wearables for body temperature measurement, respiration monitors, heart rate monitors, tools measuring ECG or EEG, and pulse oximeters
Regulatory Consideration

- DHTs do not require FDA clearance to be used in a clinical trial
- However if the DHT is to be marketed with a medical product, then the DHT is considered part of the medical product and should be evaluated by the appropriate review division

Potential Uses of DHTs for Clinical Trials

- To collect data for trial endpoints
- Safety Monitoring
- Informing dose selection, and dose optimization
- Track patient adherence
- Enrollment, screening or enrichment of a study population

Safety Monitoring

- Draft guidance for industry: A Risk-Based Approach to monitoring of Clinical Investigations: Questions and Answers
  - more efficient oversight of trials
  - use computerized algorithms that enable remote and central trial monitoring

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Enriched Trials

- Guidance for Industry: Enrichment Strategies for Clinical Trials to Support Determinations of Effectiveness of Human Drugs and Biological Products
  - defines several types of enrichment strategies
  - provides examples of potential clinical trial designs
  - discusses potential regulatory considerations

Master Protocols Trial Designs

- In parallel, can evaluate different drugs compared to their respective controls or to a single common control
- The infrastructure can last for decades
  - Can be updated to incorporate new scientific information/questions, like novel biomarkers
- Reduces administrative costs and time associated with standing up new trial sites for each drug candidate
Summary and Conclusions

- FDA continues to work with stakeholders to modernize clinical trials
- The agency is committed to develop a regulatory framework that generates robust evidence of product safety and efficacy as efficiently as possible
- The agency tries to make a positive approval decision as early as possible => patients can gain earlier access

Thank you!
Laleh.AmirKordestani@fda.hhs.gov

Discussion

Question 1
- Physician engagement is consistently cited as a primary driver of site success. In what ways are your programs using technology to enhance engagement?

Question 2
- Technology investments are typically significant, potentially out of reach for many community sites. How have your programs “sold” technology investments to administration? Are there key solutions that have demonstrated unequivocally favorable ROIs?

Question 3
- The gestation period of a functional and value-added shared investigator platform remains undefined. Despite apparent progress in the last couple of years, uptake of the SIP across industry is inconsistent and sometimes differs within a sponsor’s organization. What opportunities exist to accelerate standardization and utilization?
Consider the FDA’s ongoing commitment to modernizing the clinical trial landscape, are there specific implications or considerations sites should be considering to be positioned for success in the future?

Ramya
- We think of telemedicine as a “world thing” yet I have patients who cannot go 10 miles or drive 10 minutes. Reimbursement is a state to state thing—how can we promote expansion? Can the FDA help?

Fran
- As networks, large institutions, and large groups adopt various technologies (and accept the significant investment), how are we not going to get into the same fix as CRO’s/sponsors with different platforms. Think for example on precision medicine links, HIS ER, CTM’s, linkable data. Can ASCO help here as well? (Before we get too far down that road)

Joanne
- Individual Pharma company uses accrual data for site identification, can they see what else aside is doing? For example, you might of failed on a Lilly study simply because you were killing it on a BMS study. She also refers to “quality metrics” and “tissue metrics”. Specifically what metrics. This speaks to designing your research unit for the future. Must add love the idea of task based, virtual (on demand) training! What does Lilly see Pharma doing to standardize and improve inefficiencies across different platforms?

Laleh
- There is mention of enriched trials, master protocols. What about historical controls? What about use of synthetic control arms or RWE for regulatory approvals?
- Would be FDA a be open to so-called just in time models? What are they doing to promote innovation regarding trial design and execution that reflects the actual community of patients that we will eventually be treating?