Communication and Laboratory Leadership

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How Clinicians View Labs



Your Role

- Regardless of your job title in the lab, you are a key person for the success of IMPAACT TB trials
- That makes you a leader and responsible for quality data generated by you and your peers
- You are responsible for converting the black box into a glass house and becoming a partner to the clinicians

Closer to True...



Quality Management Laboratory Information Systems Validation Source Documents Training Facilities GCLP Specimen Transport Biosafety **Performance Indicators** Equipment Standards and Interpretation

Test Result

How Do We Get Here?



But first... how do you function with your trial site team?

- Do you talk or meet with trial team members outside the laboratory daily, monthly, weekly?
- How and when do you learn about the study protocol?
- Do all members of the lab team understand the trial design and endpoints?
- Do you talk to site staff about how to collect and transport quality specimens?
- What happens when specimens are poor quality? Missing? Mislabeled?

Do you manage or lead?

- Managers direct someone else to perform a task
 - Position of authority, small or large
 - Paid to perform a task
 - Prefer to avoid conflict
- You can manage people or projects
 - A specific study/portfolio
 - A task, such as quality assurance or data entry
 - A team

Do you manage or lead?

- Leaders motivate the people who work with/ for them (followers)
 - Instead of telling them what to do, appeal to them so they want to become better
 - Entrust others to work towards your task
 - Seek risks by exploring problems and overcoming hurdles

Leading in Research

- Research is asking questions or working to solve a puzzle
 - Ask questions
 - Engage your team
 - Demand quality

Partnership Makes a Complete Picture

No piece of the puzzle is more or less important because there is no success without all pieces



Puzzles Throughout HIstory

- Polio Vaccine
- Structure of DNA
- Penicillin and antibiotics
- Sequencing nucleic acids
- Antiretroviral therapies (ART)

Your Lab's Role in the TB Puzzle

- Laboratory testing is critical to identify the patient population and evaluate treatment efficacy
- So much more than a black box....

Your Role in the TB Puzzle

- Be familiar with the protocol- understand the questions asked and how the laboratory testing contributes to trial success
 - Each trial answers a different question

Ask questions

 Your questions may contribute to a better way to accomplish something

Your Role in the TB Puzzle

- Engage your team to understand how their work contributes to the research question
- Demand quality in every step of the process
 - From your team
 - Good Clinical Laboratory Practice
 - Peer Observation and Performance Reviews
 - Every specimen, every test, every result, every CRF
 - From the study team
 - Every specimen collected and transported

Key is Communication with Your Team

- Create opportunities for the team to learn about the protocol and how the research depends on their contribution
- Encourage feedback and opportunities for team members to ask questions or make improvements
- Talk openly about challenges and mistakes and lessons learned

Key is Communication with Site Staff

- Establish regular meetings with agendas
- Ask to review protocols in advance of opening enrollment
- Ask site about their expectations for the lab and negotiate, if needed
- Talk about enrollment pace and laboratory capacity on a weekly or monthly basis

Key is Communication with Site Staff

- Discuss quality challenges with specimens or testing and ensure the site staff understand how quality affects the trial
 - Specimen quality- collection and transport
 - Contamination rates
 - Stock outs or recalls
- Expectations for turn-around-time and reporting
 - How will results be communicated?
 - Process for discussing complex cases or indeterminate results

Be a Leader in Research

- Initiate open communication with site staff and your team
- Ask questions and ask if others have questions

Questions?