Investigator Sponsored Trials: Navigating the Regulatory and Funding Hurdles for Innovative Translational Studies

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Additional Challenges

- Consumer driving services
- Social media
  - One negative experience
- Transition to investigator-initiated studies
How can one develop successful studies?
Answer: Assemble a team

- Content specialist—Principal Investigator
  - Scientific/Medical expertise
  - Grantsmanship
  - New skills—team building
- Clinical Coordinator
- Research Navigator
Assemble clinical study team

- Content specialist—Principal Investigator
  - Science/Medical expertise
  - Grant experience
  - Leadership qualities
- Clinical Coordinator
- Research Navigator
Healthy Team Member Characteristics

• Flexible
• Ability to listen
• Make decisions fairly
• Interpersonal training/coaching

Begg et al., 2013
Questions for Evaluating Team Effectiveness:

- How do interaction characteristics of team members contribute to or hinder the development of communication networks among the team?
- How does the leader create equality of participation as well as equality in sharing the team’s rewards?

NIH Team Framework, Team Science Framework website
Case Study: ABI

• Team:
  • Surgeons, audiologists, clinical coordinator, pediatric clinical psychologist, speech language pathologist, educational liaison, statistician, basic scientist, billing specialist, hospital administrator, contracts and grants, electrophysiologist, regulatory (IRB and FDA) liaison, PALS

• 14 specialists (and counting)
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