Discussion Items

Lifecycle of a clinical trial

Quality

Patient Fit

Contracting

Budgets

Support & Training

Survey Question #1

Audience, please text MARKR855 to 22333 to join the session

What is the biggest issue running your clinical research site?

A. Finding the right study
B. Finding the patients
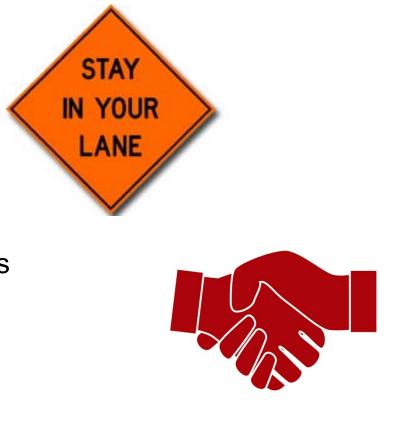C. Budgeting & Contracting
D. Support & Training
E. Other

Patient Fit – Study Initiation

- As a Site… "Stay in your Lane"

- Well Developed Protocol
- Relevant Manuals and Brochures
- Initial Disclosure of Information
- Commitment from Sponsor and CRO
- Engagement with PI and Research Teams

- Work Together for Success!

Contracting

- Good Communication
- Consideration of Institutional Requirements
- Identification of all Contacts
- Knowledgeable and Responsive CRO/Sponsor
- Building and Leveraging Past Experience
- Clear/Organized Contractual Language and Addendums
- Rapid Turnaround Time

- Work Towards ➡ Master Clinical Trial Agreements

Budgets

- Protocols Developed by Experienced Investigators
- Easy to use Study Templates
- Fair Negotiation
- Good Communication (see the theme here?)
  - Business Model
  - Unique Site Distinctions
- Realistic Cost Model
  - PI Time
  - Coordinator Time
  - SAE's, Monitor Visits, Query Resolution, etc…

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Support and Training

- Investigator Meetings
- Extensive Training for Research Teams
- Tools to Facilitate Identifying Subjects
- Ongoing Communication
- Rapid Problem Resolution
- Supportive Monitors
- Audit Support

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Quality

- "It's a Partnership"
- Clear SOP's and Guidelines
- Sharing Best Practices
- Review Constantly
- Adequate Record/Data Retention
- Training - Outside of the Specific Protocols
- Oversight & Guidance
- Be Consistent

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Alignment

- Engaged Sponsors with Site PI and Staff
- Consideration of the Mission of the Organization
- Not all sites are the same
  - Appreciation of nuances
- Consideration of Privacy and Security
- Patient Centric Approaches

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Future State

- Electronic Environment
  - Leveraging the EMR
  - e-Source
  - e-Reg
  - CTMS
- Benefit for Certified Staff
- A "Joint Commission" for Clinical Research Sites
- Machine Learning / AI
- A Holistic Genomic Repository (opt in)

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Survey Question #2

Audience, please text **MARKR855** to **22333** to join the session

What is the most important innovation to you in the near future?

A. Electronic Capabilities
B. Certification of your site
C. Machine Learning / AI
D. Holistic Genomic Repository
E. Other

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Conclusions

- Key Take Always…

- Communication is KING
- Experienced Investigators are Key
- Quality Rules
- A 360 Engagement Strategy

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Questions

Thank You!