Finding Solutions: For Sites, By Sites, During COVID-19

Jessica Anderson, CCRP, Clinical Research Site Manager, North Texas Clinical Trials: Back to Basics: Distilling site operations to the critical elements necessary to safely serve protocols and patients.

Shishuka Malhotra, M.D., Chief Executive Officer, Neuro-Behavioral Research: The Human Element: Rediscovering the positive impact and value of sites for the patients.

Zach Mitchell, Director of Business Operations, iResearch Atlanta: Community Outreach: Looking at ways to connect with advocacy organizations, using mobile teams and solidifying research sites as a part of the local healthcare ecosystem.

Woody Woodaman, Co-Founder and Chief Executive Officer, Synergy San Diego: Communicating with Partners: Exploring recommendations and guidelines to facilitate robust communication between sites, CRO’s, and sponsors.

Stay Safe and Stay Well. Wednesday, May 13, 2020
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Jessica Anderson, CCRP
Clinical Research Site Manager
North Texas Clinical Trials

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Back-to-Basics: Distilling site operations to the critical elements necessary to safely serve protocols and patients

Patient:
- Visits
  - Clinic
  - Remote
  - Home
- Safety
  - Risk Reduction
  - Proper Procedure
- Comfort
  - Compensation
  - Site Interactions
  - Care

Sponsor:
- Monitoring
  - In Person
  - Remote
- Regulation
  - FDA
  - IRB
  - GCP
- Design
  - Protocol
  - Procedures

Data Collection & Verification

Safety & Endpoints

Efficiency & Communication

Quality Experience

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Back-to-Basics: Distilling site operations to the critical elements necessary to safely serve protocols and patients

Special Thanks to:
Aiden Smith
Dr. Brian Maynard

Preparation
- SOP’s
- Study Specific Procedures
- Source

Interaction
- Compassionate
- Efficient
- Professional

Documentation
- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
- Complete
- Consistent
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Shishuka Malhotra, M.D.
Chief Executive Officer
Neuro-Behavioral Research

The Human Element: Rediscovering the positive impact and value of sites for the patients.

Stay Safe and Stay Well.

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The Human Element: Rediscovering the positive impact and value of sites for the patients.

✓ Being a part of the healthcare ecosystem in the communities you serve by giving back to patients and communities
✓ Sharing resources and expertise
✓ Unforeseen positive opportunities for sites
Community Outreach: Looking at ways to connect with advocacy organizations, using mobile teams and solidifying research sites as a part of the local healthcare ecosystem.
Community Outreach

Build Relationships with Local Advocacy Organizations
- NAMI Affiliates
- Mental Health America
- Local Mental Health Providers

Be a Resource to the Community
- Host educational, virtual meetings
- Newsletters
- Q&A with medical staff

Outreach
- Mobile teams
- Support patients (medication maintenance, referrals, etc).

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Woody Woodaman
Co-Founder and Chief Executive Officer
Synergy San Diego

Communicating with Partners: Exploring recommendations and guidelines to facilitate robust communication between sites, CRO’s, and sponsors.
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Communicating with Partners: Exploring recommendations and guidelines to facilitate robust communication between sites, CRO’s, and sponsors.

✓ People don’t do business with companies...people do business with people.
✓ Your greatest asset is YOU.
✓ The customer ISN’T always right ...BUT THEY ARE ALWAYS YOUR CUSTOMER.
✓ The hard you work, the luckier you get.
✓ Be in the right place at the right time.
✓ Always take it personally in business.
✓ WHEN YOU SCREW UP...OWN IT

Stay Safe and Stay Well.

Wednesday, May 13, 2020
Thank you!

www.TheSTARR.org