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Host



Tami Haas
Product Marketing Manager

Specialized Solutions by Forte



86,000 protocols and counting



Comprehensive clinical research management system for mid-size to large organizations with complex needs.



Cloud-based clinical trial management system that manages the operational data for small to mid-sized sites.



Electronic data capture system for sponsors and CROs that fully supports compliance with 21 CFR Part 11.



Riley Kammer
Associate Director of Operations, ClinEdge

Riley is the Associate Director of Clinical Operations at ClinEdge. He works with both sites and sponsors/CRO in a variety of capacities to optimize and streamline the site selection process. Riley and the ClinEdge team provide personalized business development to a network of elite research sites and are constantly finding new ways to make site processes operationally efficient. He holds a bachelor's degree in from Boston University and has previous experience in the healthcare financial sector.

What is Therapeutic Forecasting?

- Therapeutic Forecasting is the use of data sources to analyze and predict trends in clinical research.
- Where can we find this data?
 - It is readily available through a variety of sources including:
 - Clinicaltrials.gov
 - Sponsor Pipelines
 - Industry Reports
- Forecasting provides insights that assist sites in making strategic decisions to set them up for success in 2016 and beyond.

An Important Tool for Research Sites

- Ebbs and Flows in the Clinical Research Industry
 - Fewer study opportunities in a site's primary therapeutic area leads to increased competition for each study opportunity.
 - Increased competition and fewer opportunities can lead to decrease in future revenues.
- Adaptability in this Dynamic Environment
 - Not only beneficial, crucial to becoming a successful clinical research site.
 - Therapeutic Forecasting is a powerful tool for gaining insights on how to adapt to the ever changing clinical research environment.

Learning's from 2015

- ClinEdge saw over 800 study opportunities in 2015!
- The top 5 therapeutic areas included:
 - Neurology
 - Alzheimer's Disease , Multiple Sclerosis , Migraine
 - Dermatology
 - Acne, Psoriasis, Atopic Dermatitis
 - Endocrinology & Metabolism
 - Type 1 and 2 Diabetes, Lipid Disorders
 - Gastroenterology
 - IBS C&D, Crohn's Disease, Ulcerative Colitis
 - Psychiatry
 - ADHD, Depression, Schizophrenia

Learning's from 2015

- Growth in Phase IV Studies
 - Generally, Phase IV research investigates approved products used in line with their approved labels.
 - Objectives at this stage:
 - Comparing a drug with other drugs already in the market.
 - Monitoring drug's long-term effectiveness and impact on patient's quality of life.
 - Determining cost-effectiveness of a drug therapy relative to other traditional and new therapies. (CenterWatch)

Learning's from 2015

- Growth in Phase IV Studies: Implications for Research Sites
 - Positives
 - More Study Opportunities
 - Higher Number of Study Subjects
 - Great Resume Builder for Newer PIs
 - Negatives
 - Longer Study Durations
 - Longer Period for Patient Study Involvement
 - Lower Per-Subject Investigator Grants

Forecasting Momentum Swings

Essential Factors

- Gaining Insights on Potential Momentum Swings
 - Sponsor Pipelines:
 - Provide one of the most readily available and powerful sources of data.
 - Pre-Clinical Assets → Early Phase Studies
 - Early Phase Studies → Later Phase Studies
 - Advances in Potential Treatments:
 - Exciting pre-clinical results can direct sponsors' R&D efforts.

Forecasting Momentum Swings

Essential Factors

- Gaining Insights on Potential Momentum Swings
 - Changes in Prevalence of Diseases and Disorders:
 - Between 2010 and 2012 the number of Americans with Diabetes grew from 25.8 to 29.1 million.
 - On average, 1.4 million Americans diagnosed every year. (National Diabetes Statistical Report)
 - New Drug Approvals:
 - Approximately 10% of all drugs started in human clinical trials become an approved drug. (NYT)
 - When a new drug is approved, sponsors may shift preclinical and later phase R&D efforts away from that indication.

Shift in R&D Efforts

Large → Small Sponsors

- During the past 10 years there has been a shift in sponsors' R&D efforts:
 - Small companies now comprise the majority of early I-IIa phase research.
 - Mid-to-large sized companies sponsoring the majority of later IIb-IV phase trials.
- The R&D Expenditure Shift:
 - Between 2005 and 2013 the amount of money spent on global drug increased from \$112.6 billion to \$135.9 billion.
 - During this same period, percentage of spending by small biopharma increased from 53% to 65%. (CenterWatch/INC)

Shift in R&D Efforts

Implications for Research Sites

- In the past successful sites could rely on a few key relationships with large sponsors.
 - Maintaining and strengthening your site's existing relationships remains important.
 - Reliance on these relationships for the majority of a site's trials has become difficult.
- Developing new relationships with smaller sponsors has become crucial.
 - Top enrollers on earlier phase trials are often on the top of the list for later phase trials.
 - Opens the door for inclusion on other programs the company is planning.

Bringing It All Together

- Sites can proactively set themselves up for success when anticipating a potential slowdown in their primary therapeutic areas.
- Expanding into New Areas and Indications:
 - This might mean additional staff, PIs, equipment to ensure you are capable of conducting studies in this new area(s).
 - It also may mean being okay with taking less competitive opportunities to build up experience.
 - Sometimes getting your foot in the door means taking on Phase IV, observational, or registry studies.

Bringing it All Together

- Some PI specialties lend themselves to breaking into other therapeutic areas and indications.
 - Overlapping Patient Populations
 - Similarities in Trial Designs
- Examples:
 - Psychiatry → Pain/Addiction
 - Urology → Women's Health
 - Pulmonology → Sleep Medicine

Bringing It All Together

- During Slower Times it is Important
 - To maintain a competitive edge, even in your primary therapeutic area.
 - To establish a presence in new therapeutic areas.
- Tips for Putting Your Best Foot Forward
 - Work to Increase Your Referral Network
 - Local physicians are a powerful source for new potential subjects.
 - Online Presence: Website and Social Media
 - Mobile friendly.
 - Site capabilities and staff experience.
 - Powerful recruitment tool.

Bringing It All Together

- Tips for Putting Your Best Foot Forward
 - Feasibility Questionnaires
 - Sites: Showcasing Fit of Study Inclusion
 - Study Teams: Gauging a Potential Study Site's Suitability
 - Feasibility Questionnaires: Best Practices
 - Do not leave any questions blank or N/A!
 - Provide as much detail as possible!
 - Comment section!

Bringing It All Together

- Tips for Putting Your Best Foot Forward
 - Feasibility Questionnaires: Patient Population
 - Research Database
 - Investigator's Private Practice
 - Referral Sources
 - Feasibility Questionnaires: Enrollment Estimates
 - Be Aggressive but Realistic
 - Insure Data to Back Up Numbers

Summary

- Readily available information can assist in making key decisions and setting sites up for success.
 - Breaking into New Therapeutic Areas
 - Establishing Relationships with Smaller Biopharmaceutical Companies
 - Putting Your Best Foot Forward
- Best of Luck in 2016 and Beyond!

Thank You



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Topics include:

- Financials
- Patient Recruitment
- Compliance/regulatory
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