Project Management Challenges in Real World & Late Phase Clinical Research or Studies

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An industry:

DISRUPTED, AND DISRUPTING

Trends in the wider industry and study design are changing the way we need to behave
AGENDA

Introductions

Trends Driving Change in Project Management

- Radical Re-Orgs
- Accelerating Evidence
- Search for the Right Patients

Questions & Discussions
RADICAL RE-ORGs
Variability of Costs

Flexibility is Critical

To protect pipeline:

Replacing costly infrastructure by

Adaptable Partners

Limiting R&D
Cutting staff
Historically—the only options
Always-on Commercial Lens

Commercial teams are entering strategic discussions earlier

- Helping clinical partners define the most valuable evidence to collect
- Driving new conversations about product development

New competitive reality:

- Not every product has a market
- Not every product has the market inventors initially think it will have

Multi-disciplinary collaborations are driving growth

Syneos Health™
Radical Reorganisation Summary

Outsourcing is the new norm
Managing at a distance & influencing skills
Tools templates
The stakeholders are changing
A valued partner in and end to end drug development solution
Around the world, governments are working to speed critical treatments to market.

21st Century Cures Act

The U.S.

- **real world evidence and data**
  - can replace traditional clinical trials for approval

- **limited trial population**
  - approval process for novel antibiotics

- **expedited approval paths**
  - life-threatening diseases w/ limited treatment
Evolving use of real-world data & evidence

- Real-world data & evidence
- Safety monitoring
- Pharmacovigilance
- Pharmacoeconomic models
- Advanced disease understanding
- Regulatory decision making
- Physician/system education

Baseline
Approval submissions will include real-world evidence.

- Demonstrates value beyond incremental patient benefit
- Emerging sources of data (e.g., social media)
  - Patient-generated data
  - Claims data
  - Clinical data
Accelerating Evidence Summary

No longer the poor relation
More and more important stakeholders
Need to be adaptable understanding multiple trial designs, when to use them and the different operational delivery required for each.
……and better talent to ensure delivery
SEARCH FOR THE RIGHT PATIENT
Pre-size your study

- De-identified
- Clinical
- Genomic

Identify sites that have eligible patients (Quick and easy to find)

Estimate # of patients by specific criteria
Determine significance of population size
Today’s recruitment campaigns put the potential patient types at the center.

Find the media and messages that are most useful to them

Profile their current journey

The engagement of patient advocacy groups bring new challenges

Pre-identify the sites they are most likely to be near
The Past
Study search previously limited to traditional sites
With full infrastructure/staff

Now
Every practice is a potential site
Pharmacy

As drugstore giants’ front-of-store sales slow…

Healthcare clinics will fill in the footprint
“Third place”
Options

Local pharmacy

Local clinic

Home

“No place”
Options

Retrospective EHR Data

Traditional Trial

Visit 1  |  Visit 2  |  Visit 3  |  Visit 4  |  Visit 5  |  Visit 6  |  Visit 7  |  Visit 8 – END OF STUDY

Hybrid Virtual Research

Visit 1  |  Visit 2  |  Visit 3  |  Visit 4  |  Visit 5  |  Visit 6  |  Visit 7  |  Visit 8 – END OF STUDY

Fully Virtual Research

Visit 1  |  Visit 2  |  Visit 3  |  Visit 4  |  Visit 5  |  Visit 6  |  Visit 7  |  Visit 8 – END OF STUDY

1. Xabir Webinar: Virtual Clinical Trials Are Here: What Now?, 6, February 2019
Search for the right patients

Summary

New science
New technologies
New team members with skills
New language
New applications
The most exciting place to be:

Creative and Value Adding

To ensure medicines get to patients faster
Questions & Discussions
Shortening the Distance From Lab to Life®.