# Study Assessing Practices and Inefficiencies Associated with Site Selection, Study Start Up, and Site Activation

*Tufts CSDD Findings to goBalto*

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# Companies and Roles of Interviewees

- A total of 26 in-depth interviews were conducted with senior level executives across 21 companies including 13 **biopharmaceutical** companies and 8 **CROs**
  - Representing 13 **large** and 8 **mid-sized and small** organizations

| Roles of Individuals Interviewed | # |
|---|---|
| Director | 11 |
| Manager | 3 |
| Vice President | 2 |
| Other (including global heads of departments,, therapeutic area experts, team leaders) | 10 |

# Select Titles of Executives Interviewed

Select titles of interviewees:

- *Trial Optimization Center of Excellence Manager*
- *Vice President Global Clinical Development*
- *Senior Vice President, Global Head Site and Patient Networks*
- *Director, Study Start up, Strategic and Tactical Support*
- *Chief Operating Officer*
- *Director of Clinical Monitoring*
- *Associate Director, Clinical Science*
- *Senior Director, Head of Clinical Support and Services*
- *Strategic Director Site Startup and Regulatory*
- *Global Head of Monitoring Operations, Regulatory Documents, & Contract Management*
- *Director, Global Clinical Operations and Site Activation*
- *Head, Study Placement and Analytics*

# Tools and Solutions Used to Support Site Selection

| Tool or Solution | # of Companies |
|---|---|
| Internal tools, metrics, questionnaires | 10 |
| Citeline and Trialtrove | 9 |
| Clinical trial management systems (CTMS) | 6 |
| IMS StudyOptimizer and SiteOptimizer | 5 |
| Citeline and Trialtrove | 9 |
| Feasibility tools, Qualification checklists | 4 |
| Investigator databank | 2 |
| External partners | 1 |
| Specific contact forms that are completed for a site | 1 |
| Transcelerate 's Shared Investigator Platform | 1 |

s)

N=21 companies, multiple solutions were reported.

# New Practices Implemented by Organizations

- Implementation of a new start up function or added study start up
  - Help streamline the process from site selection to study start up.
- Cluster training
  - Core groups of sites that have had IRB approvals prior to the investigator meeting and provide site initiation visit (SIV) training
- All supporting documents sent to site within 24-48 hours of a protocol being finalized
  - Eliminates time between a site being protocol ready and site documents being sent
- Development of master service agreements (MSAs) and standard language within contracts
  - Facilitates contracting and negotiation process
- New technology including Implementing centralized systems and use of visualization and other analytics tools
  - Increases data driven site selection

# Challenges to Site Selection, Study Start up and Site Activation

- ✓ **Increased competition for sites**
  - ✓ High competition for sites in therapeutic areas such as oncology and rare disease
- ✓ **Challenges with site feasibility**
  - ✓ Difficulty in completing site feasibility in a quality manner
  - ✓ Not allowing enough time for each part of the set-up process to be completed
- ✓ **Contracting and budget negotiation process**
  - ✓ Lack of standardization in informed consent and site contract language
  - ✓ Absence of master service agreements (MSA's)
  - ✓ Need for country specific templates.
- ✓ **IRB and ethics committee**
  - ✓ Unpredictability of timelines at local IRBs
  - ✓ Delay to study start up
  - ✓ More efficiency with use of central IRBs
- ✓ **Enrollment issues**
  - ✓ Determining whether or not specific sites have patients
  - ✓ Pressure to enroll patients quickly
- ✓ **Reliance on global affiliates to understand all local processes and approvals**
  - ✓ May cause unforeseen delays

# Organizational Resources and Process Changes

## Technology

- Use of electronic medical records (EMR's) to inform numbers of patients that meet inclusion/exclusion criteria
- Integrate individual systems including data warehousing, dating mining
- Reuse available data on investigators
- Investigator Databank
- Transcelerate's Shared Investigator Platform
- Site feasibility software
- Investigator dashboard (internal)
- Use of goBalto technology

## Contracting and Budgeting Process

- Produce contracts and metrics earlier
- Need for additional resources (staff) to negotiate and execute contract
- Improve contract language
- Development of master service agreements (MSA's) with sites
- Develop and improve legal agreements and improve budget discussions
- Standardize informed consent

# Dedicated Resources to Create Efficiencies

**Dedicated resources in place that make activities more efficient:**

- Trial optimization group
- Strategic planning group
- Investigator Databank
- Transcelerate's Shared Investigator Platform
- Integrated site activation plan
- Increasing focus on site selection and start up within study management
- Added resource of site budget specialist
- Added resources of country startup specialists to facilitate regulatory submissions

# Key Findings from Interviews

- For the typical multicenter study 70% of sites are repeat and 30% are new sites
- The typical time for site selection is 3.2 months
- One third of companies report an impact on their non-enrolling sites and increased numbers of sites activated due to new organizational practices