Common Challenges and Innovative Solutions in Research Administration

Society of Research Administration International Annual Meeting

October 30, 2024

Introduction

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Consultants

- First engaged in clinical research as a research assistant at UNC Chapel Hill

- Began a professional career in clinical research at Duke University

- Masters degree in health policy and management

- Consulting career dedicated to academic healthcare with a focus in research strategy and operational improvement.

Today's Agenda

1. Industry drivers impacting clinical research administration
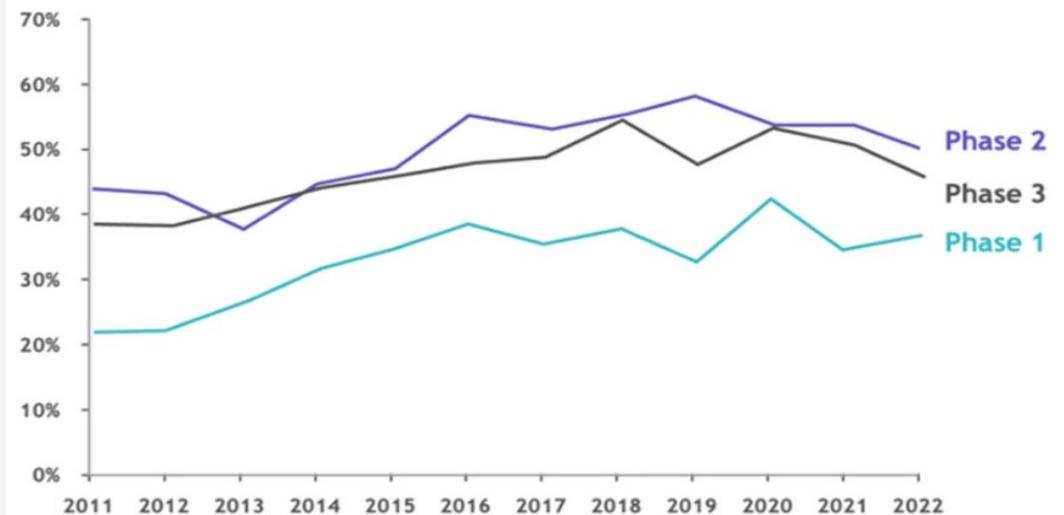
2. Common Challenges in Research Administration

3. Vision for a High Performing Research Organization

Industry Drivers

Trial Complexity and Volume

- Research organizations are taking on record numbers of clinical trials without significantly expanding clinical trials staff rosters.

- At the same time, trials are becoming significantly more complex with innovative trial formats, extensive inclusion/exclusion criteria, novel endpoints, expanded data sources, and more.

Increasing Trial Complexity Over Time

Source: Markey, N., Howitt, B., El-Mansouri, I. et al. Clinical trials are becoming more complex: a machine learning analysis of data from over 16,000 trials. Sci Rep 14, 3514 (2024).

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Industry Drivers

Evolving Regulations

- Research organizations must stay up-to-date on evolving regulations.
- Failure to maintain compliance and adjust to industry changes can result in significant risk to the organization.

FDA NEWS RELEASE

FDA Announces Additional Steps to Modernize Clinical Trials

Agency Requesting Feedback on the Draft Recommendations and How They Should Be Applied to Increasingly Diverse Trial Types and Data Sources

DOJ Continues to Eye Clinical Researchers (and the Universities and Hospitals Employing Them)

By Jonathan Porter on March 22, 2023

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Industry Drivers

Staffing Challenges and Emerging Technology

- High turnover rates across clinical research staff and a push for more hybrid and remote work options.

- Emergence of AI and growth of virtual clinical trials facilitated by adoption of tele-consenting and remote monitoring tools.

Closing the Gap: How to Overcome Clinical Trial Staffing Shortages
By Steve Matas, President of Strategic Resourcing on August, 16 2023

Now is the time to fix the clinical research workforce crisis

The Secret(s) To Solving The Clinical Trials Staffing Crisis
By Kathi Enderes, SVP, research, and global industry analyst, The Josh Bersin Company

Disruptive Technologies Redefining the Path of Clinical Trials
Clinical Researcher - June 13, 2024

Industry Drivers

Financial Pressures

- Hospital margins continue to be challenged resulting in shifting priorities for organizations.
- Considerable pressure to define the value of research to the organization and demonstrate ROI.

What's Behind Losses At Large Nonprofit Health Systems?

Christopher M. Whaley, Sebahattin Demirkan, Ge Bai

Ascension posts $1.1B net loss for 2024 after May cyberattack

New AHA Report: Hospitals and Health Systems Continue to Face Rising Costs, Economic Pressures

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Common Challenges in Research Administration Today

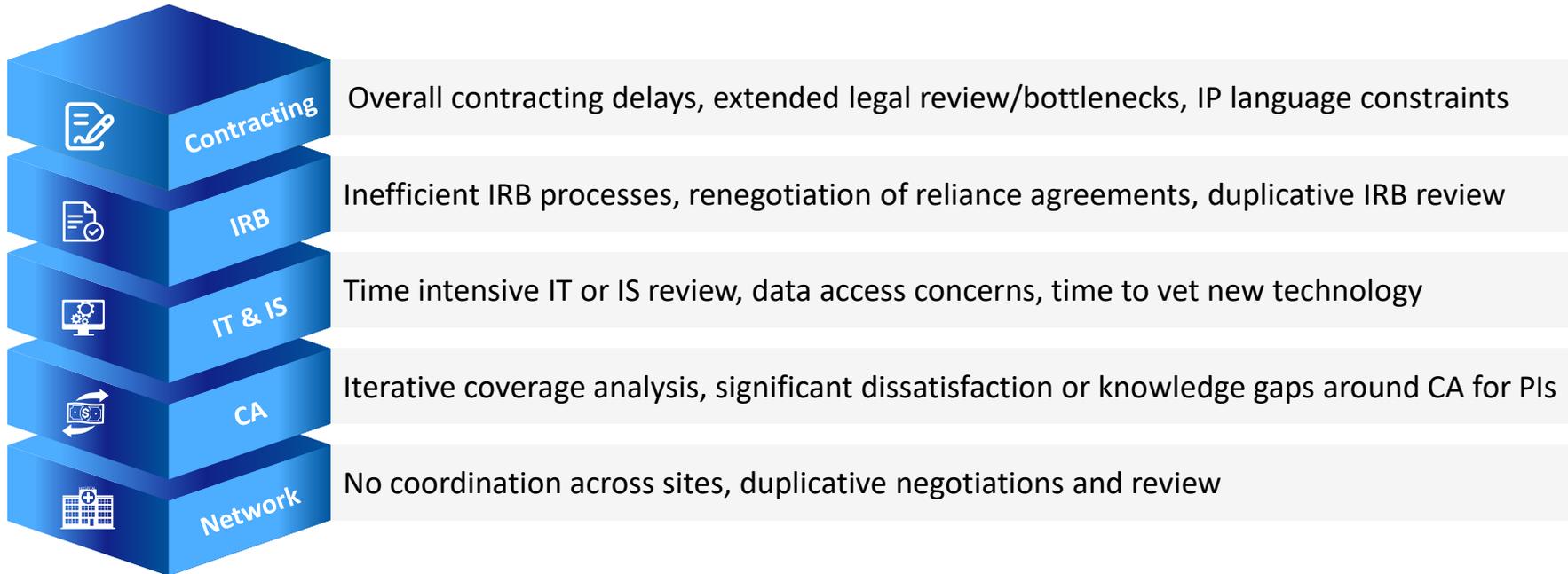**1** Excessive study start up timelines of six months or more

2 Underperforming trials that negatively impact the financial sustainability of the research organization

3 Inability to manage staffing and workload across the research enterprise

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Common Study Start Up Challenges

Contracting — Overall contracting delays, extended legal review/bottlenecks, IP language constraints

IRB — Inefficient IRB processes, renegotiation of reliance agreements, duplicative IRB review

IT & IS — Time intensive IT or IS review, data access concerns, time to vet new technology

CA — Iterative coverage analysis, significant dissatisfaction or knowledge gaps around CA for PIs

Network — No coordination across sites, duplicative negotiations and review

Common Challenges with Underperforming Trials

Failure to reach enrollment targets, high screen fail rates, low subject retention

Negative operating margin

Data entry delays, lack of integration between EHR and CTMS causing duplicative effort

No standardized reporting metrics, lack of regular study productivity assessment

Common Research Staff Management Challenges

High turnover, loss of institutional knowledge, difficulties in hiring, lack of standardized training

Uneven workload between teams, inability to assess staff workload, lack of reporting metrics and processes

Research staff not working to top of license, unclear roles and responsibilities, effort deployment not aligned with desired outcomes
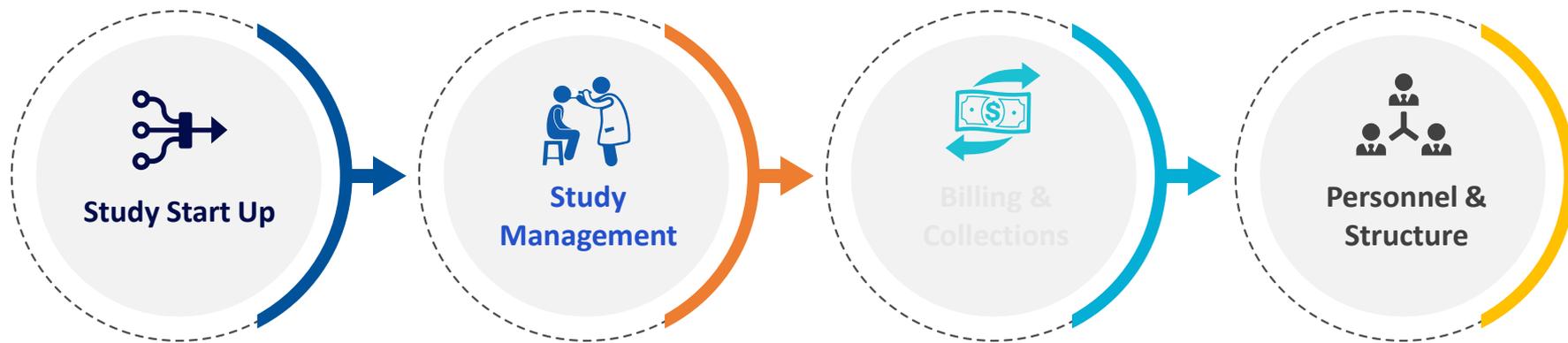
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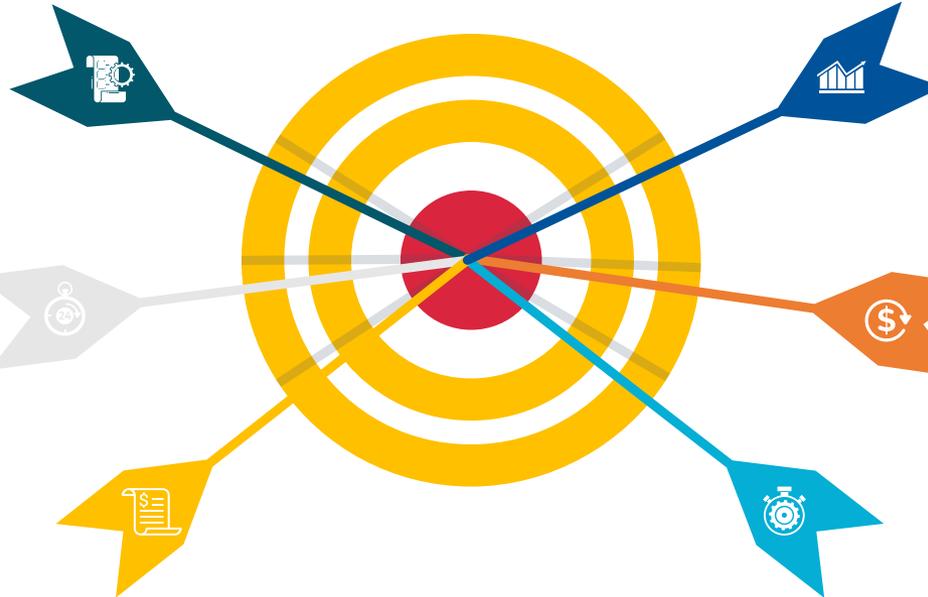
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Vision for a High Performing Research Organization

Study Start Up → **Study Management** → **Billing & Collections** → **Personnel & Structure**

Study Start Up Solutions

Develop a **consistent study feasibility** assessment and selection process with consideration for **financial feasibility**

Centralize budget development and negotiation to maximize revenue

Centralize or outsource coverage analysis

Utilize **risk assessment** and tiering to streamline IRB review; create a **unified IRB** across all clinical sites

Centralize contracting resources and develop a **defined term escalation matrix** to expedite legal review

Target study activation timeline of **90 days**[1]

[1] Consistent with guidance from the National Cancer Institute.

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Study Management Solutions

Optimize organizational data resources and EHR functionality to identify potential trial participants

Define and regularly monitor **coordinator deployment metrics** (accrual rates, protocol intensity, etc.)

Develop **consistent policies and timelines** for data entry, log management, charge review, and other elements of ongoing clinical trial management

Quarterly, review study progress and discontinue nonproductive research

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Billing and Collections Solutions

Regularly evaluate and report on **data entry timeliness**

Centralize invoicing and A/R collection management

Institute a monthly close timeline of **seven days or less**

Define a **standard financial close** timeline after study completion

Develop **consistent processes** for study build and amendments to ensure no delay in activation

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Personnel and Structure Solutions

Develop **consistent training** on key responsibilities and systems

Mandate **annual training** for all study team members

Clearly define and **regularly report on key performance metrics**

Define a **career progression framework** for research staff

Articulate and communicate a clear governance structure with **identified decision-making authority**

Create **consistent policies and roles and responsibilities** across sites and departments

Develop a **centralized research office** to support network-wide research and multi-site trials

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What solution(s) are you most likely to implement at your organization?

ⓘ Start presenting to display the poll results on this slide.

Questions & Discussion

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