Accelerating Study Activation:

Breaking Down Silos for Start-up Success

Introducing Our Speakers

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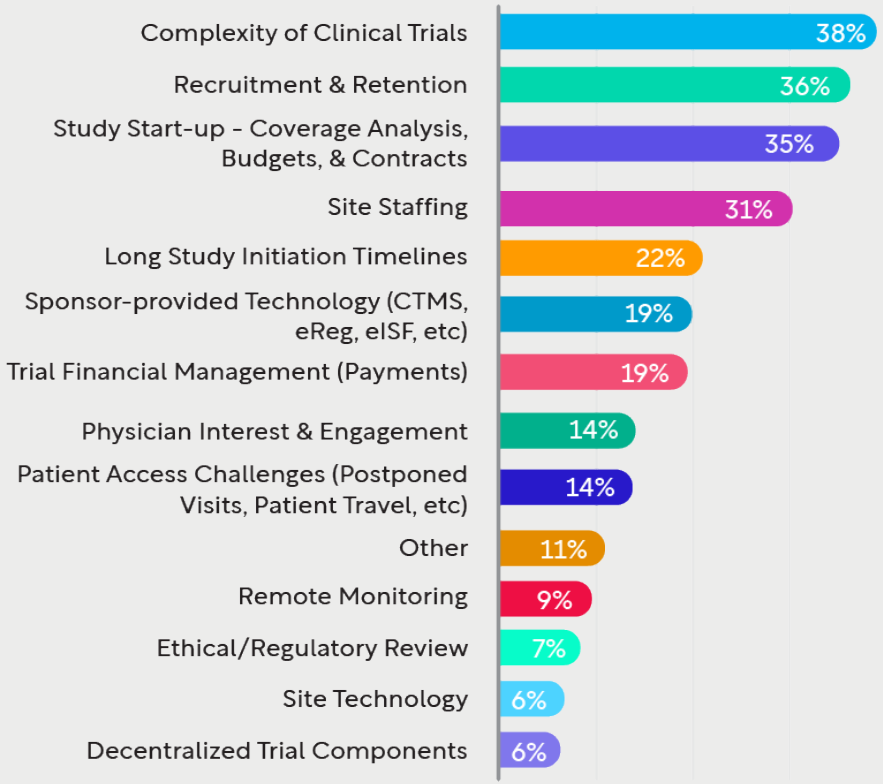
Today's Agenda

1. Introductions
2. Overview & Industry Data
3. Start-up Timelines & "White-Space"
4. Study Start-up Perspectives from Yale
5. CTMS Silos
6. Panel Discussion & Audience Questions
7. Conclusion

Studies Are Becoming Longer and More Complex, While Historical Challenges in the Industry Continue

Top Reported Site Challenges in 2024



The Real Problems

Macro Trends Continue:

31.4 weeks
Total duration from site identification to study start-up, one month longer than the average duration observed 10 years ago.

85%
Of Sites Fail to Meet Enrollment Targets and Timelines

42%
Increase in Procedures Required in Phase III Trials[1]

37%
Increase in Average Number of Planned Study Visits per Participant in Phase III Trials[1]

[1]Tufts Center for the Study of Drug Development May–June 2023 | [2]WCG Knowledge Forum Survey | [3]WCG ClinSphere™

*Industry sponsored, Ph II – Ph III trial starts with up to 250 reported sites and a PI PPSPM between 0.1 – 5.0; only active and completed trials are included with a start date between 1/1/2019 – 12/31/2022 with at least 1 site in the U.S.; Excluding COVID-19 trials.

Current Activation Timelines

Industry Averages

Across all therapeutic areas, there is disparity in median time for trial activation, defined as time from site section to completion of contract.

For the past 3 years for Phase I-III trials, the median timeframe for trial activation is at **9.4 months for AMCs and hospitals vs. 4.8 months at independent sites/physician practices**. Additionally, **budget negotiation timelines trended 5 days longer in 2024.**

Source: WCG Data Intelligence, 2023

Clinical Trial Activation & Study Start-Up Timelines

An Ideal Scenario

*NCI Recommendation for 90-day trial activation

Source: WCG Data Intelligence, 2023

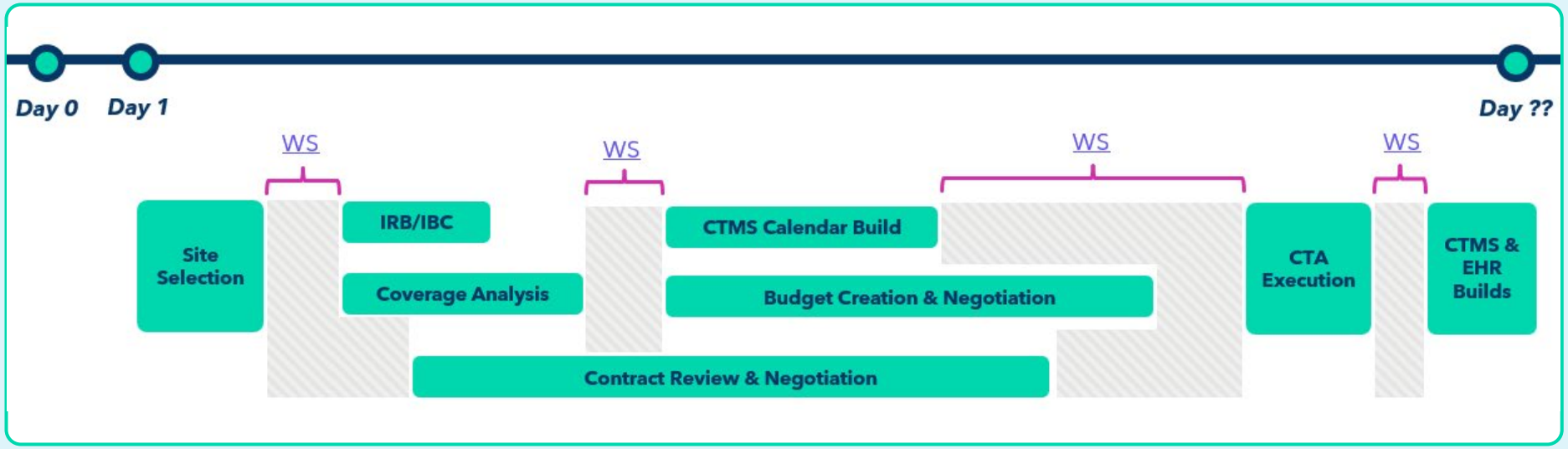
Clinical Trial Activation & Study Start-up Timelines

Start-Up Process – "White-Spaces" (WS)/Reasonable vs. Avoidable

Accelerating Clinical Trial Activation & Study Start-Up Timelines

Strategies for Streamlining SSU

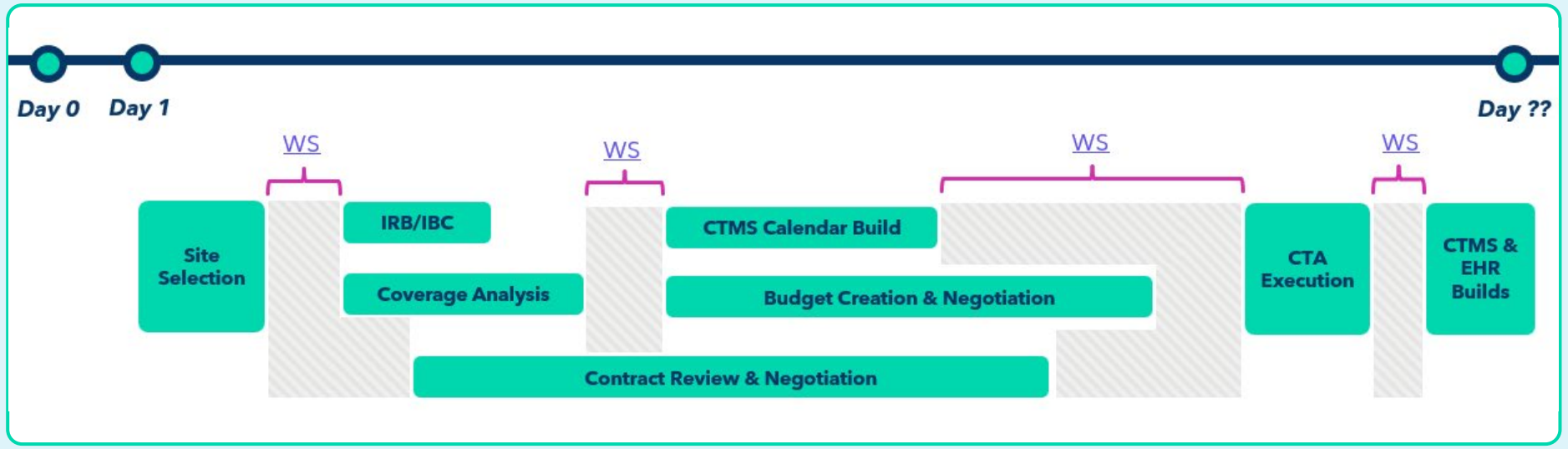
- **Map out the entire start-up process for your Institution**
  - Establish target goal (timeline)
  - Once mapped out,
    - Look at individual services
    - Look at whitespaces



Accelerating Clinical Trial Activation & Study Start-Up Timelines

Strategies for Eliminating Whitespace

- **Map out the entire start-up process for your Institution**
  - Look for unchecked bottlenecks
  - Standardize processes / role expectations
  - Check mindset and perspective of negotiators
  - Re-evaluate!



Study Start-up Perspectives from Yale Cancer Center

- Adam Roshka, Director of Finance and Operations, Yale Cancer Center
- Juliann Murphy, Assistant Director of Clinical Trials, Yale Cancer Center

Deep Evaluation of All Steps in Activation

🔍 **Identify** which steps require **input, review, or approval**.

✅ **Determine** the **essential requirements** for approval to move forward.

👥 **Define** the **role or individual responsible** for each approval.

📉 **Outcome:** At Yale, this evaluation led to a **reduction in touchpoints and approvals**, streamlining the activation process.

Documentation & Collaboration

Importance of Documenting the Workflow

📌 **Varied Perspectives:** Stakeholders, process owners, and end users often have different understandings, pain points, and barriers.

📌 **Tracking & Targets:** Do you monitor timelines and set measurable targets in your process?

Collaboration Across Units

🤝 **Inclusion Matters:** If a process extends beyond your unit, involve all relevant process owners.

💬 **Improved Communication:** Even if the process remains unchanged, collaboration fosters a shared understanding and smoother workflows.

Ongoing Evaluation

Ongoing Evaluation – Not a One-Time Process

🔄 **Continuous Improvement:** Regular reviews help identify efficiency opportunities, roadblocks, or policy impacts.

🚀 **Proactive Problem-Solving:** Identifying issues early can prevent delays or eliminate barriers altogether.

💡 **Process vs. Resources:** Evaluations should focus first on workflow improvements, then on resource allocation—including financial aspects. Efficiency gains do not always equate to cost savings.

Identify and Addressing Institutional Barriers

Are they “removable” (process inefficiencies) or “hard barriers” (regulatory/legal constraints)?

Examples:

✅ **Removable Barriers (Process Inefficiencies):**

- Repositioning touchpoints to reduce timelines.
- Maximizing efficiency by reducing redundant review and approval steps.
- Establishing recurring meetings to improve communication and streamline progress.

🚧 **Hard Barriers (Regulatory/Legal Constraints):**

- Congruency reviews, legal escalations, or contractual language challenges.
- Delays due to multiple committee approvals and sign-offs.
- Institutional requirements such as ICF (Informed Consent Form) reviews.

Optimizing Budget Processes

Budget Development

- 📊 **Leverage past data**: Use previous budget performance to guide current and future budgeting decisions.
- 🔄 **Standardize fees**: Align with recently negotiated budgets whenever possible.

Budget Negotiations

- 🚀 **Sweet Spot of Escalation**
  - Establish **clear thresholds** for escalating budget concerns.
  - Ensure the **right stakeholders** are involved at each level.
- ⚖️ **Negotiating Rules**
  - Define **preapproved thresholds** (know your data).
  - Determine what is **negotiable vs. non-negotiable**.

Lessons Learned

🤝 Building Strong Relationships

- Effective collaboration between study teams, finance, and sponsors is essential.
- Clear and proactive communication helps prevent bottlenecks.

⚠️ Challenges Identified

- Delays often stem from misalignment on financial expectations.
- Transparency in budget negotiations is crucial for efficiency.

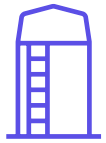
🚀 Key Process Improvements

- **Minimizing redundant reviews** streamlines approval timelines.
- **Defining clear financial approval roles** ensures accountability.
- **Aligning financial build entry earlier** in the process prevents costly delays.
- **Implementing a unified congruency review** before CTA execution has reduced amendments and build errors.

CTMS Silos

Strategies for Reconciliation

Challenge #1



Introduction of white space into study activation process

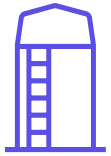
Establish well documented, clear approaches for the integration of the budget, CA and Protocol SOA into CTMS.

Conduct proactive and timely communications between relevant teams when discrepancies and anomalies are noticed.

CTMS Silos

Strategies for Reconciliation

Challenge #2



Visits/Procedures are grouped/split differently in MCA vs. budget vs. SOA

Include considerations for financial entry into the CTMS calendar build.

- ✓ Consider moving the CTMS calendar build towards the front of the study activation process after completion of MCA.
- ✓ Reference sponsor draft budget milestone/visit structure.
- ✓ Proactively combine/break out panels, as allowable per MCA and site preferences.
- ✓ Identify split designations early in the study activation process to allow for CTMS accommodations.

Accelerating Activation Timelines

Implementation of Best Practices

- Reducing interpretation of source documents will remove ambiguity and streamline process efficiency.
- Reducing or eliminating white space will prevent study activations being paused due to further information needed.
- Improving consistency of source documents will ensure situations are handled the same every time, either through communication or action.
- Separating the CTMS calendar build and financial entry to better align with concurrent study activation processes.

- Clear, accountable guidance for interpretation of source documents alleviates back and forth between internal teams with dedicated "source of truths".
- Timely communication with well-documented feedback loops and escalation pathways avoid delays, enabling quick follow-up on outstanding queries.
- Increases confidence and reliability.
- Streamlines activation with standardized processes.
- Utilize living documents, continuously updated to support activation, with accepted approaches to complex protocols to hasten turnaround times.
- Completing the CTMS calendar build and financial entry at the earliest point within the study activation process, further condenses timelines

Potential Participant Impact

- **Delayed access to new therapies**
- **Increased anxiety and stress**
- **Reduced motivation to participate**
- **Unexpected bills**

- Health conditions may deteriorate while waiting for access to clinical trials.
- Increased stress and uncertainly about health outcomes.
- Enthusiasm and motivation can decrease over time, impacting willingness to participate in the clinical trial.
- Discrepant CTMS coding can result in unexpected bills.

Thank you!

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