



Research Directors and Coordinators Working Group | 1:00 - 5:15 p.m.

Location: Avenue Ballroom (4th Floor)

Workshop Leads / Moderator: Victoria Evans / Lena Ellis / Stephanie Berger / Christina Simmons / Carrie McKenzie

LUGPA RESEARCH PLAYBOOK

1. Building a Clinical Research Program to Match the Scale of Our Practice

- a. **Why Research?**
 - i. Why a large specialty practice needs a research program that matches its clinical footprint.
- b. **Starting Out**
 - i. Small portfolio
 - ii. limited infrastructure
 - iii. early processes
 - iv. the starting team.
- c. **Building the Program**
 - i. Developing SOPs
 - ii. regulatory infrastructure
 - iii. recruitment processes
 - iv. billing/coverage analysis
 - v. IP management
 - vi. sponsor relationships
 - vii. staff expertise.
- d. **Expanding the Field**
 - i. Growing investigator participation
 - ii. Growing trial opportunities
 - iii. Developing better recruitment capabilities
 - iv. Using our technology
 - v. Providing access across locations
- e. **The Future**
- f. **Vision**
 - i. A mature clinical research program that is integrated into routine clinical care rather than operating alongside it.

2. Budgeting and Profitability: Know the Score. Know the Cost. Call the Next Play.

- a. **KPI Playbook-** Not more metrics. Better decisions. Not accounting perfection. A fair, consistent, explainable number leadership can trust.
- b. **Profitability Playbook:** Every Study Carries Its Fair Share
 - i. Study revenue – direct study expense – fair share of shared/indirect expense = true study contribution/profitability.

- 3. The Hidden Costs of Clinical Research:** You can't win the budget game if you don't know the true cost of every play.
- a. Understanding the True Cost
 - b. Standard Study Costs
 - c. Costs Behind the Scenes
 - d. Often-Missed Budget Items
 - e. Supplies & Operations
 - f. Overhead
 - g. Specialty Costs
 - h. Recruitment & Pre-Screening
 - i. Invoicing & Payment
 - j. Budget Justification
 - k. Roundtable Discussion
- 4. FDA Audit Readiness:** The best defense is a good offense
- a. Why readiness matters
 - b. Why and when FDA inspects
 - c. Regulatory foundation
 - d. Anatomy of an inspection
 - e. After the inspection
 - f. Common findings
 - g. Two-minute drill (the spot-the-finding exercise)
 - h. Building continuous readiness
 - i. Working with sponsors and CROs
 - j. Inspection day
 - k. Key takeaways
- 5. Operational Excellence in Clinical Research:** Moving from Reactive Operations to a High-Performing Research Site
- a. Roundtable discussion: What does operational excellence actually look like at the site level and how do we build systems that allow our teams to be proactive rather than constantly putting out fires?
- 6. Wrap up**