Unraveling Biospecimen Complexity in Clinical Trials: Benchmarking the Approach

Kira Pavlik[a]; Jamie Voyten[b]; Karina Bienfait[c]; Eli Stoddard[d]; Amy Ripston[e]
[a]Yale Cancer Center, [b]UPMC Hillman Cancer Center, [c]Bristol Myers Squibb, [d]Eli Lilly and Company, [e]Biospecimen Management Consortium

Background

- Growing clinical trial acuity directly impacts biospecimen management at research sites.
- Biospecimen-focused solutions are often misaligned with site needs, intensifying the problem.
- A clear definition of site-focused problems was needed to align stakeholders on comprehensive solutions.

Goals

The goal was to identify unique issues associated with biospecimen management at clinical research sites through engagement with AACI member institutions.

Focus areas included the following:

1. **Trial Design**
2. **Trial Execution at the Site Level**
3. **Study Close Out**

Solutions & Methods

A **16-question** site survey was distributed to AACI-affiliated institutions in June of 2024.

Questions focused on key challenges, priorities, and opportunities for improvement from the lens of academic research sites, specifically focused on oncology clinical trials.

From Problem to Solution

The Problem	Proposed Solutions
× Conflicting Documents	✓ Clear, aligned documents
× Kit Waste	✓ Site kit personalization
× Tight Processing	✓ Flexible processing windows
× Site Tools Needed	

A clear, site-focused articulation of the problem set unlocked **three actionable directions** for sponsors, central labs, and vendors to align around.

Key Findings at the Site Level

80% of sites create their own study-specific tools to support biospecimen collections

75% of kit supplies wasted monthly at some sites

44% destroy more than 30% of their kits each month

Tools sites create to support biospecimen collections

Sites could indicate more than one tool. Specimen processing tools were the most common.

Kit inventory management	29	26%
Specimen processing (e.g. lab templates)	32	29%
Specimen shipping	29	26%
Specimen flowchart(s)	17	15%
Other	4	4%

Outcomes

50 responses from AACI-participating Cancer Centers highlighted the following:

- Sites need to create their own study-specific tools to support biospecimen collections **(80%)**.
- Nearly half **(44%)** indicated that they destroy more than 30% of their kits monthly.
- Majority of respondents **(66%)** indicated that they'd prefer to receive specialized items in bulk supply based on individual needs and help reduce kit waste.

Highest Priority Issues

70% Reduce discrepancies between protocols and lab manuals

46% Increase sample processing window flexibility

42% Improve kit management / waste

Lessons Learned & Future Directions

Key recommendations coming out of the site survey include ensuring sponsors and vendors align key study documents such as the study protocol and laboratory manuals in advance of study activation. Additionally, central lab vendors are encouraged to allow sites to personalize kit needs to reduce site burden and kit waste. Finally, sponsors and central lab vendors are encouraged to increase flexibility with lab sample processing windows to ensure feasibility of biospecimen operations and reduce patient burden.

Additional surveys and relevant solutions will also be explored globally, across multiple disease and trial types.