Category: Cross-Cutting Innovation and Collaboration – Work in Progress

Unraveling Biospecimen Complexity in Clinical Trials: Benchmarking the Approach

K. Pavlik[1]; J. Voyten[2], K. Bienfait[3], E. Stoddard[4], A. Ripston[5]

[1]Yale Cancer Center, Yale School of Medicine; [2]UPMC Hillman Cancer Center; [3]Bristol Myers Squibb; [4]Lilly; [5]Biospecimen Management Consortium

1. Background

Clinical trial acuity continues to grow with direct impact on the management of biospecimens at clinical research sites. Additionally, the lack of efficient systems generate waste with significant financial and ecological impact. Sponsors and clinical research vendors often create separate solutions for clinical research sites. As a result, these solutions often generate site burden, amplifying a deep-rooted problem. To help create solutions for all biospecimen management stakeholders, the biospecimen management consortium (BMC) was established.

2. Goals

The BMC sought to define specific challenges across all stakeholders in the biospecimen landscape. Following an industry sponsor survey from September, 2024, the BMC partnered with the Association of American Cancer Institutes (AACI) to identify unique issues associated with biospecimen management at clinical research sites. The goal was to identify all issues associated with biospecimen management from trial design through execution and closeout to determine where meaningful solutions could be developed and subsequently deployed.

3. Solutions and Methods

A 16-question site survey was developed by members of the BMC, inclusive of academic research sites, industry sponsors and vendors. The survey was distributed to AACI-affiliated institutions in June of 2025 at the AACI-Clinical Research Initiative (CRI) annual meeting and subsequently via email. Questions focused on key challenges, priorities, and opportunities for improvement from the lens of academic research sites, specifically focused on oncology clinical trials.

4. Outcomes

Of 92 AACI-participating Cancer Centers, 50 responded to the electronic survey. Challenges included the need for sites to create their own study-specific tools to support biospecimen collections (80 percent). Nearly half (44 percent) indicated that they destroy more than 30 percent of their kits monthly. The majority of respondents (66 percent) indicated that they'd prefer to receive specialized items in bulk supply based on individual needs and help reduce kit waste. When asked to rank items in order of importance, the top three issues selected as most important included the need to reduce discrepancies between protocols and lab manuals (70 percent), the need to increase flexibility with lab sample processing windows (46 percent), and improving kit management/waste (42 percent), respectively.

5. Lessons Learned and Future Directions

While the BMC industry survey from September 2024 focused on the needs from sponsors related to data and metrics, the site survey focused largely on the operational challenges of biospecimen management in clinical trials, principally from systems generated outside their control. When solutions are created in a vacuum, without adequate input from key stakeholders, operational efficiencies suffer.

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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.

The BMC and AACI continue to work toward sustainable solutions that engage all partners across the research biospecimen landscape. Additional surveys and relevant solutions will also be explored globally, across multiple disease and trial types.

Figure 1