Development and Implementation of Patient Education and Coordinator Training to Optimize Microbiome Specimen Collection and Tracking

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BACKGROUND

Post-hoc microbiome analysis is a growing area of research in translational oncology, with recent research at the University of Florida (UF) identifying the role of the gut microbiome in predicting drug efficacy for immune checkpoint inhibitors in a NSCLC cohort (Jobin 2022). Microbiome data is frequently derived from microbiome biobanks (MB) included or embedded within therapeutic clinical trials where clinical research staff manage collecting and coding microbial patient samples for future analysis by basic science teams. This is a challenging task requiring advanced patient education skills and precise coordination to ensure successful collection across all enrollments.

Specimen collection compliance tends to decline over the course of the trial due to unclear transfer of study-specific procedures and their rationale during coordinator hand-offs. Additionally, staff and workflow changes disrupt specimen management, and variability in clinical research coordinator (CRC) experience and confidence affects how well collection requirements are communicated to patients. The potential importance of these samples for future research reinforces the need to generate and establish a durable system ensuring the collection of all future microbiome specimens which, if successful, can be applied across all clinical trials that utilize a built-in microbiome biobank.

GOALS

- Develop improved patient education and discreet take-home materials to facilitate fecal collection.
- Develop durable coordinator training to facilitate study coordinator transitions.
- Improve coordination with Microbiome Specimen Collectors (MSC) to ensure accurate sample collection and coding.

SOLUTIONS AND METHODS

We benchmarked one Phase 1/2 clinical research study (NCT05000294; currently suspended for interim analysis [IA]) which utilizes a built-in biobank for microbiome stool specimen collection, to assess specimen collection compliance over time. Over the course of 23 patients and 2 primary CRC handoffs, optional microbiome specimen collection decreased 24% and 48%, respectively, with each successive coordinator transition.

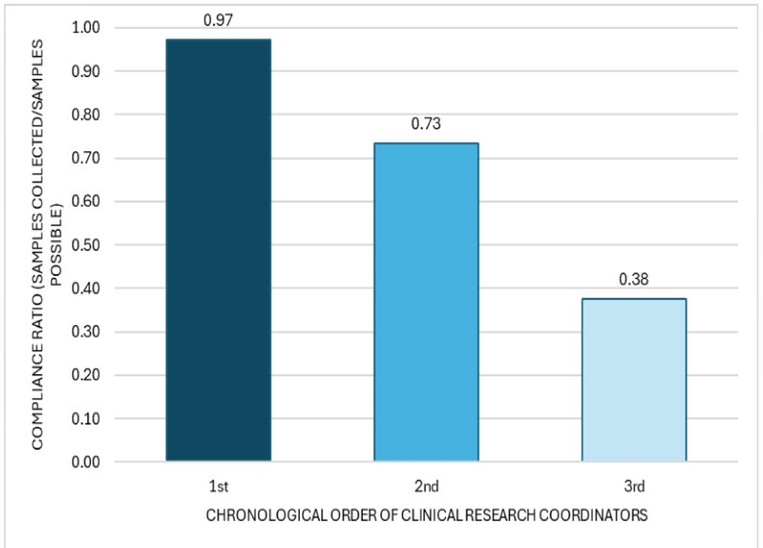

Figure 1. *Sample Compliance Ratio over the course of three Clinical Research Coordinators. Total samples collected over possible samples calculated for each coordinator and plotted chronologically.*

To address declining specimen collection compliance, a three-point solution was developed:

- A subject-facing educational brochure was created to provide transparent, clear goals, and methodology. The new brochures include rationale for the sample collection as well as written instructions for fecal specimen capture and transport to the clinic.
- Coordinator training was developed for present and future coordinators, providing written instructions on collection kit management, importance of specimen collections, pre-collection preparation, subject education, and management.
- Updated and confirmed logistics with MB to ensure clear communication between MSC and MB staff.

FUTURE DIRECTIONS

Future directions include evaluating subjects enrolled on the benchmarked trial after the IA to determine whether microbiome specimen collection compliance improved. If improvement is observed, this three-point resource management strategy can be expanded to other ongoing and future IITs utilizing the microbiome platform to enhance overall specimen collection and management.

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