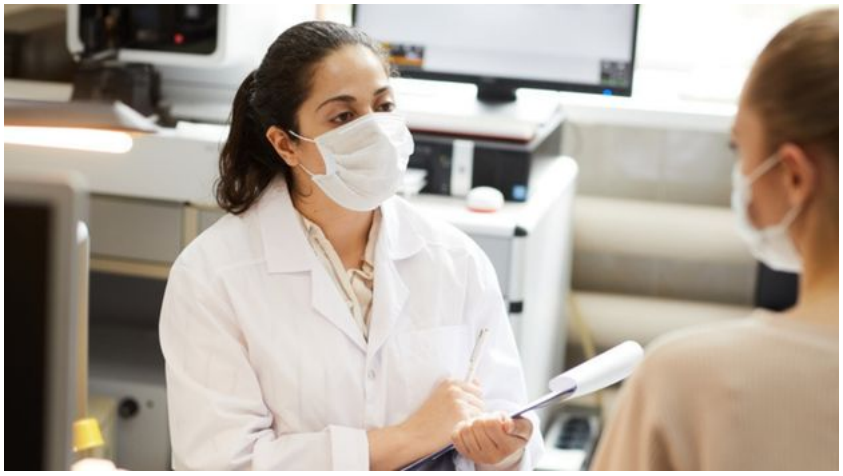
FILTER NEWS

- All (790,802)
- Topic (748,892)
- Hotbed/Location (720,658)
- Career Advice (3,847)
- Insights (158)
- Webinars (5)

Optimizing Biomarker Assays to Bridge the Clinical Trial Participation Gap

Published: Nov 01, 2023 | By BioSpace Insights Team



Estimates of **clinical trial participation** among eligible patients have remained at less than five percent **for decades**. Often cited as top culprits, the burden of participation and access to clinical trials hinder patient enrollment, **among other factors**. Trials can involve complex treatments requiring numerous doctor visits, placing the onus on patients to orchestrate the considerable logistics of their participation.

As a result, up to **20% of clinical trials** are either terminated early for failing to meet recruitment targets or are completed while failing to meet the original target. Precision medicine trials that rely on specific biomarkers can face even greater challenges for enrollment. The pandemic forced this issue to the forefront, as social distancing and quarantine prevented patients from traveling for in-office visits. This left industry sponsors wondering, "What can be done to reduce the burden for patients and increase patient enrollment?" said Naveen Dakappagari, Head of Biomarker and Diagnostic Development at Navigate BioPharma Services.

Naveen Dakappagari
Head of Biomarker &
Diagnostic Development
Navigate BioPharma Services

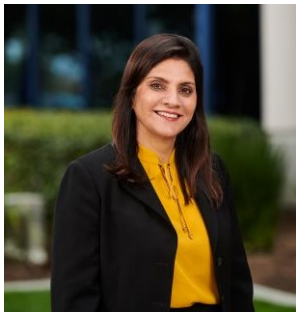
One of the most beneficial approaches to address the participation gap for both patients and sponsors is to get the most out of any in-office visit — right down to the amount of sample collected for analytical assays, Navigate BioPharma CSO Shabnam Tangri told BioSpace. "Tests should be reproducible and robust to avoid drawing sample for the sake of sample."

Tangri further explained that this approach "strategically develops precision biomarker assays for evaluating study endpoints, determining disease biology, and response to investigational therapies — one of the keys to the

future." These assays are fitted for a distinct purpose within each trial's scope and individual needs — often a better option than using more generalized approaches that may require more patient samples or a battery of assays to evaluate study endpoints.

A fit-for-purpose assay starts with a clear and well-defined clinical question. This challenges sponsors to be more precise in their focus. Instead of answering multiple questions, they should "narrow the focus and consider the intended use of any assays and how they will inform decision-making," says Tangri. The degree of intention empowers precision in evaluating trial endpoints and may go a long way toward reducing patient burden by eliminating the number of tests and sample collections required.

Getting the biomarker assay right the first time also saves time and money for sponsors. Trials span many years and can become quite burdensome to repeat if the science evolves or a sponsor receives pushback from regulators on how they evaluated study endpoints. The pressure to produce significant amounts of data for marketing applications is already high and requires substantial investment. Yet, acquiring enough data doesn't have to mean a battery of assays and a higher participation burden on patients.



Shabnam Tangri
CSO
Navigate BioPharma Services

Opportunities to minimize participation burden can also arise in combining data from multiple tests and in-office visits, an example of the heavy lifting a well-designed assay can accomplish. The goal is to obtain quality data in an efficient and succinct manner that optimizes the patient's investment, both in time and sample, while fulfilling study requirements and the sponsor's obligation to regulators.

"Creating patient-centric tools and ensuring we operate in a manner that does not create an additional burden for the patient — that should be top of mind for all of us," said Dakappagari.

Putting this approach into action requires significant investment into multi-faceted tools built for scale. Dakappagari pointed to multiplex technologies driven by artificial intelligence (AI) and integrated methodology, which could empower maximum data collection with minimum sample required from patients.

Multiplex technologies analyze many variables using only one method and one asset, creating a wealth of information best synthesized by AI technology. Navigate BioPharma **recently launched** a new multiplex digital PCR assay for comprehensive quantification of up to 5 different CAR T-cell transgenes. This technology will help monitor response and safety events during clinical trials.

Similarly, scientists are looking to drive the focus toward developing a protocol for using a single specimen across many different technologies. One team analyzes the protein in a specimen, while the other extracts DNA and RNA from the same sample.

Though still in the proof-of-concept stage, this is one of many techniques Navigate BioPharma hopes to leverage to reduce patient burden in clinical trials, added Dakappagari. “When you think about doing the right thing for patients, it just seems the right thing for everyone.”

◄ Back to news