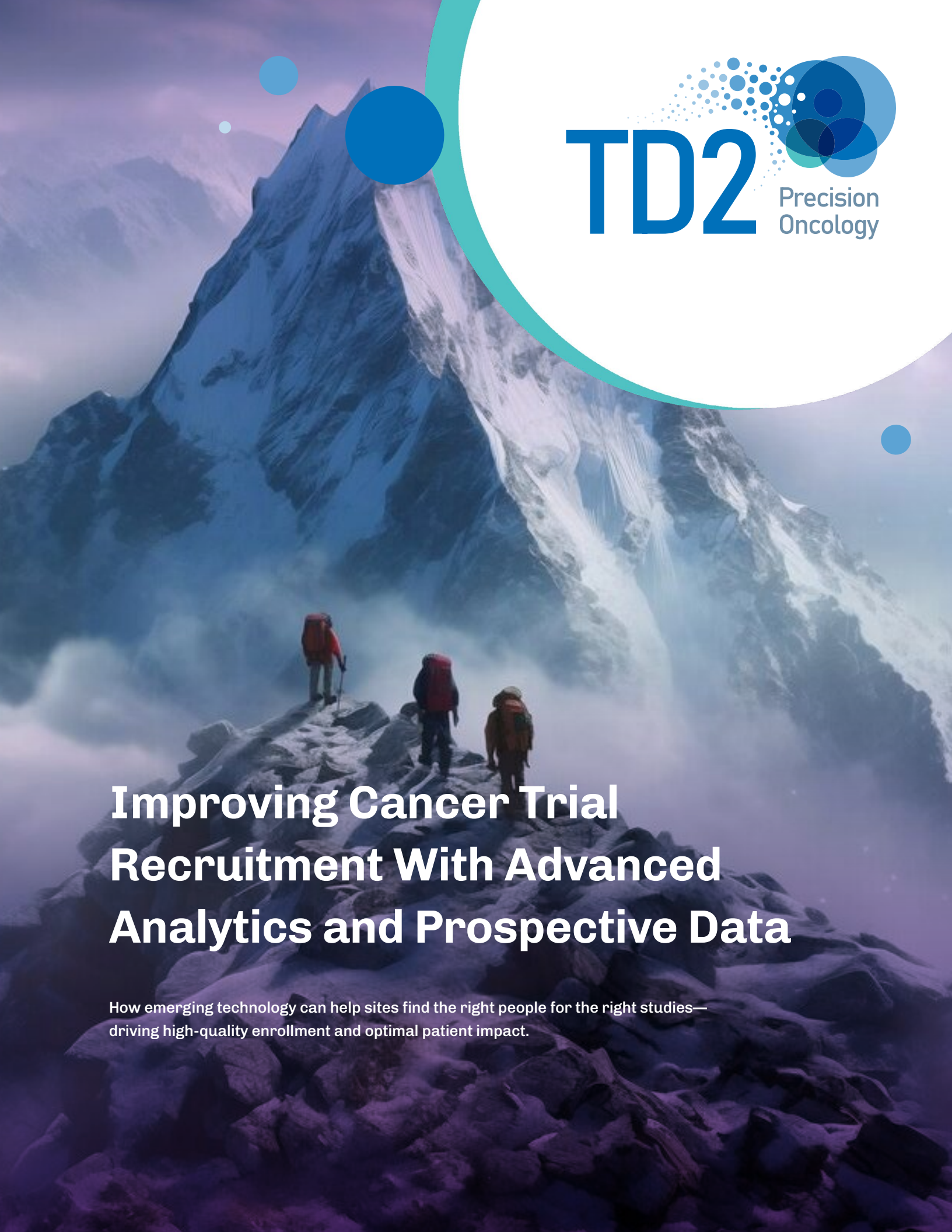


TD2 Precision Oncology

Improving Cancer Trial Recruitment With Advanced Analytics and Prospective Data

How emerging technology can help sites find the right people for the right studies—driving high-quality enrollment and optimal patient impact.

In oncology, adult clinical trials—much like other trial types—have an enrollment challenge, and it's been this way for years. Sponsors often have trouble meeting enrollment goals, forcing delays and disruptions that ultimately impact speed to market of new cancer medicines. According to the NCI, 18% of the institute's trials from 2000 to 2011 couldn't fill even half the intended participants after three years, or otherwise canceled because of low participation.[1]

These barriers stem from many factors, with one of the largest being that modern-day oncology trial enrollment focuses too heavily on accrual metrics instead of what really matters: Getting the right patients involved in the right research for them.

That's not because investigators don't focus on patient impact; they certainly do. Roughly 4 in 5 cancer patients receive care in the community oncology setting,[2] and when currently approved treatments don't work for them, clinical research is always an option. However, capacity concerns like labor shortages and burnout can limit sites' ability to recruit and enroll patients in trials.

As a result, recruitment goals can stall out, or trials simply enroll less-than-ideal patients who ultimately have a lower chance of benefit and result in faster attrition.

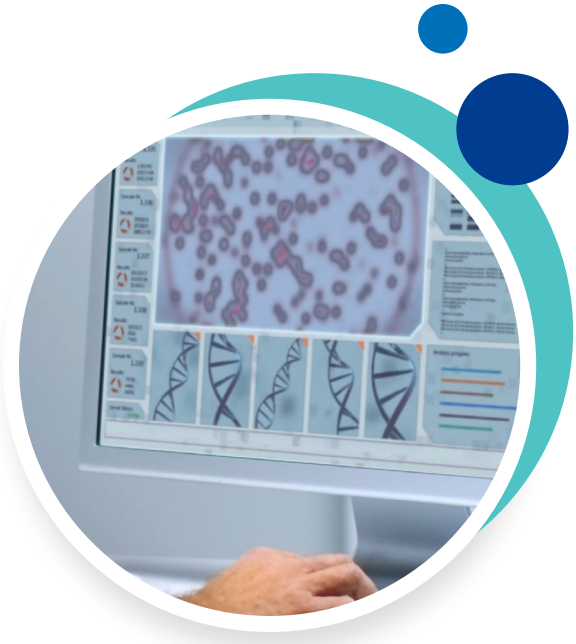
So how can sponsors shift their recruitment approach from quantitative (focusing on accrual) to qualitative (focusing on patient impact)—without compromising on time? Advanced analytics can help, but only if you're looking at the right insights. This increasingly means prospective, rather than retrospective, data.

Using Retrospective vs. Prospective Data for Patient Enrollment

At least for right now, most sponsors and CROs rely on retrospective data—as in claims or prescription data—when assessing which sites to include in a given trial. This data serves a good purpose in that it provides a fair assessment for how many patients might have at one time qualified for this study at a particular practice, but it doesn't adequately predict how well a site would carry out the current study.

"Retrospective data says nothing about who's in the practice currently for active treatment," said Stephen Gately, CEO of TD2. "Maybe you find out there is a practice in Montana that saw a lot of patients with this particular cancer two years ago, but if you open the study there based on that historical evidence, you risk discovering that there are no current patients who match the criteria."

These limitations in historical data emphasize the need to focus on real-time data for site activation. Prospective data is the answer, providing de-identified insights from the EHR and other patient medical records that describe exactly who is in the current care continuum.



Having access to that real-time data has remarkable value, now more than ever. Amid COVID-19, delays in cancer screening measurably drove late-stage diagnoses. As more patients present to community oncology practices with metastatic disease, the population of cancer patients has substantially changed even from just a year or two ago.

If sponsors relied only on historical data to drive current enrollment decisions, they wouldn't get an accurate assessment of the existing participant pool. This is why we urgently need to switch our sights to real-time, prospective data.

Emerging Roles for Automation Technology

Most everyone agrees that real-time data is preferred over historical insights for site selection. The challenge, of course, is accessing it: A large portion of prospective data is unstructured—just floating around the medical ether in physician notes, lab and imaging reports, old medical files, and other disparate sources.

"There's usually more than a dozen fields for structured data for any given patient, but very few providers complete them all," Gately said, adding that at times even structured data can be wrong, as is the case with ICD miscoding. "If that's the only source of information you use for site decisions, you're going to miss a lot of folks. Think of it as an iceberg: 30 percent of the data lives in structured fields, while 70 percent or more lives in hidden places."

By using intelligent tools like natural language processing, which pores through unstructured data to gather more insights about trial candidates and validate selection decisions, sponsors can more easily and quickly comb through the entire medical record to find sites with matching patients.

Tech powered by these advanced analytics is already impacting clinical research: One system found 16 matching patients in an hour for a cardiology trial when the previous manual search took six months to find two people.[3]

The value of this technology goes well beyond current matching, too. By configuring triggers, platforms can capture new patients as well as track patients who may become eligible in the future. With these real-time alerts, sponsors can instantly know when any site has a potentially eligible patient.

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>
> **Dr. Stephen Gately**
> **CEO, TD2**

Analytics in Action

Scenario #1

Removing Burdens from Sites

When recruitment is especially challenging—like in a highly complex trial—sites may not always have the bandwidth to take advantage of enrollment opportunities even when they have eligible patients. By providing busy sites access to technologies with advanced analytics, sponsors can make enrollment less of a barrier for sites themselves, ultimately ensuring that the right patients get matched to the right trials.

Scenario #2

Supporting Diverse Representation

Are advanced analytics the answer to the lack of diversity in early-stage clinical research? Experts think they may be. As an unbiased selector assessing data from multiple sites, intelligent technology stands to help capture more eligible patients across a broad range of geographies and demographics—ultimately helping to choose patients who better represent the broader patient population.

Scenario #3

Fast-Tracking Regulatory Approval

When advanced analytics successfully match the right patients to the right early trials, sponsors get the advantage of knowing faster whether targets work or don't so that they can move forward, pivot, or call it quits. That early work also has lasting value once therapies reach regulatory stages, says Susan Night, TD2's Vice President of Site Engagement and Network Strategy.

> **If you can recruit the right patients in phase one studies, and you have strong enough data to support evidence of benefit, there may be opportunities for accelerated approval with the FDA.**

Patient Impact as the North Star

As enrollment goals suffer, and retention and early-stage failures still plague clinical research, there's immense opportunity to engage advanced analytics to reprioritize patient impact as the North Star for oncology studies. Even so, technologies will never replace humans: While platforms can help sites achieve more by identifying patients faster, clinical research coordinators and other site staff will always be needed to validate those outputs and confirm eligibility based on the nuances only they know.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5964887/

[2] https://www.jhconline.com/cancer-care-migrates-to-outpatient-setting-2.html

[3] https://www.nature.com/articles/d41586-019-02871-3

Ready to Get Started?

Sponsors can access leading-edge analytics by partnering with a qualified CRO whose systems work in the background with de-identified data to improve site and patient selection. If you're looking to elevate your program with this modern-day technology, TD2 can help. Work with us to select a recruitment platform for your novel therapy today.

Contact us to get started today

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Contact

(602) 358-8300 sales@td2inc.com www.td2inc.com