The Power of More: Re-Imagining the Traditional Business Model for Oncology Clinical Research

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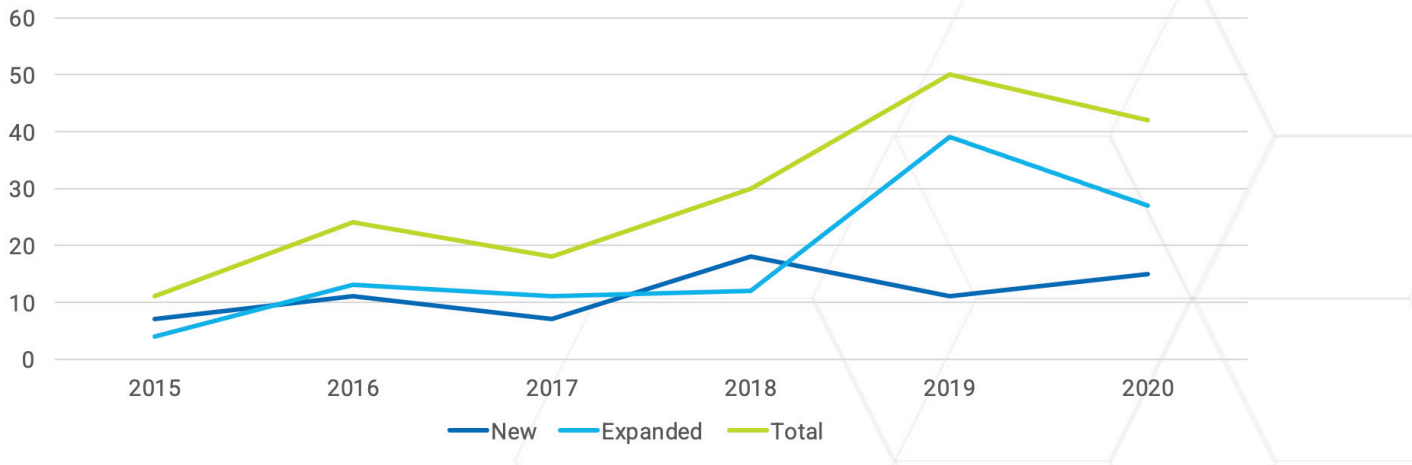
Complex challenges provide ample incentives to re-imagine the traditional business model – rising costs, shifting resources, increased pressure and "new normal" virtual settings. Motivated clinical research leaders want increased focus on patient care along with faster study starts, more patient access to trials and better performance while reducing costs and staffing burdens. Our recent webinar discussed industry trends as well as obstacles and new, practical approaches to achieving success.

Trends in Oncology Clinical Trials

Marking the 50th anniversary of the National Cancer Act, we can celebrate considerable success:

- A 30% decline in cancer death rates over the past few decades
- FDA approval of 1,501 new cancer-fighting drugs since 2006
- Accelerated FDA review: 59 novel therapeutics approved in 2019 and 53 in 2020, despite the pandemic[1]

FDA Oncology Approvals: 2015-2020



Source: https://www.asco.org/search/site/FDA%20approvals

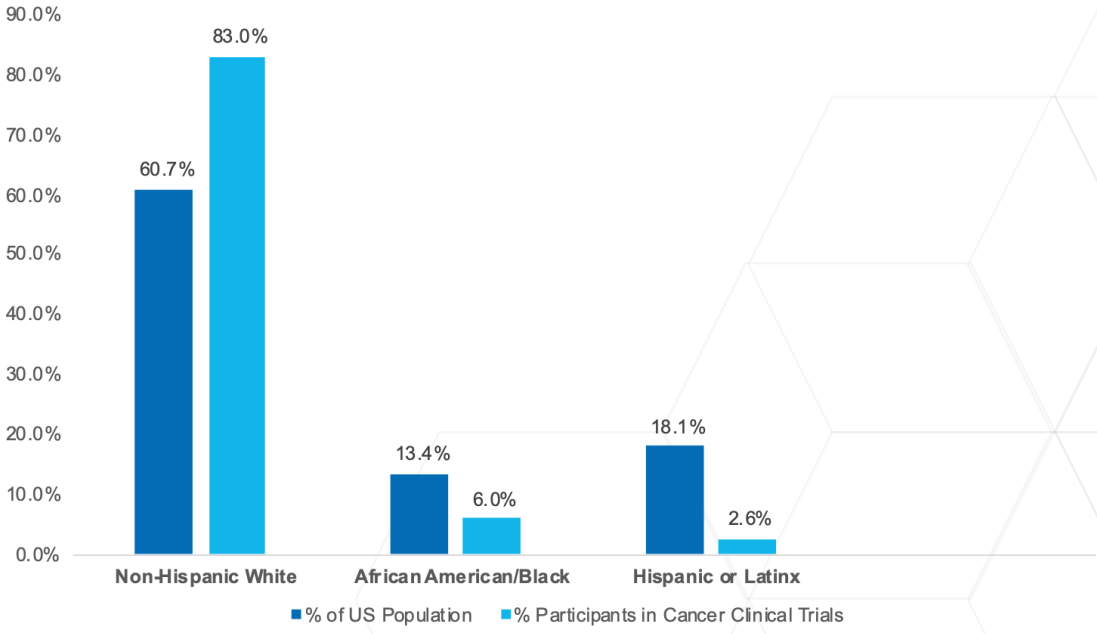
Trends in Oncology Clinical Trials

The Biden administration is proposing a $6.5 billion medical research agency aimed at curing cancer, which could emphasize higher-risk projects enabling major medical breakthroughs.

The pipeline is robust, with immunotherapy and cellular or gene therapy spurring demand for clinical trial sites. More than 50 cell therapy trials have been initiated since December 2015, focusing on hematologic malignancies as well as multiple solid tumors. Among the key ingredients for success in future oncology trials in 2021 will be molecular profiling and harmonizing these next-generation sequencing reports.

At the same time, sponsors are concerned about healthcare inequality in clinical trials. Minorities are underrepresented – as detailed in the graph. Patients living in rural areas and populations with lower income and education levels experience lower survival and higher mortality rates for many cancers.

Minorities are Underrepresented in Cancer Research



Source: Duma N, Vera Aguilera J, Paludo J, et al. Representation of Minorities and Women in Oncology Clinical Trials: Review of the Past 14 Years. J Oncol Pract. 2018 Jan;14(1):e1-e10.

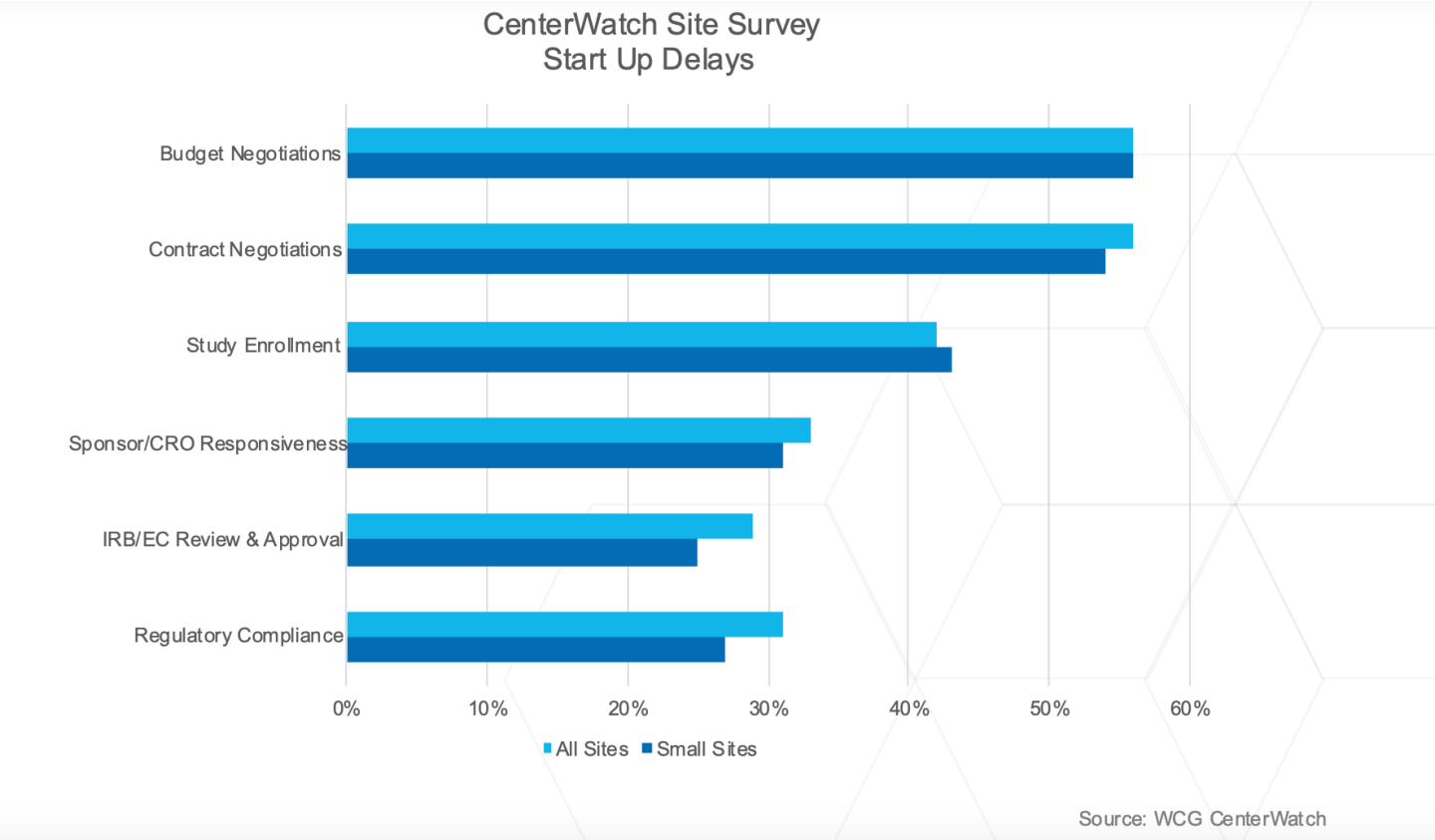
Payment parity is an obstacle for nearly 68 million patients covered by Medicaid[2]. The Clinical Treatment Act, passed December 2020 with a January 2022 start date, requires states to create Medicaid payment policies covering physician visits and lab tests in connection with clinical trials for serious and life-threatening conditions.

Along with these industry challenges and changes, medicine is more personalized and there is a greater reliance on technology. We have seen an increase in telemedicine with the COVID-19 pandemic, the use of digital tracking devices as well as expanded methodologies for study designs – including basket trials and adaptive designs. These factors increase trial complexity, resulting in additional administrative work.

Overcoming Obstacles

Research leaders face daily challenges which lead to delays in study starts[3]. See chart below.

Sites are Under Compounding Pressure



- Budget negotiations – standard pricing models, per study budgeting and CMS billing compliance
- Contract negotiations – cybersecurity, foreign laws, indemnification, holdbacks, site termination and patient confidentiality
- Study enrollment – patient populations, study protocol, staffing and technology
- Sponsor/CRO responsiveness – external factors affecting timelines
- Regulatory compliance – an essential component of study protocol
- IRB/EC review & approval – ethical standards for patient care

The COVID-19 pandemic increased pressure, with pain points including delays in study start-up, challenges to trial enrollment, staffing challenges and creating new procedures. Research programs underwent nimble pivots as trial leadership managed resources, workflows and communications in an attempt to minimize patient impact.

Ensuring Success

To overcome obstacles and refresh the research business model, today's successful site managers:

1. Know true costs to conduct each clinical trial – Start with a standard pricing model with an understanding of fair market value that reflects your costs to use in creating study budgets. Know the basis and rationale for your price. If you provide documentation, you will likely succeed in your negotiations, but sponsors don't want to see an outlier at twice the competitive price.

With financial burdens shifting to sites, it is essential to cover costs. Have a complete budget and coverage analysis, along with a regularly updated fee schedule. Time is often undervalued, so consider all the professionals – from laboratory technician to pharmacist – contributing to a study. If a trial is not financially feasible, knowing your costs helps you understand risk and make sound decisions. Finally, for longer-term studies, consider inflation.

While you may be awarded a trial, unless you have knowledgeable people preparing your budget, you may require amendments. These amendments consume staff time, delay payment and increase complexity. It's wise to invest the time up front and get the process right.

2. Utilize a planned staffing strategy

Many hospitals and institutions are facing post-pandemic challenges associated with their lower patient volumes and cancelled procedures including delayed capital projects, staff furloughs, early retirements, and pay cuts. Some have a small in-house flexible staffing pool but many have fixed staff and rely on their existing team to take on more work which can lead to burnout. For many, the option of adding headcount is not always possible.

Most sites have a fixed staff, which poses a challenge for sudden workload changes. How can your site "flex up" during high study volumes or enrollment? Beyond the options of adding new positions, paying existing staff overtime, or harnessing in-house temporary staffing, consider the use of external partners with the research expertise to complement your team.

Finding and retaining good, qualified people takes time and attention; they are a valuable resource. Sites often run lean, but ideally, you should be able to increase your capacity by 5-10% as needed. A flexible strategy can enable you to provide life-saving therapies to patients while being responsive to sponsors.

3. Measure and monitor time to first patient in, anticipating potential obstacles– Industry statistics reveal that 25% of cancer trials fail to enroll enough patients, and 18% close with less than half the target number of participants after three or more years. Clearly, enrollment is a pain point for clinical trial sites.

During the negotiation phase, it is critical to understand your patient population. How well do you know the protocol and the target population? Do your homework up front, look at your patient population and consider your analytic cases. Were you previously successful with a similar trial? If you weren't, did your team evaluate why, so history does not repeat itself? Sponsors tend not to forget poor enrollment; you want to meet or exceed the target.

Getting that first patient enrolled is an early indicator of success. Our webinar survey revealed study startup at 61-90 days for one-quarter of our audience and 91-120 days for another quarter of respondents. If an ideal target is 30-45 days, how do you get there? Using concurrent workflows can reduce the timeline by half. Other strategies include standardizing study approach and offloading administrative burdens to partners to let your staff focus on identification and screening of potential patients. If you suddenly have 15 studies to consider, a qualified service provider can help, operating in parallel to your daily workflow.

Other factors to consider: A central IRB can expedite ethical review, with an 8-10-day turnaround time accelerating study start. Helpful technology enhancements include using a clinical trial management system (CTMS), eBinders for regulatory workflows, and electronic consenting. Sometimes, factors outside of the site's control impact study start as you wait for a third party, such as a CRO, to respond. Focusing on parallel workflows and communication can pay off.

Re-Imagining Your Business Model

Embracing innovation will position you to pursue more trials and enroll more patients. WCG Managed Research Solutions measurably improve the quality and efficacy of clinical research. For sites, we provide critical components including ethical review, study startup, financial management, patient enrollment and engagement, as well as enterprise technologies. Our services are purpose-built to serve those on the front lines of science and medicine, allowing more focus on patient care.

For more information, **click here**.

References

[1] https://www.asco.org/search/site/FDA%20approvals

[2] medicaid.gov

[3] CenterWatch Site Survey: https://www.centerwatch.com/articles/25535-sites-face-trials-bottleneck-after-pandemic-but-also-opportunities

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