WHITEPAPER

# Tackling cancer therapy clinical trial management challenges

## Position your research study for success with oncology pathways

PRESENTED BY:

ELSEVIER

PUBLISHED BY:

FIERCE Healthcare

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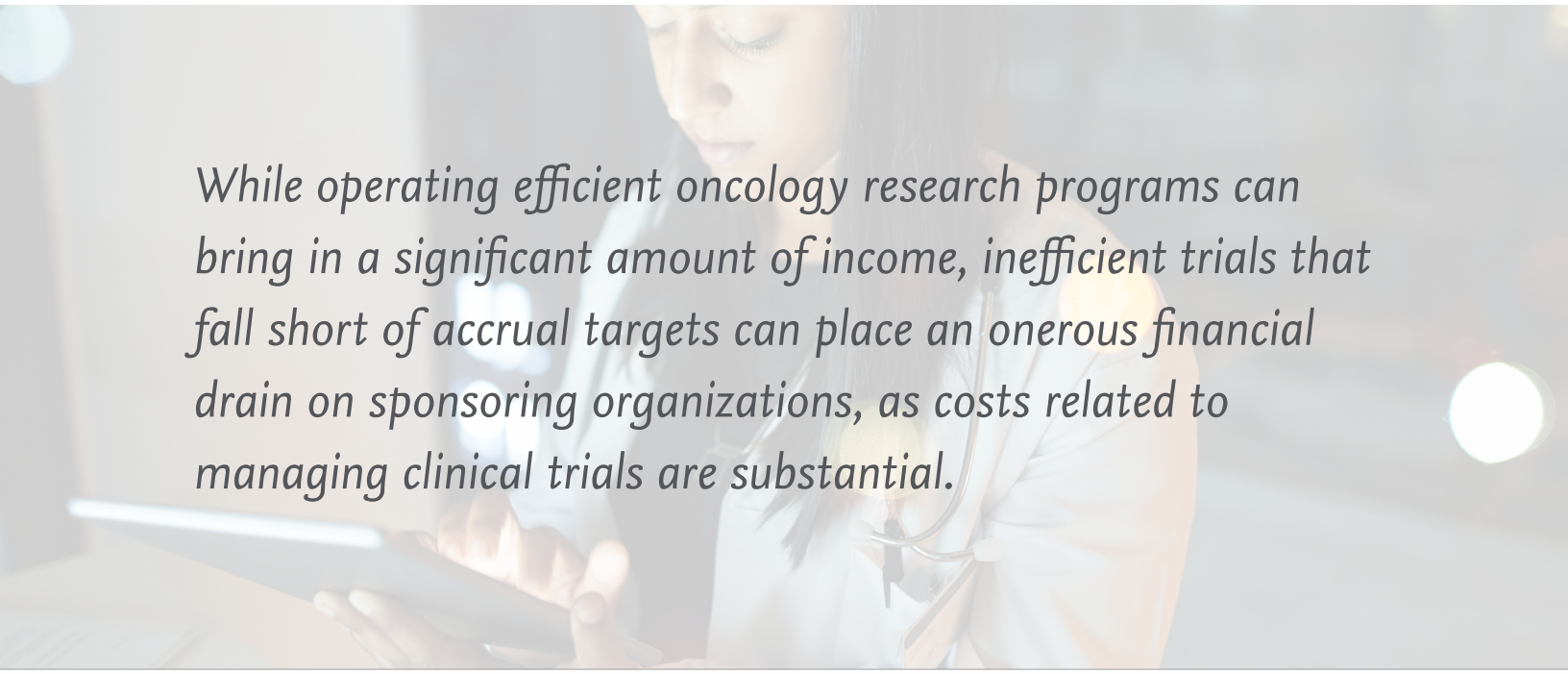
Cutting-edge technologies such as chimeric antigen receptor T-cell immunotherapy, nanomedicine, personalized vaccines, gene editing and microbiome treatments are revolutionizing cancer care. Ironically the technology platforms to support clinical trial management operations have not developed and scaled as fast as those scientific advances, leaving the impression that clinical trials operations teams are technology averse.

As a result, cancer centers struggle with manual clinical trial management, which historically has not benefitted from workflow optimization like other areas of medicine. The process is laborious with the potential for missed opportunities to enroll patients, especially those with recurrent diseases, into research studies because it is difficult to identify when sentinel events are likely to occur.

While operating efficient oncology research programs can bring in a significant amount of income, inefficient trials that fall short of accrual targets can place an onerous financial drain on sponsoring organizations, as costs related to managing clinical trials are substantial. One study, for example, found the median cost of conducting a trial from protocol approval to final clinical trial report to be $3.4 million for phase I trials involving patients, $8.6 million for phase II trials and $21.4 million for phase III trials.[1] Considering that each phase of an oncology trial takes 14 to 18 months longer than each phase of a non-oncology trial, financial risks are exponentially exacerbated for cancer centers[2]

Cancer centers can potentially help their research programs succeed by leveraging oncology pathways that place evidence-based clinical trial information within the workflow. Implementing this solution provides institutions with the necessary support to make relevant trials highly visible to physicians; minimizes the administrative burden on research teams; builds a targeted trial portfolio aligned to their patient population; and gives patients access to ground-breaking therapeutic options that could make a life-changing difference.



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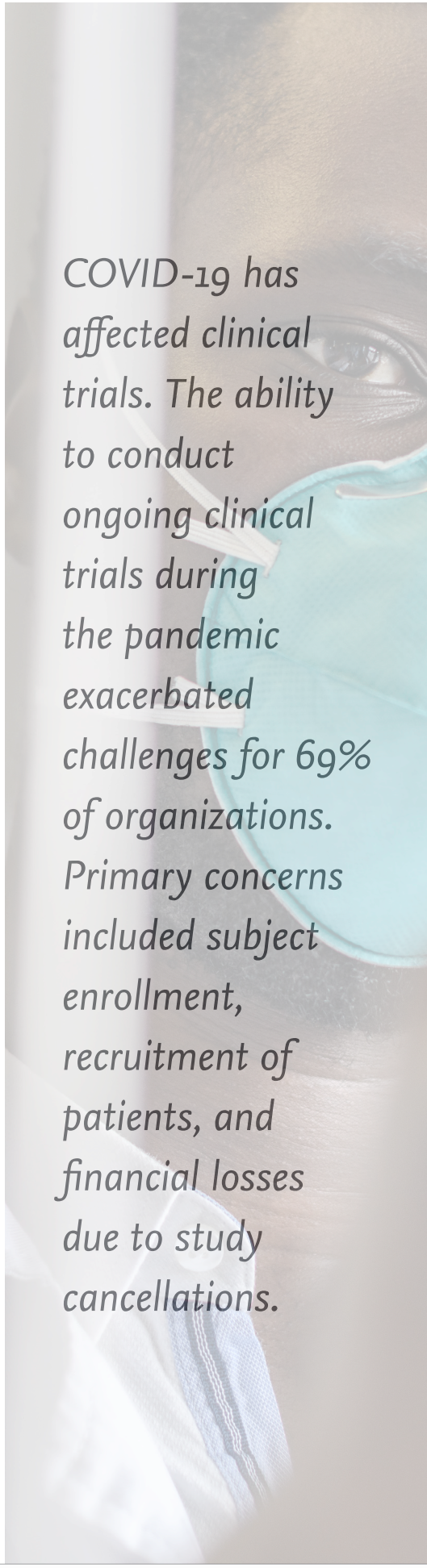
# Oncology clinical trials: Assessing the current state of affairs

The call for wider automation in clinical trial management is supported by the following observations:

- More than 70% of patients believe that there should be more opportunities to participate in clinical trials.[3] Yet, on average less than 2% of cancer patients participate in clinical trials. Barriers to participation include being unaware of trials opportunities and complexity and stringency of the protocols.[4]
- The difficulty in recruitment to oncology studies can cause overall delays to clinical trials. Indeed, less than 20% of studies accrue to target as planned and the majority of trials fail to meet expectations.[5]
- Recruiting the right patients in oncology is particularly arduous, as eligibility requirements often present a barrier to wide applicability. Reality is that patients who are diagnosed with cancer often have illness burden that produces significant symptoms, with assessment critical to rule out patients who may be too ill to complete the entire duration of the study.[6]
- COVID-19 has affected clinical trials. The ability to conduct ongoing clinical trials during the pandemic exacerbated challenges for 69% of organizations. Primary concerns included subject enrollment, recruitment of patients, and financial losses due to study cancellations. Other concerns included accessibility of patients to the trial site, health challenges for the trial team members, and the necessity for COVID-19 screening.[7]
- A total of 386 oncology trials were affected by COVID-19, with the pausing or termination of oncology trials peaking in May of 2020, according to a report from the Cancer Research Institute. In addition, patient care was negatively affected with 1,155 planned oncology slots lost due to terminated and withdrawn studies. Lab closures and shifting priorities to COVID-19 likely delayed the progression of clinical trials.[8] As the pandemic ebbs and flows, clinical trial managers will need to understand the risks involved and adopt new approaches to ensure that their studies succeed.[9]

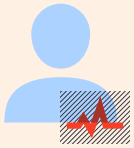


# Oncology clinical trials: Confronting challenges on all fronts

Cancer centers face many obstacles when trying to recruit patients to clinical trials including:

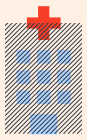
## PHYSICIAN RELATED RECRUITMENT CHALLENGES

- Lack of awareness regarding the availability of clinical trials
- Concerns about tolerability, patient age, comorbidities and poor prognosis
- Challenges regarding demands on staff; and unconscious biases and/or lack of cultural competence
- Logistical and regulatory obstacles
- Clinicians' reluctance to discuss trials with patients



## PATIENT RELATED RECRUITMENT CHALLENGES

- Lack of understanding regarding randomization or assignment to placebo or nontreatment, potential adverse effects and impact on quality of life
- Financial burden and logistics, such as driving distance
- Trust in the physician, particularly when a physician recommends a trial



## SYSTEM RECRUITMENT CHALLENGES

- Lack of institutional support
- Insufficient staffing, especially research nurses and support staff for more complex studies
- Unavailability of suitable protocols at the site
- Ineffective operational procedures
- No formal mechanism for eligibility screening[9]

# Oncology clinical trials: Improving performance

To improve oncology clinical trial recruitment, cancer centers can focus on best practices such as:

***Raising clinical trial awareness.*** A manual accrual process relies too heavily on staff surveillance and oncologists to be aware of all clinical trials being offered. With oncology pathways, cancer centers can take the guesswork out of accrual, putting available clinical trials at the point-of-care. Use of a formalized clinical pathway incorporates trials into the workflow in a way that studies are prioritized as the first consideration before "standard of care" treatment options. This heightens physician awareness of potential trials within the organization that match their patient's disease characteristics. In Case Study 1 we explore the real-world impact of placing institution-specific clinical trials ahead of standard of care recommendations and the resultant increase in patient screenings.

## Case study 1: Keeping oncologists in the clinical trial loop

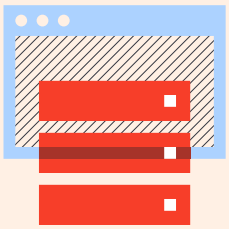
Challenge: As a research-integrated organization with multiple cancer centers providing cancer care, oncologists at a medical center need to be aware of clinical trials operating across the health system. Doing so, however, requires focused effort: trials are held at various geographic locations; the portfolio of trials is rapidly expanding; and physicians often see a patient mix that includes relatively uncommon cancer diagnoses.

Solution: To address this challenge, this medical center implemented evidence-based medical and radiation oncology pathways on a technology platform that embeds clinical trial recommendations ahead of standard-of-care recommendations. The pathways platform is a prospective way to remind medical and radiation oncologists of clinical trials available and open in their network at the point of decision, empowering consistent consideration of clinical research options across their cancer network.

Results: The medical center found that by embedding research trials into the clinical decision-making workflow it allowed oncologists to more easily request clinical research screening directly from the pathway platform. This increased communication and coordination with the research team, and increased the percentage of patients accrued to trials. This medical center also found the detailed analytics enabled optimization of their trial portfolio based on pathway decision data available for their entire cancer patient population. This data included patient clinical details as well as screening rates by clinical trial, provider, and treatment site. Furthermore, incorporating trials into pathways has enabled the medical center's oncologists to present consistent treatment options to patients, improving health equity and supporting the mission to increase diversity of patients accrued to study. Overall, the oncology pathways empower this medical center to provide patients with innovative treatment options and advance the quality of cancer care.[11]

***Streamlining communication.*** When an oncologist selects a patient for potential participation in a trial within the pathway platform, a message is immediately sent to the research team (with a variety of delivery options including email and direct-to-EMR inbox). The research team can use that trigger to start their patient contact process and initiate trial screening to determine if the patient meets eligibility. This improvement to the communication workflow empowers the right information at the right time to assist with recruiting the patients needed to successfully complete research studies.

***Screening proactively.*** Meeting accrual goals is dependent on having trials open that match the cancer center's patient mix. The detail of clinical pathways makes it possible to present patient-specific clinical trials based on trial inclusion and exclusion criteria. This enables oncologists to more narrowly consider the appropriate patients directly within the decision-making process, supporting an increase in the awareness of, and accrual to, clinical trials. By using analytics of the cancer center's patient population available within clinical pathways, the research team can refine its screening efforts by more keenly focusing on the most appropriate patients for each study. Resultant, cancer centers create better performing research programs. A multi-site oncology practice, for example, leveraged the clinical pathway functionality to raise trial participation for lung cancer patients to 25%, more than 5 times the national average.[12] (See Case Study 2)



With clinical trial analytics derived from a pathways program, healthcare leaders gain better insights into the performance of their network on dimensions that include clinical trial accrual, near-real time epidemiology of their cancer case mix, and how physician decisions compare to evidence-based recommendations at the disease and network site level.

## Case study 2: Moving clinical trials to the top of the list

Challenge: To support its mission to provide services close to home, another regional cancer center aspired to significantly improve access to and enrollment of clinical trials at their cancer centers throughout eastern Wisconsin. The problem: Many physicians simply were not aware of the various clinical trials available to patients. In addition, while all initial consult patients were manually screened, they were not screened for subsequent lines of therapy.

Solution: This cancer center chose to leverage implementation of an electronic health record- integrated clinical pathway decision support tool to provide physicians with access to recommended treatment considerations based on information about the patient, their disease and goals of care. Within the recommendation algorithms for each disease state, an appropriate available clinical trial is suggested as the primary recommendation.

Results: With this technology in place for 11 months, providers adopted to the new decision support workflow quickly with a utilization rate of 82.7% of examination and management visits. With 3,844 decisions made, 83.9% of all treatment decisions were concordant with a pathway recommendation. Clinical trial enrollment increased substantially, from 122 patients in the 459 days prior to pathways implementation to 102 patients in the 271 days afterwards. This increase represented a greater than 40% increase in the accrual rate compared to the pre-period and was statistically significant ($p = 0.00174$.) [13]

***Optimizing workflow.*** When moving prescreening into the physician workflow, institutions free up research coordinators to focus on clinical trial operations instead of patient identification, making it easier to match trials to patients experiencing disease progression, and not just patients with early-stage disease. As a result, oncologists can prescreen patients and present potential trial participants to research coordinators, thereby increasing efficiencies and potentially supporting more accruals to trials. (See Case Study 3)

## Case study 3: Increasing accruals while improving care

Challenge: A regional cancer center was looking to assess the impact that oncology pathways had on costs, trial enrollment, emergency department utilization within 30 days of chemotherapy, and hospital admissions within 30 days of chemotherapy. A driver of this interest was to assess the emergency department utilizations and hospital readmissions as it is a Centers for Medicare and Medicaid Services (CMS) reimbursement measure (CMS OP-35).

Solution: Within three months of the oncology pathways implementation, 42 medical oncologists at 19 sites working with a common electronic health record treated more than 85% of patients concordant with the pathway recommendations ("on pathway").

Newly diagnosed non-small cell lung cancer (NSCLC) patients were identified from the tumor registry. The oncology pathways database was queried to separate these patients into two groups – those treated on pathway, and those treated not following the pathway recommendation ("off pathway"). Cohorts were established for three primary groups - early diagnosis, advanced/curative and advanced/non-curative. The analysis performed was to determine the total charges of adjuvant medical oncology treatment for these patients and to identify patients who sought ED evaluation and or hospital admission within 30 days of chemotherapy treatment (CMS-35).

Results: Use of a standardized evidence-based pathway across 40 medical oncology providers over wide geography resulted in a significant rise in clinical trial entry. During a two-year period, 407 (81.4%) NSCLC pts were treated on pathway (including clinical trials) while 93 (18.6%) were treated off pathway. Clinical trial enrollment in NSCLC increased 2.4 times from the time that providers did not use pathways to the first use of a pathways tool. 25.8% of on pathway compared to 29% of off pathway fell into the CMS OP-35 group, suggesting on pathway treatments are more effective at avoiding undesired ED/hospital events. Mean cost for treating the on-pathway group was $104,436 compared to $183,717 for the off-pathway group ($p = 0.01$). Overall, adherence to pathways resulted in a 2.4x increase in clinical trial entry, as well as substantial cost savings.[14]

***Leveraging data and analytics at the site and provider level.*** Detailed analytics in pathways platforms provide insight into the number of patient treatment decisions for specific disease presentations, whether research was considered as part of that decision, and operational data such as facility or individual provider to enable leadership teams to make informed decisions. With clinical trial analytics derived from a pathways program, healthcare leaders gain better insights into the performance of their network on dimensions that include clinical trial accrual, near-real time epidemiology of their cancer case mix, and how physician decisions compare to evidence-based recommendations at the disease and network site level. The pathways program heightens awareness of which trials might be the right ones to consider adding to the practice portfolio, and in turn, more successful. When leaders are given data to inform decisions on which trials to commission and which ones to close, they can better manage a trial portfolio tailored to the patient population they serve.

In addition, the analysis can assist with clinical oversight discussions to engage physicians with reporting data suggesting trial enrollment improvement opportunities exist. The analysis further helps to identify which facilities are the highest enrolling, which providers are or are not enrolling patients into clinical trials and which studies are not accruing patients, in order to focus where trials are opened within a cancer care network.

## Conclusion

With oncology pathways, cancer centers gain new opportunities that can elevate their clinical trial programs to more productive levels. By providing evidence-based content that presents trials as the best treatment options at the point of decision, pathways simplify patient identification. In addition, workflow optimization significantly eliminates the burden associated with manually accruing patients and managing clinical trials to support higher accrual rates. Using analytic tools these cancer centers can not only ensure that their studies are resulting in optimal financial returns – but also that clinical trials are helping to provide much-needed innovative treatments to cancer patients who can truly benefit from such care.

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# References


1. Martin, L., Hutchens, M., Hawkins, C. et al. How much do clinical trials cost? Nat Rev Drug Discov. https://doi.org/10.1038/nrd.2017.70. Published May 19, 2017.
2. WCG Institute. Emerging challenges in oncology trials. https://www.wcgclinical.com/insights/institute/emerging-challenges-in-oncology-trials. Published N.D.
3. Sacristain, J. et.al. Patient involvement in clinical research: why, when, and how. Patient Prefer Adherence. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4854260/. Published April 27, 2016.
4. Rimel BJ. Clinical trial accrual: obstacles and opportunities. Front Oncol. 2016;6:103. doi:10.3389/fonc.2016.00103. Published 2016.
5. Clinical Trials Arena. How to recruit and retain patients for oncology trials. https://www.clinicaltrialsarena.com/comment/how-to-recruit-and-retain-patients-for-oncology-trials-6045362-2/. Updated February 4, 2018.
6. Ibid
7. Sathjan, B. et. al. Impact of COVID-19 on clinical trials and clinical research: A systematic review. Nepal J Epidemiol. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7538012/. Published 2020.
8. Levine, R. COVID-19's Impact on Oncology Trials: A One-Year Follow Up Analysis. Cancer Research Institute. https://www.cancerresearch.org/en-us/blog/may-2021/covid-19-impact-oncology-clinical-trials-2020-2021. Published May 17, 2021.
9. Sathjan, B. et. al. Impact of COVID-19 on clinical trials and clinical research: A systematic review. Nepal J Epidemiol. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7538012/. Published 2020.
10. The National Cancer Institute-American Society of Clinical Oncology Cancer Trial Accrual Symposium: summary and recommendations. Journal of Oncology Practice. https://www.ncbi.nlm.nih. gov/pubmed/24130252. Published November 2013.
11. Panikkar, R. Increasing physician awareness of clinical trials through oncology pathways. Journal of Clinical Pathways. https://www.hmpgloballearningnetwork.com/site/jcp/editorial/increasing-physician-awareness-clinical-trials-through-oncology-pathways. Published October 2021.
12. Elsevier. Clinical Trial Accrual. https://www.elsevier.com/__data/assets/pdf_file/0005/918896/Clinical-Trial-Accrual-_FINALREVISED_DIGI.pdf. Published 2019.
13. Shamah, C. e. al. Effect of clinical trial participation by integration of a clinical pathway program into an electronic healthcare record (EHR). ASCO Meeting Library. https://meetinglibrary.asco.org/record/121477/abstract. Published 2016.
14. Weese, J. et. al. Use of treatment pathways reduce cost and increase entry into clinical trials in patients (pts) with non-small cell lung cancer (NSCLC). ASCO Meeting Library. https://meetinglibrary.asco.org/record/187713/abstract. Published 2020.


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