How an Innovative Patient-Centric Approach between Sites, CRO, and Sponsor Accelerated First Patient In and Drove More Patients, Faster, into Oncology Clinical Trials

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Introduction
A Just-in-Time (JIT) enrollment methodology helped Cancer Treatment Centers of America® (CTCA) expedite its oncology research by increasing clinical trial opportunities to a diverse group of patients. The JIT methodology improved traditional site enrollment by broader access to oncology patients and faster enrollment, all with no quality loss.

• Taken in partnership between the CRO and the sponsor enabled the sites to be utilized quickly and efficiently according to patient availability.
• Every identified patient was randomized into a trial.
• The methodology was repeated across 23,000 physicians, driving patients into trials within 6 weeks of trial availability.

Background
• More than 7,400 oncology clinical trials are currently enrolling.
• 5% will not meet enrollment (60% failure rate).
• 45% of patients with cancer are diagnosed and treated in community settings, but only 3% are enrolled in clinical trials.

Results
• Underrepresented Demographics: Patients are often underrepresented across racial and ethnic populations, age ranges, and across disease types.

Methodology
• Oncology sites across the US and select European countries were engaged in to serve as JIT sites.

Underrepresented Demographics:

30%

Non-Represented: African-American • Hispanic • Asian

The patient demographics across the 7 trials represented a range of ages and ethnicities:

• African-American
• Hispanic
• Asian

Performance
The clinical trials using JIT methodology had the following results, regardless of site location:

<table>
<thead>
<tr>
<th>Site Type</th>
<th>Patients Randomized to Clinical Trials</th>
<th>Time To First Patient Randomized</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional Sites</td>
<td>375</td>
<td>30 days</td>
</tr>
<tr>
<td>JIT Sites</td>
<td>575</td>
<td>7 days</td>
</tr>
</tbody>
</table>

Impact of Just-In-Time Trials: Site Operations

Impact on Cost (Average)

Traditional Sites | $1,800
JIT Sites | $1,200

Impact on Time (Average)

Traditional Sites | 135 Days
JIT Sites | 35 Days

Impact on Trial Experience

Aligns all parties with the primary goal of eliminating unnecessary administrative and protocol burdens and achieves patient and sponsor expectations for clinical trial conduct.

Impact of JIT Supplementing Patient Enrollment: Timeline Reductions

Average Cost of Site Management (U.S.)

Traditional Sites | $280,000
JIT Sites | $200,000

Average Number of Non-Enrolling Sites

Traditional Sites | 153
JIT Sites | 98

Preliminary Work in These Non-Enrolling Sites

Traditional Sites | $700,000
JIT Sites | $300,000

JIT helps alleviate patient and caregiver anxiety about treatment, as well as providing a feeling of security knowing that the provider save the need to spend extended time away from home. The on-demand approach offers patients rapid access to high-impact trials that can reassure potential patients that they will have better access to trial availability. JIT studies are a game changer for clinical research and open up a new horizon in oncology clinical trials. The on-demand approach is a cost-effective solution, delivering a 75% reduction in timeline for Phase III global trials. The on-demand approach is also a game changer for clinical research.

Conclusions
• JIT trials impact the time and cost scale of oncology patient recruitment for both sponsors and investigators.
• JIT allows for more efficient and effective recruitment, resulting in faster timelines for clinical trials.

References
For more information, please contact kowalczyk@aesglobal.com


https://academic.oup.com/jnci/article/111/3/245/5307078

https://www.wsj.com/articles/clinical-trials-need-more-subjects-1460407076


Impact of Just-In-Time Trials: Clinical Operations

Impact on Enrollment Patient Recruitment By Region

CTCA Sites | 500

Impact on Site Management: Efficient and Productive Site Activations

For JIT studies, the NGS process has been very efficient; they understand the urgency of the treatment and quickly enrolling and starting patients on the clinical trial.

Non-enrolling sites in the space can drive significant costs, as evidenced below.

- Site identification and pre-study prep can be taken care of in a timely manner and not left in a holding pattern.
- For JIT studies, the NGS process is very efficient; they understand the urgency of the treatment and quickly enrolling and starting patients on the clinical trial.

Impact of JIT Supplementing Patient Enrollment: Site Operations

Effect: Reduction in trial timelines and associated costs

JIT Studies are a game changer for clinical research and open up a new horizon in oncology clinical trials. The on-demand approach offers patients rapid access to high-impact trials that can reassure potential patients that they will have better access to trial availability.