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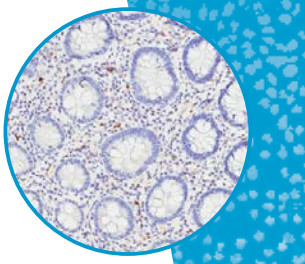
TISSUE IMAGE ANALYSIS AND BIOMARKER ASSESSMENT IMPLEMENTATION BENEFITS

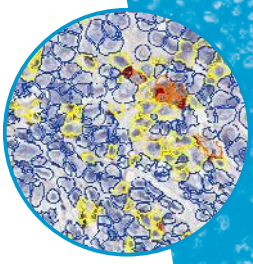
Improve Your Return on Investment, Accelerate Trials, and Minimize Budget

INTRODUCTION

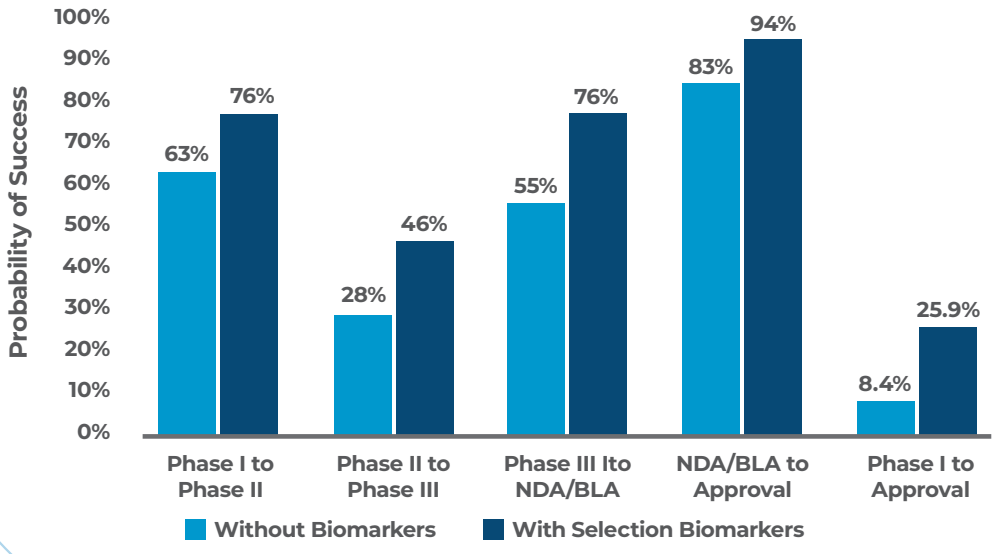
The success of clinical trials is highly dependent on the intricacies of patient recruitment. Other challenges, from the costs of clinical supplies to the specific procedural requirements that can extend physicians' time, can increase costs. There are also possible budgetary impacts of testing and regulatory requirements. Gaining a better understanding of what is involved in the cost of a clinical trial can help the entire process, enabling your procurement and finance teams to more accurately budget and execute the tasks needed for success.

In this paper we will demonstrate how using image analysis (IA) while implementing biomarker assessment can improve your return on investment (ROI), accelerate trials, and minimize budget impacts.





Probability of Success
With or Without Selection Biomarkers



Source: Clinical Development Success Rates 2006-2015 - BIO, Biomedtracker, Amplion 2016

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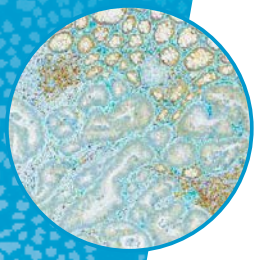
THE CHALLENGES OF RECRUITMENT COSTS

Multiple sources put clinical trials patient recruitment/enrollment costs at a median of $41,117 per patient (40% of total trial budget) and $3,562 per patient visit ($102,000 per patient per trial) during conduct of the trial. Each patient costs a median of $143,000 to enroll and complete a trial.

Approximately 80% of trials are delayed or closed due to problems with recruitment.

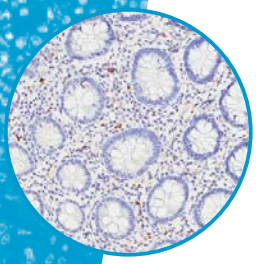


- 9 out of 10 trials require the original timeline to be doubled to meet enrollment goals
- 11% of research sites fail to enroll a single patient
- Clinical trials account for nearly 40% of the US pharma research budget and total around $7B per year, with the estimated cost of patient recruitment being 40% of the total budget, or $1.89B
- Delays can cost sponsors between $600,000 and $8 million for each day that a trial delays a product's development and launch
- Screen failure rates are significantly costly for sponsors and the cost (on average) across the industry is roughly $1,200 per failure.

FACTORS AFFECTING COSTS OF CLINICAL TRIALS

When deciding whether to participate in a clinical trial, more than 92% of patients in all categories said it was "important" or "very important" for them to know they would be willing to undergo the medical procedures or tests in a study. In oncology, this becomes more critical as tissue samples are a necessity for determining expression, enrollment, and ongoing response.

Numerous major factors affect the cost of a clinical trial including:



- Increased costs of clinical supplies and equipment
- Extended timelines of clinical trials
- Increased regulations, particularly at the clinical and CMC levels
- Monitoring complexities
- Patient recruitment intricacies
- Workforce competence
- Data collection and synergy complexities

Additional clinical trial cost factors include:

- Detailed biomarker analysis samples are often sent to different external labs, which attract higher fees.
- Due to specific procedural requirements, physicians may need to perform specialized tests for particular disease indications along with regular physical examinations of patients, resulting in higher costs.
- All the data collected is required to go through stringent data management protocols to ensure data integrity and patient safety. This might require study coordinators to spend more time to fulfill the requirements of GCP guidelines, which further adds to the costs.

PROCUREMENT AND FINANCE TEAMS NEED TO UNDERSTAND THE CLINICAL TRIALS PROCESS

A good understanding of the various intricacies involved in the cost of a clinical trial helps procurement and finance teams in budgeting and efficient execution of the whole process. They must first understand the criticality of the study and the respective study requirements. There are many service providers in the market, ranging from generalists to specialists. The best approach to selecting the most suitable CRO starts with understanding study requirements and specificities.

There is a growing concern among sponsors that the large CROs will increasingly focus on money from big pharma to the exclusion of small or medium pharmaceutical companies. Hence, their procurement and finance teams must weigh the annual volume of their businesses against the annual business of the CROs they are considering. Technical competency, service commitments, and cost are among the other factors to analyze to find a suitable CRO partner. The selection process should include an in-depth accurate comparison. A CRO may appear cost-effective while in reality it lacks efficiency and productivity, which in turn increases the overall cost of a clinical study. An effective analysis should also give weight to communication frequency and innovation.

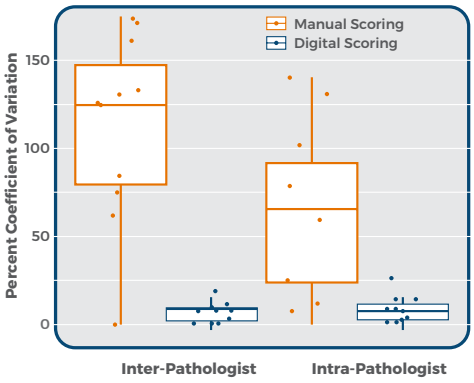
COST BENEFITS OF USING TISSUE IMAGE ANALYSIS (IA) IN CLINICAL TRIALS

An image analysis result for a histologically prepared tissue sample is much more precise than what can be achieved with the human eye. This is important when categorizing patients near the cut-off point or with new biomarkers. Understanding the specific level of reactivity within the overall context of the patient's disease state may also be important. For example, a patient with 20% and 40% positivity rates are treated the same in the current paradigm because it is difficult to consistently discern that difference with the human eye. Image analysis can clearly distinguish those two patients, which presents the opportunity to tailor treatment accordingly.

PD-L1 PERFORMANCE

Eliminates the error associated with manual slide reads, providing a truly reproducible, quantitative PD-L1 result

Comparison of Intra-Sample %CV



Poster – AACR 2017 Evaluating Benefits of PD-L1 Image Analysis for Clinical Setting

Measurements based on non-small cell lung cancer (NSCLC) clinical samples manually scored with Dako's PD-L1 test.

Flagship Biosciences image analysis offers objective and precise quantitation results

Recent studies indicate a correlation between the nature of the tumor microenvironment and patient response to immunotherapy. Image analysis provides information that a treating oncologist can use in the context of the latest scientific studies.

FOR EXAMPLE

$143,000 / patient / trial

Assuming 100 patients: $14.3 M total patient budget

IA (oncology package) + lymphocyte = $36,000 (100 patients)

Manual pathology = $24,000 (100 patients)

Delta = $12,000 or 0.17% of total patient budget

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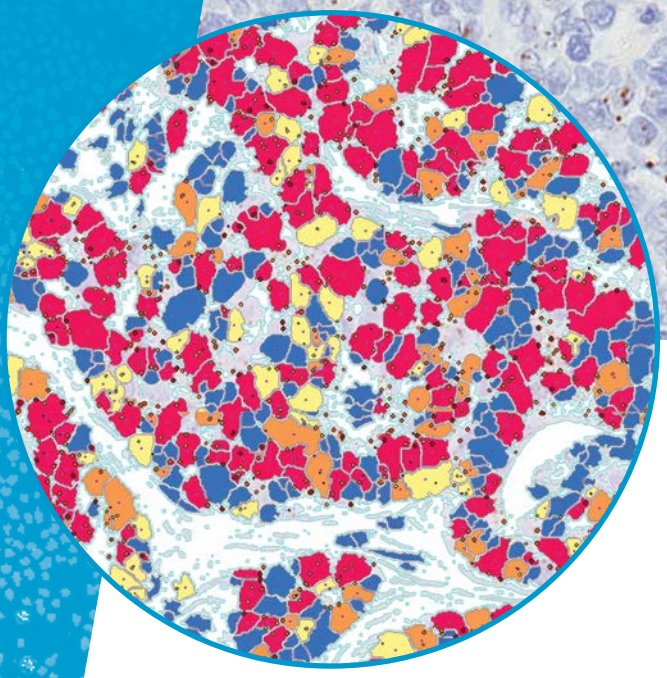

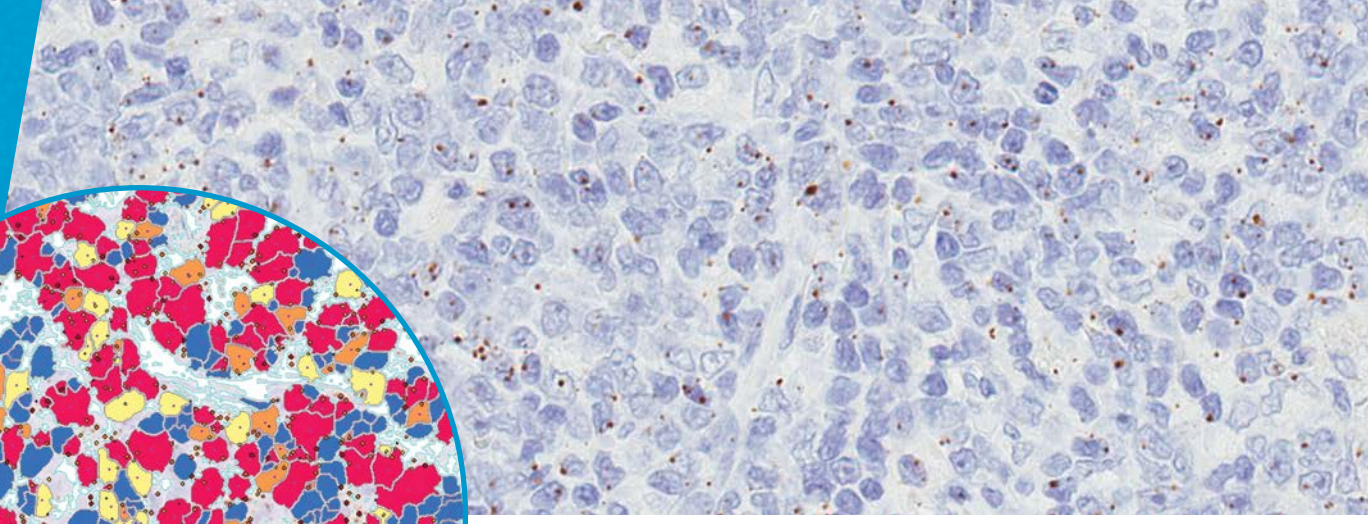

CONCLUSION

Selecting patients using the larger, more robust data set provided by IA will result in fewer patients needing to be screened. This will deliver a faster start-up time and a shorter time needed to close the trial. Further, it will enroll patients who are more suited to the treatment, ensuring a higher rate of response. The combination of these factors provides a more cost-effective patient enrollment, easily offsetting the minimal extra investment required to initiate an IA solution. Implementing an image analysis and biomarker assessment solution improves your clinical trials ROI, accelerates timing, and minimizes budget.

ABOUT US

Founded in 2009 and headquartered in Westminster, Colorado, Flagship Biosciences, Inc. is a technology-driven tissue analysis services company delivering the most accurate and informative data available. We are revolutionizing tissue analysis to improve drug development and diagnostics using the power of AI with a consultative approach.

Our services and technology dramatically improve on the data and interpretation from traditional pathology methods, eliminating variability associated with typical tissue assessments, and bringing new insights to tissue analysis results.

We provide expert scientific consultation for every client. Our team interprets results, contextualizes tissue biology, and identifies the best course for success.

TO LEARN MORE ABOUT FLAGSHIP

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