STAT

3 Advances Driving Oncology Clinical Trial Success

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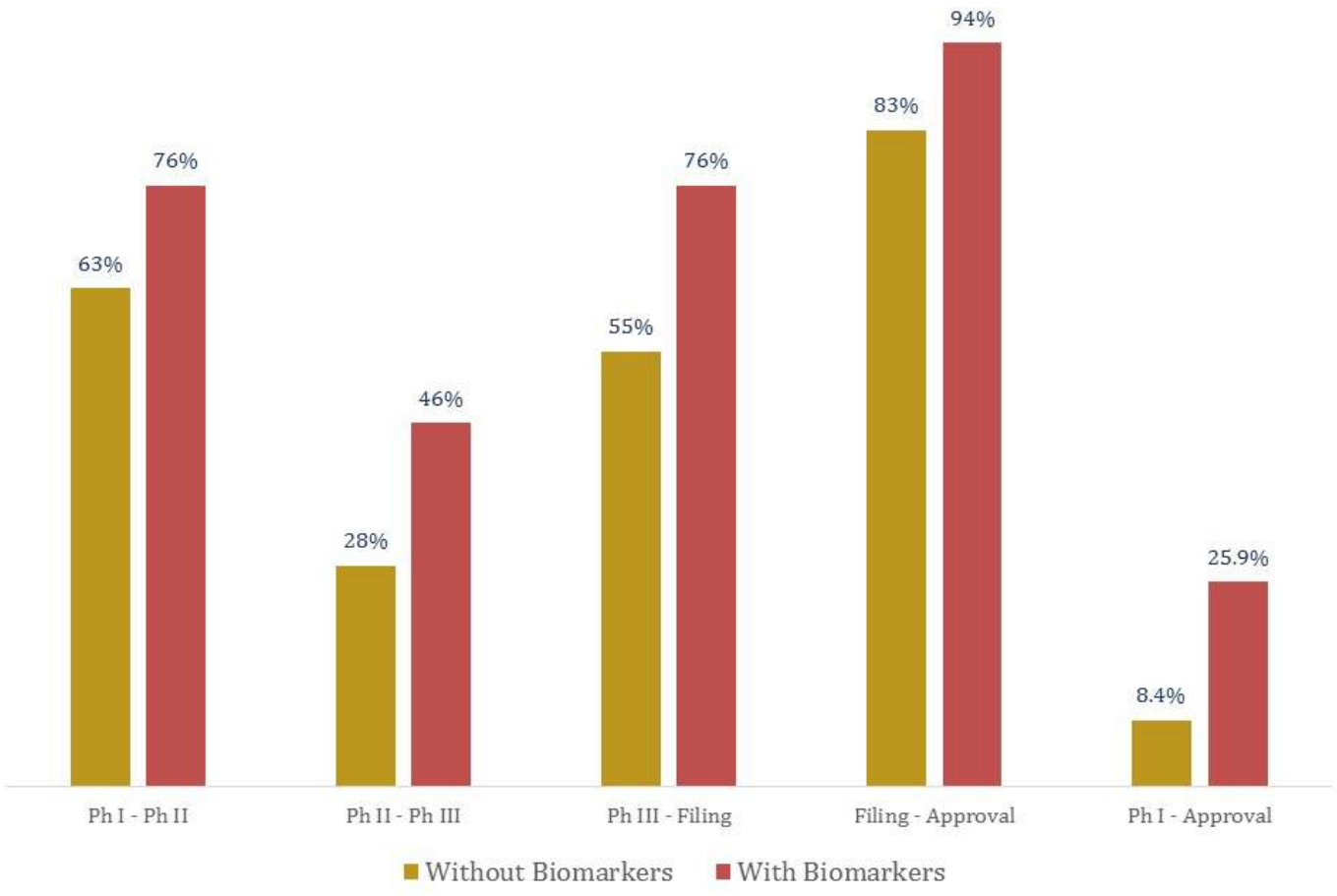
This is the first in a series of articles from Precision Medicine Group addressing advances in clinical trials and new strategies for market access and reimbursement.

The announcement of the Cancer Moonshot in February 2016 brought mainstream global attention to the race for innovation in oncology treatments. We are witnessing unprecedented acceleration in the research and development of precision medicines that can attack cancer's defenses through distinct mechanisms of action. At the same time, more oncology drug developers than ever are benefitting from the expanded FDA Accelerated Approval Program. Here are 3 advances biotech drug developers are using to achieve accelerated clinical trial success with the evidence the FDA needs to see.

1. Biomarkers. Drug applications with validated biomarkers have a 3 times greater likelihood of FDA approval compared to applications without a biomarker strategy. Integrating custom biomarkers into clinical trial design from the beginning allows researchers to validate objective methods to identify early responders, optimize doses based on the biologic impact, and focus efforts on the patient subtype that would benefit most from the therapy. As we continue to improve our strength of knowledge of matching specific drugs to specific receptors and patients, we are able to improve the accuracy of our proof-of-concept trial conclusions and to achieve registration success with fewer patients, shorter timeframes, and

reduced risk of late-stage failure. Validated and relevant biomarkers identified early in the development process will ensure that the continued development of a compound is based on robust data and insights.

Probability of success with or without biomarkers



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

2. Adaptive trial design. Adaptive designs are commonly applied to facilitate efficient decision-making during a clinical trial and to lend early insight into anticancer activity. Such designs prospectively plan for modifications of 1 or more study aspects, allowing for seamless and faster transition as the trial progresses, thereby saving time and money. In basket studies, patient selection is refined by evaluating a novel agent across multiple tumor types; the study combines biomarker and clinical data to drive decisions on the optimal tumor target(s) for further pursuit. As the patient population is defined, a smaller patient group is sufficient to see significant differences in response—within a shorter timeframe.

3. Real-time analytics. Dramatic increases in computing power are resulting in faster insights that inform drug development pathways. Machine-learning approaches can now identify variants, genes, and mechanisms responsible for driving disease severity and treatment responses. Advanced Bayesian analytics can stratify patients in real time, allowing developers to assess genomic and immunomics data together with clinical outcome data at the click of a mouse. Interactive reports provide real-time insights. Researchers can identify which trial arms are worth pursuing or stopping early, maximizing time and

investment on the patient groups and study variables, such as dose levels, with the greatest probability of impact.

Precision Medicine Group (PMG) supports next-generation approaches to drug development and commercialization. PMG provides the infrastructure and expertise that extracts and enhances the long-term value of biotech and pharma products. Precision Oncology, part of PMG, has over 16 years of experience managing complex and innovative oncology clinical trials. To learn more about how to leverage an accelerated approval pathway for oncology drugs, visit precisionforoncology.com

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