



# Streamlining the Selection and Qualification of Biomarker Laboratories

Research Report

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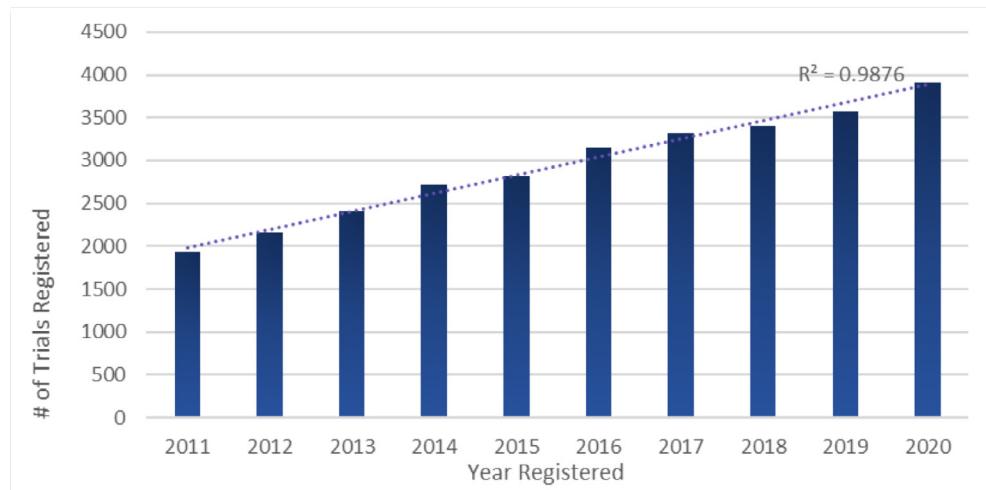
## The Demands and Challenges of Biomarker Research

**3915**  
worldwide clinical trials used 1 or more biomarkers in 2020

The number of clinical trials involving biomarkers has risen consistently in the last 10 years (Figure 1) and the global biomarkers market is projected to grow 12.1% through 2026 (USD \$97.51 billion).<sup>1</sup> Sponsors and CROs are leveraging clinically useful biomarkers to select the most favorable drug candidates and enable development decisions. Biomarkers are also used to facilitate the regulatory review process and increase the likelihood of approval from Phase 1.

Over half of drug approvals at the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have been supported by biomarker data during at least one stage of development (2015 to 2019).<sup>2</sup> Drug development programs with trials employing patient preselection biomarkers have a 2-fold higher likelihood of approval (15.9%) than those that do not (7.6%).<sup>3</sup>

**Figure 1: Clinical Trials Involving Biomarkers 2011 through 2020**



(Sources: WHO International Clinical Trials Registry Platform,<sup>4</sup> ClinicalTrials.gov,<sup>5</sup> International Standard Randomised Controlled Trial Number,<sup>6</sup> and Australia New Zealand Clinical Trials<sup>7</sup>)



Drug development  
programs using  
biomarkers are

**2X**  
as likely to be  
approved



New  
Biomarkers  
are continually  
being  
discovered

Biomarkers are crucial tools in the drug development and approval process, but biomarker development presents unique challenges during drug development:

- New biomarkers are continually being discovered and need to be developed and validated before they can be used clinically
- Biomarker trial strategy has become more complex over time; biomarker trials using 2 or more biomarkers has risen consistently over time.<sup>8,9</sup>
- Biomarkers are often associated with additional testing requirements, while validation and qualification processes and regulations are continually evolving.<sup>2</sup>
- Finally, a biomarker lab that focuses on novel assay development for a new biomarker may not meet all the GCLP requirements for the intended purpose of evaluating clinical trial samples for the biomarker (eg, GCP standards for a primary endpoint in a clinical trial) or may not wish to obtain appropriate certification. Sponsors need a “fit-for-purpose” approach to qualify each Biomarker Lab for their intended use in support of their drug development strategy



## A Risk-Based Approach to Qualifying Biomarker Lab Providers



Regulators expect sponsors and CROs to use a formal risk-based approach to verify that their contracted vendors have the appropriate qualifications and processes (ICH E6 R2 and ICH Q10), but the vendor qualification process varies within and between companies.<sup>10,11</sup> Biomarkers carry a higher risk burden given the continually evolving biomarker qualification process and the unique scientific approach to each individual biomarker assay.

The Avoca Quality Consortium® (AQC) has developed a comprehensive set of qualification standards with the goal of improving effectiveness and reducing variability during the vendor qualification process.<sup>12</sup> AQC Qualification Standards are dynamic and are updated as regulatory requirements evolve. In addition to core standards that apply to all vendors, AQC developed a set of biomarker standards – last updated just a few months ago – that labs

are expected to meet to comply with the increasing requirements of regulators and needs of the industry.

The [Diligent® Qualification Platform](#) service builds on the AQC standards using a risk-based assessment of development program requirements.<sup>13</sup> This innovative approach helps companies to manage vendor risk effectively and to document their vendor qualifications as required by global health authority regulations. The opportunity for companies to outsource vendor qualification to Diligent reduces variability and improves compliance. Once assembled, request for information details (RFIs) and vendor qualification assessments (VQAs) can be used many times by multiple trial sponsors, thus reducing costs and cycle times.<sup>14</sup> Diligent can also customize the approach to assess biomarker labs including labs who want to develop biomarkers but may not want to participate in a clinical trial.



## Conclusion

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The Diligent Qualification Platform supports a risk-based assessment of biomarker labs against best in class industry standards

Qualification of biomarker lab providers is a foundational first step to realizing the benefits of biomarkers in drug development programs. [The Diligent Qualification Platform](#) service offers an effective approach that the industry can utilize to reduce variability, costs, and cycle times and effectively manage risk in selecting and qualifying biomarker lab providers.

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