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Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

IMPACT REPORT

ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Vendor qualification process volume and complexity require substantial time and cost

New benchmark study identifies opportunities to streamline and improve process

- Drug developers worldwide spent an estimated $375 million in 2018 to conduct approximately 25,000 new vendor qualification and requalification assessments.
- A high percentage of assessments—most notably those conducted by large companies—involve customized areas of inquiry that challenge efforts to streamline the process.
- Small companies using leaner operating models have more productive qualification processes, compared to medium and large companies.
- The average total cycle time, from a request for information to a signed contract, is 19 weeks for single-service providers and 26 weeks for multi-service providers.
- More than 90% of all vendor assessments, including those requiring remediation, ultimately lead to qualification.
- Vendor requalification cycle times are two to four weeks faster, on average, than new vendor qualifications.

During the past decade, reliance on contract service vendors to provide drug development capacity and expertise has been high and has grown rapidly. At the same time, the vendor qualification process has become far more complex, as sponsors must assess a multitude of factors, including regulatory and ethical compliance, information technology expertise and data privacy, confidentiality and security, and operating and financial controls and oversight.

This *Tufts CSDD Impact Report* highlights the results of a recent Tufts CSDD study, in collaboration with The Avoca Group, that establishes the first comprehensive effort to benchmark the vendor qualification process across small, medium, and large drug companies. With the number of assessments needed to identify potential vendors expected to increase, uncovering and acting on opportunities to improve the qualification process will help companies streamline drug development. The study's findings suggest that, among other areas, prioritization, standardization, and risk-based approaches could help optimize the qualification assessment process.

Most assessments are conducted in-person with a high degree of customization

Assessment infrastructure and process

Sponsor Size	Share of Companies with Dedicated Teams Managing Process	Mean Number of FTEs Performing Assessments per Company	Share of Companies Maintaining Preferred Vendor Lists	Share of Assessments Conducted Entirely or Partially in-Person	Share of Assessment Questions Commonly Asked
Small	43%	3.6	59%	97%	64%
Medium	68%	11.0	84%	100%	65%
Large	78%	35.5	100%	88%	50%

Source: Tufts Center for the Study of Drug Development

- The majority of medium and large sponsors have dedicated teams managing the assessment process, with an average of 11 and 36 FTEs, respectively.
- Most new vendor assessments are conducted in person, whereas most vendor requalifications are conducted remotely.
- A high percentage of assessments involve customized areas of inquiry, with broad involvement from many functional areas, challenging efforts to consistently conduct and streamline the process.

Small drug developers are more productive than other sponsors

Staff productivity and expected growth in assessment volume

Sponsor Size	Total Number of Completed New Vendor Assessments 2018	Projected Total New Vendor Assessments in 2020	Annual Growth, 2018 – 2020	New Vendor Assessments Completed per Dedicated FTE in 2018
All sponsor companies	15.9	21.0	14.9%	1.7
Small	9.1	13.8	23.2%	2.5
Medium	18.7	20.8	5.5%	1.7
Large	51.8	60.6	8.2%	1.5

n.b.: All figures are means
Source: Tufts Center for the Study of Drug Development

- An estimated 25,000 new and existing vendor assessments were performed by global drug developers in 2018.
- Each large company conducted an average of 52 new vendor assessments in 2018, a substantially higher volume than the number performed by medium and small companies.
- Small sponsors use leaner operating models and conduct more assessments per dedicated FTE, compared to medium and large companies.

Single-service vendor assessments are seven weeks faster than those for multi-service vendors

Assessment cycle time for new single- and multi-service vendors

Sponsor Size	Request for Information Completion	Vendor Qualification Request to Process Completion	Process Completion to Contract Signed	Average Total Cycle Time
All sponsor companies (single-service vendor)	3.1	7.7	8.2	19.0
All sponsor companies (multi-service)	4.6	11.9	10.0	26.1
Small (single-service)	3.6	6.3	6.2	16.1
Small (multi-service)	5.3	9.8	8.4	23.4
Medium (single-service)	2.6	9.5	8.3	20.5
Medium (multi-service)	4.0	13.8	9.0	26.1
Large (single-service)	2.7	6.5	14.3	23.4
Large (multi-service)	3.7	12.4	17.5	33.8

n.b.: All figures are mean time in weeks
Source: Tufts Center for the Study of Drug Development

- The average total cycle time, from a request for information (RFI) to a signed contract, is 19 weeks for single-service providers and 26.1 weeks for multi-service providers.
- The time from qualification request to process completion tends to be the longest stage in the process with observed variance, suggesting room for improvement.
- Large sponsors have significantly longer and more variable process completion to contract stages.

More than 90% of all vendor assessments ultimately lead to qualification

Assessment outcomes

Sponsor Size	Share of New Vendor Assessments Resulting in Qualification	Share of New Vendor Assessments Requiring Remediation before Qualification	Share of New Vendor Assessments that Fail to Qualify	Share of Clinical Trials with Delayed Start-Up Due to the Assessment Process
All sponsor companies	77.1%	16.6%	6.1%	7.3%
Small	78.9%	14.8%	5.9%	9.4%
Medium	75.3%	19.7%	5.0%	2.4%
Large	69.3%	19.2%	11.5%	9.4%

Source: Tufts Center for the Study of Drug Development

- Overall, more than 90% of assessments—including those requiring some remediation—result in a vendor being qualified to work with the sponsor.
- Despite longer total assessment cycle times, large drug companies have the highest rates of vendors failing to qualify (11.5%), likely due to deeper inquiry into vendor practices.
- Sponsors report that, on average, less than 10% of clinical trials are delayed due to the assessment process.

Vendor requalifications are 2-4 weeks faster on average than new vendor qualifications

Assessment cycle times (from new qualification or requalification request to process completion)

Sponsor Size	New Single-Service Vendor Assessment	Single-Service Vendor Requalification	New Multi-Service Vendor Assessment	Multi-Service Vendor Requalification
All sponsor companies	7.7	5.3	11.9	7.9
Small	6.3	4.9	9.8	8.0
Medium	9.5	6.2	13.8	7.6
Large	6.5	5.1	12.4	8.3

n.b.: All figures are mean time in weeks
Source: Tufts Center for the Study of Drug Development

- For all sponsor companies, vendor requalifications are 2.4 weeks and 4.0 weeks faster on average than new single- and multi-service vendors, respectively.
- For medium sponsors, requalification cycle times of single and multi-service vendors are substantially faster than new qualification cycle times.
- Small companies see very little time savings between requalifications and new vendor assessments.

Factors associated with vendor qualification assessment (VQA) speed and cost

Subgroup	Hypothesis	Results
In-person vs. remote	Qualifications done remotely take less time than those done in person	Remote qualification assessments were slower to initiate, but were completed significantly faster than in-person assessments leading to a signed contract. Remote assessments were relatively less expensive. In-person qualification cycle times were more predictable with lower variation.
New assessments vs. requalifications	Requalifications are faster and require fewer resources.	Cycle time differences between new vendor and requalification assessments were not significant.
Type of endpoint supported by service provider	VQAs supporting primary/secondary/safety endpoints are of higher priority than those supporting exploratory endpoints.	Assessments of services supporting primary and key secondary endpoints were completed faster overall, but required more time to initiate the process and took longer to sign the contract. These assessments had higher variability.
Strategic vs. tactical service	VQAs supporting tactical needs are faster, compared to those supporting strategic needs.	Qualifications conducted to support tactical needs were slightly longer on average than those supporting strategic needs, but no significant differences exist.

Source: Tufts Center for the Study of Drug Development

About this study

Tufts CSDD and the AVOCA Group conducted a global survey of pharmaceutical companies during May–July 2019. A total of 76 companies responded (9 large, 19 medium, and 48 small). Between May and August of 2019, nine major and mid-sized pharmaceutical companies—Allergan, AstraZeneca, Biogen, EMD Serono, Janssen, Merck, Otsuka, Pfizer, and Vertex—also provided data on 163 completed new vendor qualifications and requalifications.

Small drug companies are those annually spending less than $250 million on R&D; medium companies are those spending between $250 million and $2 billion annually; large companies are those spending more than $2 billion on R&D annually.

This analysis was conducted by Michael Wilkinson, MS, Project Manager, and Ken Getz, MBA, Professor and Deputy Director, both at Tufts CSDD; and Jay Turpen, Senior Consultant, and Dennis Solotti, Chief Operating Officer, both at The Avoca Group.

Definition of terms

Request for information (RFI) — Formal request for a vendor to respond to a series of questions aimed at understanding their capabilities to deliver needed goods or services. The RFI is usually developed by a sponsor company based on input from cross-functional team members.

Remediation — Action to modify and correct a capability or operational ability by a vendor after the company requesting information has identified a deficiency in the qualification process.

Vendor qualification assessment (VQA) — Evaluation of a vendor's comprehensive capabilities and operational ability to deliver requested goods and services in compliance with all applicable laws and regulations, as well as meet the sponsor's performance expectations. This process begins upon completion of the RFI and ends with the vendor qualification decision.

Vendor requalification — Sponsors may specify, according to their standards, a time period by which existing vendors need to be requalified. Steps for vendor requalification can be similar to the new VQA process, or it may be modified. Some sponsors specify that periodic vendor audits serve the purpose of requalifying an existing vendor.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development at Tufts University provides data-driven analysis and strategic insight to help drug developers, regulators, and policy-makers improve the quality and efficiency of pharmaceutical R&D. Tufts CSDD also offers professional development courses and hosts workshops and public forums on a wide range of drug development issues.

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