Tufts Center for the
Study of Drug Development
TUFTS UNIVERSITY

BENCHMARKING AND OPTIMIZING THE PROCESS FOR ADOPTING INNOVATIONS SUPPORTING CLINICAL TRIAL EXECUTION

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Executive Summary

Although there are conceptual frameworks and an extensive body of work in the literature examining the barriers and challenges associated with the adoption of new innovations supporting clinical trial execution, there is no empirical data benchmarking the process. As part of a working group study, Tufts CSDD conducted 26 in-depth interviews followed by an online survey that yielded 631 responses from the global community of drug development professionals. This study found that the four stages of the innovation adoption process – Initiation, Evaluation, Adoption Decision, and Full Implementation — takes 5.8 years on average with mid-sized companies taking one year longer than large companies and nearly two years longer than small companies. CROs are able to complete the innovation adoption process in half the time. High variation around the mean duration was observed overall and by company size showing highly inconsistent experience and the difficulty that companies face in navigating the process. The latter two stages of the process — Adoption Decision and Full Implementation — take the longest, are the most variable, and are regarded as the most difficult. Factors and approaches to accelerate the process and optimize innovation adoption are discussed.

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Background, Research Methods, Detailed Findings, Discussion and Implications

The drug development industry – like all heavily regulated, research-intensive industries — places a premium on innovations that drive differentiation and competitive scientific, operating and performance advantages. There is a rich history of conceptual frameworks that assist organizations and analysts in understanding and mapping the innovation adoption process. Two of the most well-known frameworks include Everett Roger's Innovation Diffusion Model and the Gartner Group's Hype Cycle[iii]. The former, introduced in 1962, suggested that the adoption of innovation can best be understood as a social system within organizations dictated by opportunistic behavior and the aversion to risk. Organizations that are highly receptive to risk, keenly aware of and willing to act quickly on the need to innovate are dubbed Pioneers and Early Adopters. Those organizations that are highly risk averse, lacking awareness and slow to act are characterized as Late Majority and Laggards[iii].

The Gartner Hype Cycle, first introduced in 1995, focuses on the evolution of organizational expectations for a given innovation. Organizations, and entire industries, first look at an innovation with unrealistic and exuberant expectations that contribute to initial adoption behaviors. As organizations gain real world experience with an innovation, their expectations plateau at the 'Peak of Inflated Expectation' and fall precipitously into the 'Trough of Disillusionment' where they must temper and revise their expectations. Over a protracted period of time, expectations align with reality when organizations begin to realize the true benefits and value of an innovation[iv].

Numerous articles in the literature have discussed the challenges and barriers to the adoption of innovations supporting clinical care and clinical research[vvi]. Swift et al., for example, discussed the opportunities and challenges in adopting real-world data to supplement and inform clinical research data collected during clinical trials[vii]. Members of the TransCelerate eSource and Patient Technology initiative identified several major barriers that limit the adoption of digital technologies supporting patient engagement and convenience in clinical trials[viiiix]. These barriers include cultural and operating challenges, lack of organizational alignment, technical risks, financial risks, lack of regulatory clarity and encouragement, and staff concerns about the risk and burden of tackling an innovation while simultaneously managing daily tasks.

Although there are conceptual frameworks and an extensive body of work in the literature — based on anecdotal experiences and case examples — examining barriers and challenges, to our knowledge there is no empirical data benchmarking the process of adopting innovations supporting the execution of clinical trials. A more granular and empirical approach would establish baseline measures, help identify practical and actionable opportunities to optimize the innovation adoption process and inform efforts to monitor progress in improvement initiatives. In mid-2021, the Tufts Center for the Study of Drug Development (Tufts CSDD) undertook a robust study to gather more empirical data.

Research Methods

For the purposes of this study, Tufts CSDD looked specifically at innovations supporting all aspects of clinical trial execution including protocol planning; investigative site selection and management; study initiation, ongoing management and close-out; patient screening, enrollment and retention; administration of protocol procedures; data collection, management, analysis and reporting. Innovations in biomedical science and pharmacology fall outside the scope of this study as they occur largely within scientific functions and do not require cross-functional changes, integration and coordination in operating practices, procedures and processes.

Tufts CSDD formed a working group of 17 companies in early 2021 to assist in designing the interview guide, developing and implementing the survey instrument, and in reviewing and discussing preliminary study results. Participating companies included Abbvie, Almirall, Amgen, AstraZeneca, BioMarin, Bristol Myers-Squibb, Cerevel Therapeutics, Daiichi-Sankyo, Janssen, Novartis, Novo Nordisk, Organon, Otsuka, Regeneron, Roche, Sanofi and UCB. Members of the WCG Clinical Avoca Group also participated in the study and provided valuable input and assistance.

Tufts CSDD, with help from the WCG Avoca Group, conducted 26 in-depth interviews among senior and mid-level clinical development managers from pharmaceutical and biotechnology companies to solicit insight into specific stages in the innovation adoption process to guide the development of the survey instrument. Each interview ran for 45- to 60-minutes. Table 1 presents the innovation adoption stages characterized and defined in the in-depth interviews.

Table 1: Definition of Stages in the Innovation Process:

Stage	Primary Activities and Objectives
INITIATION	Identifying and characterizing need, gauging organizational interest/appetite, initial planning
EVALUATION	Identifying, engaging solution providers; assessing and piloting innovative solutions
ADOPTION DECISION	Reviewing pilot experience, building internal consensus to move forward with enterprise-wide adoption; finalizing and announcing decision
FULL IMPLEMENTATION	Enterprise-wide implementation planning, roll-out, communication, training, monitoring, continuously improving

In addition to verifying and characterizing innovation adoption stages, the in-depth interviews also gathered insight into primary barriers and challenges impacting the efficiency and success of the overall adoption process and its components.

Next, using the Qualtrics design tool/platform, Tufts CSDD developed and implemented a global survey online between August and September 2021. Proprietary and commercially-available contact lists were used in survey outreach efforts. Companies participating in the working group also assisted in the review of the survey and outreach to raise awareness about the online survey.

The survey entailed 47 questions — most of them closed-ended – and took 20 – 25 minutes to complete. Questions focused on overall innovation adoption attitudes and experience, and the timing and challenges associated with each stage in the innovation adoption process. Examples of historical and recent innovations supporting clinical trial execution were provided in the survey as references for survey respondents. Examples included electronic data capture (EDC), electronic clinical outcomes and patient reported outcomes assessment technologies (eCOA/ePRO), electronic source documents, clinical trial management systems (CTMS), electronic informed consent, risk-based monitoring (RBM) and interactive voice response systems (IVRS). The survey was reviewed and approved by the Tufts University institutional review board. Tufts University's data privacy specialist also conducted an independent assessment and determined that the use of contact names in Europe was GDPR compliant.

Survey data was stored in an excel file and saved on a secure, shared, online drive. Descriptive statistics, coefficients of variation, and chi-square analyses to assess significant differences between subgroup means, were performed using SAS 9.4.

Study Results

The survey yielded self-reported perceptions and experiences from 631 total responses. This convenience sample had good representation by company size, geographic location of company headquarters, and therapeutic area(s) of focus (e.g., 62% focus on oncology; 25% on immunology and infectious diseases, 16% on cardiovascular diseases, 14% on neurological disorders, and 7% on rare diseases). Respondents indicated that they are employed by 225 distinct companies.

Nearly half of respondents indicates having a role in a clinical operations function. The highest percentage (54%) operates within a large pharmaceutical company, 28% in mid-sized and 18% in small companies. Half (49%) are based in Europe and 39% are based in North America. Table 2 summarizes the characteristics of survey respondents.

Table 2: Respondent Characteristics

N = 631 Total Responses	Percent of Total
Company Type	
Pharmaceutical Company	69.7%
Biotechnology Company	23.7%
CRO/Other	6.6%
Company Headquarters	
North America	38.8%
Europe (includes UK)	49.3%
Rest of World (all other geographic areas)	11.9%
Company Size	
Large (2020 annual revenue >$20 billion)	53.9%
Mid-Sized (2020 annual revenue between $2 billion and $20 billion)	28.0%
Small (2020 annual revenue <$2 billion)	18.1%
Role Within Company	
Clinical Operations	46.0%
Innovation Management	16.9%
Data Science/Data Management	10.1%
Clinical	9.1%
IT/Other	17.9%

More than two-thirds (69%) indicates that the four stages presented are consistent with their company's innovation adoption process. One-out-of-four (27%) indicates that they follow some but not all stages due to organizational efforts to consolidate and streamline steps. The Evaluation and Adoption Decision stages, for example, are two stages most often combined among this group. A very small percentage (4%) reports that their organization does not follow a formal process and/or they prefer to be a late adopter, waiting for other companies to assume the risk, gain experience, and learn from mistakes.

A majority (85%) of respondents reports that their company approach innovation in a decentralized fashion, relying on individual functional areas to promote, pilot and evaluate new operating innovations. One-in-seven (15%) reports using a more centralized approach with a dedicated innovation function driving the full process.

Table 3 presents general attitudes and perceptions of the innovation adoption process. Approximately one-third (31%) of respondents rates the overall process within their organization as 'Poor' or 'Very Poor'. Nearly 80% perceives that the process takes 'Somewhat' or 'Much' longer than expected with 61% believing that the process for their organization takes longer than it does for peer companies.

Table 3. General Attitudes and Perceptions about the Innovation Adoption Process

(n=314)	**Percent of Total**
Perceived Effectiveness of Organization's Overall Process (rate)	
Excellent/Good	69.1%
Poor/Very Poor	30.9%
Perceived Length of Time to Adopt Innovations (percent agree):	
The process takes Somewhat/Much Longer than expected	78.2%
The process takes longer than it does for peer companies	61.0%
Perceived Difficulty of Innovation Adoption Stage (rate 'Most Difficult')	
Initiation	14%
Evaluation	14%
Adoption Decision	33%
Full Implementation	39%
Perceived Ability to Complete Innovation Adoption Stage (rate 'Best Ability')	
Initiation	38%
Evaluation	30%
Adoption Decision	17%
Full Implementation	15%

Overall, the highest percentage considers the latter two stages of the innovation adoption process to be the 'Most Difficult' with 33% selecting the Adoption Decision stage and 39% choosing the Full Implementation stage. A significantly smaller percentage — half — rates the first two stages as 'Most Difficult'. The corollary is shown when respondents rated their organization's competence and effectiveness in completing each stage in the innovation process. The earliest two stages received the highest percentage of companies indicating 'Best Able', and the latter two stages received the lowest percentages.

Perceptions about the difficulties in the last two stages of the innovation adoption process is company size agnostic. The highest percentage of respondents across all size cohorts considers the Full Implementation stage to be the most difficult and for which they are the least able to complete competently.

A much higher proportion of respondents in mid-size and small companies rates the first two stages in the process as 'Most Difficult'. Respondents in mid-size companies, in particular, are more likely to positively rate their ability to complete each stage in the process.

Table 4: General Attitudes and Perceptions by Company Size

	Large *(n=154)*	Mid-Size *(n=97)*	Small *(n=53)*
Perceived Effectiveness of Organization's Overall Process (rate)			
Excellent/Good	65%	76%	60%
Poor/Very Poor	35%	24%	40%
Perceived Length of Time to Adopt Innovations (percent agree):			
The process takes Somewhat/Much Longer than expected	83%	68%	77%
The process takes longer than it does for peer companies	82%	61%	83%
Perceived Difficulty of Innovation Adoption Stage (rate 'Most Difficult')			
Initiation	6%	19%	26%
Evaluation	6%	16%	17%
Adoption Decision	43%	32%	20%
Full Implementation	45%	32%	37%
Perceived Ability to Complete Innovation Adoption Stage (rate 'Best Ability')			
Initiation	45%	26%	42%
Evaluation	28%	32%	36%
Adoption Decision	13%	22%	13%
Full Implementation	14%	20%	9%

Compared to that in mid-size and small companies, respondents in the largest organizations are more likely to perceive that peer companies experience a faster relative adoption process (See Table 4).

Tables 5 and 6 provide data on the overall innovation adoption process duration and individual stage durations. Overall, the average time to move through all stages of the innovation adoption process is 5.8 years with one-third of that total time — the largest proportion — spent in Full Implementation. Respondents in mid-size companies report taking the longest time — an average of 6.6 years — to complete the process. The reported process duration from respondents in small companies is 9 months faster than large companies and nearly two years faster (21 months) than mid-size companies. Wide variation around the mean duration is observed overall and by company size in each innovation stage. Larger coefficients of variation around mean reported durations are seen among small and mid-size companies most notably in the earliest innovation adoption stages. Full Implementation durations are similar for companies across company size cohorts.

Table 5: Innovation Adoption Process Durations, Total and Individual Stages, by Company Size

Stage ***(Mean Time in Months and CoV)***	**Overall (n=250)**	**Large (n=135)**	**Mid-Size (n=70)**	**Small (n=45)**
Initiation	14 (0.92)	12 (0.75)	17 (0.96)	12 (0.92)
Evaluation	16 (0.80)	15 (0.58)	19 (0.91)	12 (0.74)
Adoption Decision	17 (0.84)	17 (0.74)	19 (0.90)	13 (0.85)
Full Implementation	23 (0.66)	23 (0.58)	24 (0.74)	21 (0.65)
Total Duration	5.8 years	5.6 years	6.6 years	4.8 years

Table 6: Innovation Adoption Process Durations, Total and Individual Stages, by Company Type

Stage *(Mean Time in Months and CoV)*	**Pharmaceutical and Biotechnology Companies** (n=223)	**Contract Research Organizations** (n=36)
Initiation	14 (0.92)	7 (0.62)
Evaluation	16 (0.80)	8 (0.88)
Adoption Decision	17 (0.84)	8 (0.78)
Full Implementation	23 (0.66)	14 (0.53)
Total Duration	5.8 years	3.1 years

CROs are able to complete the innovation adoption process in nearly half the time — 3.1 years compared to 5.8 years for pharmaceutical companies. A significant speed advantage and much lower variation around mean durations are observed among CROs at each innovation adoption stage compared to pharmaceutical companies.

In-depth interviews and open-ended survey responses consistently highlighted six major areas that most challenge the effectiveness of each stage in the process and the smooth transitions between stages. These six areas are:

1. Lack of senior management and cross-functional support and engagement across all stages;
2. Poorly designed and executed pilots/evaluations including the failure to gather sufficient evidence to assess and compare innovations, and to demonstrate the return-on-investment (ROI) supporting an adoption decision;
3. Lack of regulatory clarity and support resulting in substantial concern and resistance from regulatory and legal affairs functions;
4. The absence or late preparation of a comprehensive change management plan to guide the organization through full implementation;
5. Misaligned incentives dissuading personnel and functions from embracing risk and commitment to new innovations; and
6. Failure to adequately invest in the adoption process resulting in insufficient evaluation and weak continuity between an adoption decision and full implementation.

Discussion and Implications

The results of this study present the first empirical data that can be used to benchmark the process for adopting innovations supporting clinical trial execution. The entire four stage process – from initiation through full implementation — takes 5.8 years on average, with mid-sized companies taking one year longer than large companies and nearly two years longer than small companies. High variation around the mean duration was observed overall and by company size showing the highly inconsistent experience and difficulty that companies face in navigating the process. The larger coefficients of variation around mean durations are seen among small and mid-size companies, especially in the earliest innovation adoption stages. CROs are able to complete the innovation adoption process in half the time with far more consistent experience (i.e., lower coefficients of variation around the mean stage durations).

Two primary subgroups were considered for this analysis – company size and company type. Research in the literature suggests that company size is positively correlated with the rate of innovation adoption due to the availability of resources, staffing and infrastructure[xxixii]. The results of this study – that mid-sized companies have the longest innovation adoption durations relative to their larger and smaller counterparts - are not entirely consistent with the conclusions drawn in the literature. Company size in our analysis is based on annual revenue, a well-accepted classification. The observed large coefficients of variation around the mean durations of the Initiation and Evaluation stages for mid-sized companies may reflect more limited experience in identifying and qualifying vendors offering novel solutions, and in integrating innovative approaches into established operating practice. Resource constraints and limited experience may also increase reliance among mid-sized companies in using external partners to support adoption. We plan to do further research in this area to understand innovation adoption experience among companies of varying sizes.

Small companies — and more notably, CROs — appear to bring speed advantages to the innovation adoption process but for different reasons. Smaller companies are generally more nimble than their larger counterparts with less siloed functional relationships and with personnel often responsible for cross-functional activities. With more constrained capital & resources, and pressure from outside investors, smaller companies must often take more risks and arrive at decisions faster. For CROs, executional innovation is central to their ability to differentiate their services and capabilities and retain their clients. Tufts CSDD plans to gather more insight into the factors contributing to innovation adoption speed among smaller companies and CROs.

Nearly all companies verified that their organization follows all or most of the four primary stages that characterize the innovation adoption process. The latter two stages of the process — Adoption Decision and Full Company-Wide Implementation — are regarded as the most difficult. The highest proportion of companies considers the final stage (Full Implementation) to be the most difficult and to which they are least able to complete. The mean reported durations for each of the stages are consistent with the perceived level of difficulty and organizational competency.

The first two stages — Initiation and Evaluation — are more insular in nature. Although senior management and cross-functional support plays an important role in these stages, more coordination and cross-functional participation and collective commitment is required for the organization to make a final determination and move forward with full implementation. From the interviews and survey responses, factors that most contribute to optimizing the Innovation Adoption process include:

- Regulatory clarity and encouragement
- Strong evaluation assessment process (e.g., planning, execution, measurement)
- Well-planned and executed change management strategy
- Extensive and effective communication and training
- Senior management and cross-functional participation and support
- Investment and incentives better aligned with piloting and implementing innovations

Interestingly, the study findings suggest that more extensive and careful planning and execution in the earlier stages — particularly senior management and cross-functional engagement, evaluation assessment, and change management — can help drive a smoother transition and support a more effective adoption process downstream. Future research is also planned to understand more about the impact of early planning and practices on innovation process speed and efficiency.

We were surprised to see that only a relatively small percentage of companies have a dedicated, centralized innovation adoption mechanism. This finding may be due to challenges associated with empowering and enabling an intermediary group to influence decisions that impact other, separate functional areas. There were some indications in this study that centralized groups may offer speed and efficiency. Tufts CSDD plans to conduct additional research to understand this mechanism and others associated with more effective and efficient adoption processes.

As stakeholders throughout the clinical research enterprise look to accelerate the drug development paradigm — particularly in light of lessons and successes during the COVID-19 pandemic — the ability to quickly adopt novel solutions supporting clinical trial execution and improving patient engagement is paramount. The results of this study provide important and useful insights into optimizing the innovation adoption process.

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