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COVID-19 Impact on the Biopharmaceutical Industry and CRO Outsourcing – 2021 Update

Insights and metrics into biopharmaceutical clinical development budgets, activity, outsourcing to CROs and future outlook

May 2021

Confidential & Proprietary

About the Author

Life Science Strategy Group, LLC (LSSG) report authors draw upon extensive business, consulting and life science experience and backgrounds.

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Mr. Meyer is a Founder and Principal Consultant with the Life Science Strategy Group, LLC (LSSG). With 20 years of contract research services consulting experience, Mr. Meyer leads LSSG's contract research services consulting division which serves the leading global contract research organizations (CROs) across all phases of pharmaceutical discovery, development and commercialization.

Mr. Meyer has managed consulting engagements in a variety of commercialization and market research areas including strategic planning, opportunity assessments, pricing and reimbursement analyses, forecasting, competitive benchmarking, positioning and messaging strategy and clinical trial benchmarking and analysis. Prior to LSSG, Mr. Meyer was a Director in the Life Sciences Division at Navigant Consulting, Inc. and conducted preclinical drug development in the department of inflammatory disease at Roche Bioscience. Mr. Meyer holds Masters Degrees in Biomedical Science and Business Administration.

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Goal and Objectives

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GOAL

- To better understand the how the impact of COVID-19 on Biopharma's clinical development activities has changed from 2020 to 2021 including:
 - Clinical development and outsourcing budgets
 - Clinical trial starts, patient enrollment, and cancellations
 - Utilization of remote monitoring technology/virtual trials
 - Perceived leading CROs and unmet needs for COVID-19 clinical services
 - Impact of COVID-19 on future volume of RFPs for outsourced services

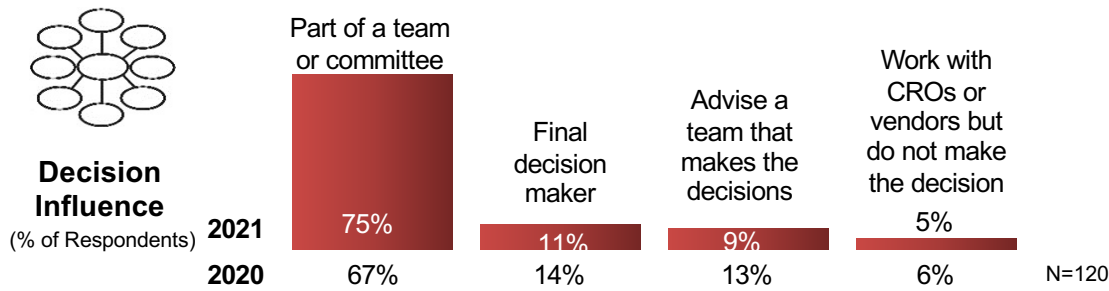
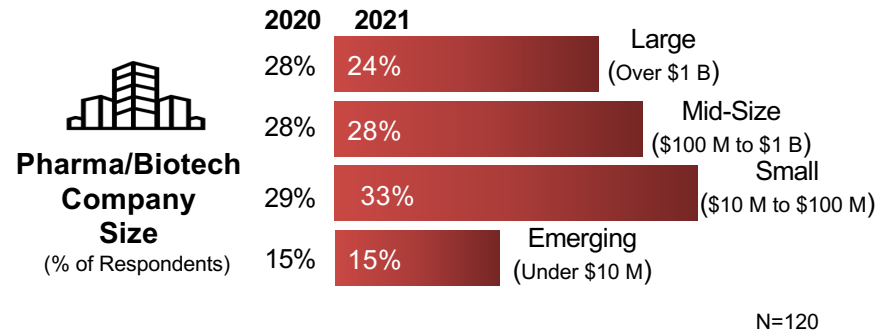
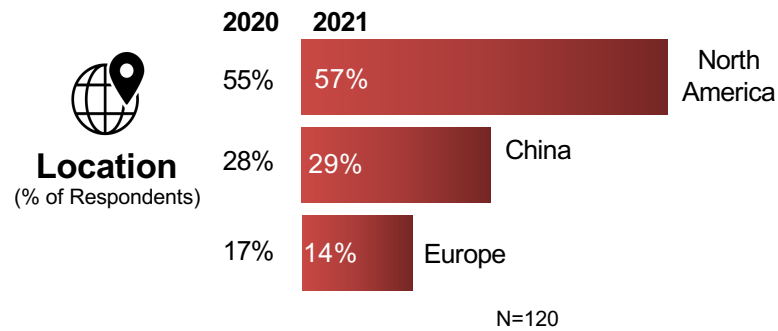
METHODOLOGY

- Study participants (N=120) are all involved with drug development and employed by a biopharmaceutical company in North America, Europe and/or China.
- All study participants were prescreened by LSSG to ensure a high level of involvement and/or key decision-making authority for clinical development and outsourced services. All data analysis and reporting was performed by LSSG.

Respondent Demographics

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- All respondents have visibility (42%) or responsibility (58%) into clinical development budget(s).
- More than 100 unique biopharmaceutical companies are represented by the research sample.

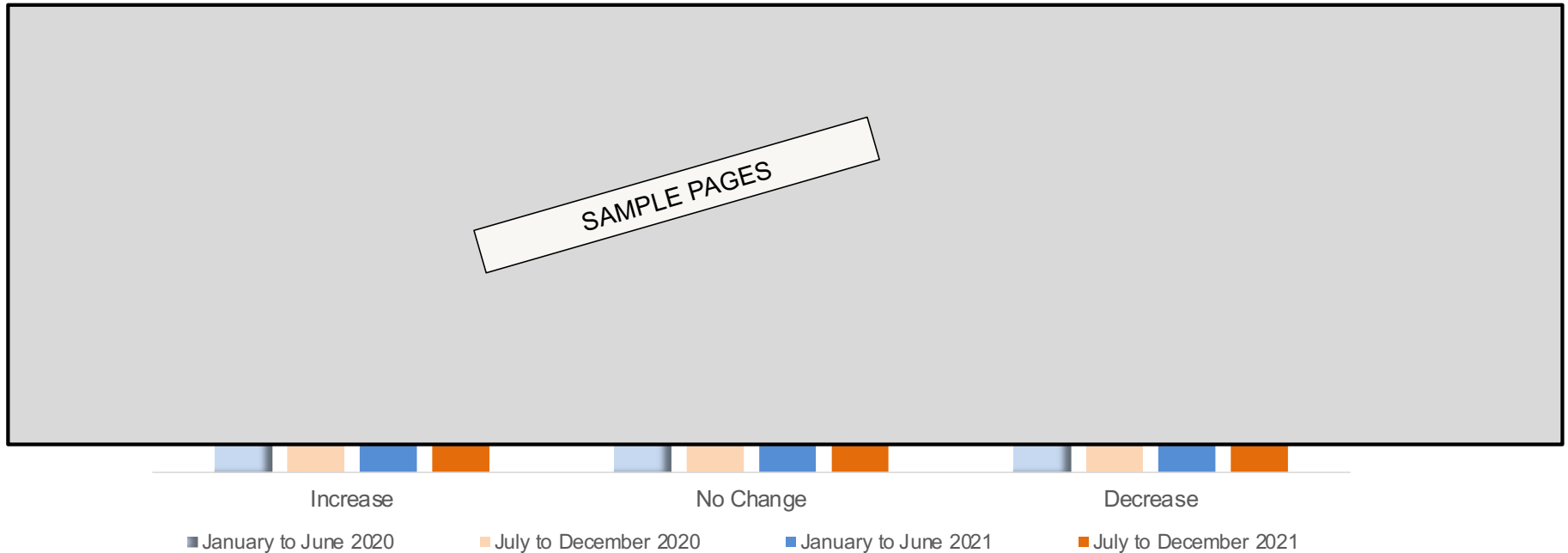


Q. Which best describes your responsibility for or visibility into a clinical development budget(s) at your company?
 Q. Where are you located?
 Q. Which BEST describes the type of company that you currently work for?
 Q. Which best describes your role as it relates to the identification, selection and/or day-to-day interaction with CROs or vendors in your primary functional area(s) of responsibility?

While COVID-19 initially had an overall negative impact on clinical development budgets in 1H 2020, since then COVID-19 is driving a net increase in clinical development budgets.

COVID-19 Impact on Clinical Development Budgets (2020 vs. 2021)

Market Aggregate
N=120



* Clinical budget increase not necessarily driven by COVID-19 therapy or vaccine development.

Text color:
Grey = % of respondents Green = 2021 increase % Red = 2021 decrease %

Q. How will COVID-19 impact your/your company's clinical development budgets for each of the following time periods?

Source: Life Science Strategy Group, LLC

Respondents note the major activities impacted by the xxxxxx due to COVID-19 are increased YYYYYY and added ZZZZ (xxxxxxx).

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Activities Impacted by an INCREASE in 2020 vs. 2021 Clinical Development Budgets

January to June

(unaided)*

Market Aggregate

Activities	1H 2020 (n=34)	2H 2020 (n=51)	1H 2021 (n=58)	2H 2021 (n=62)
Scope of studies (e.g., sample size, protocols, recruitment and retention, enrollment, site location)	SAMPLE PAGES			
Added cost (e.g., site shutdowns, patient travel, patient follow ups, workload of CRC and CRA, direct-to-patient, at home visits, site startup and activations, shipping costs, fees)				
Monitoring activities (e.g., including data collection, management, analysis, laboratory activities, clinical reporting, remote monitoring)				
Staffing Operations (e.g., training, adding personnel)				
New Clinical Activities/Research (e.g., COVID-19 research, new research projects)				
Delays (e.g., speed of clinical trials, patient enrollment/recruitment delays, delay in site startup)				
Engagement with CROs (e.g., CRO to run mid-stage development, higher CRO expenditure)				



(1H 2021) "Patient recruitment delays, study site costs"
-North America, Small Pharma, Senior Director/Director

(1H 2021) "Increasing contingency measures due to COVID-19 for clinical trials (e.g., more home nursing services, additional transportation support, increased remote monitoring and associated site fees, etc.)"
- North America, Small Pharma, Senior Manager

(1H 2021) "Remote monitoring activities will be more widespread, this will necessitate home visits by monitors and nursing staff increasing costs"
- Europe, Large Pharma, Senior Director/Director

(1H 2021) "It affects employee travel and the increasing of R&D personnel"
-Asia Pacific, Emerging Pharma, Senior Manager

Q. What activities are being/will be impacted by the increase in your/your company's clinical development budgets from January to June 2020(2021)? Please separate each activity by a comma.

From 1H 2020 to 1H 2021, respondents from all segments expect zzzzz in XXXXXX due to COVID-19. From 2H 2020 to 2H 2021, all segments expect increase in XXXXXX due to COVID-19, AAA and BBB expect smaller increases than other segments.

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COVID-19 Impact on Outsourced Clinical Development Spend on CROs/Vendors

January to June 2020			
Increase	No Change	Decrease	Not Sure/Don't Know
36% (+10%)	34%	25% (-23%)	4%
21% (+12%)	40%	40% (-21%)	0%
26% (+12%)	32%	37% (-23%)	5%
44% (+9%)	32%	24% (-20%)	0%
14% (+13%)	57%	29% (-21%)	0%
July to December 2020			
43% (+14%)	24%	16% (-20%)	16%
28% (+17%)	25%	30% (-27%)	17%
38% (+15%)	26%	20% (-31%)	15%
41% (+13%)	15%	29% (-21%)	15%
24% (+17%)	33%	19% (-10%)	24%

Segment Analysis

- Large/Mid-sized**
< n=67 n=62 >
- Emerging/Small**
< n=53 n=58 >
- North America**
< n=65 n=68 >
- China**
< n=34 n=35 >
- Europe**
< n=21 n=17 >
- Large/Mid-sized**
< n=67 n=62 >
- Emerging/Small**
< n=53 n=58 >
- North America**
< n=65 n=68 >
- China**
< n=34 n=35 >
- Europe**
< n=21 n=17 >

January to June 2021			
Increase	No Change	Decrease	Not Sure/Don't Know
[Redacted]			
July to December 2021			
[Redacted]			

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Q. How will COVID-19 impact your/your company's outsourced clinical development spend to CROs/vendors for each of the following time periods?

Source: Life Science Strategy Group, LLC

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Text color:
Grey = % of respondents, Green = increase %, Red = decrease %



The need for new technologies and increased utilization of CROs A and Y in 2021.

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Strategies to Engage Patients and Drive Patient Recruitment in Clinical Trials as a Result of COVID-19

(% of Respondents)

	Market Aggregate N=120		Large/ Mid-sized n=67 n=51		Emerging/Small n=53 n=58		North America n=65 n=68		China n=34 n=35		Europe n=21 n=17	
	2020	2021	2020	2021	2020	2021	2020	2021	2020	2021	2020	2021
	Adopting/adding technology such as telemedicine and/or apps to expand patient reach/engagement	57%										
Greater use of CROs/vendors to assist with recruiting	44%											
Using social media to connect directly with patients	34%											
Partnering with patient advocacy groups	31%											
Increasing advertising to drive engagement/recruitment	25%											
Not Sure/Don't Know	4%											

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Q. As a result of COVID-19, what are you/is your company doing differently to engage patients and drive patient recruitment in clinical trials? Please select all that apply.

Source: Life Science Strategy Group, LLC