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Clinical Trial Outsourcing Survey

ClinicalInformaticsNews.com Clinical Trials to the Clinic

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With clinical trials being run all over the world, outsourcing is a near-inevitability. Only 3% of our survey respondents said they didn't outsource any part of their trial planning and operations. Equally unsurprising, trial monitoring is the most frequently outsourced step; 83% of our survey-takers outsourced this step. 76% of respondents outsourced data management and patient enrollment and site selection weren't far behind, with 58% of respondents outsourcing each of these steps.

The activities that remain in house were more evenly distributed besides managing investigator brochures; 80% of respondents did that in house. Other tasks including electronic patient reported outcomes and signal detection were only managed in house for 33% of groups.

For groups that are outsourcing work internationally, 83% found it challenging to manage global project teams across cultures. China and Russia topped the list of countries on which firms are focusing. The other two BRIC countries—Brazil and India—are only seeing attention from 17% of our respondents.

In many ways it makes sense to outsource operations abroad. Respondents reported not having enough internal staff to dedicate to those countries and the cost-savings and local expertise realized when working with teams on the ground.

But communication issues with CROs is the top complaints for companies—51% of survey takers had concerns about that—and the list of challenges was diverse. Nearly a third of respondents had had challenges in every area we asked about: delivery of results in a timely manner, sticking to the study budget, technology issues, and more. While outsourcing is needed, developing strong relationships is still an area of concern for most sponsors.

That may be why 42% of the survey-takers rely on historic site partners. Just at half—51%--outsource site selection, leaving only 7% of respondents reporting that they use a site selection software that might introduce them to newer partners or sites around the world.

Outsourcing is certainly here to stay, but it's clear that sponsors and sites are still working out the kinks. Smoothing the ways trials are outsourced still holds much promise and room for growth in the industry.



Answers for "Other:" Clinical and ePRO data collection; Full service; Labs electronic data capture system; Medical writing; Pharmacovigilance; Statistics; Stats, PVG

Which aspect(s) of clinical trials are you keeping in house?	Investigator brochure Signal detection		
	Electronic patient reported outcomes	32%	
	Other	29 %	

Answers for "Other:" Biostatistics; Copies of all administrative documents for GCP compliance; Data analysis; Medical monitoring, oversite; Medical writing; N/A; None; Patient recruitment; Project managment; Protocol creation, stats; Protocol design; Protocols; Site selection; Statistics; We oversight the work of CRO



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Thinking about the CRO you've been most pleased with, how many times have you outsourced to this same CRO?

First time	27%	
2-5 times	42%	
6-9 times	7%	
10-15 times	7%	
16-20 times	3%	
21-24 times	0%	
More than 25 times	12%	
Not applicable, do not outsource to a CRO	2%	



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What tactors are most important	Good communication and transparency	68%									
Vhat factors are most important vhen choosing a CRO?	Past experiences with CRO							•			
	Ability to understand customer requirements										
	On-time delivery										
	Therapeutic experience	54%									
	Cost-effectiveness	54%		•	•	•					
	Proven track record	51%									
	Range of services	47%									
	Priority to resolve issues	47%									
	Project management	47%									
	Adaptability to sponsor methodologies	46%									
	Technical expertise	44%									
	Confidentiality/security procedures	36%									
	Financial stability and operations	32%									
	Industry reputation	25%									
	Billing practices	14%									
swers for "Other:" Global capabilities; Global tprint; Global reach; Quality of the work	Already working with other divisions of my company	7%									
potprint; Global reach; Quality of the work	Other	7%									
What type of vendors are you outsourcing o outside of a CRO? nswers for "Other:" Evaluation of radiology; Patient recruitment;	Central lab Clinical trial supply organization Consultants Clinical trial specific software vendor	53% 47%					I				
ettere ette	Other	7%									
ecruitment specialists; Site managment organizations		1% 									_
)o you allow your CRO partner to subcontract w	vith third	78%					•			•	
o you allow your CRO partner to subcontract w	vith third	78%								•	
ecruitment specialists; Site managment organizations Do you allow your CRO partner to subcontract w party vendors to meet the needs of your agreem	vith third	78%									_

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INFORMATICS NEWS

FORMATICS Clinical Trial Outsourcing Survey



What best describes your job function?	Clinical Operations	32%	
	Clinical Research	15%	
	Other	15%	
	C-Level Executive (CEO, CIO, CFO, etc)	12%	
	Scientist	8%	
	Clinical Project Management	5%	
	Lab/Medical Director	5%	
	Clinical Trials Management	3%	
Answers for "Other:" Advisor; Clinical Procurement; Contracts &	Informatics/IT/Data Management	2%	1
Outsourcing; Executive Management; Quality; Quality Assurance; Regulatory Affairs; Senior Director Patient Advocacy	Professor	2%	

Clinical Trial Outsourcing Survey

	Other	39%					
In which research areas are your clinical trials?	Lung cancer	33% 32%					
	Infectious diseases/vaccines	32%					
	Breast cancer	31%					
	Cardiovascular/heart failure	29%					
	Respiratory diseases	27%					
	CNS diseases	24%					
	Pain	22%					
	Devices	19%					
	Colon cancer	15%					
	Alzheimer's	15%					
	Pediatric cancer	14%					
	Cervical cancer	14%					
Answers for "Other:" CIDP/GBS/SMS; CRPC; Diabetes; CKD; Hypertension;	Pancreatic cancer	12%					
Gastrointestinal Disease; Genetic/orphan; Hematological Malignacies; Hematology; Immunology; Interventional Radiology and Intervential Cardiology;	Ovarian cancer	10%					
MS; Pharmacogenomics; Prostate cancer; Rare disease; Renal; Hematology;	Parkinson's	10%					
Rheumatology; Surgery; Transplant; Nephrology; Urology; Ultra rare disease	Dementia	8%	_				
	Less than 50	29%					
How many employees are in your organization?		190/					
How many employees are in your organization?	51-150	12%					
How many employees are in your organization?	51-150 151-250	12% 2%					
How many employees are in your organization?			-				

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