

Best Practices in the Oversight and Management of Investigator Initiated Trials in CNS Therapeutic Area

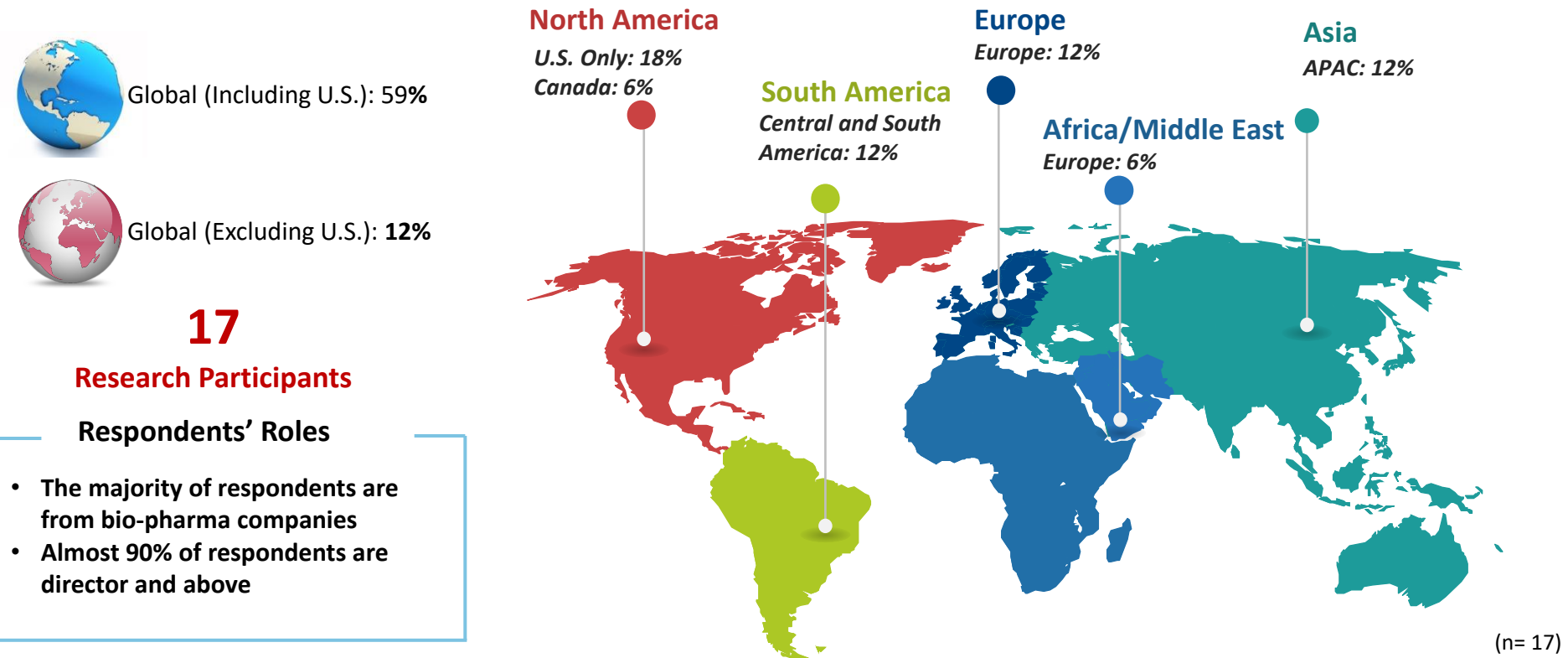
Strategic Benchmarking Research & Analysis



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Research Overview: Objectives, Methodology and Topics



Research Overview & Objective	Methodology	Topics Covered
With a significant increase in the number of investigator initiated trial (IIT) submissions occurring in the healthcare industry, it is critical for bio-pharmaceutical companies to properly vet each proposal and approve the ones that demonstrate scientific merit and align with shifting corporate objectives. This benchmarking study is designed to provide a detailed roadmap for improving IIT management at bio-pharmaceutical companies, capturing critical metrics and insights on IIT management team structure, staffing, budget and performance metrics.	Best Practices, LLC engaged 17 leaders from 13 bio-pharmaceutical and medical device companies through a benchmarking survey.	• IIT Submission Review and Systems • Functional Involvement • IIT Funding • Future Improvements • Challenges • Important Criteria for IIT Evaluation • Key Reasons for Rejecting IIT Proposals

Universe of Learning: Leading Bio-pharmaceutical Firms

This study engaged 17 leaders from 13 organizations offering CNS products. Nearly 90% of the respondents served at the director level or above.

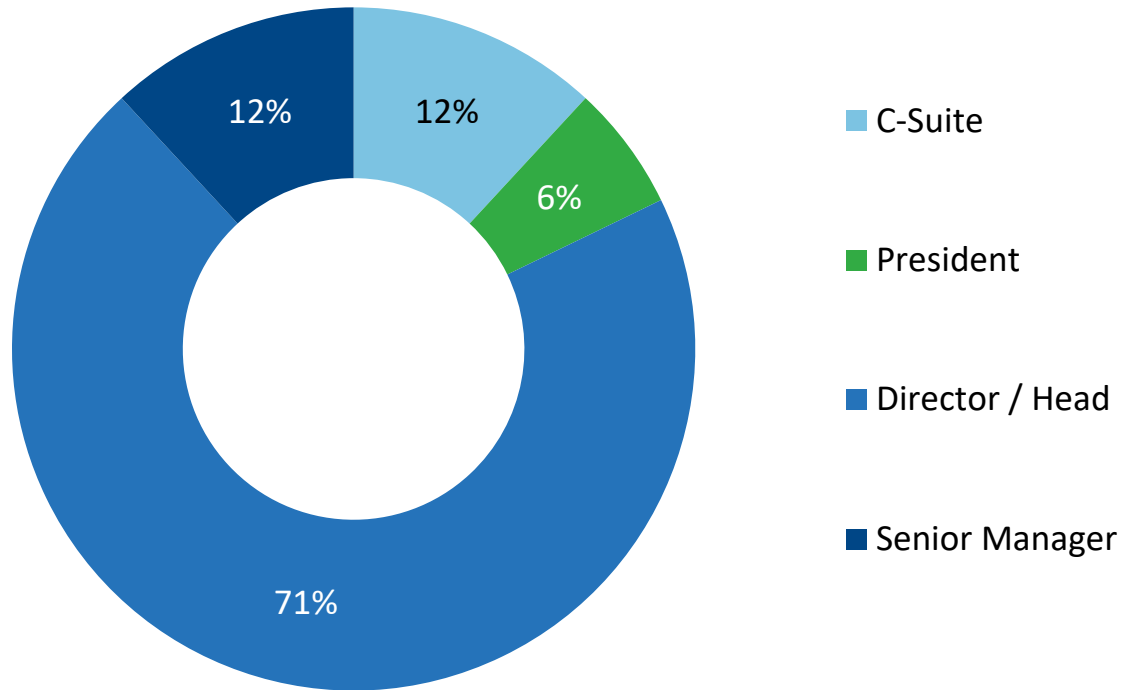
Companies of Respondents

The Merck logo, featuring the word "MERCK" in a bold, blue, sans-serif font.The Novartis logo, consisting of a stylized orange and blue flame-like icon followed by the word "NOVARTIS" in a blue, sans-serif font.The EMD Serono logo, with "EMD" in red above "SERONO" in red, both in a bold, sans-serif font.The Allergan logo, featuring a cluster of green and blue dots above the word "Allergan" in a blue, sans-serif font.The Lundbeck logo, with the word "Lundbeck" in a script font next to an orange starfish icon.The Jazz Pharmaceuticals logo, featuring a purple and yellow circular icon with a stylized 'J' followed by the text "Jazz Pharmaceuticals" in a purple, sans-serif font.The Sanofi logo, with a stylized blue and yellow wave icon above the word "SANOFI" in a blue, sans-serif font.The Blue Earth Diagnostics logo, featuring a cluster of blue and white dots above the text "BLUE EARTH" in a bold, sans-serif font, with "DIAGNOSTICS" in a smaller font below.The Guerbet logo, with the word "Guerbet" in a bold, sans-serif font next to a grid of blue and orange squares.The Sage Therapeutics logo, featuring an orange and blue circular icon next to the text "Sage Therapeutics" in a bold, sans-serif font.The Gedeon Richter logo, with a circular icon containing the letters "RG" next to the text "GEDEON RICHTER" in a bold, sans-serif font.The IPSEN logo, featuring a stylized blue and white icon next to the text "IPSEN" in a bold, sans-serif font, with "Innovation for patient care" in a smaller font below.The SolidPharma logo, with the text "SOLIDPHARMA" in a bold, sans-serif font inside a dark blue rectangular box.

Over 70% of the respondents belong to Director / Head level

Very few responses were received from C-Suite and President level.

Demographics



N=17

Select Key Findings from the Study

Select key insights uncovered from this report are noted below. Detailed findings are available in the full report.

Approvals

Scientific merit most often determine IIT approval while strategic misalignment led to IIT denials

The most important criteria for evaluating new IIT proposals are “scientific value” of the study and “strategic fit” with the company’s objectives.

Some organizations also evaluate based on “relevant potential data” and “clinical feasibility”. Rejection of IIT proposals mainly occur because of “strategic misalignment” and “high cost”.

Engagement

MSLs are the bridge connecting sponsors and investigators

MSLs act as the “bridge” connecting sponsors and investigators, facilitate engagement with them as well as provide updates and clarifications throughout the study process.

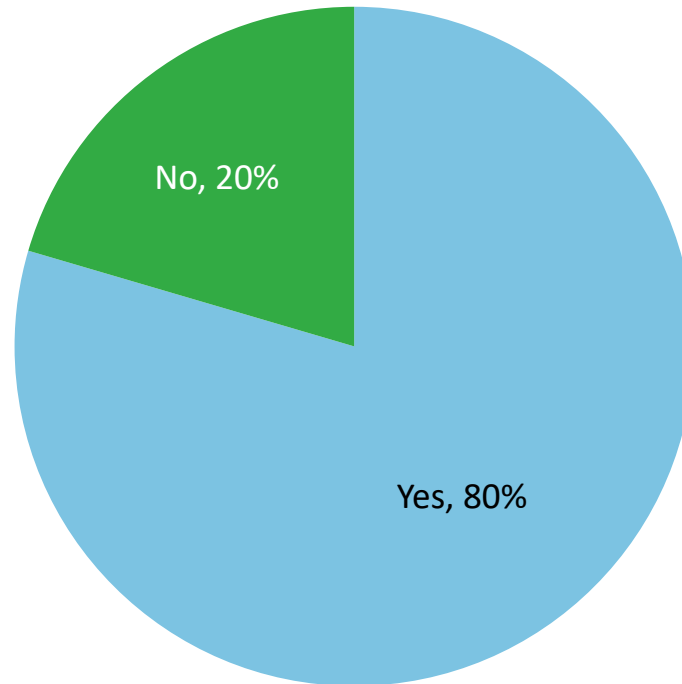
Most IIT submissions occur in an online setting

More than 40% of companies use tools like online portals, trackers and database tools to facilitate submission review.

Companies have a dedicated group to manage IITs

Most benchmark companies have established a dedicated department to manage IITs. Only 20% do not have a dedicated IIT group at present.

Dedicated IIT Group



N=15

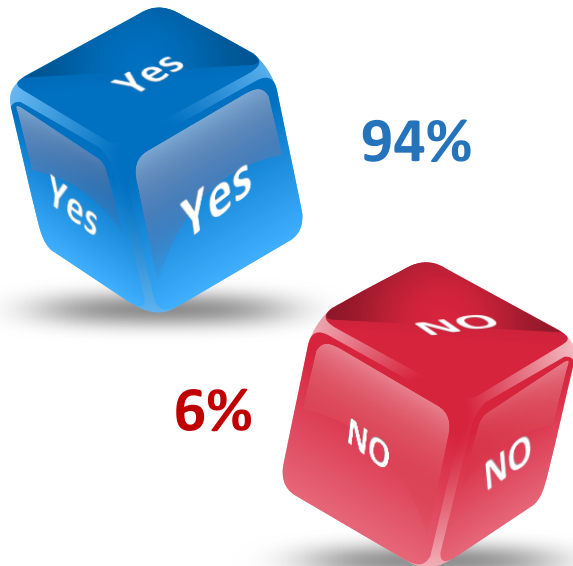
Q. Do you have a dedicated IIT management department?

Companies use SOPs to govern IIT process, provide study road map and define rules and regulations

Written SOPs, which have been adopted by 94% of companies, provide a critical structure for the entire IIT process and support compliance.

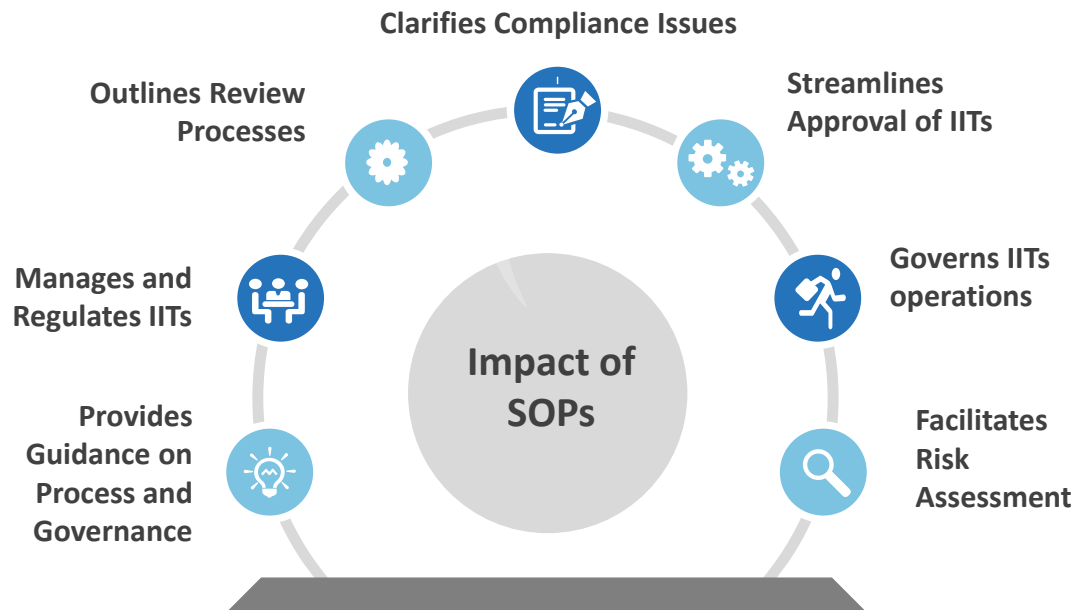
SOPs & Impact on IIT Process

Q. Do you have written SOPs for IIT processes?



N=17

Q. Please explain how your SOPs impact the IIT process.

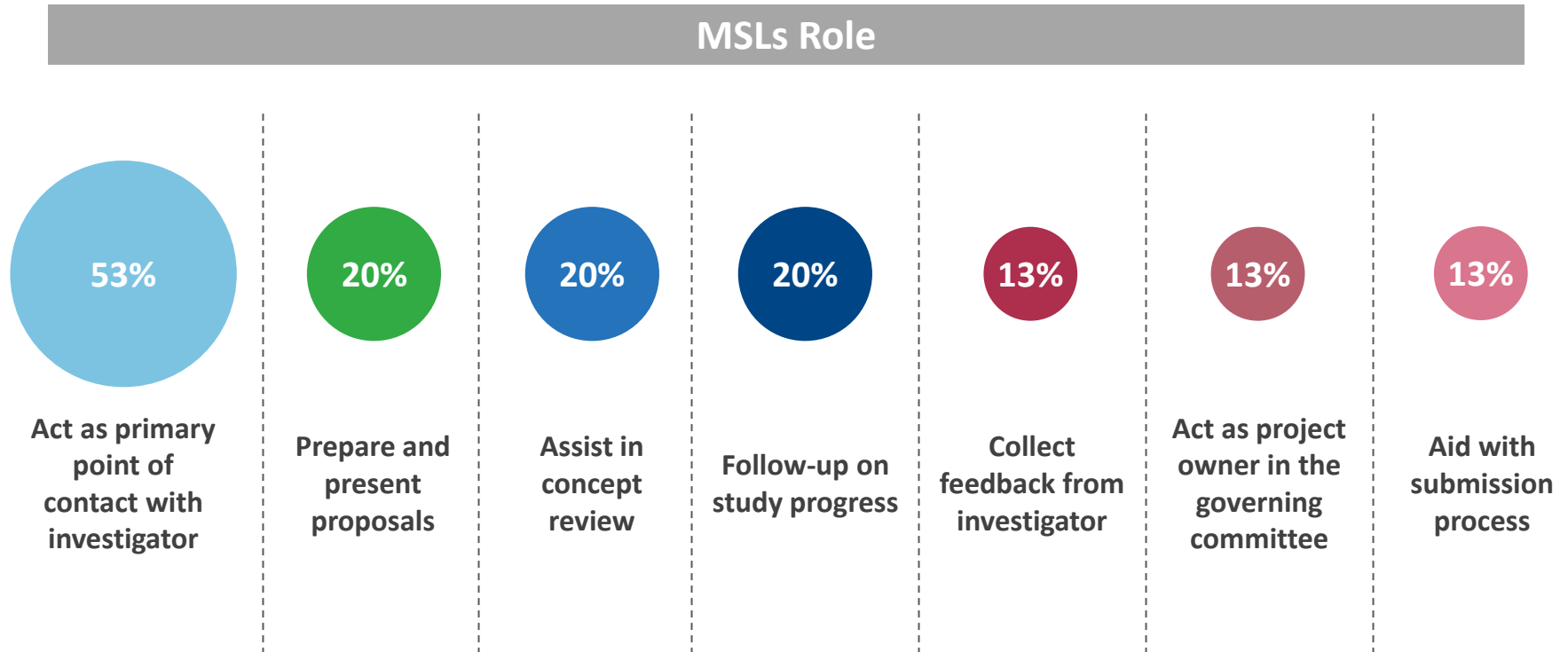


"You really have to step out of your templates for externally-sponsored trials because you have to start going back to the basics of all of the research requirements. It's not necessarily always going to be written into your SOPs."

- Associate Director, Global Medical Affairs

MSLs act as primary point of contact with investigator

Most MSLs act as primary point of contact with investigators, prepare proposals, review concepts, and follow-up on study progress.



“I want to empower the customer-facing elements at our company. If we have an MSL, we want him or her to look good, look informed in front of doctors. We want them to take ownership.”

- Executive Director Global Phase 4 / IIT Trial Management

N=15

Q. What role do MSLs play in IIT management?

Scientific value of the study is the most important factor while evaluating an IIT proposal

Along with scientific value, strategic fit with company objectives and relevance of study data are critically important to evaluate an IIT proposal.

Important Criteria for IIT Evaluation



Scientific value, 75%



Strategic fit, 58%



Relevance of potential data and results, 42%



Clinical feasibility, 33%



Budget, 25%



Others, 17%

- Quality of the core protocol/concept sheet
- Patient safety

N=12

Q. What are the most important criteria when evaluating an IIT proposal?

Medical Affairs typically funds IIT programs at companies

Followed by Medical Affairs, R&D is the leading function to provide financial support in a quarter of companies. In CNS area, Regulatory Affairs, Marketing and Publications usually do not support IITs financially.

Budget by Function

Functions		Percentage of Companies Funding IITs
	Medical Affairs	94%
	R&D	25%
	Commercial	6%
	Market Research	6%
	Others	19%

*Other - Clinical Development, Global Trial Management

“From a U.S. perspective, we’re one of the few affiliates and we are the largest affiliate for our company. The benefit is that as we develop, we’re able to own the space from concepts to publication, and are able to support the investigators and support the internal organization, key indications, training, payment, contracting, etc.”

“So, our trials move faster, I think we’re better supported, our payments have been approved, and we now provide all our consultation and support to the investigators [from the U.S. affiliate].”

- Head, U.S. Medical Operations

N=16

Q. What functions provide financial support to IITs?



Our company is an internationally recognized thought leader in the field of best practice benchmarking®. We provide research, consulting, benchmark database, publishing and advisory services to the biopharmaceutical and medical device sectors. We work closely with business intelligence groups. Our work is based on the simple yet profound principle that organizations can chart a course to superior economic performance by leveraging the best business practices, operating tactics and winning strategies of world-class companies.

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