

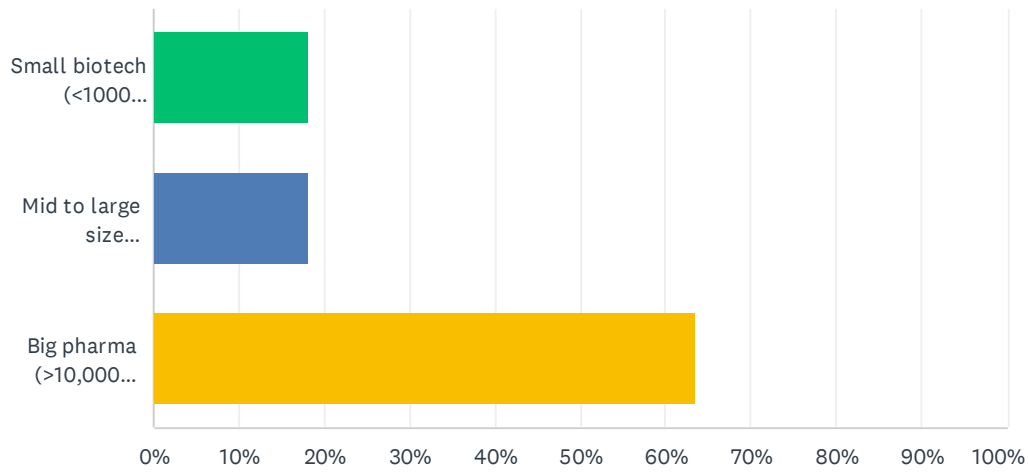
Q1 Please enter you unique Survey Monkey Code provided to you by Julian Arbuckle:

Answered: 8 Skipped: 3

#	RESPONSES	DATE
1	7744	9/2/2022 12:43 PM
2	8008	8/26/2022 2:58 PM
3	2229	8/25/2022 12:53 PM
4	2772	8/24/2022 7:15 PM
5	9213	8/23/2022 4:24 PM
6	8354	8/19/2022 9:34 PM
7	2276	8/16/2022 6:53 PM
8	3287	8/16/2022 5:47 PM

Q2 What is the size of your Pharma/Biotech company:

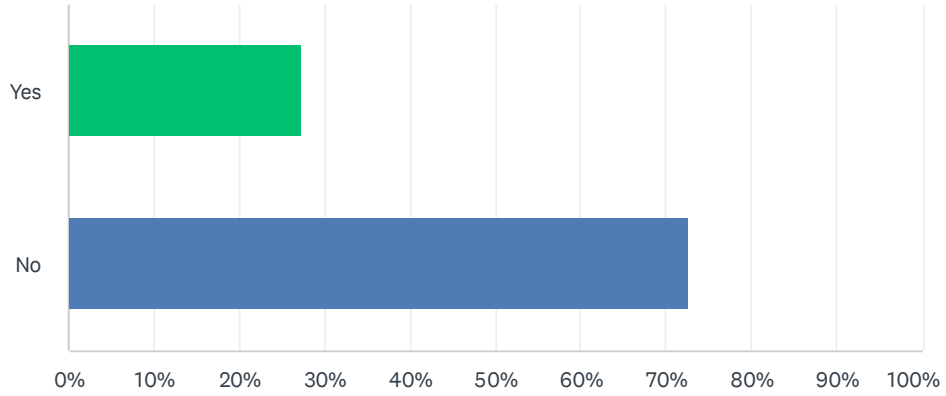
Answered: 11 Skipped: 0



ANSWER CHOICES	RESPONSES	
Small biotech (<1000 employees)	18.18%	2
Mid to large size biotechnology (>1000 - ≤10,000 employees)	18.18%	2
Big pharma (>10,000 employees)	63.64%	7
TOTAL		11

Q3 Does your company return genetic/genomic/biomarker results to study participants currently (not for enrollment/stratification)?

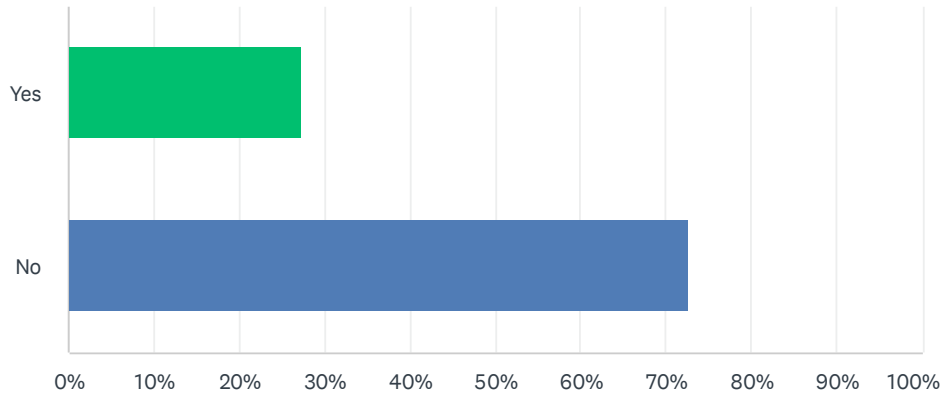
Answered: 11 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	27.27%	3
No	72.73%	8
TOTAL		11

Q4 When exploratory research is conducted on a CLIA, commercial-ready panel, does your company permit full CLIA reports to be provided to PIs?

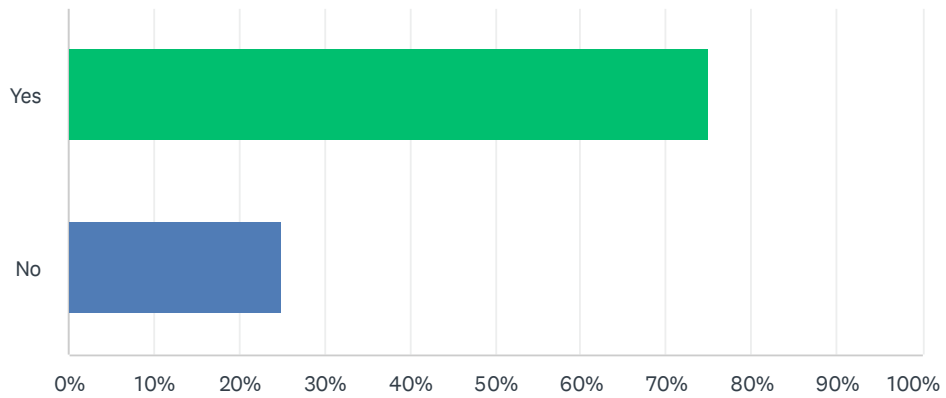
Answered: 11 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	27.27%	3
No	72.73%	8
TOTAL		11

Q5 Are there limitations to return of these full results?

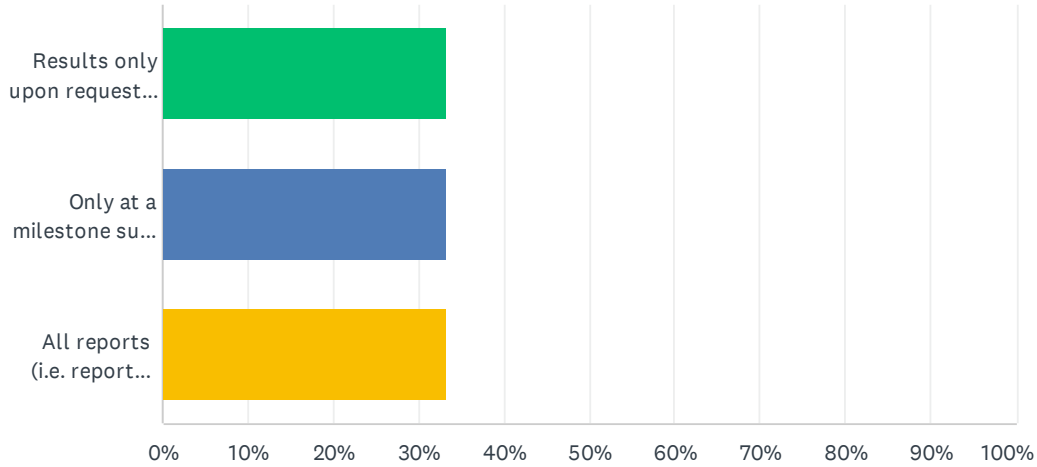
Answered: 4 Skipped: 7



ANSWER CHOICES	RESPONSES	
Yes	75.00%	3
No	25.00%	1
TOTAL		4

Q6 When returning these results, does your company return (select all that apply):

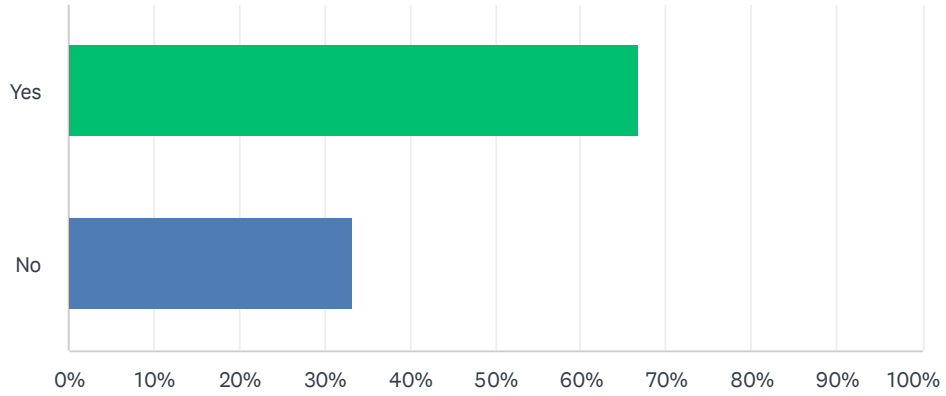
Answered: 3 Skipped: 8



ANSWER CHOICES	RESPONSES	
Results only upon request (limited)	33.33%	1
Only at a milestone such as screen failure or treatment discontinuation, upon request (limited)	33.33%	1
All reports (i.e. reports accessible to all PIs in the trial)	33.33%	1
TOTAL		3

Q7 If limited, are your vendors able to release CLIA reports only by request of your company?

Answered: 3 Skipped: 8



ANSWER CHOICES	RESPONSES	
Yes	66.67%	2
No	33.33%	1
TOTAL		3

Q8 Please provide any additional information or clarification around your company's return of results process:

Answered: 6 Skipped: 5

#	RESPONSES	DATE
1	Our company is working on a solution for RoR to subjects as a pilot on a few trials. The results returned would be CLIA only. Incidental Findings is considered as well. The question 5. is seen as critical because impacts the concept and logistic behind. To Q6 only very little vendors may have setup a solution already. Popular genomic vendors doing exploratory work in clinical trial haven't.	9/2/2022 9:34 AM
2	The company policy is not to return any research grade results. The example in which we provided CLIA results back to patients and PIs, was confirmation of disease mutations. These patients had already been genotyped/sequenced. The confirmation was needed to enroll in the clinical trial and these confirmatory results were returned to the PIs and patients.	8/26/2022 2:58 PM
3	experience above is from 1 study only	8/25/2022 12:53 PM
4	The Ionis process to enable exploratory research on clinical samples has been described in Mignon et al, Contemporary Clinical Trials 2022;119:106819.	8/16/2022 6:53 PM
5	Regarding CLIA approved panels, do others have CLIA labs internal or is all CLIA work outsourced?	8/16/2022 5:47 PM
6	Ethics requirements, and usually it is in the event that a patient request's the genetic results for a sample type we may have pursued	8/16/2022 5:31 PM