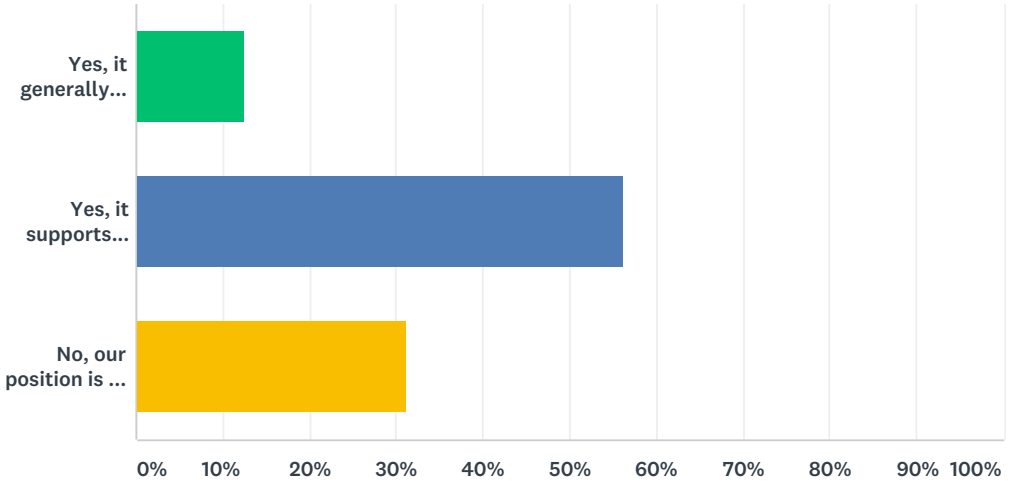
Q1 Does your company's current stance allow for the return of any individual genomic research results?

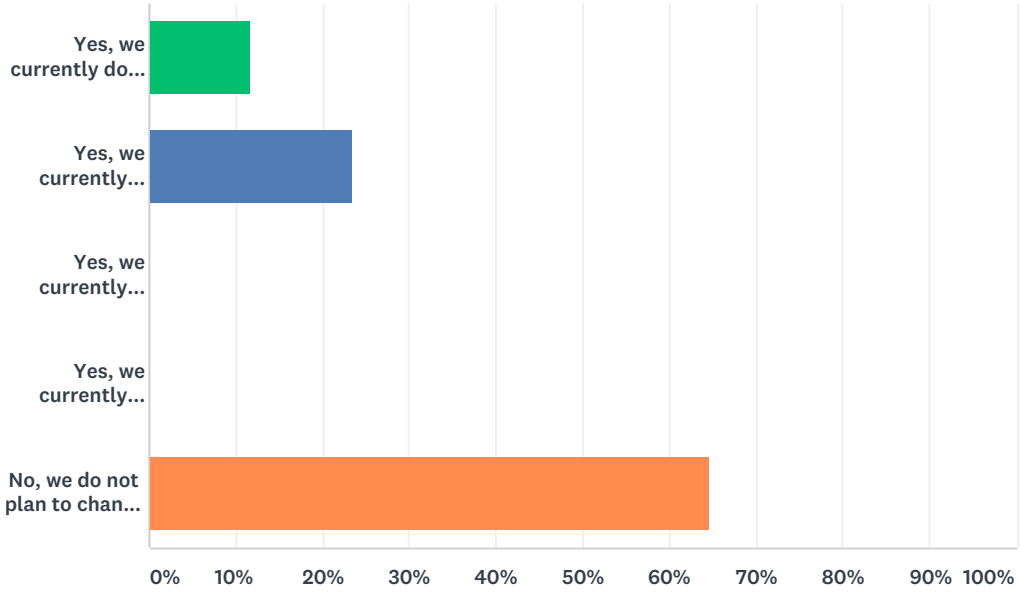
Answered: 16 Skipped: 1



ANSWER CHOICES	RESPONSES	
Yes, it generally supports returning results	12.50%	2
Yes, it supports returning results but only in limited circumstances	56.25%	9
No, our position is to not return results under any circumstances	31.25%	5
TOTAL		16

Q2 Does your company plan to change its current stance?

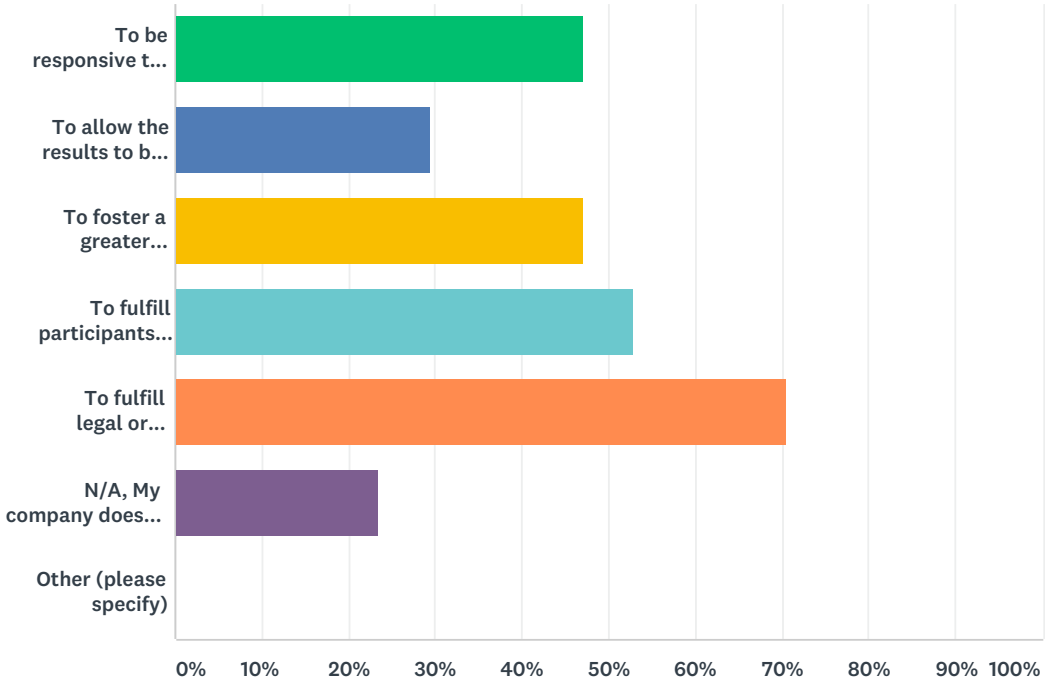
Answered: 17 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes, we currently do not return and we plan to transition to returning results	11.76%	2
Yes, we currently return results and we plan to transition to returning significantly more results than we currently do	23.53%	4
Yes, we currently return results and we plan to transition to returning significantly fewer results than we currently do	0.00%	0
Yes, we currently return results and we plan to transition to no return	0.00%	0
No, we do not plan to change our stance	64.71%	11
TOTAL		17

Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)

Answered: 17 Skipped: 0

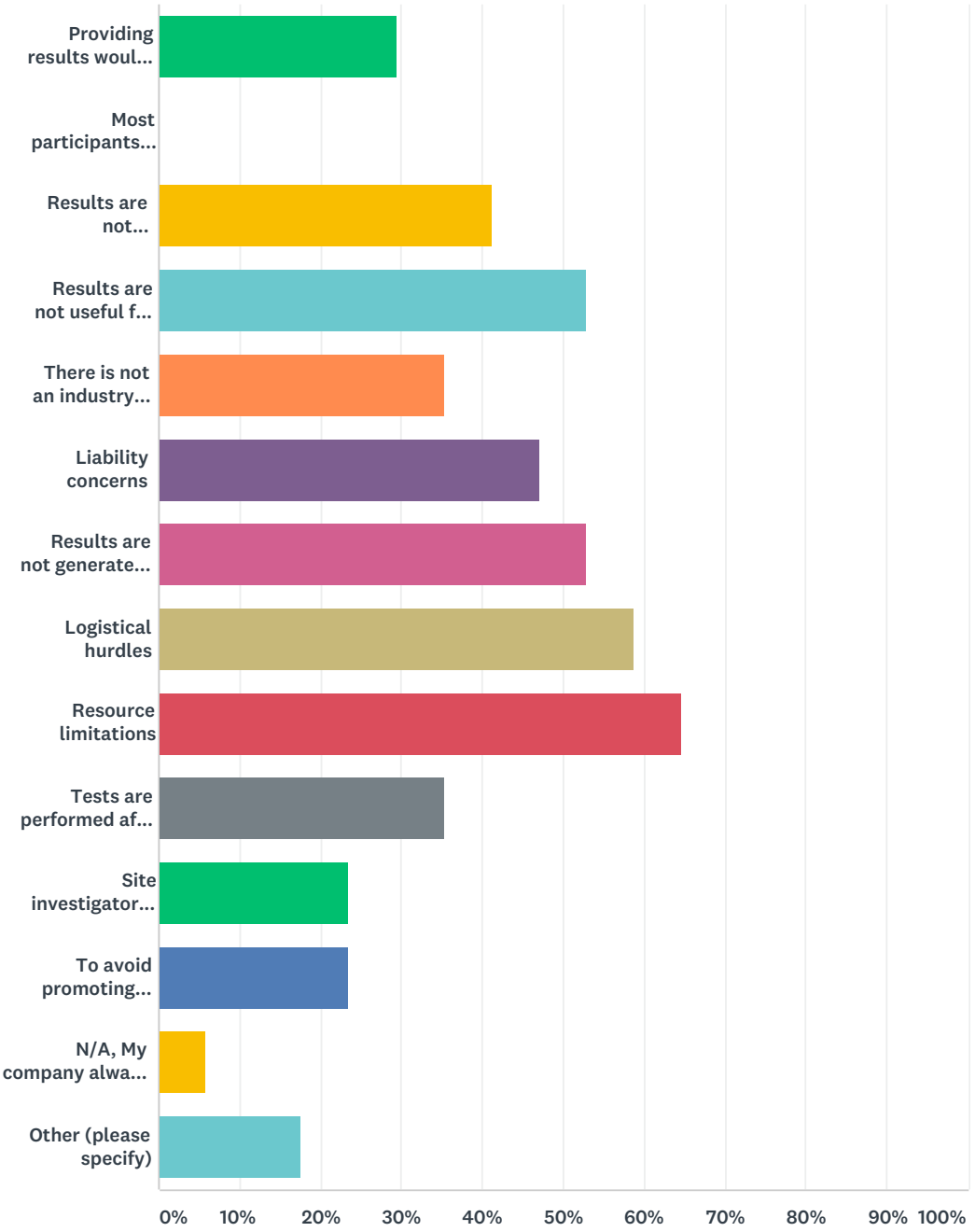


ANSWER CHOICES	RESPONSES	
To be responsive to participants' desire to receive their results	47.06%	8
To allow the results to be incorporated into the management of the study participant's health	29.41%	5
To foster a greater partnership and/or transparency in the relationship between my company and study participants	47.06%	8
To fulfill participants' right to receive data generated from their biological samples	52.94%	9
To fulfill legal or regulatory obligations to return the results	70.59%	12
N/A, My company does not support any return of individual genomic research results	23.53%	4
Other (please specify)	0.00%	0
Total Respondents: 17		

#	OTHER (PLEASE SPECIFY)	DATE
	There are no responses.	

Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)

Answered: 17 Skipped: 0



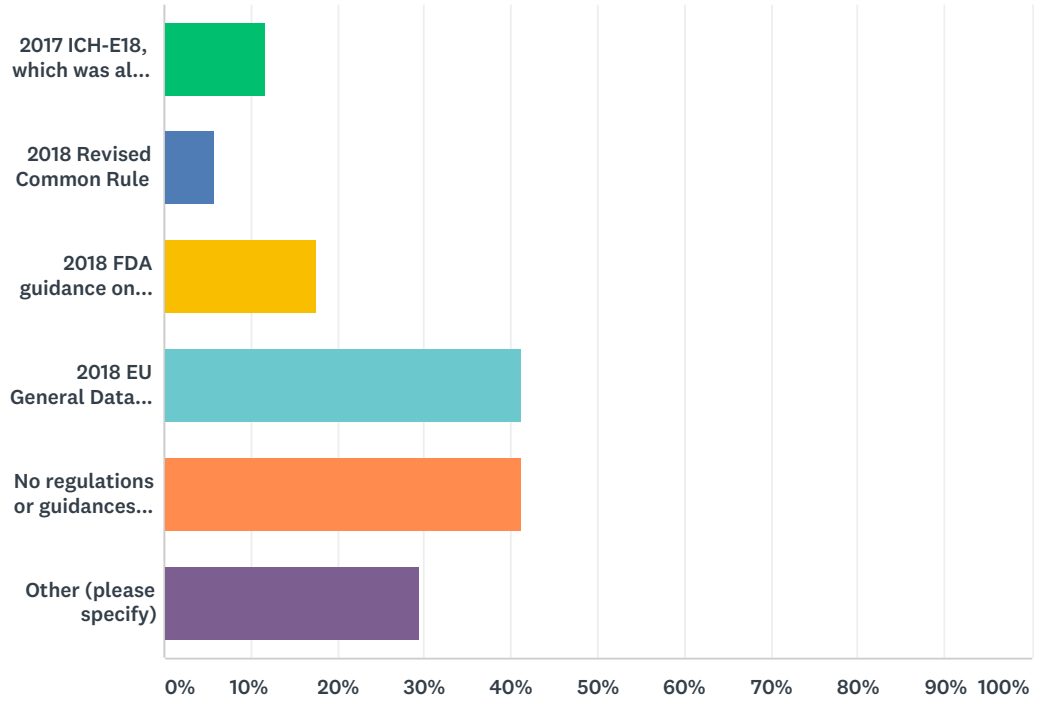
ANSWER CHOICES	RESPONSES	
Providing results would compromise the integrity of the clinical trial	29.41%	5
Most participants are not interested in receiving them	0.00%	0
Results are not interpretable at the individual level	41.18%	7

Results are not useful for clinical decision-making	52.94%	9
There is not an industry standard to return results	35.29%	6
Liability concerns	47.06%	8
Results are not generated in a CLIA-certified laboratory setting	52.94%	9
Logistical hurdles	58.82%	10
Resource limitations	64.71%	11
Tests are performed after they would be of value to study participants and/or after the participants' last study visit	35.29%	6
Site investigators are not comfortable conveying results to participants	23.53%	4
To avoid promoting therapeutic misconception (participant may conflate the purpose of research with that of clinical care)	23.53%	4
N/A, My company always returns individual genomic research results	5.88%	1
Other (please specify)	17.65%	3
Total Respondents: 17		

#	OTHER (PLEASE SPECIFY)	DATE
1	My company supports returning results to study participants but uses a third party as the data controller. The company itself is not directly involved in the process, i.e. e.g. associated genetic counseling and doesn't store the samples and sequencing data. These are stored at the Data Controller (third party).	12/6/2019 2:57 PM
2	A patient can request access to their data (generated as part of the Genomics Initiative) and the CGR will provide a copy but this will be as received from sequencing vendor and without any processing, analysis or interpretation.	11/14/2019 4:13 PM
3	To protect subject confidentiality	11/6/2019 9:18 PM

Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)

Answered: 17 Skipped: 0

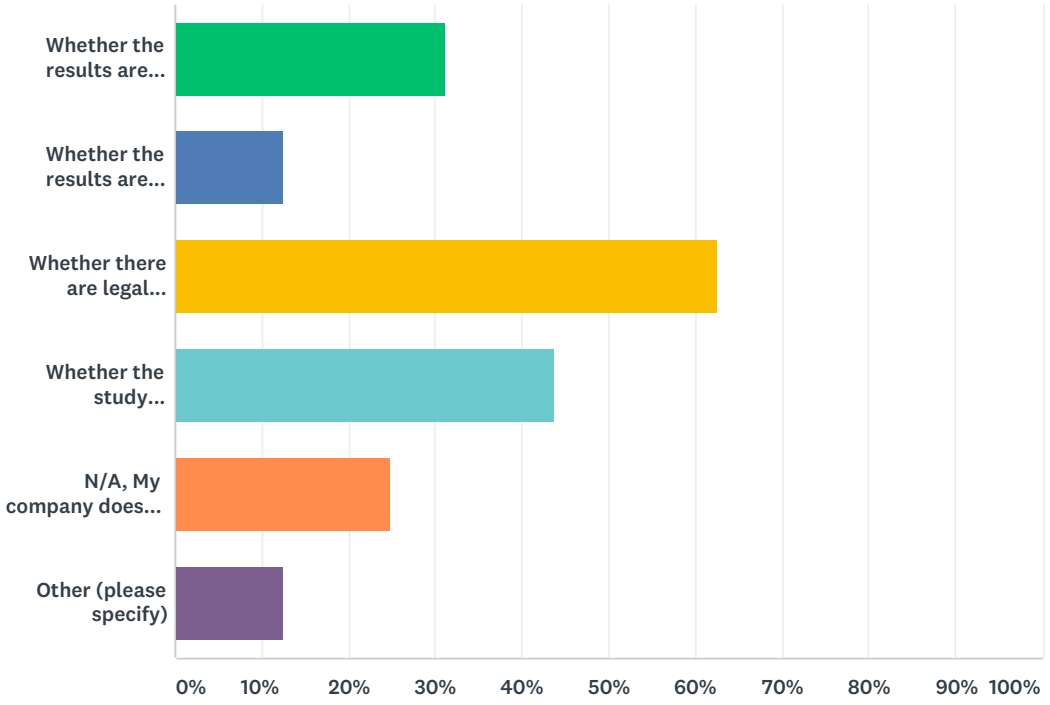


ANSWER CHOICES	RESPONSES	
2017 ICH-E18, which was also adopted by FDA	11.76%	2
2018 Revised Common Rule	5.88%	1
2018 FDA guidance on revised Common Rule	17.65%	3
2018 EU General Data Protection Regulation	41.18%	7
No regulations or guidances influenced my company's position	41.18%	7
Other (please specify)	29.41%	5
Total Respondents: 17		

#	OTHER (PLEASE SPECIFY)	DATE
1	NBAC, ACMG	12/6/2019 2:57 PM
2	Not applicable since we do not return results	11/20/2019 8:18 PM
3	Country specific laws (e.g., Denmark National Ethics Committee guidance on full genome mapping; Spain Biomedical Research Act etc)	11/12/2019 4:07 PM
4	Don't know	11/6/2019 9:18 PM
5	Increasing demand from some ECs/IRBs	11/5/2019 3:33 PM

Q6 What factors make a difference in your company's case-by-case decisions regarding whether to return individual genomic research results? (select all that apply)

Answered: 16 Skipped: 1

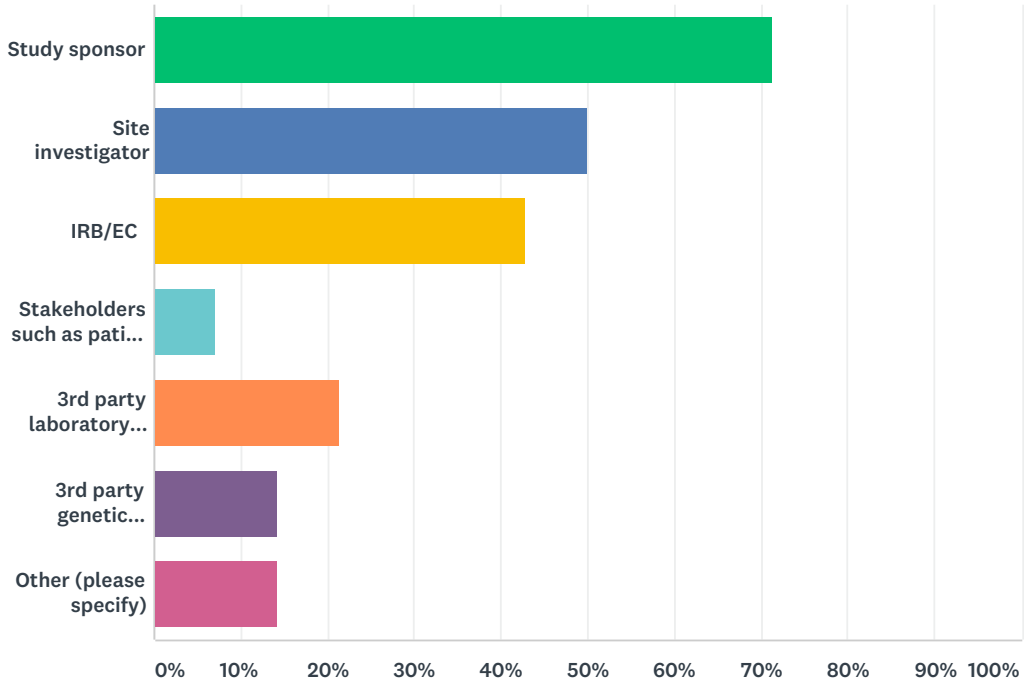


ANSWER CHOICES	RESPONSES	
Whether the results are appropriate for clinical decision-making	31.25%	5
Whether the results are those that were the focus of the research for which your company tested the biological samples	12.50%	2
Whether there are legal and/or regulatory requirements to return the results	62.50%	10
Whether the study participant initiated a request for the results	43.75%	7
N/A, My company does not support any return of individual genomic research results (SKIP TO QUESTION 20)	25.00%	4
Other (please specify)	12.50%	2
Total Respondents: 16		

#	OTHER (PLEASE SPECIFY)	DATE
1	The company doesn't decide the return of results, this is an interaction between the clinical trial participant and the Data Controller (3rd party).	12/6/2019 2:57 PM
2	Data is only returned on request (by patient)	11/14/2019 4:13 PM

Q7 Which parties are involved in your company's decision-making about whether, how, and/or which individual genomic research results to return? (select all that apply)

Answered: 14 Skipped: 3



ANSWER CHOICES	RESPONSES	
Study sponsor	71.43%	10
Site investigator	50.00%	7
IRB/EC	42.86%	6
Stakeholders such as patient advocacy groups	7.14%	1
3rd party laboratory generating the result	21.43%	3
3rd party genetic counselor not affiliated with the sponsor, analysis lab, or site investigator	14.29%	2
Other (please specify)	14.29%	2
Total Respondents: 14		

#	OTHER (PLEASE SPECIFY)	DATE
1	The study participant, i.e. sample donor, and the Data Controller. The company is not a party in this process.	12/6/2019 2:57 PM
2	N?A	11/14/2019 4:13 PM

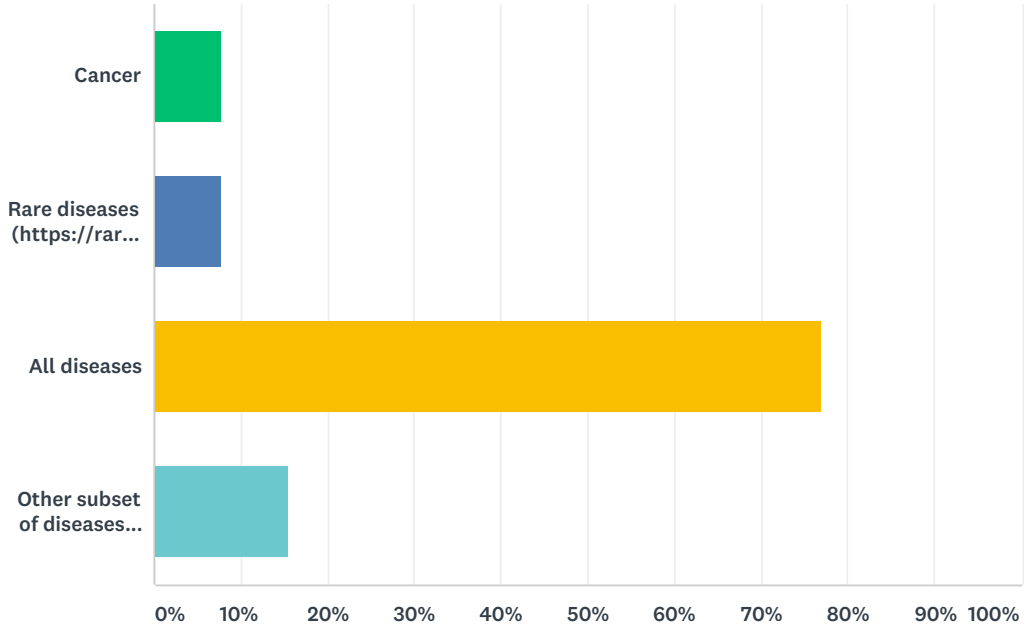
Q8 If you selected the answer "Study sponsor" in Q7 please specify the roles within the sponsor that are involved?

Answered: 9 Skipped: 8

#	RESPONSES	DATE
1	Not applicable	12/6/2019 2:57 PM
2	Human tissue network colleagues Legal HAs function	11/18/2019 4:03 PM
3	Medical director, legal, biomarker discovery, study management	11/16/2019 12:15 AM
4	Genetics/Genomics, Clinical Development head	11/12/2019 4:07 PM
5	Lab performing the test, trial's Clinician, Biomarker Representative on trial team, Biobank Custodian, Legal	11/12/2019 1:25 PM
6	legal and genomics laboratory	11/5/2019 5:33 PM
7	Clinical Study Director, Pharmacogenomics representative(s) from Translational Medicine, Bioethics committee	11/5/2019 3:45 PM
8	Legal department, Biomarker team, Ethics & Compliance team	11/5/2019 3:33 PM
9	study director, protocol manager, site management, informed consent SMEs, safety team as needed, legal, regulatory, biomarker scientists	11/5/2019 3:11 PM

Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)

Answered: 13 Skipped: 4

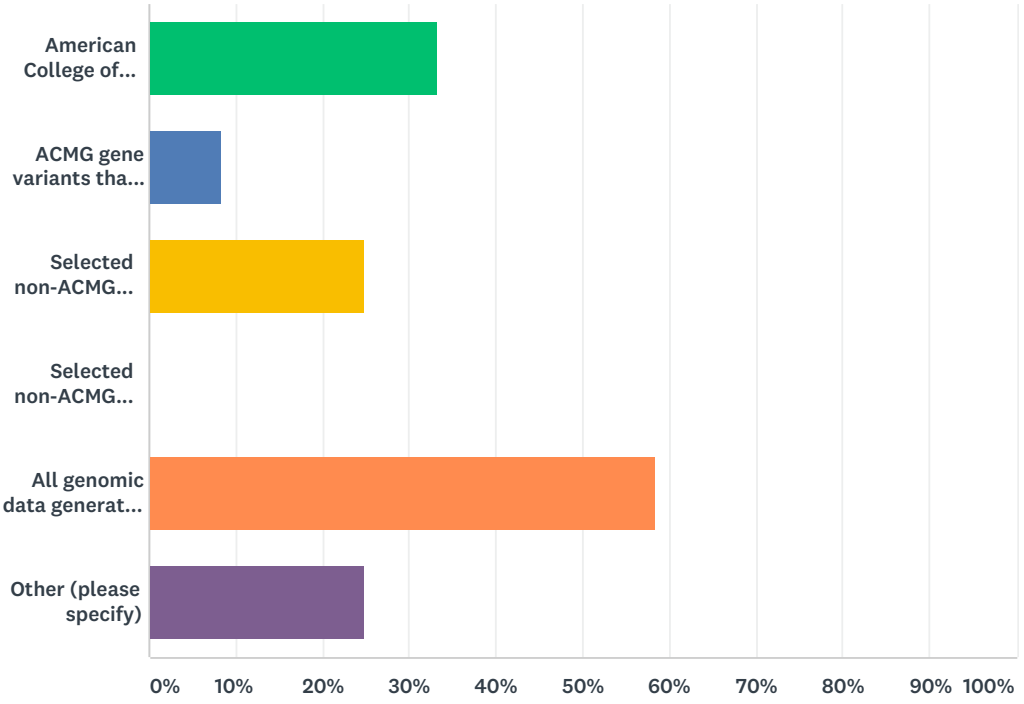


ANSWER CHOICES	RESPONSES	
Cancer	7.69%	1
Rare diseases (https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases)	7.69%	1
All diseases	76.92%	10
Other subset of diseases (please specify)	15.38%	2
Total Respondents: 13		

#	OTHER SUBSET OF DISEASES (PLEASE SPECIFY)	DATE
1	The scope is determined by the study participant (sample donor).	12/6/2019 2:57 PM
2	none, results not returned	11/5/2019 5:33 PM

Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)

Answered: 12 Skipped: 5

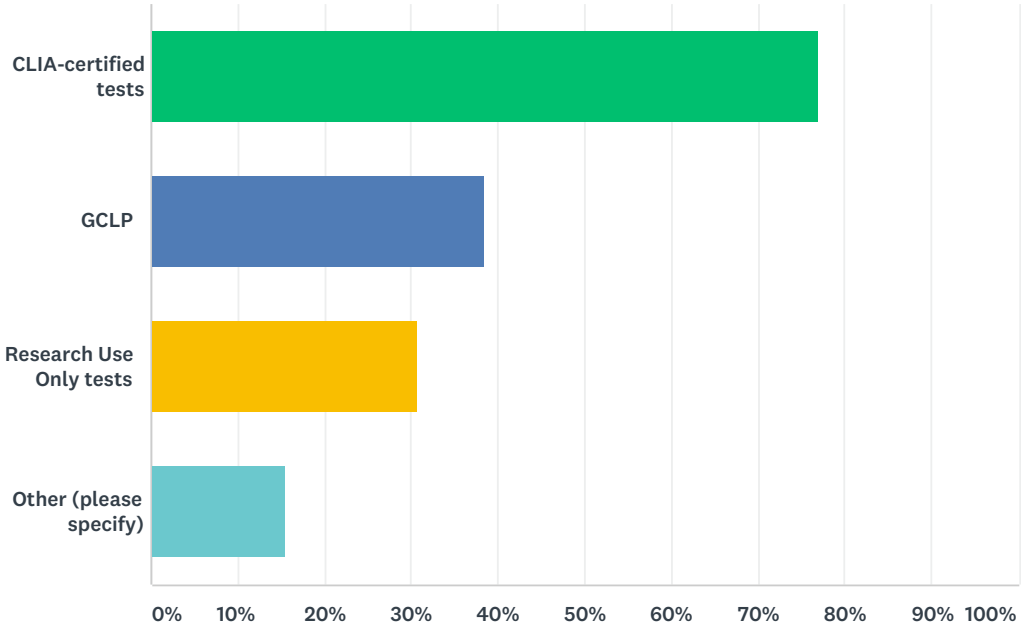


ANSWER CHOICES	RESPONSES	
American College of Medical Genetics (ACMG) gene variants that are the focus of the test	33.33%	4
ACMG gene variants that are included in the assay but are not the focus of the test	8.33%	1
Selected non-ACMG variants that are the focus of the test	25.00%	3
Selected non-ACMG variants that are included in the assay but are not the focus of the test	0.00%	0
All genomic data generated as part of a given test	58.33%	7
Other (please specify)	25.00%	3
Total Respondents: 12		

#	OTHER (PLEASE SPECIFY)	DATE
1	The data controller (honest broker) is responsible for the interaction with the sample donor.	12/6/2019 2:57 PM
2	As received from sequencing vendor and without any processing, analysis or interpretation.	11/14/2019 4:13 PM
3	All genomic data may be allowed typically depends on what is being asked to be returned. Decision to date is on case by case basis	11/5/2019 3:11 PM

Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)

Answered: 13 Skipped: 4

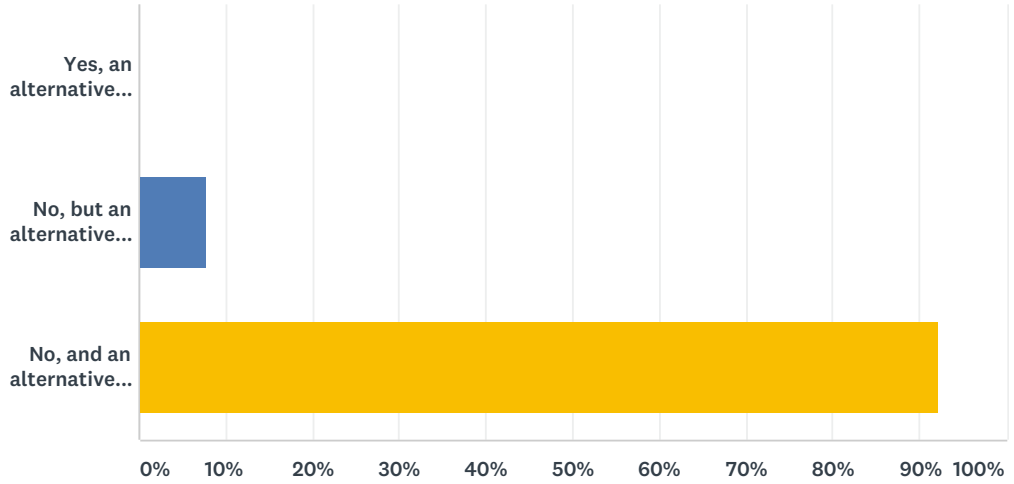


ANSWER CHOICES	RESPONSES	
CLIA-certified tests	76.92%	10
GCLP	38.46%	5
Research Use Only tests	30.77%	4
Other (please specify)	15.38%	2
Total Respondents: 13		

#	OTHER (PLEASE SPECIFY)	DATE
1	The WGS data are being generated by a vendor and deposited at the data controller (honest broker). The company accesses the data through a virtual space provided by the data controller.	12/6/2019 2:57 PM
2	N?A	11/14/2019 4:13 PM

Q12 Does your company use (or is development underway for) a qualified/validated process as an alternative to CLIA certification for use when individual genomic research results may be returned to study participants but a CLIA-certified test is not available?

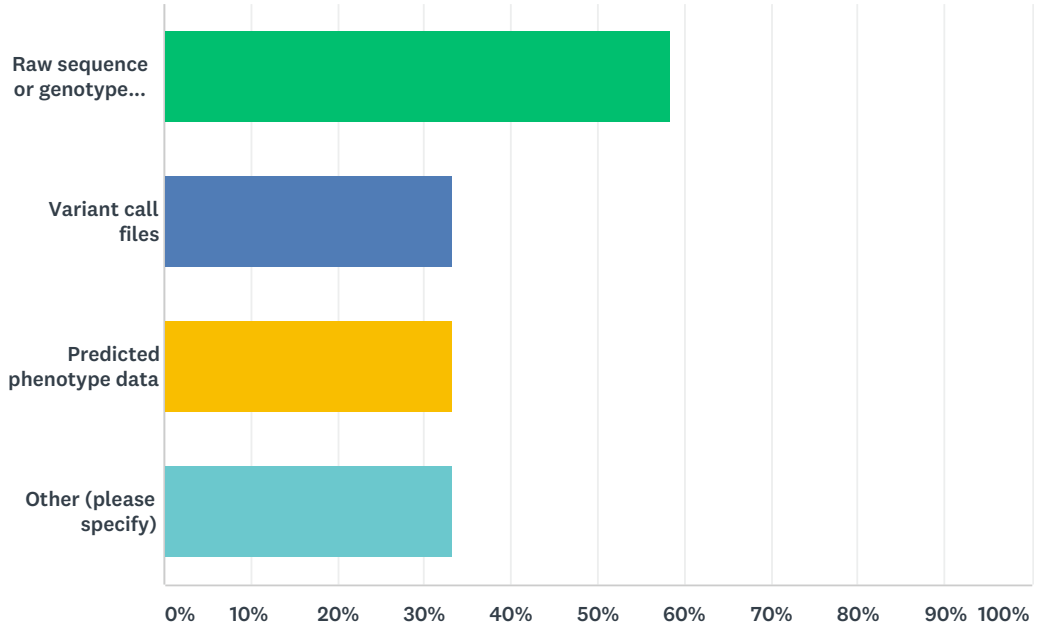
Answered: 13 Skipped: 4



ANSWER CHOICES	RESPONSES	
Yes, an alternative qualified/validated process is used	0.00%	0
No, but an alternative qualified/validated process is being developed	7.69%	1
No, and an alternative qualified/validated process is not in development	92.31%	12
TOTAL		13

Q13 What type of information is in scope at your company for return to participants? (select all that apply)

Answered: 12 Skipped: 5

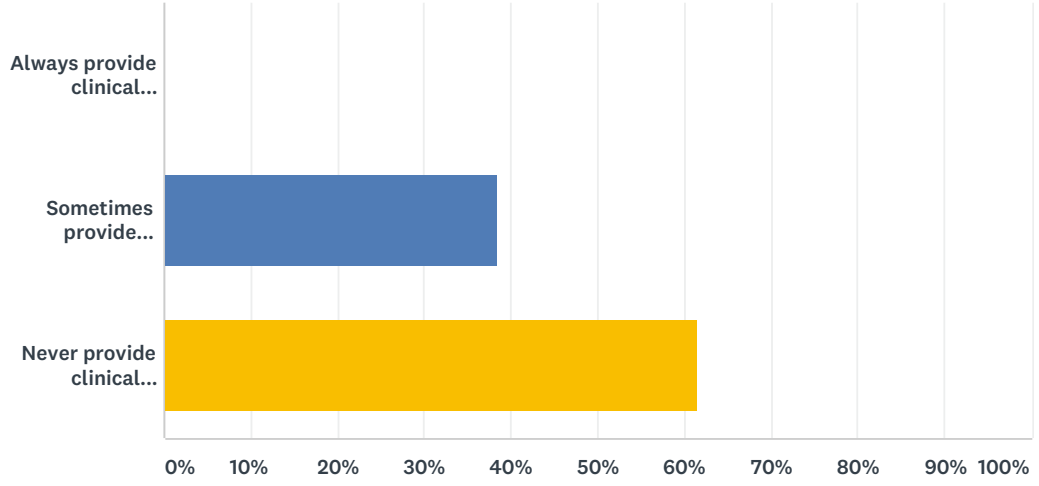


ANSWER CHOICES	RESPONSES	
Raw sequence or genotype data	58.33%	7
Variant call files	33.33%	4
Predicted phenotype data	33.33%	4
Other (please specify)	33.33%	4
Total Respondents: 12		

#	OTHER (PLEASE SPECIFY)	DATE
1	The scope is determined by the study participant and the Data Controller. Any of the three options may apply.	12/6/2019 2:57 PM
2	managed per patient/investigator request	11/19/2019 9:37 PM
3	Single SNP	11/12/2019 4:07 PM
4	All in scope but decisions are made on case by case basis.	11/5/2019 3:11 PM

Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?

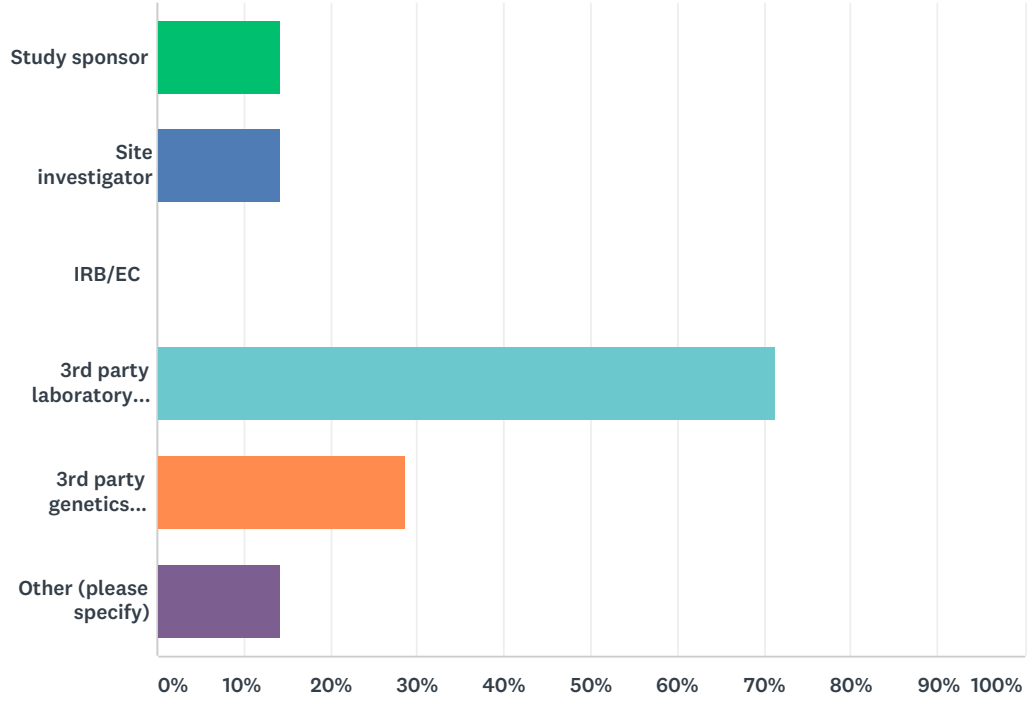
Answered: 13 Skipped: 4



ANSWER CHOICES	RESPONSES	
Always provide clinical annotation/interpretation	0.00%	0
Sometimes provide clinical annotation/interpretation	38.46%	5
Never provide clinical annotation/interpretation (SKIP TO QUESTION 17)	61.54%	8
TOTAL		13

Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)

Answered: 7 Skipped: 10



ANSWER CHOICES	RESPONSES	
Study sponsor	14.29%	1
Site investigator	14.29%	1
IRB/EC	0.00%	0
3rd party laboratory generating the result	71.43%	5
3rd party genetics counselor not affiliated with the sponsor, analysis lab, or site investigator	28.57%	2
Other (please specify)	14.29%	1
Total Respondents: 7		

#	OTHER (PLEASE SPECIFY)	DATE
1	As outlined, the Data Controller (3rd party) is the party that interacts with the study participant.	12/6/2019 2:57 PM

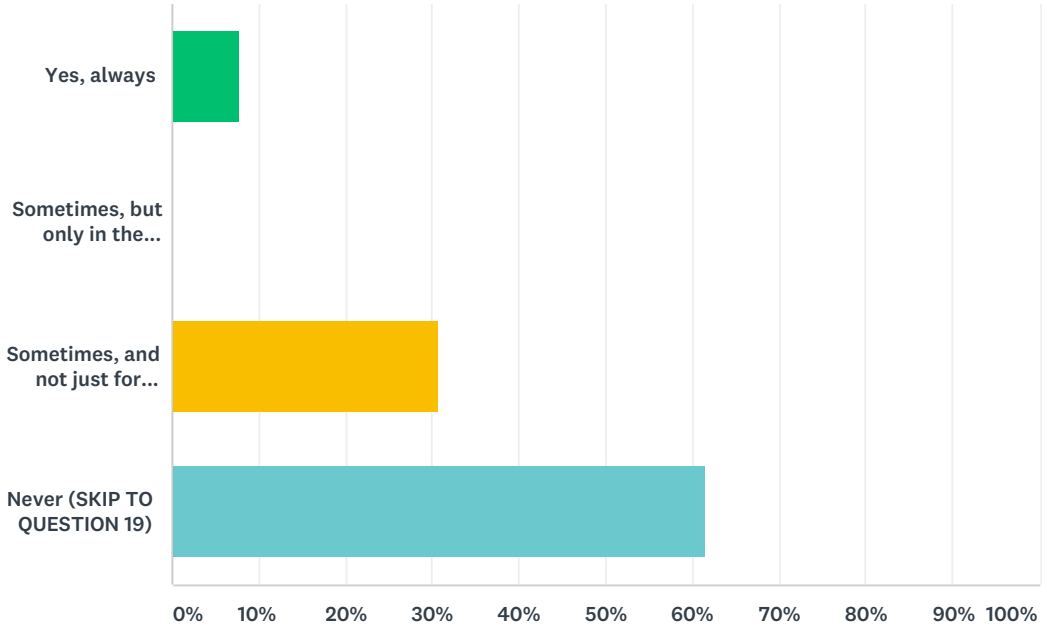
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?

Answered: 2 Skipped: 15

#	RESPONSES	DATE
1	Study Director, Translational Medicine, Clinical Scientist	11/5/2019 3:45 PM
2	na	10/31/2019 8:12 PM

Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?

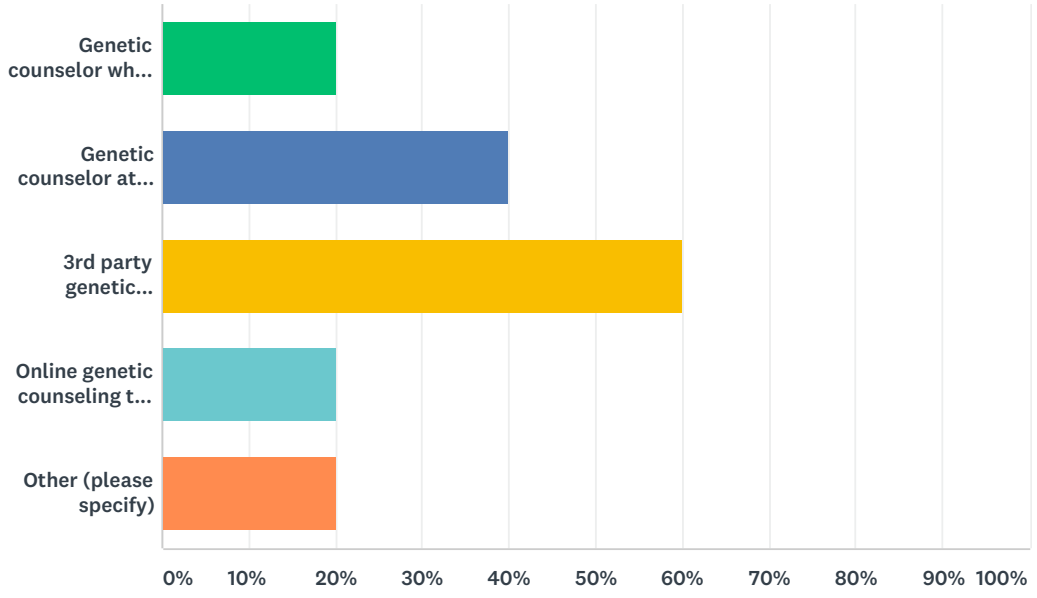
Answered: 13 Skipped: 4



ANSWER CHOICES	RESPONSES	
Yes, always	7.69%	1
Sometimes, but only in the case of ACMG variants	0.00%	0
Sometimes, and not just for ACMG variants	30.77%	4
Never (SKIP TO QUESTION 19)	61.54%	8
TOTAL		13

Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)

Answered: 5 Skipped: 12

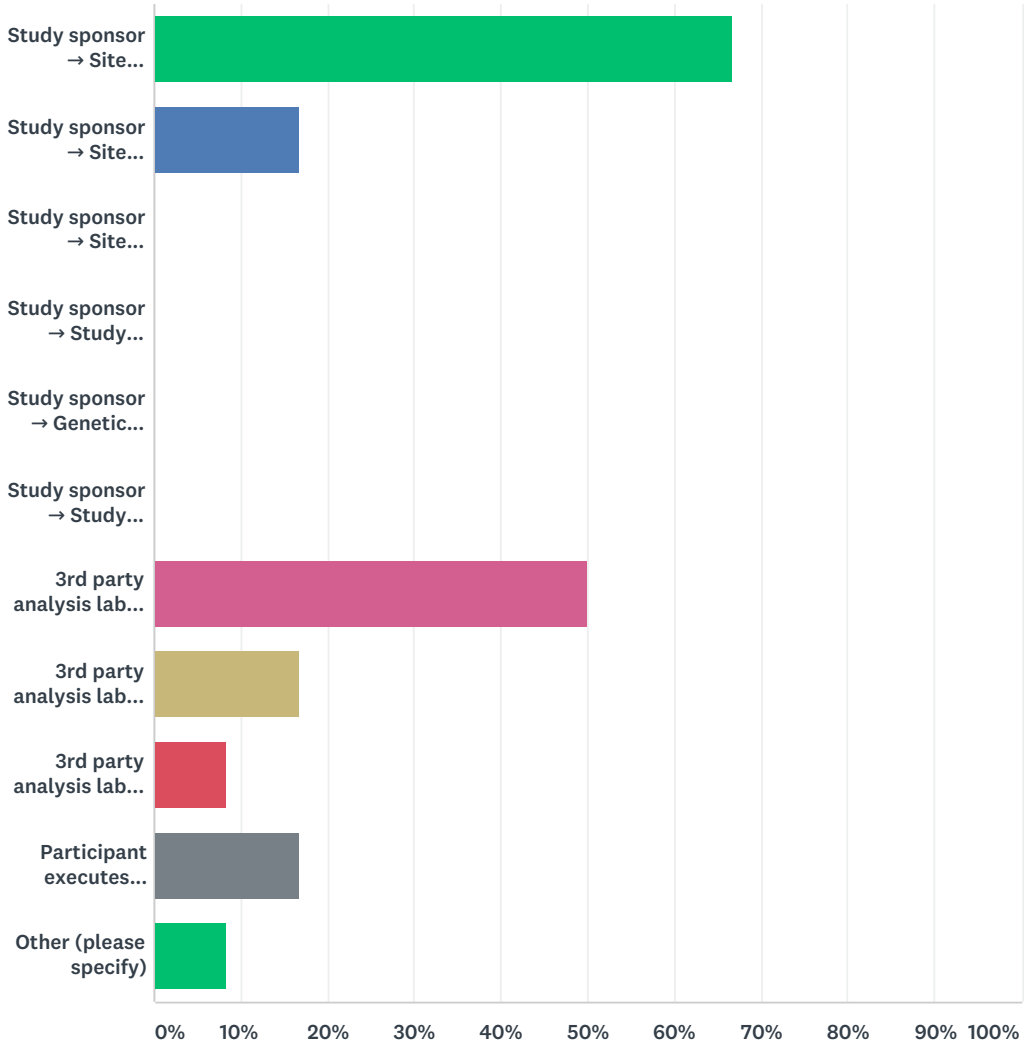


ANSWER CHOICES	RESPONSES	
Genetic counselor who is part of the clinical trial team at the research site	20.00%	1
Genetic counselor at the research institute who is not a member of the clinical trial team	40.00%	2
3rd party genetic counseling service outside the research institute	60.00%	3
Online genetic counseling tool	20.00%	1
Other (please specify)	20.00%	1
Total Respondents: 5		

#	OTHER (PLEASE SPECIFY)	DATE
1	The Data Controller (3rd party) provides the service and interacts directly with the study participant. The company is not part of this process.	12/6/2019 2:57 PM

Q19 What is your company's process for returning results? (select all that apply)

Answered: 12 Skipped: 5



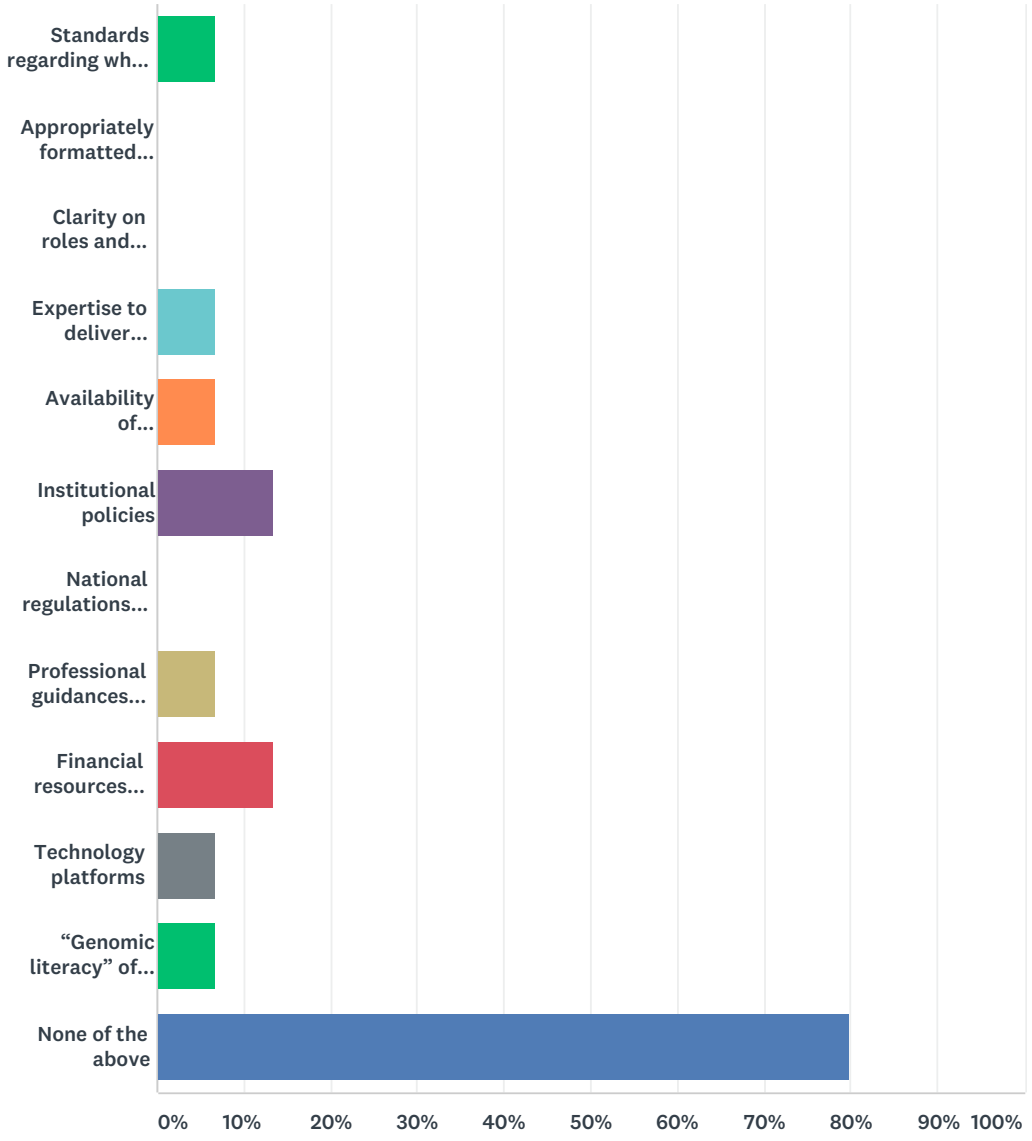
ANSWER CHOICES	RESPONSES	
Study sponsor → Site investigator → Study participant	66.67%	8
Study sponsor → Site investigator → Genetic counselor → Study participant	16.67%	2
Study sponsor → Site investigator → Study participant's Primary Care Provider → Study participant	0.00%	0
Study sponsor → Study participant	0.00%	0
Study sponsor → Genetic counselor → Study participant	0.00%	0
Study sponsor → Study participant's Primary Care Provider → Study participant	0.00%	0
3rd party analysis lab → Site investigator → Study participant	50.00%	6
3rd party analysis lab → Genetic counselor → Study participant	16.67%	2
3rd party analysis lab → Study participant's Primary Care Provider → Study participant	8.33%	1

Participant executes self-service access via a portal	16.67%	2
Other (please specify)	8.33%	1
Total Respondents: 12		

#	OTHER (PLEASE SPECIFY)	DATE
1	Process as yet unmapped (no requests to date)	11/14/2019 4:13 PM

Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:

Answered: 15 Skipped: 2

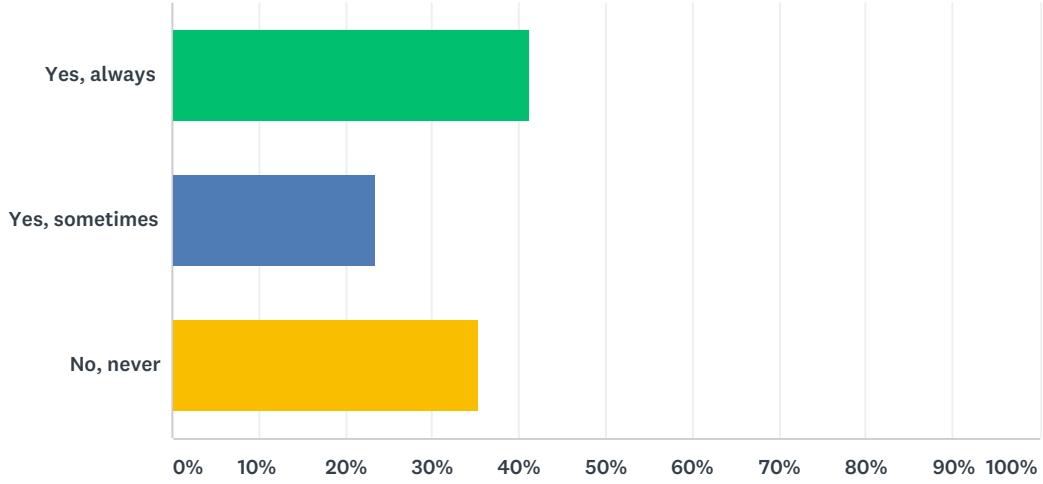


ANSWER CHOICES	RESPONSES	
Standards regarding which test results to return	6.67%	1
Appropriately formatted reports	0.00%	0
Clarity on roles and responsibilities	0.00%	0
Expertise to deliver results	6.67%	1
Availability of support/follow up services (e.g. genetic counseling)	6.67%	1
Institutional policies	13.33%	2
National regulations	0.00%	0

Professional guidances	6.67%	1
Financial resources	13.33%	2
Technology platforms	6.67%	1
“Genomic literacy” of participants	6.67%	1
None of the above	80.00%	12
Total Respondents: 15		

Q21 Regardless of whether or not individual genomic research results will be returned, does your company include the topic of individual results return in its study protocols?

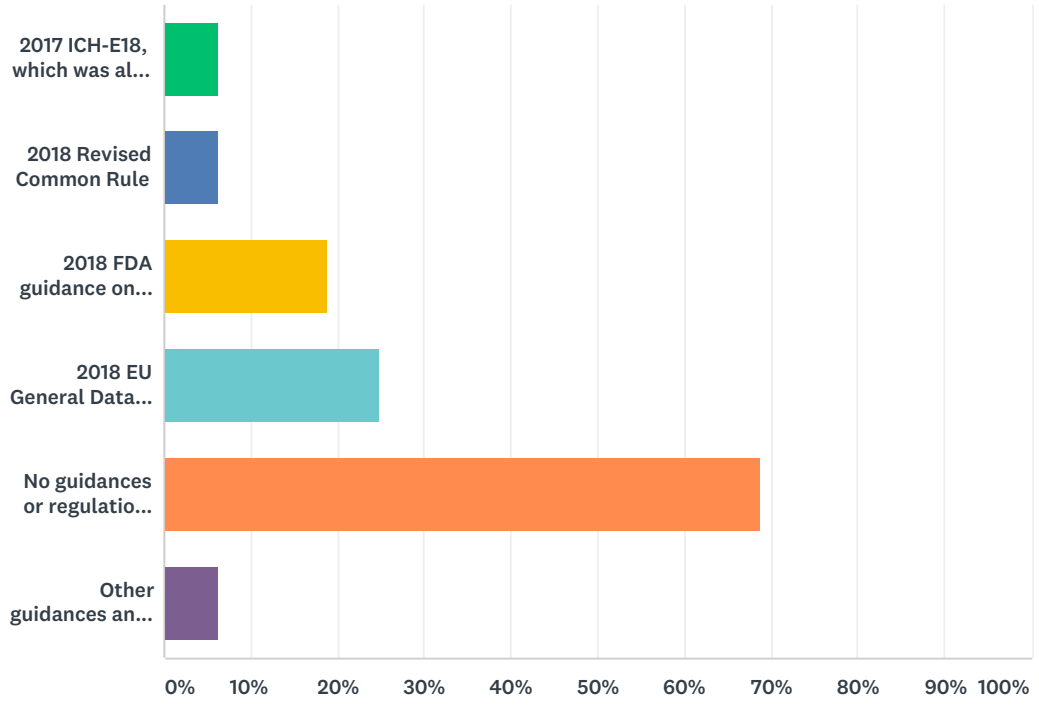
Answered: 17 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes, always	41.18%	7
Yes, sometimes	23.53%	4
No, never	35.29%	6
TOTAL		17

Q22 Which of the following influenced your company's practice regarding discussing the return of individual genomic research results in the study protocol? (select all that apply)

Answered: 16 Skipped: 1

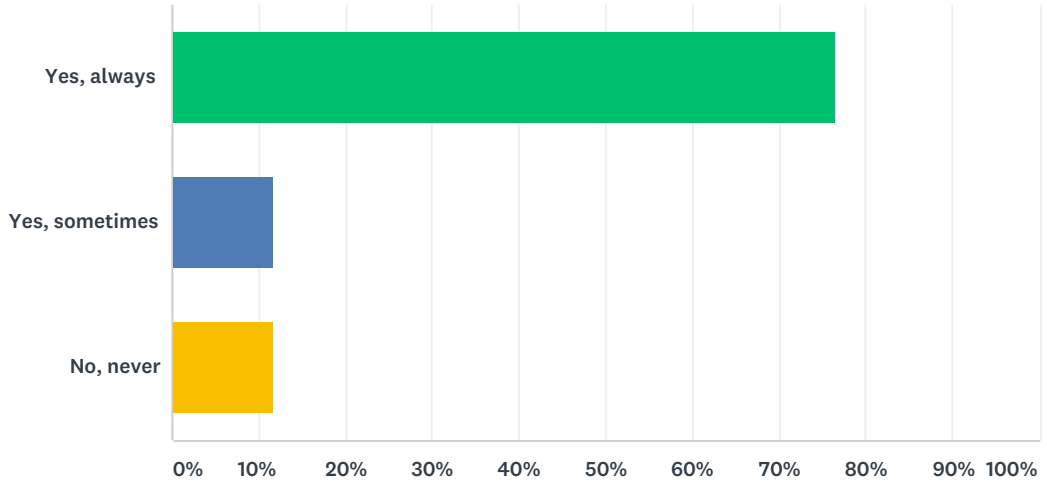


ANSWER CHOICES	RESPONSES	
2017 ICH-E18, which was also adopted by FDA	6.25%	1
2018 Revised Common Rule	6.25%	1
2018 FDA guidance on revised Common Rule	18.75%	3
2018 EU General Data Protection Regulation	25.00%	4
No guidances or regulations influenced it	68.75%	11
Other guidances and regulations (please specify)	6.25%	1
Total Respondents: 16		

#	OTHER GUIDANCES AND REGULATIONS (PLEASE SPECIFY)	DATE
1	NBAC, ACMG	12/6/2019 2:57 PM

Q23 Regardless of whether or not individual genomic research results will be returned, does your company include the topic of individual results return in its study informed consent documents?

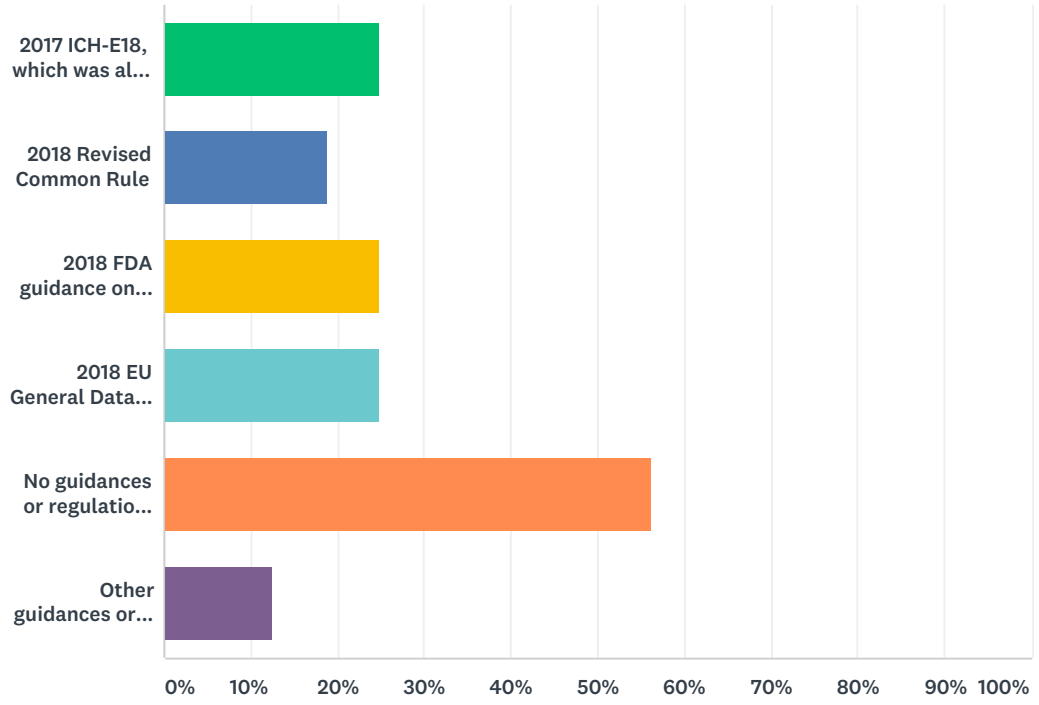
Answered: 17 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes, always	76.47%	13
Yes, sometimes	11.76%	2
No, never	11.76%	2
TOTAL		17

Q24 Which of the following influenced your company's practice or approach for discussing the return of individual genomic research results in the informed consent document? (select all that apply)

Answered: 16 Skipped: 1

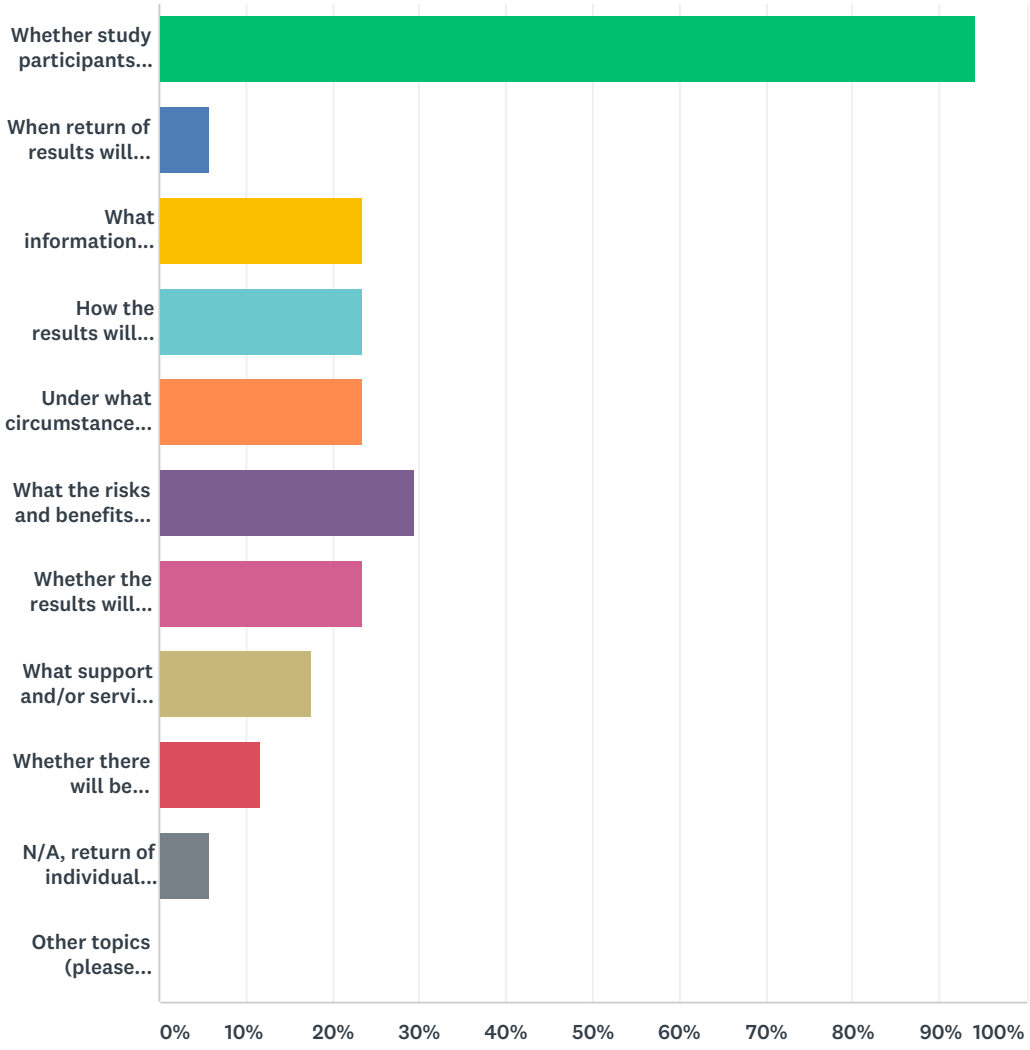


ANSWER CHOICES	RESPONSES	
2017 ICH-E18, which was also adopted by FDA	25.00%	4
2018 Revised Common Rule	18.75%	3
2018 FDA guidance on revised Common Rule	25.00%	4
2018 EU General Data Protection Regulation	25.00%	4
No guidances or regulations influenced it	56.25%	9
Other guidances or regulations (please specify)	12.50%	2
Total Respondents: 16		

#	OTHER GUIDANCES OR REGULATIONS (PLEASE SPECIFY)	DATE
1	Relevant wording in place before these recent guidance. I-PWG publication on ICF elements is relevant.	11/16/2019 12:15 AM
2	MRCT IRR Guidelines; NASEM Report	11/12/2019 1:25 PM

Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)

Answered: 17 Skipped: 0



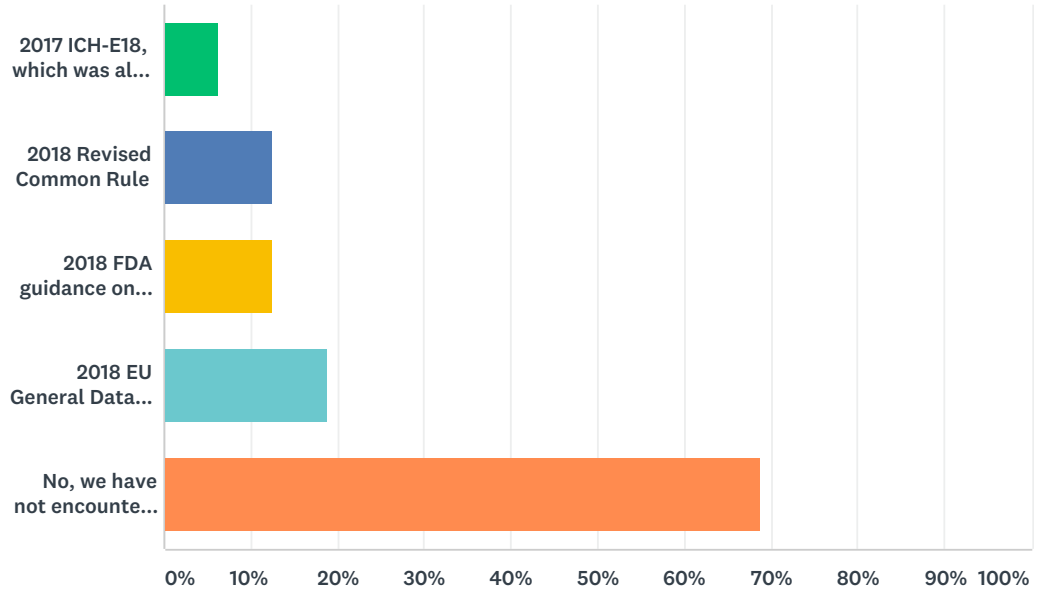
ANSWER CHOICES	RESPONSES	
Whether study participants will receive individual results of tests performed on their biological samples	94.12%	16
When return of results will occur in relation to the lifecycle of the study	5.88%	1
What information will be shared	23.53%	4
How the results will be communicated	23.53%	4
Under what circumstances will results be communicated	23.53%	4
What the risks and benefits of receiving the results are	29.41%	5
Whether the results will go to the participant's primary care provider or into their medical record	23.53%	4
What support and/or services will be provided	17.65%	3

Whether there will be re-contact in the future (e.g. if new tests are performed after the study is over or if the interpretation of a previous test result changes)	11.76%	2
N/A, return of individual genomic research results is never discussed in my company's informed consent documents	5.88%	1
Other topics (please specify)	0.00%	0
Total Respondents: 17		

#	OTHER TOPICS (PLEASE SPECIFY)	DATE
	There are no responses.	

Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?

Answered: 16 Skipped: 1



ANSWER CHOICES	RESPONSES	
2017 ICH-E18, which was also adopted by FDA	6.25%	1
2018 Revised Common Rule	12.50%	2
2018 FDA guidance on revised Common Rule	12.50%	2
2018 EU General Data Protection Regulation	18.75%	3
No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)	68.75%	11
Total Respondents: 16		

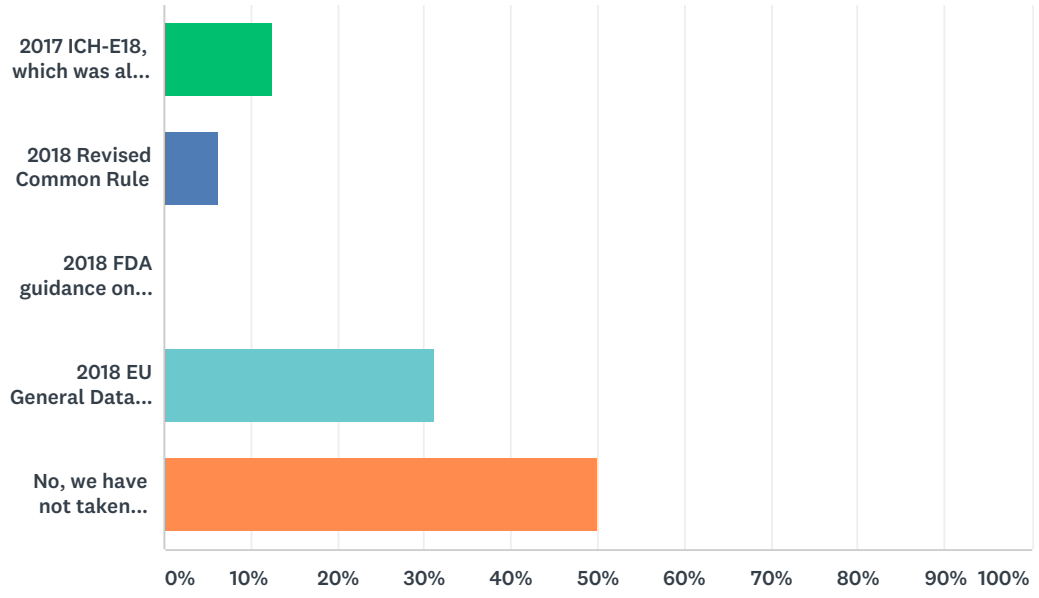
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):

Answered: 4 Skipped: 13

#	RESPONSES	DATE
1	We are in the process of rolling this out, so some answers are admittedly 'aspirational' as we haven't had the very broad exposure in many countries yet.	12/6/2019 2:57 PM
2	It is not clear when to share (CLIA and alike only?) and how to do it with making results clear to patients. Site investigators not always trained to understand results and so are PCPs.	11/18/2019 4:03 PM
3	Sites who want to comply with revised common rule are adding statement about WGS to the ICF, which may trigger inquiries on whether/how to share incidental findings of individual genomic research results.	11/16/2019 12:15 AM
4	na	10/31/2019 8:12 PM

Q28 Are there particular measures your company has taken that have proven effective for complying with the following regulations/guidances in relation to returning individual genomic research results? Select all regulations/guidances for which your company has taken measures to comply:

Answered: 16 Skipped: 1



ANSWER CHOICES	RESPONSES	
2017 ICH-E18, which was also adopted by FDA	12.50%	2
2018 Revised Common Rule	6.25%	1
2018 FDA guidance on revised Common Rule	0.00%	0
2018 EU General Data Protection Regulation	31.25%	5
No, we have not taken measures to comply with any of these regulations/guidances in relation to returning individual genomic research results. (SKIP TO QUESTION 30)”	50.00%	8
TOTAL		16

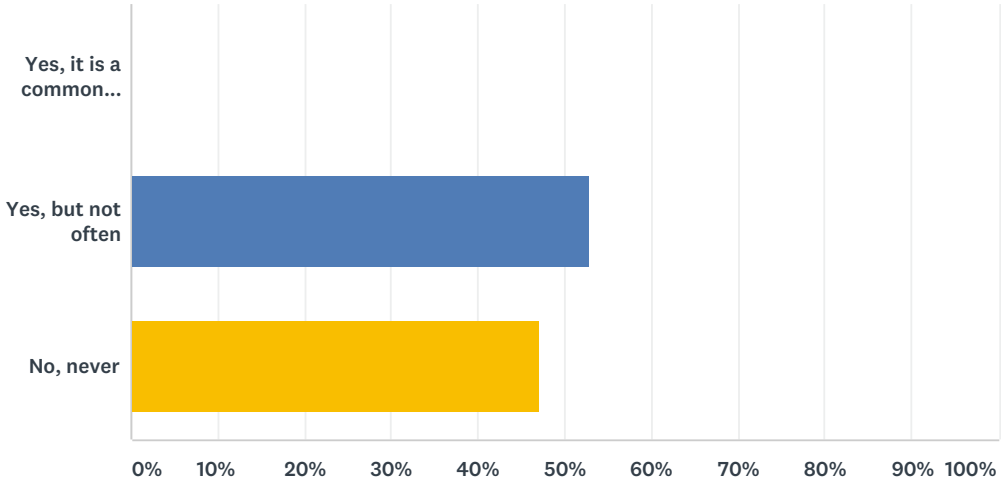
Q29 If you selected "Yes" to any of the options listed in Q28 please provide further information to explain your answer:

Answered: 9 Skipped: 8

#	RESPONSES	DATE
1	We believe that the process where the 'honest broker' (and not the company) is the Data Controller will be appealing to regulators and study subjects.	12/6/2019 2:57 PM
2	Inform patients in informed consent form of non-return of genomic results	11/20/2019 8:18 PM
3	We started pilots with third party's that provide a return of results service and also serve as the external vendor for generating the genomics data.	11/18/2019 4:03 PM
4	We have limited experience trying to accommodate WGS statement per revised common rule. We are handling data return inquiries on a case-by-case basis. Can't say it's proven effective yet.	11/16/2019 12:15 AM
5	Updated MICF language	11/14/2019 4:13 PM
6	Process to track and manage individual data requests per EU GDPR requirements.	11/12/2019 4:07 PM
7	Addressed in our ICF as well as considered in discussions with EU-based CROs.	11/6/2019 9:18 PM
8	Revision of the return of result text in the template ICF Implementation of a specific process to address any subject's request	11/5/2019 3:33 PM
9	na	10/31/2019 8:12 PM

Q30 Has your company actually returned individual genomic research results to clinical trial participants?

Answered: 17 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes, it is a common occurrence	0.00%	0
Yes, but not often	52.94%	9
No, never	47.06%	8
TOTAL		17

Q31 Do you have any additional comments that you think would be useful to include in this survey:

Answered: 9 Skipped: 8

#	RESPONSES	DATE
1	As mentioned previously, the company is in the process of finalizing this policy and will roll this out in 2020.	12/6/2019 2:57 PM
2	Requests for return of results have been very rare	11/19/2019 9:37 PM
3	These recent guidance documents are prompting sponsors to be more forthcoming about data return. As the general public becomes more educated on precision medicine and genetic counseling becomes more readily available, industry may need to return more data.	11/16/2019 12:15 AM
4	These responses reflect only the experience of the Centre for Genomics Research and not AstraZenca as a whole; which includes the parts of the company which might be responsible for returning results from mandatory genetic, or study specific genetic analysis. This is because information from these functions was not available to the survey respondent.	11/14/2019 4:13 PM
5	We are primarily returning results in oncology but not other TAs, unless it's intrinsic to the design of the study (i.e., genomic marker being used for enrollment).	11/12/2019 4:07 PM
6	Q.9: Predominantly cancer, but if required by law to return ADME results for studies in other diseases then return is possible. Q.17: Site may choose to use a genetic counselor, but if this occurs Sponsor it is independent of Sponsor (e.g. Sponsor is not involved in setting this up or even in reviewing or evaluating site's internal process for returning results).	11/12/2019 1:25 PM
7	too generic a questionnaire - a lot of the answers differ depending on the test, indication and what it'll be used for.	11/5/2019 5:22 PM
8	Default in the US has been to only permit return of results from CLIA certified testing, but return of non-CLIA research results are being considered based on common rule and national academies recommedations	11/5/2019 3:45 PM
9	no	10/31/2019 8:12 PM

Q32 Please enter your unique indiviual survey code that has been given to you by Julian Arbuckle:

Answered: 14 Skipped: 3

#	RESPONSES	DATE
1	2276	12/6/2019 2:57 PM
2	8354	11/19/2019 9:37 PM
3	2088	11/18/2019 9:57 PM
4	1744	11/18/2019 4:03 PM
5	4099	11/16/2019 12:15 AM
6	1927	11/14/2019 8:09 PM
7	2999	11/14/2019 4:13 PM
8	2910	11/12/2019 4:07 PM
9	2772	11/12/2019 1:25 PM
10	7507	11/6/2019 9:18 PM
11	3309	11/5/2019 5:22 PM
12	7333	11/5/2019 3:45 PM
13	3444	11/5/2019 3:33 PM
14	9901	11/5/2019 3:11 PM