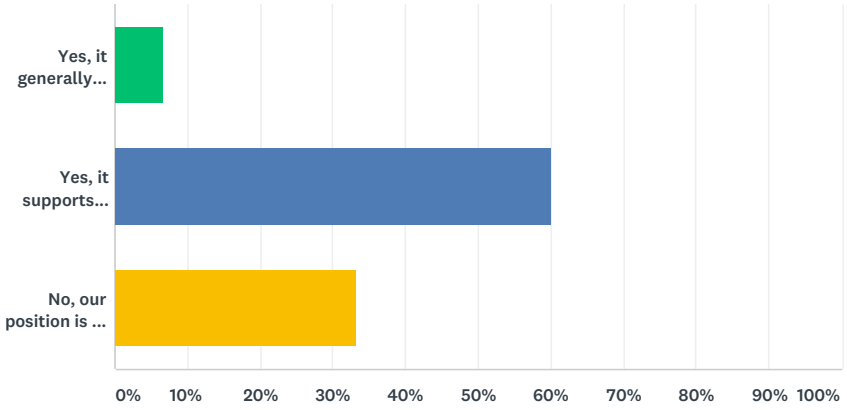
Q1 Does your company's current stance allow for the return of any individual genomic research results?

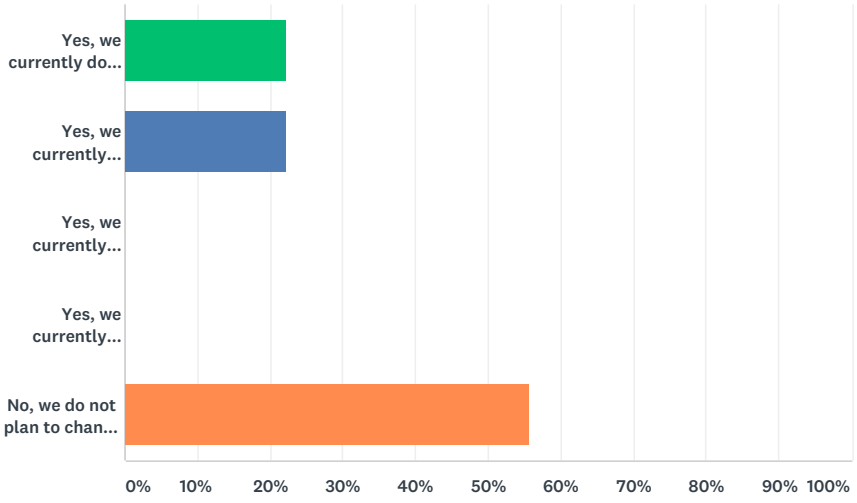
Answered: 15 Skipped: 3



ANSWER CHOICES	RESPONSES	
Yes, it generally supports returning results	6.67%	1
Yes, it supports returning results but only in limited circumstances	60.00%	9
No, our position is to not return results under any circumstances	33.33%	5
TOTAL		15

Q2 Does your company plan to change its current stance?

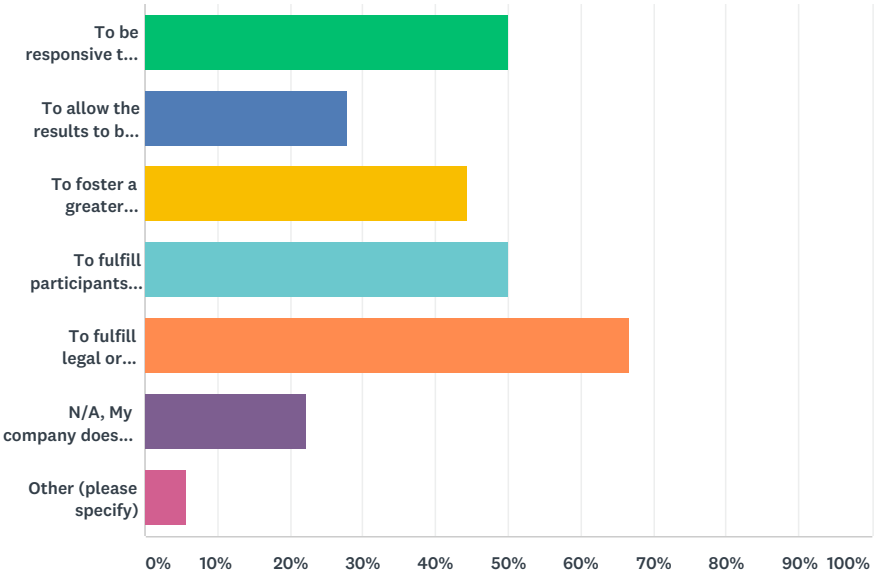
Answered: 18 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes, we currently do not return and we plan to transition to returning results	22.22%	4
Yes, we currently return results and we plan to transition to returning significantly more results than we currently do	22.22%	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	55.56%	10
TOTAL		18

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

Answered: 18 Skipped: 0

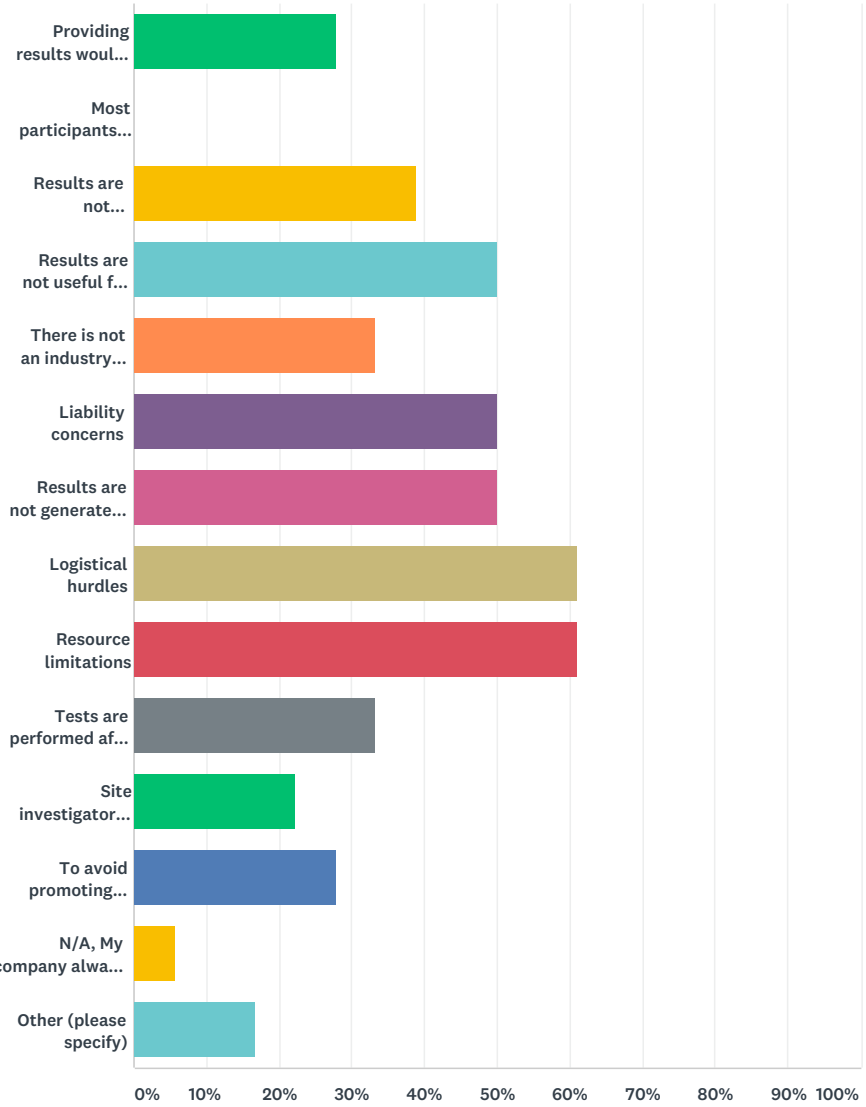


ANSWER CHOICES	RESPONSES	
To be responsive to participants' desire to receive their results	50.00%	9
To allow the results to be incorporated into the management of the study participant's health	27.78%	5
To foster a greater partnership and/or transparency in the relationship between my company and study participants	44.44%	8
To fulfill participants' right to receive data generated from their biological samples	50.00%	9
To fulfill legal or regulatory obligations to return the results	66.67%	12
N/A, My company does not support any return of individual genomic research results	22.22%	4
Other (please specify)	5.56%	1
Total Respondents: 18		

#	OTHER (PLEASE SPECIFY)	DATE
1	I want to make clear that the position pertains to return of data to the patient, not results in the sense of a report,	10/31/2019 2:52 PM

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: 18 Skipped: 0



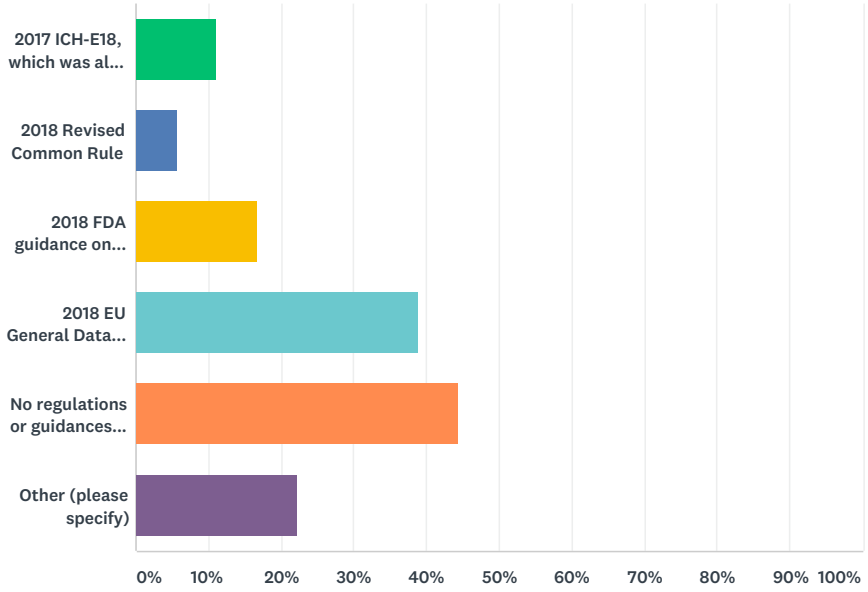
ANSWER CHOICES	RESPONSES	
Providing results would compromise the integrity of the clinical trial	27.78%	5
Most participants are not interested in receiving them	0.00%	0
Results are not interpretable at the individual level	38.89%	7
Results are not useful for clinical decision-making	50.00%	9
There is not an industry standard to return results	33.33%	6
Liability concerns	50.00%	9
Results are not generated in a CLIA-certified laboratory setting	50.00%	9
Logistical hurdles	61.11%	11
Resource limitations	61.11%	11
Tests are performed after they would be of value to study participants and/or after the participants’ last study visit	33.33%	6

Site investigators are not comfortable conveying results to participants	22.22%	4
To avoid promoting therapeutic misconception (participant may conflate the purpose of research with that of clinical care)	27.78%	5
N/A, My company always returns individual genomic research results	5.56%	1
Other (please specify)	16.67%	3
Total Respondents: 18		

#	OTHER (PLEASE SPECIFY)	DATE
1	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
2	To protect subject confidentiality	11/6/2019 9:18 PM
3	The company's position is that genomic data will be returned, not a report detailing interpreted results.	10/31/2019 2:52 PM

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

Answered: 18 Skipped: 0

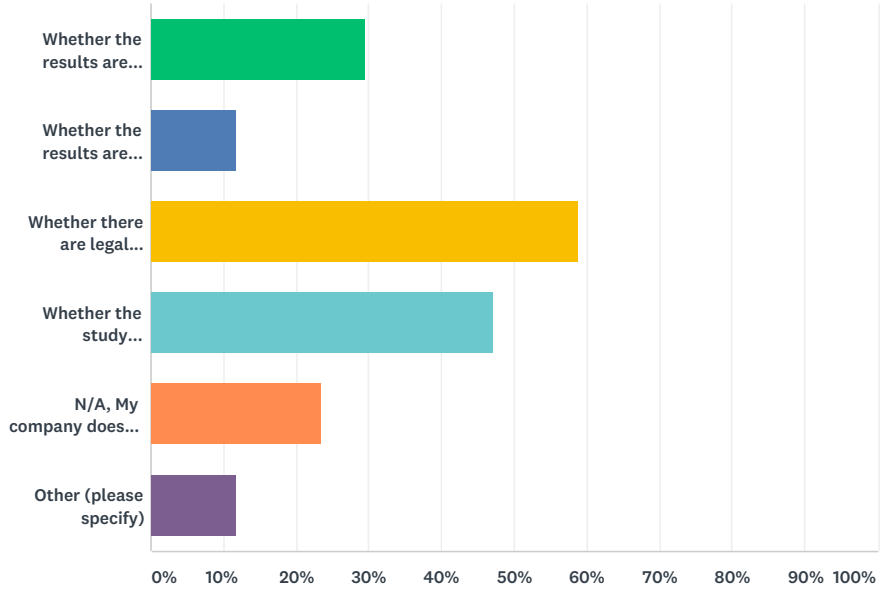


ANSWER CHOICES	RESPONSES	
2017 ICH-E18, which was also adopted by FDA	11.11%	2
2018 Revised Common Rule	5.56%	1
2018 FDA guidance on revised Common Rule	16.67%	3
2018 EU General Data Protection Regulation	38.89%	7
No regulations or guidances influenced my company's position	44.44%	8
Other (please specify)	22.22%	4
Total Respondents: 18		

#	OTHER (PLEASE SPECIFY)	DATE
1	Not applicable since we do not return results	11/20/2019 8:18 PM
2	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
3	Don't know	11/6/2019 9:18 PM
4	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: 17 Skipped: 1

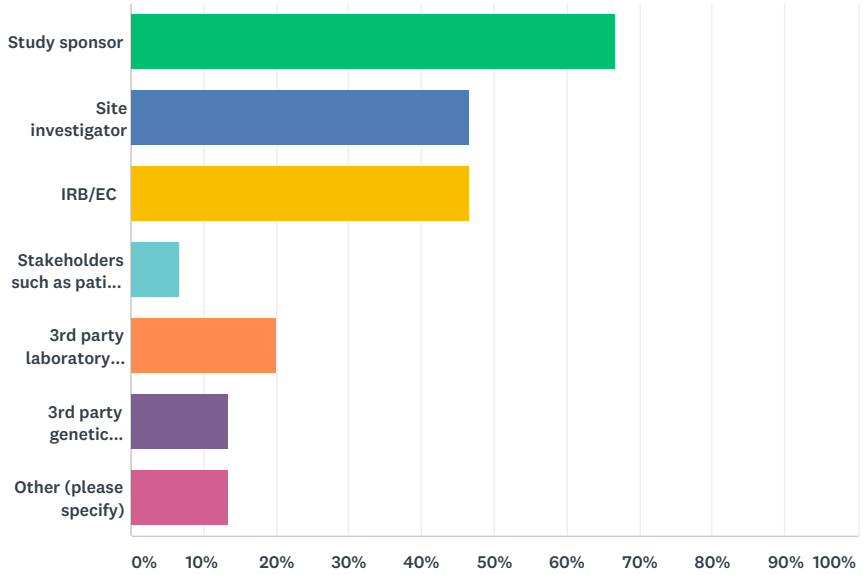


ANSWER CHOICES	RESPONSES	
Whether the results are appropriate for clinical decision-making	29.41%	5
Whether the results are those that were the focus of the research for which your company tested the biological samples	11.76%	2
Whether there are legal and/or regulatory requirements to return the results	58.82%	10
Whether the study participant initiated a request for the results	47.06%	8
N/A, My company does not support any return of individual genomic research results (SKIP TO QUESTION 20)	23.53%	4
Other (please specify)	11.76%	2
Total Respondents: 17		

#	OTHER (PLEASE SPECIFY)	DATE
1	Data is only returned on request (by patient)	11/14/2019 4:13 PM
2	Data will be returned, ie deposited at a third party (data controller)	10/31/2019 2:52 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: 15 Skipped: 3



ANSWER CHOICES	RESPONSES	
Study sponsor	66.67%	10
Site investigator	46.67%	7
IRB/EC	46.67%	7
Stakeholders such as patient advocacy groups	6.67%	1
3rd party laboratory generating the result	20.00%	3
3rd party genetic counselor not affiliated with the sponsor, analysis lab, or site investigator	13.33%	2
Other (please specify)	13.33%	2
Total Respondents: 15		

#	OTHER (PLEASE SPECIFY)	DATE
1	N?A	11/14/2019 4:13 PM
2	The third party vendor or 'honest broker' serves as data controller and has the relationship with the sample donor, i.e. the subject can submit a request for analysis of the data deposited at the 'honest broker'. The company is not involved in this process.	10/31/2019 2:52 PM

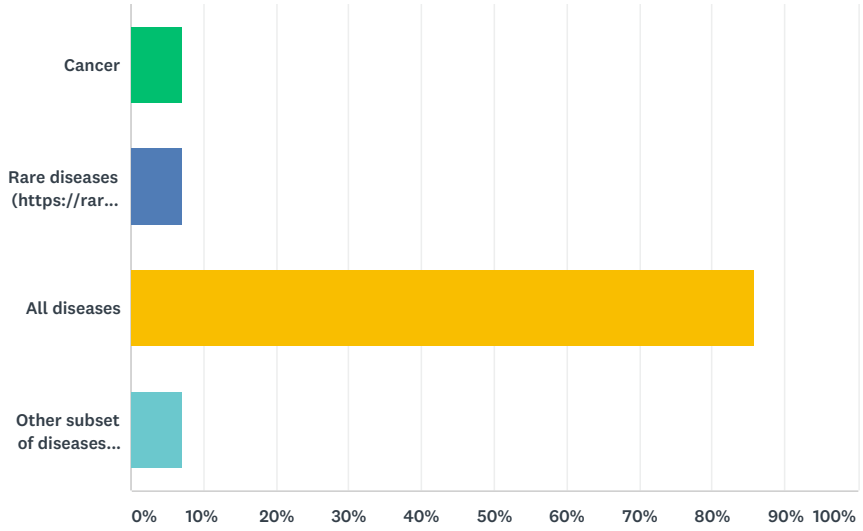
Q8 If you selected the answer "Study sponsor" in Q7 please specify the roles within the sponsor that are involved?

Answered: 8 Skipped: 10

#	RESPONSES	DATE
1	Human tissue network colleagues Legal HAs function	11/18/2019 4:03 PM
2	Medical director, legal, biomarker discovery, study management	11/16/2019 12:15 AM
3	Genetics/Genomics, Clinical Development head	11/12/2019 4:07 PM
4	Lab performing the test, trial's Clinician, Biomarker Representative on trial team, Biobank Custodian, Legal	11/12/2019 1:25 PM
5	legal and genomics laboratory	11/5/2019 5:33 PM
6	Clinical Study Director, Pharmacogenomics representative(s) from Translational Medicine, Bioethics committee	11/5/2019 3:45 PM
7	Legal department, Biomarker team, Ethics & Compliance team	11/5/2019 3:33 PM
8	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: 14 Skipped: 4

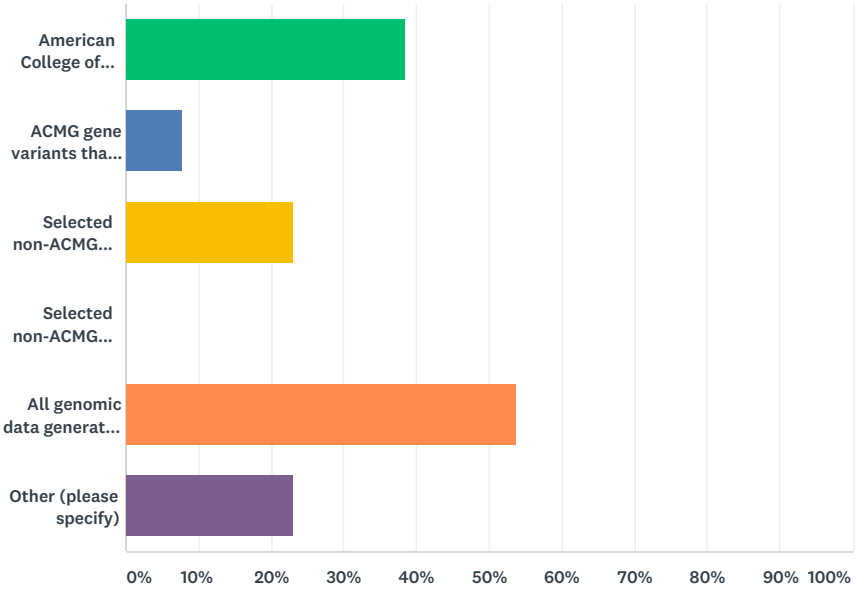


ANSWER CHOICES	RESPONSES	
Cancer	7.14%	1
Rare diseases (https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases)	7.14%	1
All diseases	85.71%	12
Other subset of diseases (please specify)	7.14%	1
Total Respondents: 14		

#	OTHER SUBSET OF DISEASES (PLEASE SPECIFY)	DATE
1	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: 13 Skipped: 5

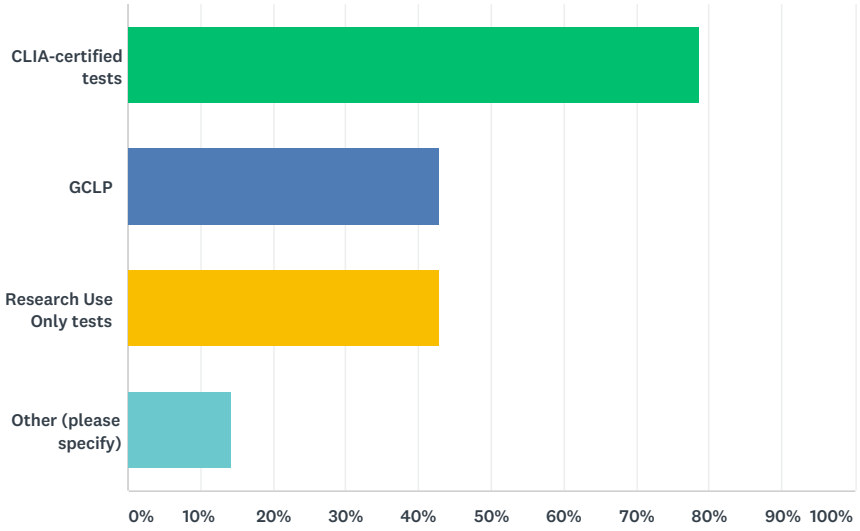


ANSWER CHOICES	RESPONSES	
American College of Medical Genetics (ACMG) gene variants that are the focus of the test	38.46%	5
ACMG gene variants that are included in the assay but are not the focus of the test	7.69%	1
Selected non-ACMG variants that are the focus of the test	23.08%	3
Selected non-ACMG 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	53.85%	7
Other (please specify)	23.08%	3
Total Respondents: 13		

#	OTHER (PLEASE SPECIFY)	DATE
1	As received from sequencing vendor and without any processing, analysis or interpretation.	11/14/2019 4:13 PM
2	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
3	The data controller (honest broker) is responsible for the interaction with the sample donor.	10/31/2019 2:52 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: 14 Skipped: 4

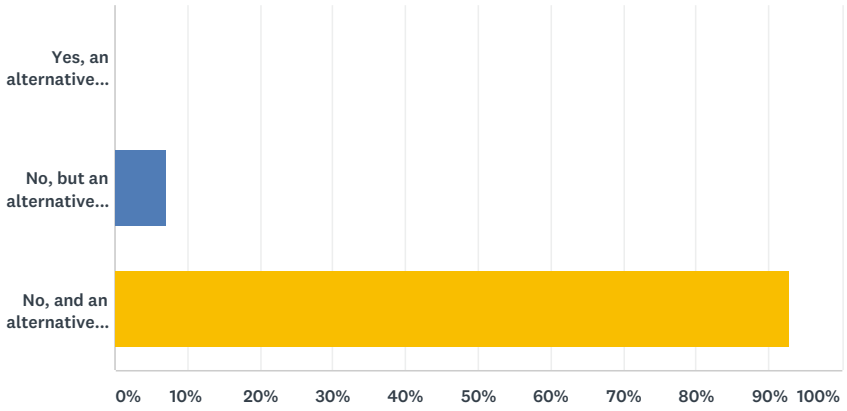


ANSWER CHOICES	RESPONSES	
CLIA-certified tests	78.57%	11
GCLP	42.86%	6
Research Use Only tests	42.86%	6
Other (please specify)	14.29%	2
Total Respondents: 14		

#	OTHER (PLEASE SPECIFY)	DATE
1	N?A	11/14/2019 4:13 PM
2	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.	10/31/2019 2:52 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?

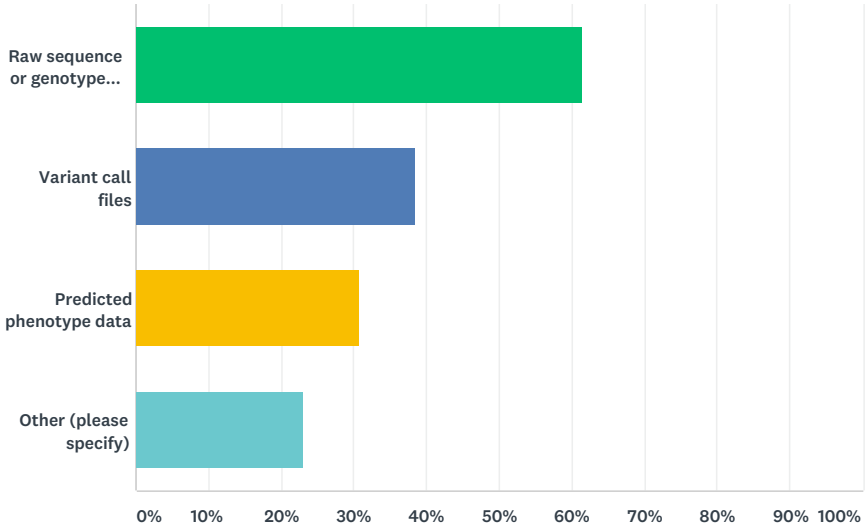
Answered: 14 Skipped: 4



ANSWER CHOICES	RESPONSES	
Yes, an alternative qualified/validated process is used	0.00%	0
No, but an alternative qualified/validated process is being developed	7.14%	1
No, and an alternative qualified/validated process is not in development	92.86%	13
TOTAL		14

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

Answered: 13 Skipped: 5

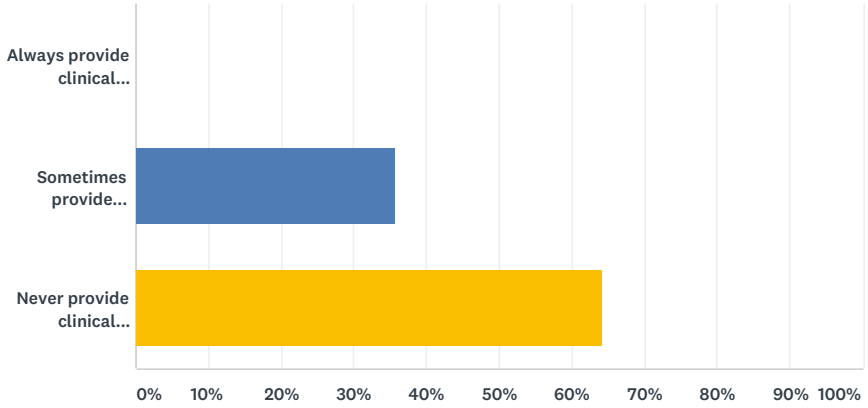


ANSWER CHOICES	RESPONSES	
Raw sequence or genotype data	61.54%	8
Variant call files	38.46%	5
Predicted phenotype data	30.77%	4
Other (please specify)	23.08%	3
Total Respondents: 13		

#	OTHER (PLEASE SPECIFY)	DATE
1	managed per patient/investigator request	11/19/2019 9:37 PM
2	Single SNP	11/12/2019 4:07 PM
3	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?

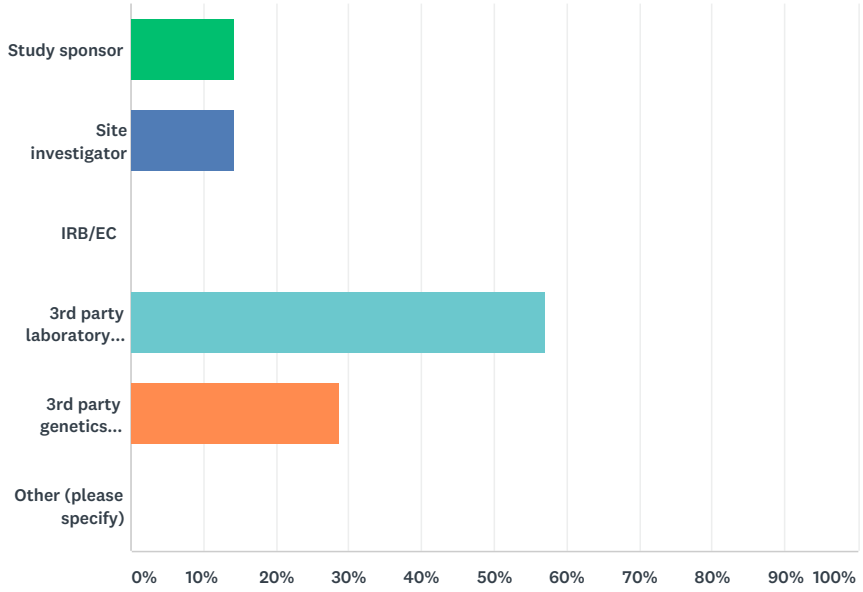
Answered: 14 Skipped: 4



ANSWER CHOICES	RESPONSES	
Always provide clinical annotation/interpretation	0.00%	0
Sometimes provide clinical annotation/interpretation	35.71%	5
Never provide clinical annotation/interpretation (SKIP TO QUESTION 17)	64.29%	9
TOTAL		14

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: 11



ANSWER CHOICES	RESPONSES	
Study sponsor	14.29%	1
Site investigator	14.29%	1
IRB/EC	0.00%	0
3rd party laboratory generating the result	57.14%	4
3rd party genetics counselor not affiliated with the sponsor, analysis lab, or site investigator	28.57%	2
Other (please specify)	0.00%	0
Total Respondents: 7		

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

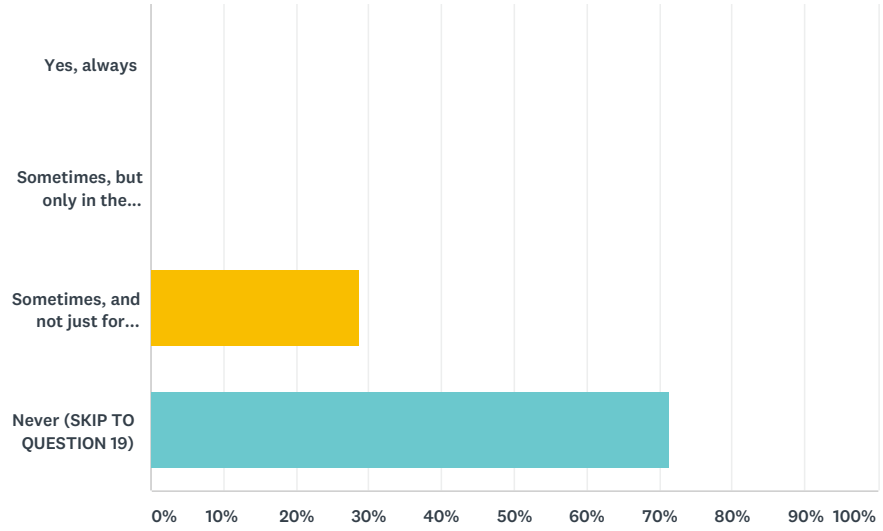
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?

Answered: 2 Skipped: 16

#	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?

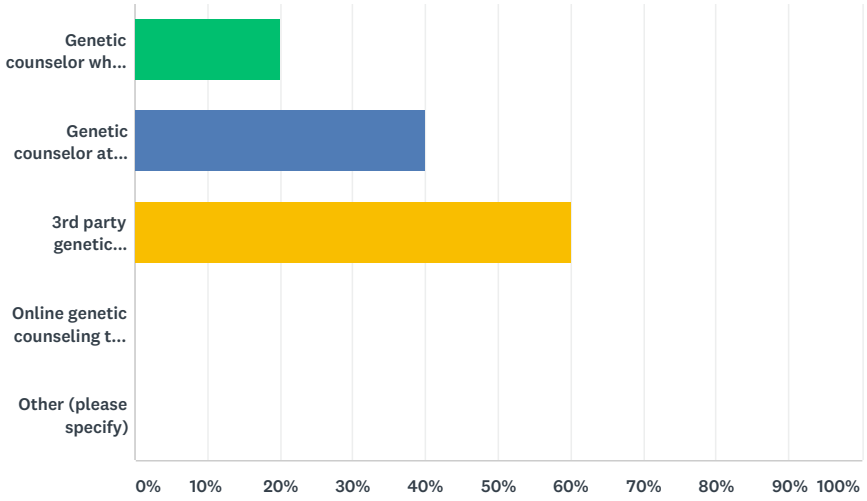
Answered: 14 Skipped: 4



ANSWER CHOICES	RESPONSES	
Yes, always	0.00%	0
Sometimes, but only in the case of ACMG variants	0.00%	0
Sometimes, and not just for ACMG variants	28.57%	4
Never (SKIP TO QUESTION 19)	71.43%	10
TOTAL		14

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

Answered: 5 Skipped: 13

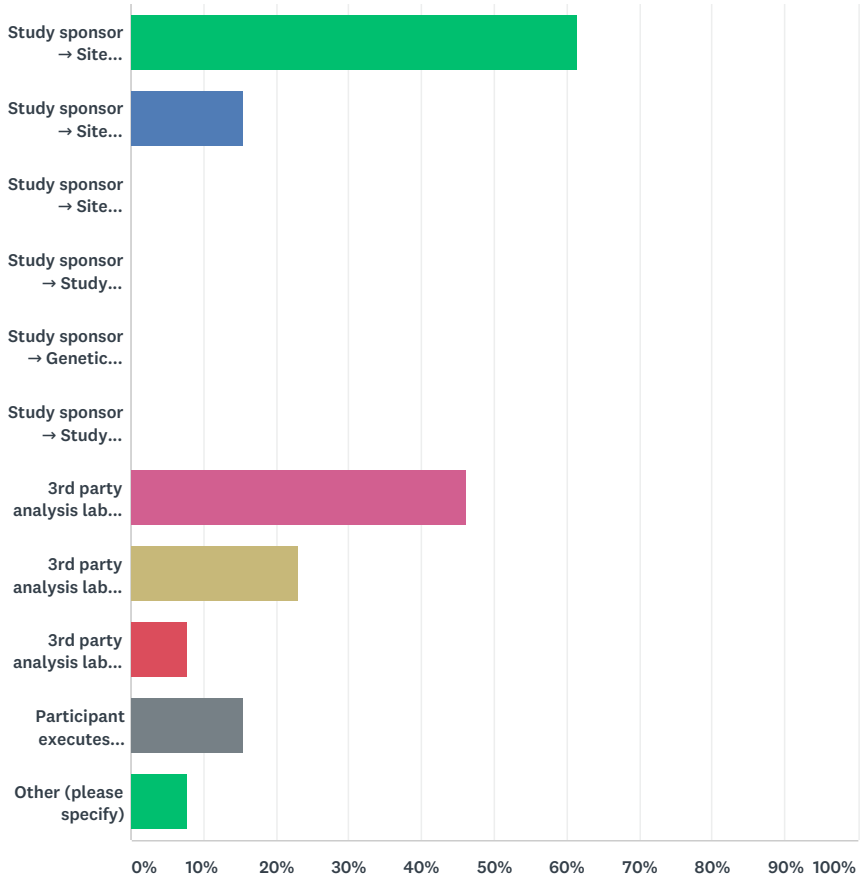


ANSWER CHOICES	RESPONSES	
Genetic counselor who is part of the clinical trial team at the research site	20.00%	1
Genetic counselor at the research institute who is not a member of the clinical trial team	40.00%	2
3rd party genetic counseling service outside the research institute	60.00%	3
Online genetic counseling tool	0.00%	0
Other (please specify)	0.00%	0
Total Respondents: 5		

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

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

Answered: 13 Skipped: 5

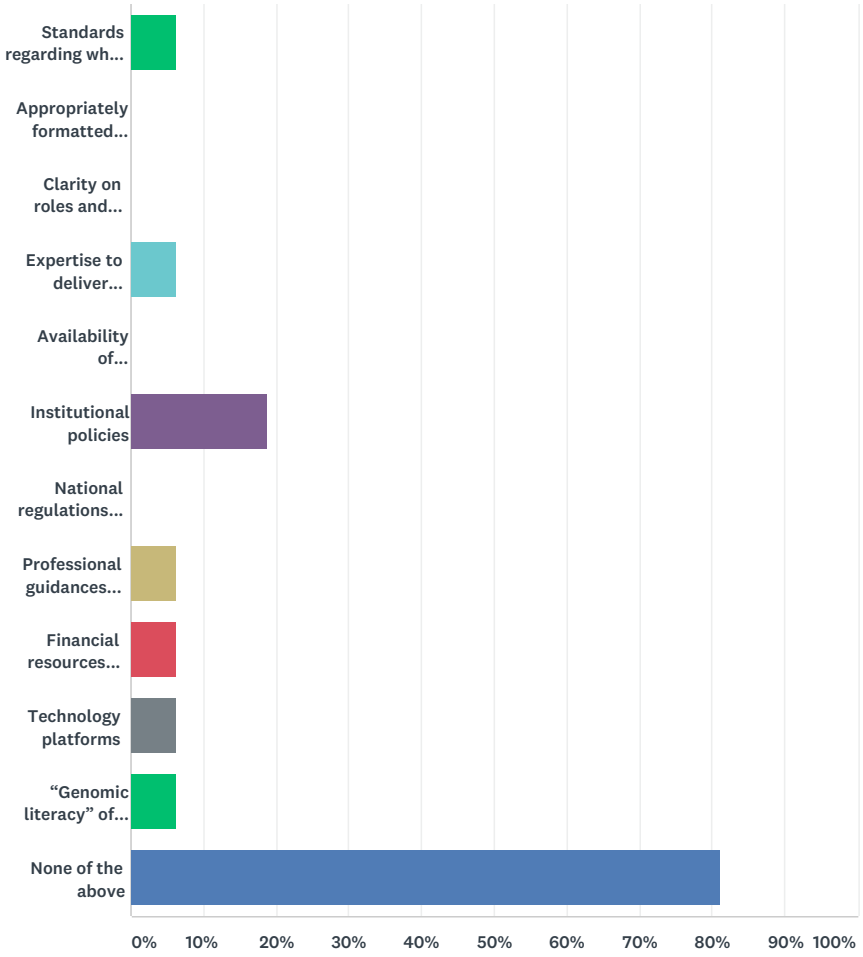


ANSWER CHOICES	RESPONSES	
Study sponsor → Site investigator → Study participant	61.54%	8
Study sponsor → Site investigator → Genetic counselor → Study participant	15.38%	2
Study sponsor → Site investigator → Study participant's Primary Care Provider → Study participant	0.00%	0
Study sponsor → Study participant	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	46.15%	6
3rd party analysis lab → Genetic counselor → Study participant	23.08%	3
3rd party analysis lab → Study participant's Primary Care Provider → Study participant	7.69%	1
Participant executes self-service access via a portal	15.38%	2
Other (please specify)	7.69%	1
Total Respondents: 13		

#	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:

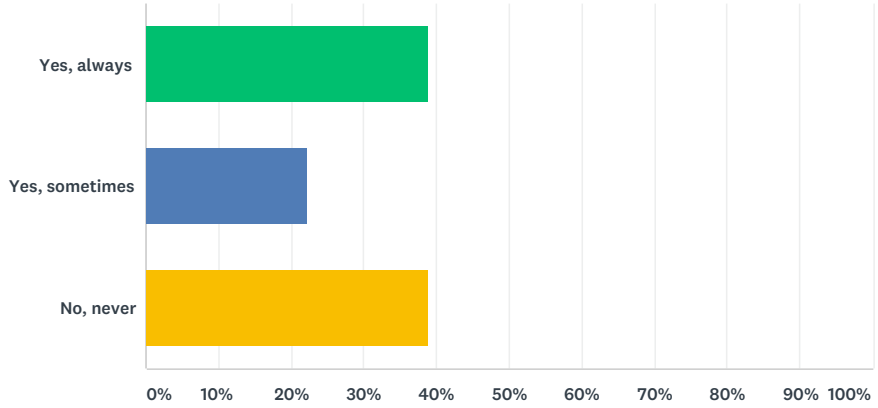
Answered: 16 Skipped: 2



ANSWER CHOICES	RESPONSES	
Standards regarding which test results to return	6.25%	1
Appropriately formatted reports	0.00%	0
Clarity on roles and responsibilities	0.00%	0
Expertise to deliver results	6.25%	1
Availability of support/follow up services (e.g. genetic counseling)	0.00%	0
Institutional policies	18.75%	3
National regulations	0.00%	0
Professional guidances	6.25%	1
Financial resources	6.25%	1
Technology platforms	6.25%	1
“Genomic literacy” of participants	6.25%	1
None of the above	81.25%	13
Total Respondents: 16		

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?

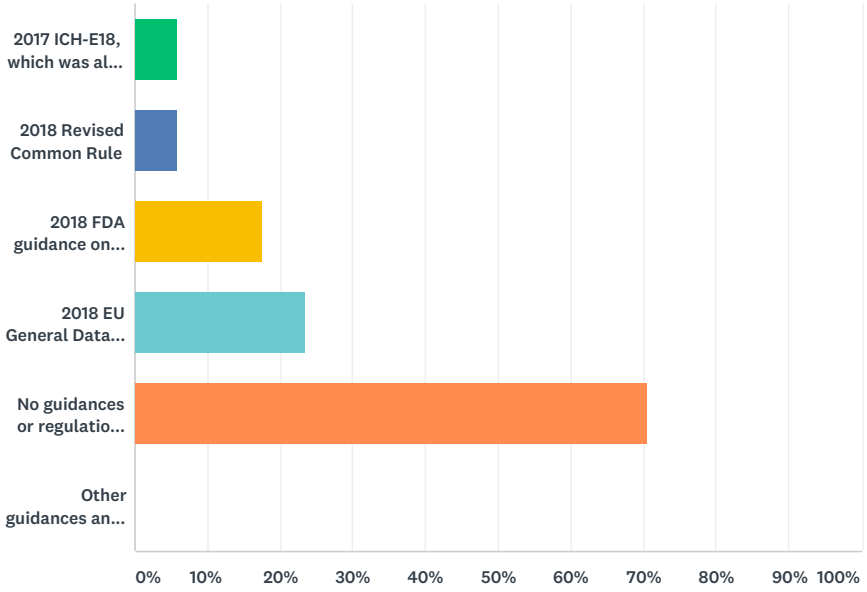
Answered: 18 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes, always	38.89%	7
Yes, sometimes	22.22%	4
No, never	38.89%	7
TOTAL		18

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: 17 Skipped: 1

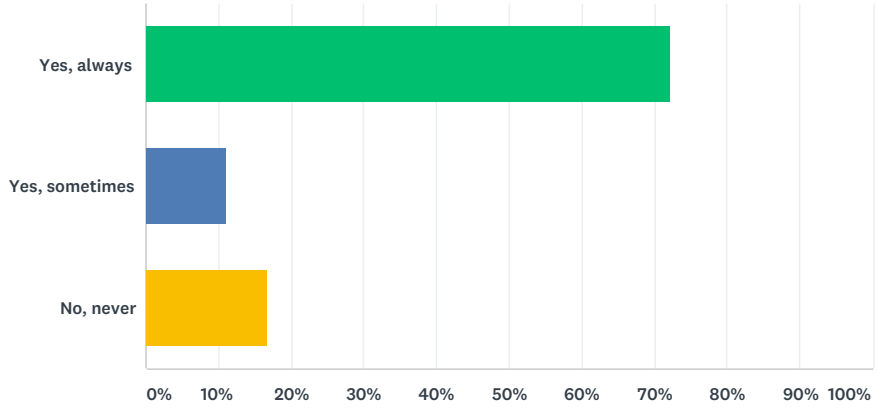


ANSWER CHOICES	RESPONSES	
2017 ICH-E18, which was also adopted by FDA	5.88%	1
2018 Revised Common Rule	5.88%	1
2018 FDA guidance on revised Common Rule	17.65%	3
2018 EU General Data Protection Regulation	23.53%	4
No guidances or regulations influenced it	70.59%	12
Other guidances and regulations (please specify)	0.00%	0
Total Respondents: 17		

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

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?

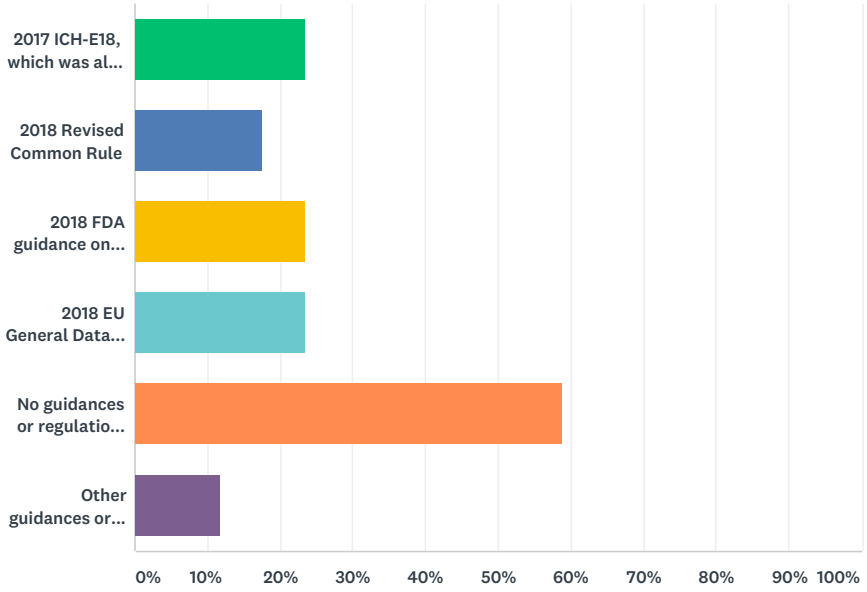
Answered: 18 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes, always	72.22%	13
Yes, sometimes	11.11%	2
No, never	16.67%	3
TOTAL		18

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: 17 Skipped: 1

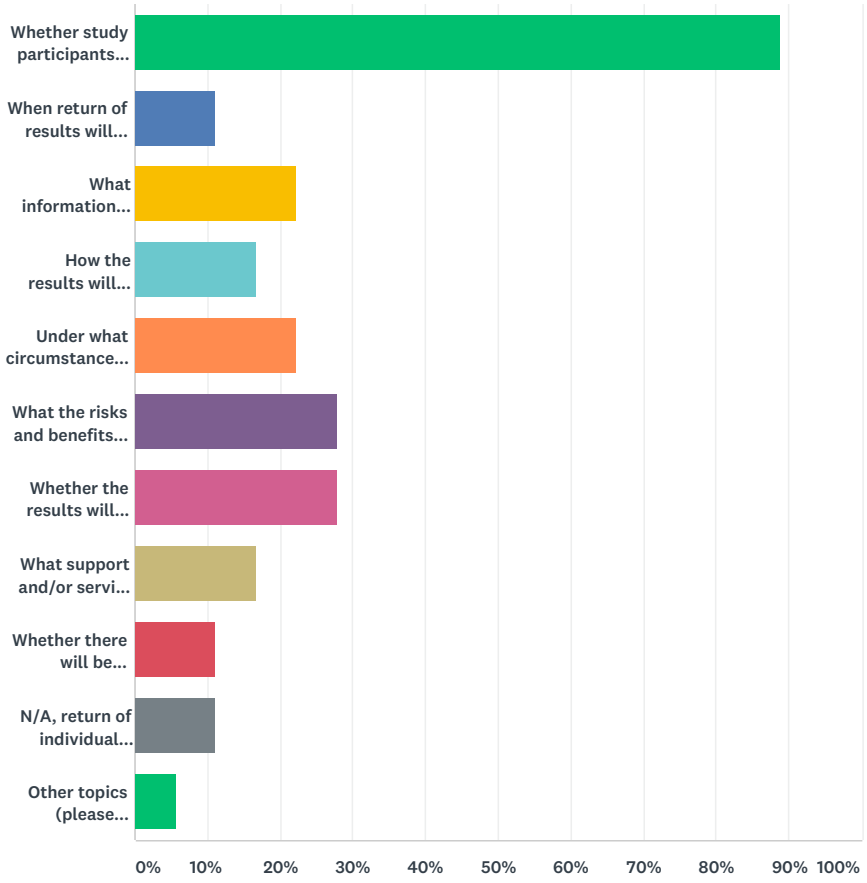


ANSWER CHOICES	RESPONSES	
2017 ICH-E18, which was also adopted by FDA	23.53%	4
2018 Revised Common Rule	17.65%	3
2018 FDA guidance on revised Common Rule	23.53%	4
2018 EU General Data Protection Regulation	23.53%	4
No guidances or regulations influenced it	58.82%	10
Other guidances or regulations (please specify)	11.76%	2
Total Respondents: 17		

#	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: 18 Skipped: 0

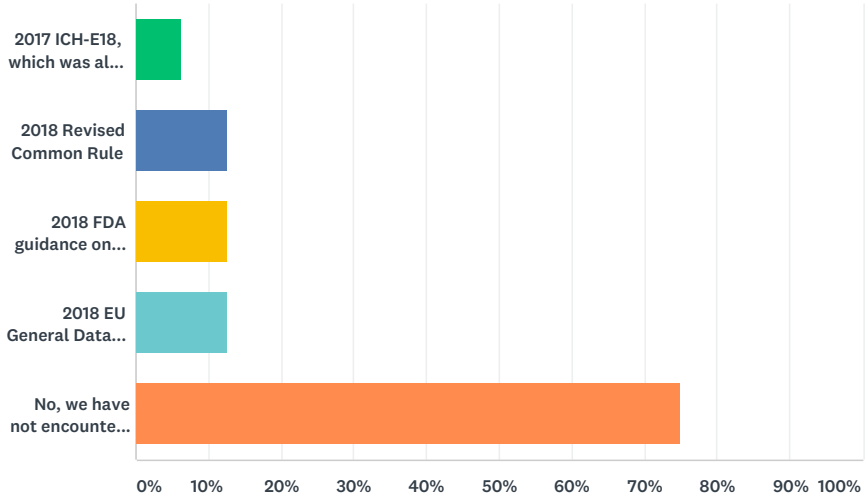


ANSWER CHOICES	RESPONSES	
Whether study participants will receive individual results of tests performed on their biological samples	88.89%	16
When return of results will occur in relation to the lifecycle of the study	11.11%	2
What information will be shared	22.22%	4
How the results will be communicated	16.67%	3
Under what circumstances will results be communicated	22.22%	4
What the risks and benefits of receiving the results are	27.78%	5
Whether the results will go to the participant's primary care provider or into their medical record	27.78%	5
What support and/or services will be provided	16.67%	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)	11.11%	2
N/A, return of individual genomic research results is never discussed in my company's informed consent documents	11.11%	2
Other topics (please specify)	5.56%	1
Total Respondents: 18		

#	OTHER TOPICS (PLEASE SPECIFY)	DATE
1	Within this survey all answers pertain to 'raw data', not interpreted results in a report for the individual subject.	10/31/2019 2:52 PM

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

Answered: 16 Skipped: 2



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	12.50%	2
No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)	75.00%	12
Total Respondents: 16		

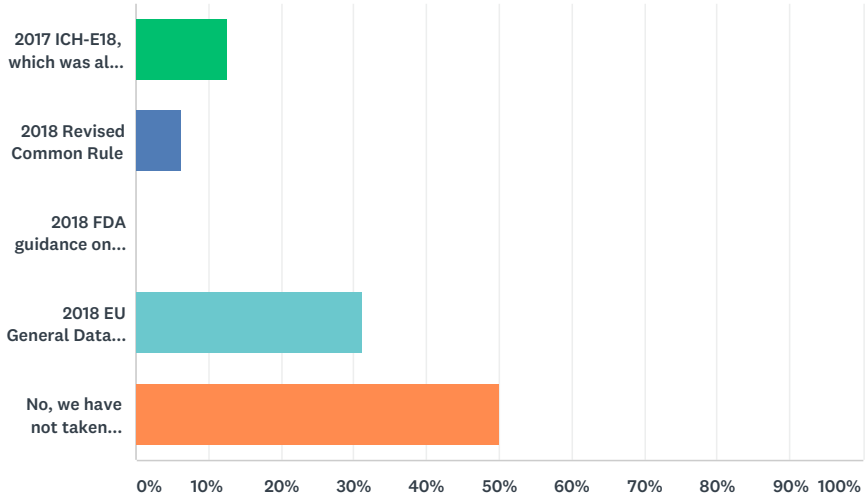
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):

Answered: 4 Skipped: 14

#	RESPONSES	DATE
1	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
2	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
3	na	10/31/2019 8:12 PM
4	We are in the process of implementing this policy so we haven't actually had exposure yet.	10/31/2019 2:52 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: 2



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

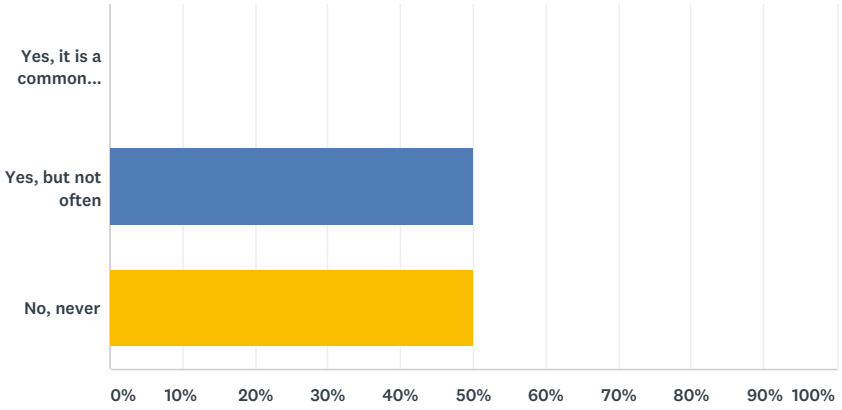
Q29 If you selected "Yes" to any of the options listed in Q28 please provide further information to explain your answer:

Answered: 9 Skipped: 9

#	RESPONSES	DATE
1	Inform patients in informed consent form of non-return of genomic results	11/20/2019 8:18 PM
2	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
3	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
4	Updated MICF language	11/14/2019 4:13 PM
5	Process to track and manage individual data requests per EU GDPR requirements.	11/12/2019 4:07 PM
6	Addressed in our ICF as well as considered in discussions with EU-based CROs.	11/6/2019 9:18 PM
7	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
8	na	10/31/2019 8:12 PM
9	The choice of a third party being the data controller was influenced by the European privacy protection regulation.	10/31/2019 2:52 PM

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

Answered: 18 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes, it is a common occurrence	0.00%	0
Yes, but not often	50.00%	9
No, never	50.00%	9
TOTAL		18

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

Answered: 9 Skipped: 9

#	RESPONSES	DATE
1	Requests for return of results have been very rare	11/19/2019 9:37 PM
2	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
3	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
4	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
5	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
6	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
7	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
8	no	10/31/2019 8:12 PM
9	Again, all answers provided reflect a policy that we are in the process of implementing, but the elements are clear and supported throughout the organization. We feel that it is the right thing to do.	10/31/2019 2:52 PM

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

Answered: 13 Skipped: 5

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