#1

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Thursday, October 31, 2019 2:29:29 PM
Last Modified:	Thursday, October 31, 2019 2:52:09 PM
Time Spent:	00:22:39
Email:	
IP Address:	

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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**Respondent skipped this question**
Q2 Does your company plan to change its current stance?	**Yes, we currently do not return and we plan to transition to returning results**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**To be responsive to participants' desire to receive their results ,** **To allow the results to be incorporated into the management of the study participant's health ,** **To foster a greater partnership and/or transparency in the relationship between my company and study participants ,** **To fulfill participants' right to receive data generated from their biological samples ,** **To fulfill legal or regulatory obligations to return the results ,** Other (please specify): I want to make clear that the position pertains to return of data to the patient, not results in the sense of a report,
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	Other (please specify): The company's position is that genomic data will be returned, not a report detailing interpreted results.
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**2018 EU General Data Protection Regulation**
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)	Other (please specify): Data will be returned, ie deposited at a third party (data controller)
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)	Other (please specify): 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.

Q8 If you selected the answer "Study sponsor" in Q7 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**All diseases**
Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	Other (please specify): The data controller (honest broker) is responsible for the interaction with the sample donor.
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**CLIA-certified tests,** **GCLP,** **Research Use Only tests,** Other (please specify): 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.
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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Raw sequence or genotype data**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Never provide clinical annotation/interpretation (SKIP TO QUESTION 17)**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Respondent skipped this question**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Never (SKIP TO QUESTION 19)**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**
Q19 What is your company's process for returning results? (select all that apply)	**Participant executes self-service access via a portal**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**Institutional policies,** **Technology platforms**

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?	**Yes, always**
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)	**2018 EU General Data Protection Regulation**
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?	**Yes, always**
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)	**2018 EU General Data Protection Regulation**
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**When return of results will occur in relation to the lifecycle of the study** **,** **What the risks and benefits of receiving the results are** **,** **Whether the results will go to the participant's primary care provider or into their medical record** **,** **What support and/or services will be provided** **,** **Whether study participants will receive individual results of tests performed on their biological samples** **,** Other topics (please specify): Within this survey all answers pertain to 'raw data', not interpreted results in a report for the individual subject.
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)**

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

We are in the process of implementing this policy so we haven't actually had exposure yet.

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:	**2018 EU General Data Protection Regulation**

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

The choice of a third party being the data controller was influenced by the European privacy protection regulation.

Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**No, never**

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

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.

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

Respondent skipped this question

#2

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Thursday, October 31, 2019 4:18:09 PM
Last Modified: Thursday, October 31, 2019 4:24:48 PM
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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**Respondent skipped this question**
Q2 Does your company plan to change its current stance?	**Yes, we currently do not return and we plan to transition to returning results**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**To be responsive to participants' desire to receive their results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Liability concerns** , **Logistical hurdles** , **To avoid promoting therapeutic misconception (participant may conflate the purpose of research with that of clinical care)**
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**No regulations or guidances influenced my company's position**
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)	**Whether the study participant initiated a request for the results**
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)	**IRB/EC**
Q8 If you selected the answer "Study sponsor" in Q7 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**All diseases**
Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**American College of Medical Genetics (ACMG) gene variants that are the focus of the test**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**Research Use Only tests**

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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Variant call files**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Never provide clinical annotation/interpretation (SKIP TO QUESTION 17)**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**3rd party genetics counselor not affiliated with the sponsor, analysis lab, or site investigator**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Never (SKIP TO QUESTION 19)**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**3rd party genetic counseling service outside the research institute**
Q19 What is your company's process for returning results? (select all that apply)	**3rd party analysis lab → Genetic counselor → Study participant**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**No, never**
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)	**No guidances or regulations influenced it**
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?	**No, never**
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)	**No guidances or regulations influenced it**
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**N/A, return of individual genomic research results is never discussed in my company's informed consent documents**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**Respondent skipped this question**

Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**Respondent skipped this question**
Q29 If you selected "Yes" to any of the options listed in Q28 please provide further information to explain your answer:	**Respondent skipped this question**
Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**No, never**
Q31 Do you have any additional comments that you think would be useful to include in this survey:	**Respondent skipped this question**
Q32 Please enter your unique indiviual survey code that has been given to you by Julian Arbuckle:	**Respondent skipped this question**

#3

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Thursday, October 31, 2019 4:34:00 PM
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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**Respondent skipped this question**
Q2 Does your company plan to change its current stance?	**No, we do not plan to change our stance**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**To be responsive to participants' desire to receive their results ,** **To foster a greater partnership and/or transparency in the relationship between my company and study participants ,** **To fulfill legal or regulatory obligations to return the results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Providing results would compromise the integrity of the clinical trial ,** **Results are not interpretable at the individual level,** **Liability concerns**
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**2018 FDA guidance on revised Common Rule**
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)	**Whether there are legal and/or regulatory requirements to return the results**
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)	**Site investigator,** **IRB/EC,** **Stakeholders such as patient advocacy groups**
Q8 If you selected the answer "Study sponsor" in Q7 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**All diseases**

Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**All genomic data generated as part of a given test**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**Research Use Only tests**
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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Raw sequence or genotype data**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Never provide clinical annotation/interpretation (SKIP TO QUESTION 17)**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**3rd party laboratory generating the result**

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

na

Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Sometimes, and not just for ACMG variants**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**3rd party genetic counseling service outside the research institute**
Q19 What is your company's process for returning results? (select all that apply)	**3rd party analysis lab → Study participant's Primary Care Provider → Study participant**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**Standards regarding which test results to return ,** **Expertise to deliver results ,** **Institutional policies,** **Professional guidances ,** **Financial resources ,** **"Genomic literacy" of participants**
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?	**No, never**

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)	**2018 FDA guidance on revised Common Rule**
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?	**No, never**
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)	**2018 FDA guidance on revised Common Rule**
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**N/A, return of individual genomic research results is never discussed in my company's informed consent documents**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**2018 FDA guidance on revised Common Rule**

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

na

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:	**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)"**

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

na

Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**No, never**

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

no

Q32 Please enter your unique indiviual survey code that has been given to you by Julian Arbuckle:	**Respondent skipped this question**

#4

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Tuesday, November 05, 2019 2:55:47 PM
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Email:
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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**Yes, it supports returning results but only in limited circumstances**
Q2 Does your company plan to change its current stance?	**Yes, we currently return results and we plan to transition to returning significantly more results than we currently do**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**To be responsive to participants' desire to receive their results ,** **To allow the results to be incorporated into the management of the study participant's health ,** **To foster a greater partnership and/or transparency in the relationship between my company and study participants ,** **To fulfill participants' right to receive data generated from their biological samples**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Providing results would compromise the integrity of the clinical trial ,** **Results are not interpretable at the individual level,** **Results are not useful for clinical decision-making ,** **Liability concerns ,** **Results are not generated in a CLIA-certified laboratory setting ,** **Resource limitations**
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**2018 EU General Data Protection Regulation**
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)	**Whether the results are appropriate for clinical decision-making ,** **Whether there are legal and/or regulatory requirements to return the results ,** **Whether the study participant initiated a request for the results**

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)	**Study sponsor ,** **Site investigator,** **3rd party laboratory generating the result**

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

study director, protocol manager, site management, informed consent SMEs, safety team as needed, legal, regulatory, biomarker scientists

Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**All diseases**
Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	Other (please specify): 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
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**CLIA-certified tests,** **GCLP,** **Research Use Only tests**
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?	**No, but an alternative qualified/validated process is being developed**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	Other (please specify): All in scope but decisions are made on case by case basis.
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Never provide clinical annotation/interpretation (SKIP TO QUESTION 17)**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Respondent skipped this question**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Never (SKIP TO QUESTION 19)**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**
Q19 What is your company's process for returning results? (select all that apply)	**Study sponsor → Site investigator → Study participant ,** **3rd party analysis lab → Site investigator → Study participant**

Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**No, never**
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)	**Respondent skipped this question**
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?	**Yes, sometimes**
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)	**No guidances or regulations influenced it**
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**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)** , **Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**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)"**
Q29 If you selected "Yes" to any of the options listed in Q28 please provide further information to explain your answer:	**Respondent skipped this question**
Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**Yes, but not often**
Q31 Do you have any additional comments that you think would be useful to include in this survey:	**Respondent skipped this question**

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

9901

#5

COMPLETE

Collector: Email Invitation 1 (Email)
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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**Yes, it supports returning results but only in limited circumstances**
Q2 Does your company plan to change its current stance?	**Yes, we currently return results and we plan to transition to returning significantly more results than we currently do**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**To be responsive to participants' desire to receive their results** , **To foster a greater partnership and/or transparency in the relationship between my company and study participants** , **To fulfill participants' right to receive data generated from their biological samples** , **To fulfill legal or regulatory obligations to return the results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Providing results would compromise the integrity of the clinical trial** , **Logistical hurdles** , **Tests are performed after they would be of value to study participants and/or after the participants' last study visit**
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**No regulations or guidances influenced my company's position** , Other (please specify): Increasing demand from some ECs/IRBs
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)	**Whether there are legal and/or regulatory requirements to return the results** , **Whether the study participant initiated a request for the results**

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)	**Study sponsor**, **3rd party laboratory generating the result**, **3rd party genetic counselor not affiliated with the sponsor, analysis lab, or site investigator**

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

Legal department, Biomarker team, Ethics & Compliance team

Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**All diseases**
Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**American College of Medical Genetics (ACMG) gene variants that are the focus of the test**, **Selected non-ACMG variants that are the focus of the test**, **All genomic data generated as part of a given test**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**CLIA-certified tests,** **GCLP**
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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Raw sequence or genotype data**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Never provide clinical annotation/interpretation (SKIP TO QUESTION 17)**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Respondent skipped this question**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Sometimes, and not just for ACMG variants**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Genetic counselor at the research institute who is not a member of the clinical trial team**

Q19 What is your company's process for returning results? (select all that apply)	**Study sponsor → Site investigator → Study participant** **3rd party analysis lab → Site investigator → Study participant**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**Yes, always**
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)	**No guidances or regulations influenced it**
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?	**Yes, always**
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)	**No guidances or regulations influenced it**
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**When return of results will occur in relation to the lifecycle of the study** **,** **What information will be shared ,** **How the results will be communicated ,** **Under what circumstances will results be communicated ,** **What the risks and benefits of receiving the results are ,** **Whether the results will go to the participant's primary care provider or into their medical record** **,** **Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**2018 EU General Data Protection Regulation**

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

Revision of the return of result text in the template ICF
Implementation of a specific process to address any subject's request

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

Yes, but not often

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

Respondent skipped this question

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

3444

#6

COMPLETE

Collector: Email Invitation 1 (Email)
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Q1 Does your company's current stance allow for the return of any individual genomic research results?

Yes, it supports returning results but only in limited circumstances

Q2 Does your company plan to change its current stance?

Yes, we currently return results and we plan to transition to returning significantly more results than we currently do

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

To be responsive to participants' desire to receive their results ,

To fulfill participants' right to receive data generated from their biological samples

,

To fulfill legal or regulatory obligations to return the results

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

Results are not interpretable at the individual level,

Results are not generated in a CLIA-certified laboratory setting

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

2017 ICH-E18, which was also adopted by FDA,

2018 FDA guidance on revised Common Rule,

2018 EU General Data Protection Regulation

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)

Whether there are legal and/or regulatory requirements to return the results

,

Whether the study participant initiated a request for the results

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)

Study sponsor ,

Site investigator,

IRB/EC

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

Clinical Study Director, Pharmacogenomics representative(s) from Translational Medicine, Bioethics committee

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

All diseases

Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**All genomic data generated as part of a given test**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**CLIA-certified tests,** **GCLP,** **Research Use Only tests**
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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Raw sequence or genotype data ,** **Variant call files,** **Predicted phenotype data**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Sometimes provide clinical annotation/interpretation**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Study sponsor**

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

Study Director, Translational Medicine, Clinical Scientist

Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Never (SKIP TO QUESTION 19)**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**
Q19 What is your company's process for returning results? (select all that apply)	**Study sponsor → Site investigator → Study participant**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**Yes, always**
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)	**2018 FDA guidance on revised Common Rule,** **2018 EU General Data Protection Regulation**

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?	**Yes, always**
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)	**2017 ICH-E18, which was also adopted by FDA,** **2018 FDA guidance on revised Common Rule,** **2018 EU General Data Protection Regulation**
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**What the risks and benefits of receiving the results are ,** **What support and/or services will be provided ,** **Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**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)"**
Q29 If you selected "Yes" to any of the options listed in Q28 please provide further information to explain your answer:	**Respondent skipped this question**
Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**Yes, but not often**

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

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

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

7333

#7

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Tuesday, November 05, 2019 2:58:15 PM
Last Modified:	Tuesday, November 05, 2019 5:21:34 PM
Time Spent:	02:23:19
Email:	
IP Address:	

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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**Yes, it supports returning results but only in limited circumstances**
Q2 Does your company plan to change its current stance?	**Yes, we currently return results and we plan to transition to returning significantly more results than we currently do**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**To be responsive to participants' desire to receive their results ,** **To foster a greater partnership and/or transparency in the relationship between my company and study participants ,** **To fulfill participants' right to receive data generated from their biological samples ,** **To fulfill legal or regulatory obligations to return the results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Results are not useful for clinical decision-making ,** **There is not an industry standard to return results ,** **Liability concerns ,** **Results are not generated in a CLIA-certified laboratory setting ,** **Logistical hurdles ,** **Resource limitations,** **Site investigators are not comfortable conveying results to participants**
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**2018 EU General Data Protection Regulation**
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)	**Whether the results are those that were the focus of the research for which your company tested the biological samples ,** **Whether there are legal and/or regulatory requirements to return the results**

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)	**Study sponsor ,** **Site investigator**
Q8 If you selected the answer "Study sponsor" in Q7 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**All diseases**
Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**All genomic data generated as part of a given test**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**CLIA-certified tests,** **GCLP**
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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Variant call files,** **Predicted phenotype data**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Sometimes provide clinical annotation/interpretation**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Site investigator**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Never (SKIP TO QUESTION 19)**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**
Q19 What is your company's process for returning results? (select all that apply)	**Study sponsor → Site investigator → Study participant**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**Yes, always**

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)	**No guidances or regulations influenced it**
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?	**Yes, always**
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)	**No guidances or regulations influenced it**
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**Under what circumstances will results be communicated** , **What the risks and benefits of receiving the results are** , **Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**Respondent skipped this question**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**Respondent skipped this question**
Q29 If you selected "Yes" to any of the options listed in Q28 please provide further information to explain your answer:	**Respondent skipped this question**
Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**Yes, but not often**

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

too generic a questionnaire - a lot of the answers differ depending on the test, indication and what it'll be used for.

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

3309

#8

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Tuesday, November 05, 2019 5:23:45 PM
Last Modified: Tuesday, November 05, 2019 5:33:28 PM
Time Spent: 00:09:43
Email:
IP Address:

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

No, our position is to not return results under any circumstances

Q2 Does your company plan to change its current stance?

No, we do not plan to change our stance

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

N/A, My company does not support any return of individual genomic research results

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

Results are not useful for clinical decision-making ,

There is not an industry standard to return results ,

Liability concerns ,

Results are not generated in a CLIA-certified laboratory setting ,

Logistical hurdles ,

Resource limitations

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

No regulations or guidances influenced my company's position

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)

N/A, My company does not support any return of individual genomic research results (SKIP TO QUESTION 20)

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)

Study sponsor

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

legal and genomics laboratory

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

Other subset of diseases (please specify):

none, results not returned

Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**Respondent skipped this question**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**Respondent skipped this question**
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?	**Respondent skipped this question**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Respondent skipped this question**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Respondent skipped this question**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Respondent skipped this question**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Respondent skipped this question**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**
Q19 What is your company's process for returning results? (select all that apply)	**Respondent skipped this question**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**Respondent skipped this question**
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?	**Yes, always**
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)	**No guidances or regulations influenced it**
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?	**Yes, always**
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)	**No guidances or regulations influenced it**

Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**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)"**
Q29 If you selected "Yes" to any of the options listed in Q28 please provide further information to explain your answer:	**Respondent skipped this question**
Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**No, never**
Q31 Do you have any additional comments that you think would be useful to include in this survey:	**Respondent skipped this question**
Q32 Please enter your unique indiviual survey code that has been given to you by Julian Arbuckle:	**Respondent skipped this question**

#9

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Wednesday, November 06, 2019 9:06:21 PM
Last Modified: Wednesday, November 06, 2019 9:17:53 PM
Time Spent: 00:11:31
Email:
IP Address:

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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**No, our position is to not return results under any circumstances**
Q2 Does your company plan to change its current stance?	**No, we do not plan to change our stance**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**N/A, My company does not support any return of individual genomic research results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Results are not useful for clinical decision-making** , Other (please specify): To protect subject confidentiality
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	Other (please specify): Don't know
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)	**N/A, My company does not support any return of individual genomic research results (SKIP TO QUESTION 20)**
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)	**Respondent skipped this question**
Q8 If you selected the answer "Study sponsor" in Q7 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**Respondent skipped this question**
Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**Respondent skipped this question**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**Respondent skipped this question**

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?	**Respondent skipped this question**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Respondent skipped this question**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Respondent skipped this question**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Respondent skipped this question**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Respondent skipped this question**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**
Q19 What is your company's process for returning results? (select all that apply)	**Respondent skipped this question**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**Yes, sometimes**
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)	**No guidances or regulations influenced it**
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?	**Yes, always**
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)	**No guidances or regulations influenced it**
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**What information will be shared** , **Whether the results will go to the participant's primary care provider or into their medical record** , **Whether study participants will receive individual results of tests performed on their biological samples**

Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**2018 EU General Data Protection Regulation**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**2018 EU General Data Protection Regulation**

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

Addressed in our ICF as well as considered in discussions with EU-based CROs.

Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**No, never**
Q31 Do you have any additional comments that you think would be useful to include in this survey:	**Respondent skipped this question**

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

7507

#10

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Tuesday, November 12, 2019 12:52:54 PM
Last Modified: Tuesday, November 12, 2019 1:25:07 PM
Time Spent: 00:32:12
Email:
IP Address:

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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**Yes, it supports returning results but only in limited circumstances**
Q2 Does your company plan to change its current stance?	**No, we do not plan to change our stance**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**To allow the results to be incorporated into the management of the study participant's health** **,** **To fulfill legal or regulatory obligations to return the results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Providing results would compromise the integrity of the clinical trial** **,** **Results are not interpretable at the individual level,** **Results are not useful for clinical decision-making ,** **There is not an industry standard to return results ,** **Liability concerns ,** **Results are not generated in a CLIA-certified laboratory setting ,** **Logistical hurdles ,** **Resource limitations,** **Tests are performed after they would be of value to study participants and/or after the participants' last study visit** **,** **Site investigators are not comfortable conveying results to participants** **,** **To avoid promoting therapeutic misconception (participant may conflate the purpose of research with that of clinical care)**
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**No regulations or guidances influenced my company's position**

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)	**Whether the results are appropriate for clinical decision-making** , **Whether the results are those that were the focus of the research for which your company tested the biological samples** , **Whether there are legal and/or regulatory requirements to return the results**
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)	**Study sponsor** , **Site investigator**

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

Lab performing the test, trial's Clinician, Biomarker Representative on trial team, Biobank Custodian, Legal

Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**All diseases**
Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**American College of Medical Genetics (ACMG) gene variants that are the focus of the test** , **Selected non-ACMG variants that are the focus of the test**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**CLIA-certified tests**
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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Predicted phenotype data**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Sometimes provide clinical annotation/interpretation**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**3rd party laboratory generating the result**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Never (SKIP TO QUESTION 19)**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**

Q19 What is your company's process for returning results? (select all that apply)	**Study sponsor → Site investigator → Study participant ,** **3rd party analysis lab → Site investigator → Study participant**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**Yes, sometimes**
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)	**No guidances or regulations influenced it**
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?	**Yes, always**
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)	**2017 ICH-E18, which was also adopted by FDA,** **2018 Revised Common Rule,** Other guidances or regulations (please specify): MRCT IRR Guidelines; NASEM Report
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**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)"**
Q29 If you selected "Yes" to any of the options listed in Q28 please provide further information to explain your answer:	**Respondent skipped this question**
Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**Yes, but not often**

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

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).

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

2772

#11

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Tuesday, November 12, 2019 3:55:29 PM
Last Modified: Tuesday, November 12, 2019 4:06:40 PM
Time Spent: 00:11:10
Email:
IP Address:

Page 1: Education & Communication Task Force

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

Yes, it supports returning results but only in limited circumstances

Q2 Does your company plan to change its current stance?

No, we do not plan to change our stance

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

To be responsive to participants' desire to receive their results ,

To allow the results to be incorporated into the management of the study participant's health ,

To foster a greater partnership and/or transparency in the relationship between my company and study participants ,

To fulfill participants' right to receive data generated from their biological samples ,

To fulfill legal or regulatory obligations to return the results

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

Providing results would compromise the integrity of the clinical trial ,

Results are not useful for clinical decision-making ,

There is not an industry standard to return results ,

Liability concerns ,

Results are not generated in a CLIA-certified laboratory setting ,

Logistical hurdles ,

Resource limitations,

Tests are performed after they would be of value to study participants and/or after the participants' last study visit ,

Site investigators are not comfortable conveying results to participants ,

To avoid promoting therapeutic misconception (participant may conflate the purpose of research with that of clinical care)

Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**2018 EU General Data Protection Regulation** , Other (please specify): Country specific laws (e.g., Denmark National Ethics Committee guidance on full genome mapping; Spain Biomedical Research Act etc)
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)	**Whether the results are appropriate for clinical decision-making** , **Whether there are legal and/or regulatory requirements to return the results** , **Whether the study participant initiated a request for the results**
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)	**Study sponsor** , **IRB/EC**

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

Genetics/Genomics, Clinical Development head

Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**Cancer,** **All diseases**
Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**American College of Medical Genetics (ACMG) gene variants that are the focus of the test** , **ACMG gene variants that are included in the assay but are not the focus of the test**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**CLIA-certified tests**
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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Raw sequence or genotype data** , Other (please specify): Single SNP
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Sometimes provide clinical annotation/interpretation**

Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**3rd party laboratory generating the result**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Sometimes, and not just for ACMG variants**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Genetic counselor who is part of the clinical trial team at the research site** **,** **Genetic counselor at the research institute who is not a member of the clinical trial team**
Q19 What is your company's process for returning results? (select all that apply)	**Study sponsor → Site investigator → Study participant** **Study sponsor → Site investigator → Genetic counselor → Study participant** **,** **3rd party analysis lab → Site investigator → Study participant** **,** **3rd party analysis lab → Genetic counselor → Study participant**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**Yes, sometimes**
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)	**No guidances or regulations influenced it**
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?	**Yes, always**
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)	**2017 ICH-E18, which was also adopted by FDA,** **2018 Revised Common Rule,** **2018 FDA guidance on revised Common Rule,** **No guidances or regulations influenced it**

Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**What information will be shared** , **How the results will be communicated** , **Under what circumstances will results be communicated** , **Whether the results will go to the participant's primary care provider or into their medical record** , **What support and/or services will be provided** , **Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**2018 EU General Data Protection Regulation**

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

Process to track and manage individual data requests per EU GDPR requirements.

Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**Yes, but not often**

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

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).

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

2910

#12

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Wednesday, November 13, 2019 1:07:14 PM
Last Modified: Thursday, November 14, 2019 4:13:07 PM
Time Spent: Over a day
Email:
IP Address:

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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**Yes, it generally supports returning results**
Q2 Does your company plan to change its current stance?	**No, we do not plan to change our stance**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**To fulfill legal or regulatory obligations to return the results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**N/A, My company always returns individual genomic research results** , Other (please specify): 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.
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**2018 EU General Data Protection Regulation**
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)	Other (please specify): Data is only returned on request (by patient)
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)	Other (please specify): N?A
Q8 If you selected the answer "Study sponsor" in Q7 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**All diseases**

Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**All genomic data generated as part of a given test ,** Other (please specify): As received from sequencing vendor and without any processing, analysis or interpretation.
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	Other (please specify): N?A
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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Raw sequence or genotype data**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Never provide clinical annotation/interpretation (SKIP TO QUESTION 17)**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Respondent skipped this question**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Never (SKIP TO QUESTION 19)**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**
Q19 What is your company's process for returning results? (select all that apply)	Other (please specify): Process as yet unmapped (no requests to date)
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**Yes, always**
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)	**2018 EU General Data Protection Regulation**
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?	**Yes, always**

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)	**2018 EU General Data Protection Regulation**
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**2018 EU General Data Protection Regulation**

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

Updated MICF language

Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**No, never**

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

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.

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

2999

#13

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Thursday, November 14, 2019 8:04:21 PM
Last Modified: Thursday, November 14, 2019 8:08:41 PM
Time Spent: 00:04:19
Email:
IP Address:

Page 1: Education & Communication Task Force

Q1 Does your company's current stance allow for the return of any individual genomic research results?	**No, our position is to not return results under any circumstances**
Q2 Does your company plan to change its current stance?	**Yes, we currently do not return and we plan to transition to returning results**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**To be responsive to participants' desire to receive their results** , **To allow the results to be incorporated into the management of the study participant's health** , **To foster a greater partnership and/or transparency in the relationship between my company and study participants** , **To fulfill participants' right to receive data generated from their biological samples** , **To fulfill legal or regulatory obligations to return the results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Logistical hurdles** , **Resource limitations**
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**No regulations or guidances influenced my company's position**
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)	**N/A, My company does not support any return of individual genomic research results (SKIP TO QUESTION 20)**
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)	**Respondent skipped this question**
Q8 If you selected the answer "Study sponsor" in Q7 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**Respondent skipped this question**

Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**Respondent skipped this question**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**Respondent skipped this question**
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?	**Respondent skipped this question**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Respondent skipped this question**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Respondent skipped this question**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Respondent skipped this question**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Respondent skipped this question**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**
Q19 What is your company's process for returning results? (select all that apply)	**Respondent skipped this question**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**Yes, always**
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)	**No guidances or regulations influenced it**
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?	**Yes, always**
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)	**No guidances or regulations influenced it**

Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**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)"**
Q29 If you selected "Yes" to any of the options listed in Q28 please provide further information to explain your answer:	**Respondent skipped this question**
Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**No, never**
Q31 Do you have any additional comments that you think would be useful to include in this survey:	**Respondent skipped this question**

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

1927

#14

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Friday, November 15, 2019 11:51:53 PM
Last Modified: Saturday, November 16, 2019 12:14:38 AM
Time Spent: 00:22:45
Email:
IP Address:

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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**Yes, it supports returning results but only in limited circumstances**
Q2 Does your company plan to change its current stance?	**No, we do not plan to change our stance**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**To fulfill legal or regulatory obligations to return the results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Results are not useful for clinical decision-making ,** **Liability concerns ,** **Results are not generated in a CLIA-certified laboratory setting ,** **Logistical hurdles ,** **Resource limitations,** **Tests are performed after they would be of value to study participants and/or after the participants' last study visit ,** **To avoid promoting therapeutic misconception (participant may conflate the purpose of research with that of clinical care)**
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**No regulations or guidances influenced my company's position**
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)	**Whether the results are appropriate for clinical decision-making ,** **Whether there are legal and/or regulatory requirements to return the results ,** **Whether the study participant initiated a request for the results**

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)	**Study sponsor ,** **Site investigator,** **IRB/EC,** **3rd party laboratory generating the result**

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

Medical director, legal, biomarker discovery, study management

Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**Rare diseases (https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases)**
Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**American College of Medical Genetics (ACMG) gene variants that are the focus of the test** **,** **Selected non-ACMG variants that are the focus of the test**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**CLIA-certified tests**
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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Raw sequence or genotype data ,** **Variant call files**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Never provide clinical annotation/interpretation (SKIP TO QUESTION 17)**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Respondent skipped this question**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Never (SKIP TO QUESTION 19)**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**

Q19 What is your company's process for returning results? (select all that apply)	**Study sponsor → Site investigator → Study participant ,** **3rd party analysis lab → Site investigator → Study participant**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**No, never**
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)	**No guidances or regulations influenced it**
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?	**Yes, always**
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)	Other guidances or regulations (please specify): Relevant wording in place before these recent guidance. I-PWG publication on ICF elements is relevant.
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**What the risks and benefits of receiving the results are ,** **Whether the results will go to the participant's primary care provider or into their medical record ,** **Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**2018 Revised Common Rule**

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

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.

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:	**2018 Revised Common Rule**

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

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.

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

Yes, but not often

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

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.

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

4099

#15

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Monday, November 18, 2019 3:46:04 PM
Last Modified: Monday, November 18, 2019 4:02:35 PM
Time Spent: 00:16:31
Email:
IP Address:

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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**Yes, it supports returning results but only in limited circumstances**
Q2 Does your company plan to change its current stance?	**Yes, we currently do not return and we plan to transition to returning results**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**To foster a greater partnership and/or transparency in the relationship between my company and study participants** **,** **To fulfill participants' right to receive data generated from their biological samples** **,** **To fulfill legal or regulatory obligations to return the results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Results are not interpretable at the individual level,** **Results are not useful for clinical decision-making ,** **There is not an industry standard to return results ,** **Liability concerns ,** **Results are not generated in a CLIA-certified laboratory setting ,** **Logistical hurdles ,** **Resource limitations,** **Site investigators are not comfortable conveying results to participants**
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**2017 ICH-E18, which was also adopted by FDA,** **2018 Revised Common Rule,** **2018 FDA guidance on revised Common Rule,** **2018 EU General Data Protection Regulation**

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)	**Whether the results are appropriate for clinical decision-making**, **Whether there are legal and/or regulatory requirements to return the results**, **Whether the study participant initiated a request for the results**
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)	**Study sponsor**, **IRB/EC**, **3rd party genetic counselor not affiliated with the sponsor, analysis lab, or site investigator**

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

Human tissue network colleagues
Legal
HAs function

Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**All diseases**
Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**All genomic data generated as part of a given test**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**CLIA-certified tests**
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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Raw sequence or genotype data**, **Variant call files**, **Predicted phenotype data**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Sometimes provide clinical annotation/interpretation**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**3rd party laboratory generating the result**, **3rd party genetics counselor not affiliated with the sponsor, analysis lab, or site investigator**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**

Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Sometimes, and not just for ACMG variants**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**3rd party genetic counseling service outside the research institute**
Q19 What is your company's process for returning results? (select all that apply)	**Study sponsor → Site investigator → Genetic counselor → Study participant** **,** **3rd party analysis lab → Genetic counselor → Study participant** **,** **Participant executes self-service access via a portal**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**Yes, sometimes**
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)	**2017 ICH-E18, which was also adopted by FDA,** **2018 Revised Common Rule,** **2018 FDA guidance on revised Common Rule,** **2018 EU General Data Protection Regulation**
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?	**Yes, sometimes**
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)	**2017 ICH-E18, which was also adopted by FDA,** **2018 Revised Common Rule,** **2018 FDA guidance on revised Common Rule,** **2018 EU General Data Protection Regulation**
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**2017 ICH-E18, which was also adopted by FDA,** **2018 Revised Common Rule,** **2018 FDA guidance on revised Common Rule,** **2018 EU General Data Protection Regulation**

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

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.

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:	**2017 ICH-E18, which was also adopted by FDA**

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

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.

Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**Yes, but not often**
Q31 Do you have any additional comments that you think would be useful to include in this survey:	**Respondent skipped this question**

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

1744

#16

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Monday, November 18, 2019 9:48:29 PM
Last Modified:	Monday, November 18, 2019 9:56:56 PM
Time Spent:	00:08:27
Email:	
IP Address:	

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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**No, our position is to not return results under any circumstances**
Q2 Does your company plan to change its current stance?	**No, we do not plan to change our stance**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**N/A, My company does not support any return of individual genomic research results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Results are not interpretable at the individual level,** **Resource limitations**
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**No regulations or guidances influenced my company's position**
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)	**N/A, My company does not support any return of individual genomic research results (SKIP TO QUESTION 20)**
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)	**Study sponsor**
Q8 If you selected the answer "Study sponsor" in Q7 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**Respondent skipped this question**
Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**Respondent skipped this question**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**Respondent skipped this question**
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?	**Respondent skipped this question**

Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Respondent skipped this question**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Never provide clinical annotation/interpretation (SKIP TO QUESTION 17)**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Respondent skipped this question**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Never (SKIP TO QUESTION 19)**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**
Q19 What is your company's process for returning results? (select all that apply)	**Respondent skipped this question**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**Respondent skipped this question**
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?	**No, never**
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)	**No guidances or regulations influenced it**
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?	**No, never**
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)	**No guidances or regulations influenced it**
Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**What information will be shared** , **How the results will be communicated** , **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)** , **Whether study participants will receive individual results of tests performed on their biological samples**

Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**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)”**
Q29 If you selected "Yes" to any of the options listed in Q28 please provide further information to explain your answer:	**Respondent skipped this question**
Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**No, never**
Q31 Do you have any additional comments that you think would be useful to include in this survey:	**Respondent skipped this question**

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

2088

#17

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Tuesday, November 19, 2019 7:48:06 PM
Last Modified:	Tuesday, November 19, 2019 9:36:54 PM
Time Spent:	01:48:47
Email:	
IP Address:	

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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**Yes, it supports returning results but only in limited circumstances**
Q2 Does your company plan to change its current stance?	**No, we do not plan to change our stance**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**To fulfill participants' right to receive data generated from their biological samples** **,** **To fulfill legal or regulatory obligations to return the results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Logistical hurdles** **,** **Resource limitations,** **Tests are performed after they would be of value to study participants and/or after the participants' last study visit**
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	**No regulations or guidances influenced my company's position**
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)	**Whether there are legal and/or regulatory requirements to return the results** **,** **Whether the study participant initiated a request for the results**
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)	**Site investigator,** **IRB/EC**
Q8 If you selected the answer "Study sponsor" in Q7 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**All diseases**
Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**All genomic data generated as part of a given test**

Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**CLIA-certified tests,** **GCLP,** **Research Use Only tests**
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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	Other (please specify): managed per patient/investigator request
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Never provide clinical annotation/interpretation (SKIP TO QUESTION 17)**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Respondent skipped this question**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Never (SKIP TO QUESTION 19)**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**
Q19 What is your company's process for returning results? (select all that apply)	**Study sponsor → Site investigator → Study participant ,** **3rd party analysis lab → Site investigator → Study participant**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**Institutional policies**
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?	**No, never**
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)	**No guidances or regulations influenced it**
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?	**Yes, always**
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)	**No guidances or regulations influenced it**

Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**Under what circumstances will results be communicated ,** **Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**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)"**
Q29 If you selected "Yes" to any of the options listed in Q28 please provide further information to explain your answer:	**Respondent skipped this question**
Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**Yes, but not often**

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

Requests for return of results have been very rare

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

8354

#18

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Wednesday, November 20, 2019 8:03:58 PM
Last Modified: Wednesday, November 20, 2019 8:18:03 PM
Time Spent: 00:14:05
Email:
IP Address:

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Q1 Does your company's current stance allow for the return of any individual genomic research results?	**No, our position is to not return results under any circumstances**
Q2 Does your company plan to change its current stance?	**No, we do not plan to change our stance**
Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)	**N/A, My company does not support any return of individual genomic research results**
Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)	**Results are not interpretable at the individual level,** **Results are not useful for clinical decision-making ,** **There is not an industry standard to return results ,** **Results are not generated in a CLIA-certified laboratory setting ,** **Logistical hurdles ,** **Resource limitations,** **Tests are performed after they would be of value to study participants and/or after the participants' last study visit ,** **To avoid promoting therapeutic misconception (participant may conflate the purpose of research with that of clinical care)**
Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)	Other (please specify): Not applicable since we do not return results
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)	**Respondent skipped this question**
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)	**Respondent skipped this question**
Q8 If you selected the answer "Study sponsor" in Q7 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q9 Which diseases are in scope at your company for returning individual genomic research results? (select all that apply)	**Respondent skipped this question**

Q10 What types of information are in scope at your company for return of individual genomic research results? (select all that apply)	**Respondent skipped this question**
Q11 What types of analytic platforms are permissible at your company for the return of individual genomic research results? (select all that apply)	**CLIA-certified tests**
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?	**No, and an alternative qualified/validated process is not in development**
Q13 What type of information is in scope at your company for return to participants? (select all that apply)	**Respondent skipped this question**
Q14 What is your company's position regarding providing clinical annotation or interpretation with an individual genomic research test result?	**Respondent skipped this question**
Q15 Which party(ies) are involved in preparing the annotation/interpretation to accompany the returned individual genomic research results? (Select all that apply)	**Respondent skipped this question**
Q16 If you selected the answer "Sponsor" in Q15 please specify the roles within the sponsor that are involved?	**Respondent skipped this question**
Q17 Does your company's process for returning individual genomic research results involve genetic counseling for study participants?	**Respondent skipped this question**
Q18 Which of the following methods for genetic counseling does your company use? (select all that apply)	**Respondent skipped this question**
Q19 What is your company's process for returning results? (select all that apply)	**Respondent skipped this question**
Q20 Which of the following do you feel are adequately in place to support individual genomic research results return? Select all that apply:	**None of the above**
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?	**No, never**
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)	**No guidances or regulations influenced it**
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?	**Yes, always**
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)	**Respondent skipped this question**

Q25 Which of the following are discussed in your company's informed consent documents? (select all that apply)	**Whether study participants will receive individual results of tests performed on their biological samples**
Q26 Has your company encountered challenges in complying with the following regulations/guidances in relation to returning individual genomic research results?	**No, we have not encountered any challenges with these regulations/guidances (SKIP TO QUESTION 28)**
Q27 If you selected any of the regulations/guidances in Question 26, please provide further information to explain the challenge(s):	**Respondent skipped this question**
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:	**2017 ICH-E18, which was also adopted by FDA**

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

Inform patients in informed consent form of non-return of genomic results

Q30 Has your company actually returned individual genomic research results to clinical trial participants?	**No, never**
Q31 Do you have any additional comments that you think would be useful to include in this survey:	**Respondent skipped this question**
Q32 Please enter your unique indiviual survey code that has been given to you by Julian Arbuckle:	**Respondent skipped this question**