

#1

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Thursday, October 31, 2019 4:34:00 PM
Last Modified: Thursday, October 31, 2019 8:11:54 PM
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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?

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

Respondent skipped this question

#2

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 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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

9901

#3

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

3444

#4

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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 recommendations

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

7333

#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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

3309

#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?

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)

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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)

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

Respondent skipped this question

#7

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:
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? **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**

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

7507

#8

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:
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 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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

2772

#9

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:
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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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.

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

2910

#10

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:
Email:
IP Address:

Page 1: Education & Communication Task Force

<p>Q1 Does your company's current stance allow for the return of any individual genomic research results?</p>	<p>Yes, it generally supports returning results</p>
<p>Q2 Does your company plan to change its current stance?</p>	<p>No, we do not plan to change our stance</p>
<p>Q3 What are your company's motivation(s) to return individual genomic research results? (select all that apply)</p>	<p>To fulfill legal or regulatory obligations to return the results</p>
<p>Q4 What reasons underpin your company's decision not to return individual genomic research results in some or all cases? (select all that apply)</p>	<p>N/A, My company always returns individual genomic research results</p> <p>,</p> <p>Other (please specify):</p> <p>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.</p>
<p>Q5 What regulations or guidances, if any, influenced your company's position regarding returning individual genomic results? (select all that apply)</p>	<p>2018 EU General Data Protection Regulation</p>
<p>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)</p>	<p>Other (please specify):</p> <p>Data is only returned on request (by patient)</p>
<p>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)</p>	<p>Other (please specify):</p> <p>N?A</p>

I-PWG Return of Results Survey

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)

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

2999

#11

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:
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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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)

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

1927

#12

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:
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 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**

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

4099

#13

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:
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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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**

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

1744

#14

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:
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 |

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

2088

#15

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:
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 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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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 individual survey code that has been given to you by Julian Arbuckle:

8354

#16

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:
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?

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)

I-PWG Return of Results Survey

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

I-PWG Return of Results Survey

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

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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 individual survey code that has been given to you by Julian Arbuckle:

Respondent skipped this question

#17

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Friday, December 06, 2019 2:18:21 PM
Last Modified: Friday, December 06, 2019 2:56:35 PM
Time Spent:
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 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)

Other (please specify):

My company supports returning results to study participants but uses a third party as the data controller. The company itself is not directly involved in the process, i.e. e.g. associated genetic counseling and doesn't store the samples and sequencing data. These are stored at the Data Controller (third party).

I-PWG Return of Results Survey

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):
NBAC, ACMG

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):
The company doesn't decide the return of results, this is an interaction between the clinical trial participant and the Data Controller (3rd party).

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 study participant, i.e. sample donor, and the Data Controller. The company is not a party in this process.

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

Not applicable

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):
The scope is determined by the study participant (sample donor).

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)

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

I-PWG Return of Results Survey

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

Other (please specify):

The scope is determined by the study participant and the Data Controller. Any of the three options may apply.

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

3rd party genetics counselor not affiliated with the sponsor, analysis lab, or site investigator

Other (please specify):

As outlined, the Data Controller (3rd party) is the party that interacts with the study participant.

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?

Yes, always

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

Online genetic counseling tool

Other (please specify):

The Data Controller (3rd party) provides the service and interacts directly with the study participant. The company is not part of this process.

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

Participant executes self-service access via a portal

I-PWG Return of Results Survey

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

Availability of support/follow up services (e.g. genetic counseling)

,

Financial resources

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

Other guidances and regulations (please specify):

NBAC, ACMG

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)

How the results will be communicated

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?

2018 EU General Data Protection Regulation

I-PWG Return of Results Survey

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 rolling this out, so some answers are admittedly 'aspirational' as we haven't had the very broad exposure in many countries 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:

We believe that the process where the 'honest broker' (and not the company) is the Data Controller will be appealing to regulators and study subjects.

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:

As mentioned previously, the company is in the process of finalizing this policy and will roll this out in 2020.

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

2276
