# #1

COMPLETE

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| **Collector:** | Email Invitation 1 (Email) |
| **Started:** | Friday, May 20, 2022 8:15:14 AM |
| **Last Modified:** | Friday, May 20, 2022 8:34:25 AM |
| **Time Spent:** | 00:19:11 |
| **Email:** | |
| **IP Address:** | |

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**Q1**

Please provide your company identifying code provided to you by Julian Arbuckle:

**Respondent skipped this question**

**Q2**

What type of company are you representing? [Multiple choice, one answer]:

**Big pharma (>10,000 employees)**

**Q3**

What is your most common stage of data that you work on within the company? [multiple choice, one answer]

**Clinical research**

**Q4**

In broad terms, what role best describes your position at the company (e.g. statistical geneticist?) [open text]

genomic Operational Expert

**Q5**

Is your company currently using (internally or externally sourced) Next Generation Sequencing (NGS) technologies for clinical PGx studies?

**Yes**

**Q6**

How often does your company currently use NGS technologies for clinical PGx studies? [Multiple choice, choose one answer]

**Rarely used**

| | |
|---|---|
| **Q7**<br>For DNA sequencing, what approaches are being used? [Check all that apply] | **Whole Genome Sequencing,**<br>**Whole Exome Sequencing,**<br>**Targeted panels** |
| **Q8**<br>Which indications are using NGS for clinical PGx studies at your company? [Check all that apply] | **Opt out of answering** |
| **Q9**<br>Which phases of clinical development have utilized NGS technologies at your company? [Check all that apply] | **Respondent skipped this question** |
| **Q10**<br>To what extent are you using WES/WGS in your trials? [Choose one] | **Minority of trials** |
| **Q11**<br>What are your main motivations for generating WES/WGS in trials? [Select all that apply] | Other (please specify):<br>investigation with multiple scope from the above |
| **Q12**<br>Is WES/WGS data being generated retrospectively in older completed studies? [Choose one] | **Yes, for specific trials when a specific question arises** |
| **Q13**<br>Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one] | **No WES/WGS generated** |
| **Q14**<br>If you answered "Yes" to Q13, did mandatory WES/WGS cause a significant challenge to recruitment into trials? (more than any other form of genetic data collection) [Select one option] | **Respondent skipped this question** |
| **Q15**<br>In general, when requesting WES/WGS in trials does it lead to reduced uptake of enrolment in the trial, or other logistical challenges? [Select one option] | **Yes, to a large degree** |

**Q16**

To what extent have the American College of Medical Genetics' guidelines for returning genomic results to participants influenced your decision to include WES/WGS in trials? [Select one option]

**Not a factor**

**Q17**

Where do you receive the most pushback around inclusion of WES/WGS in trials? [One choice]

**IRBs,**

**Country specific laws/guidelines,**

**Internal – Finance**

**Q18**

Are there any common pushbacks from patients around WES/WGS? [Free text]

**Respondent skipped this question**

**Q19**

Are there any common pushbacks from sites/IRBs around WES/WGS? [Free text]

Ethic Committees

**Q20**

Are there any particular countries where you have difficulty implementing WES/WGS? [Free text]

yes

**Q21**

Have you identified any particularly successful strategies for increasing patient uptake of WES/WGS? [Multiple choice]

**Respondent skipped this question**

**Q22**

Which methods do you use for WES/WGS in clinical trials? [Select all that apply]

**Deep sequencing**

**Q23**

Do you generate WES/WGS to a CLIA standard or equivalent? [Select one]

**NA**

**Q24**

Do you generate WES/WGS alongside other data? [select all that apply]

**Genome-wide genotyping**

**Q25**

Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply]

**Respondent skipped this question**

**Q26**

Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one]

**Respondent skipped this question**

**Q27**

What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply]

**Local laws and regulations,**

**Insufficient scientific justification**

**Q28**

Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one]

**No**

**Q29**

Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one]

**Yes, though it is a minor consideration**

**Q30**

Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries?

**No**

**Q31**

Would easier/clearer rules around WES/WGS data collection in trials in a given country/site/jurisdiction increase the likelihood of your company basing a trial there?

**No**

**Q32**

Would your answers have changed if we had asked only about WES or WGS, rather than both? [Free text]

**Respondent skipped this question**

**Q33**

Are there any other comments or clarifications you would like to make? [Free text]

Feeling a trend for WGS/WES in US still an option, whereas in Europe (and other countries such as Israel) seems to become more complicated with stringent push-backs from ECs/IRBs when no very precise justification is given.

# #2

COMPLETE

**Collector:** Email Invitation 1 (Email)
**Started:** Friday, May 20, 2022 1:45:59 PM
**Last Modified:** Friday, May 20, 2022 2:03:17 PM
**Time Spent:** 00:17:18
**Email:**
**IP Address:**

Page 1

**Q1**

Please provide your company identifying code provided to you by Julian Arbuckle:

3444

**Q2**

What type of company are you representing? [Multiple choice, one answer]:

**Big pharma (>10,000 employees)**

**Q3**

What is your most common stage of data that you work on within the company? [multiple choice, one answer]

**Clinical research**

**Q4**

In broad terms, what role best describes your position at the company (e.g. statistical geneticist?) [open text]

Consent management expert, with a focus on consent for genetic analysis

**Q5**

Is your company currently using (internally or externally sourced) Next Generation Sequencing (NGS) technologies for clinical PGx studies?

**Yes**

**Q6**

How often does your company currently use NGS technologies for clinical PGx studies? [Multiple choice, choose one answer]

**Widely used**

| | |
|---|---|
| **Q7**<br>For DNA sequencing, what approaches are being used? [Check all that apply] | **Whole Genome Sequencing,**<br>**Whole Exome Sequencing,**<br>**Targeted panels** |
| **Q8**<br>Which indications are using NGS for clinical PGx studies at your company? [Check all that apply] | **Neuroscience,**<br>**Immunology,**<br>**Infectious disease,**<br>**Rare disease,**<br>**Oncology,**<br>**Other** |
| **Q9**<br>Which phases of clinical development have utilized NGS technologies at your company? [Check all that apply] | **Preclinical or research focused,**<br>**Phase I,**<br>**Phase IIa,**<br>**Phase IIb,**<br>**Phase III** |
| **Q10**<br>To what extent are you using WES/WGS in your trials? [Choose one] | **Majority of trials** |
| **Q11**<br>What are your main motivations for generating WES/WGS in trials? [Select all that apply] | **Ability to detect somatic mutations,**<br>**Exploratory research into disease/new targets,**<br>**Pharmacogenetics and predicting response** |
| **Q12**<br>Is WES/WGS data being generated retrospectively in older completed studies? [Choose one] | **Yes, for many trials as part of broader company wide effort** |
| **Q13**<br>Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one] | **Yes, in some trials** |

**Q14**

If you answered "Yes" to Q13, did mandatory WES/WGS cause a significant challenge to recruitment into trials? (more than any other form of genetic data collection) [Select one option]

**Yes, but minor challenges**

**Q15**

In general, when requesting WES/WGS in trials does it lead to reduced uptake of enrolment in the trial, or other logistical challenges? [Select one option]

**Yes, to a small degree**

**Q16**

To what extent have the American College of Medical Genetics' guidelines for returning genomic results to participants influenced your decision to include WES/WGS in trials? [Select one option]

**Not a factor**

**Q17**

Where do you receive the most pushback around inclusion of WES/WGS in trials? [One choice]

**IRBs,**

**Country specific laws/guidelines**

**Q18**

Are there any common pushbacks from patients around WES/WGS? [Free text]

**Respondent skipped this question**

**Q19**

Are there any common pushbacks from sites/IRBs around WES/WGS? [Free text]

- some countries require that this is optional for study participants. Others require that the scope of use of generated data is restricted to research on the disease under investigation in the trial. Countries in EU ask that study participants be informed of incidental findings.

**Q20**

Are there any particular countries where you have difficulty implementing WES/WGS? [Free text]

Difficulties if WGS is mandatory for broad scope of research - very much challenged in Spain and other EU countries

**Q21**

Have you identified any particularly successful strategies for increasing patient uptake of WES/WGS? [Multiple choice]

**Modifying consent wording to clarify risks/reason for research**

| | |
|---|---|
| **Q22**<br>Which methods do you use for WES/WGS in clinical trials? [Select all that apply] | **Respondent skipped this question** |
| **Q23**<br>Do you generate WES/WGS to a CLIA standard or equivalent? [Select one] | **Never** |
| **Q24**<br>Do you generate WES/WGS alongside other data? [select all that apply] | **Genome-wide genotyping** |
| **Q25**<br>Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply] | **Respondent skipped this question** |
| **Q26**<br>Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one] | **Yes – limited enthusiasm for selected projects** |
| **Q27**<br>What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply] | **Local laws and regulations,**<br>**Insufficient scientific justification** |
| **Q28**<br>Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one] | **No** |
| **Q29**<br>Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one] | **No** |
| **Q30**<br>Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries? | **No** |

**Q31**

Would easier/clearer rules around WES/WGS data collection in trials in a given country/site/jurisdiction increase the likelihood of your company basing a trial there?

**No**

**Q32**

Would your answers have changed if we had asked only about WES or WGS, rather than both? [Free text]

No

**Q33**

Are there any other comments or clarifications you would like to make? [Free text]

**Respondent skipped this question**

# #3

COMPLETE

**Collector:** Email Invitation 1 (Email)
**Started:** Thursday, June 02, 2022 7:51:28 PM
**Last Modified:** Thursday, June 02, 2022 8:06:23 PM
**Time Spent:** 00:14:55
**Email:**
**IP Address:**

Page 1

**Q1**

Please provide your company identifying code provided to you by Julian Arbuckle:

2299

**Q2**

What type of company are you representing? [Multiple choice, one answer]:

**Mid to large size biotechnology (>1000 - ≤10,000 employees)**

**Q3**

What is your most common stage of data that you work on within the company? [multiple choice, one answer]

**Clinical research**

**Q4**

In broad terms, what role best describes your position at the company (e.g. statistical geneticist?) [open text]

Clinical geneticist

**Q5**

Is your company currently using (internally or externally sourced) Next Generation Sequencing (NGS) technologies for clinical PGx studies?

**Yes**

**Q6**

How often does your company currently use NGS technologies for clinical PGx studies? [Multiple choice, choose one answer]

**Widely used**

| | |
|---|---|
| **Q7**<br>For DNA sequencing, what approaches are being used? [Check all that apply] | **Whole Genome Sequencing,**<br>**Whole Exome Sequencing,**<br>**Targeted panels** |
| **Q8**<br>Which indications are using NGS for clinical PGx studies at your company? [Check all that apply] | **Neuroscience,**<br>**Rare disease,**<br>**Other** |
| **Q9**<br>Which phases of clinical development have utilized NGS technologies at your company? [Check all that apply] | **Phase I,**<br>**Phase IIa,**<br>**Phase IIb,**<br>**Phase III,**<br>**Phase IV** |
| **Q10**<br>To what extent are you using WES/WGS in your trials? [Choose one] | **Majority of trials** |
| **Q11**<br>What are your main motivations for generating WES/WGS in trials? [Select all that apply] | **Biobanking data that may be hard to retrieve later,**<br>**Exploratory research into disease/new targets,**<br>**Pharmacogenetics and predicting response,**<br>**Inclusion/exclusion criteria,**<br>**Use of genomic variables for stratification/covariates in trial** |
| **Q12**<br>Is WES/WGS data being generated retrospectively in older completed studies? [Choose one] | **Yes, for specific trials when a specific question arises** |
| **Q13**<br>Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one] | **Yes, in some trials** |

**Q14**

If you answered "Yes" to Q13, did mandatory WES/WGS cause a significant challenge to recruitment into trials? (more than any other form of genetic data collection) [Select one option]

**No meaningful impact on recruitment**

**Q15**

In general, when requesting  WES/WGS in trials does it lead to reduced uptake of enrolment in the trial, or other logistical challenges? [Select one option]

**No/Negligible**

**Q16**

To what extent have the American College of Medical Genetics' guidelines for returning genomic results to participants influenced your decision to include WES/WGS in trials? [Select one option]

**Not a factor**

**Q17**

Where do you receive the most pushback around inclusion of WES/WGS in trials? [One choice]

**Country specific laws/guidelines**

**Q18**

Are there any common pushbacks from patients around WES/WGS? [Free text]

**Respondent skipped this question**

**Q19**

Are there any common pushbacks from sites/IRBs around WES/WGS? [Free text]

**Respondent skipped this question**

**Q20**

Are there any particular countries where you have difficulty implementing WES/WGS? [Free text]

China, mostly.

**Q21**

Have you identified any particularly successful strategies for increasing patient uptake of WES/WGS? [Multiple choice]

**Modifying consent wording to clarify risks/reason for research**

| | |
|---|---|
| **Q22**<br>Which methods do you use for WES/WGS in clinical trials? [Select all that apply] | **Respondent skipped this question** |
| **Q23**<br>Do you generate WES/WGS to a CLIA standard or equivalent? [Select one] | **Always** |
| **Q24**<br>Do you generate WES/WGS alongside other data? [select all that apply] | **Targeted clinical genotyping/gene panels** |
| **Q25**<br>Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply] | **Use of GxP compliant platforms** |
| **Q26**<br>Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one] | **Yes – limited enthusiasm for selected projects** |
| **Q27**<br>What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply] | **Cost,**<br>**Return of results,**<br>**Too small a sample size in trials,**<br>**Data management requirements** |
| **Q28**<br>Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one] | **Yes, it is a major consideration** |
| **Q29**<br>Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one] | **Yes, though it is a minor consideration** |
| **Q30**<br>Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries? | **Yes, though it is a minor consideration** |

**Q31**

Would easier/clearer rules around WES/WGS data collection in trials in a given country/site/jurisdiction increase the likelihood of your company basing a trial there?

**Yes, it would be a lesser factor**

**Q32**

Would your answers have changed if we had asked only about WES or WGS, rather than both? [Free text]

no

**Q33**

Are there any other comments or clarifications you would like to make? [Free text]

**Respondent skipped this question**

# #4

COMPLETE

**Collector:** Email Invitation 1 (Email)
**Started:** Tuesday, June 07, 2022 12:06:20 PM
**Last Modified:** Tuesday, June 07, 2022 12:22:12 PM
**Time Spent:** 00:15:52
**Email:**
**IP Address:**

Page 1

**Q1**

Please provide your company identifying code provided to you by Julian Arbuckle:

4099

**Q2**

What type of company are you representing? [Multiple choice, one answer]:

**Mid to large size biotechnology (>1000 - ≤10,000 employees)**

**Q3**

What is your most common stage of data that you work on within the company? [multiple choice, one answer]

**Clinical research**

**Q4**

In broad terms, what role best describes your position at the company (e.g. statistical geneticist?) [open text]

Analysis of clinical trial genomic data

**Q5**

Is your company currently using (internally or externally sourced) Next Generation Sequencing (NGS) technologies for clinical PGx studies?

**Yes**

**Q6**

How often does your company currently use NGS technologies for clinical PGx studies? [Multiple choice, choose one answer]

**Occasionally used**

| | |
|---|---|
| **Q7**<br>For DNA sequencing, what approaches are being used? [Check all that apply] | **Whole Genome Sequencing,**<br>**Targeted panels** |
| **Q8**<br>Which indications are using NGS for clinical PGx studies at your company? [Check all that apply] | **Metabolism,**<br>**Rare disease,**<br>**Oncology,**<br>**Other** |
| **Q9**<br>Which phases of clinical development have utilized NGS technologies at your company? [Check all that apply] | **Preclinical or research focused,**<br>**Phase I,**<br>**Phase IIa,**<br>**Phase IIb,**<br>**Phase III** |
| **Q10**<br>To what extent are you using WES/WGS in your trials? [Choose one] | **Majority of trials** |
| **Q11**<br>What are your main motivations for generating WES/WGS in trials? [Select all that apply] | **Biobanking data that may be hard to retrieve later,**<br>**Ability to detect somatic mutations,**<br>**Expansion opportunities,**<br>**Pharmacogenetics and predicting response,**<br>**Inclusion/exclusion criteria** |
| **Q12**<br>Is WES/WGS data being generated retrospectively in older completed studies? [Choose one] | **Yes, for many trials as part of broader company wide effort** |
| **Q13**<br>Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one] | **No and never has been** |

**Q14**

If you answered "Yes" to Q13, did mandatory WES/WGS cause a significant challenge to recruitment into trials? (more than any other form of genetic data collection) [Select one option]

**NA**

**Q15**

In general, when requesting  WES/WGS in trials does it lead to reduced uptake of enrolment in the trial, or other logistical challenges? [Select one option]

**No/Negligible**

**Q16**

To what extent have the American College of Medical Genetics' guidelines for returning genomic results to participants influenced your decision to include WES/WGS in trials? [Select one option]

**To a small extent – decreasing likelihood of WES/WGS use**

**Q17**

Where do you receive the most pushback around inclusion of WES/WGS in trials? [One choice]

**IRBs**

**Q18**

Are there any common pushbacks from patients around WES/WGS? [Free text]

Concerns about local IRBs/rules making it difficult - and that impacting clinical operations.

**Q19**

Are there any common pushbacks from sites/IRBs around WES/WGS? [Free text]

Restrictions on use of samples for WGS, whether it is scientifically justified, return of results.

**Q20**

Are there any particular countries where you have difficulty implementing WES/WGS? [Free text]

South Africa, Brazil, Taiwan

**Q21**

Have you identified any particularly successful strategies for increasing patient uptake of WES/WGS? [Multiple choice]

Other (please specify):
Engaging PIs, FAQs for IRBs [multiple choice did not work]

| | |
|---|---|
| **Q22**<br>Which methods do you use for WES/WGS in clinical trials? [Select all that apply] | **Low depth sequencing** |
| **Q23**<br>Do you generate WES/WGS to a CLIA standard or equivalent? [Select one] | **Never** |
| **Q24**<br>Do you generate WES/WGS alongside other data? [select all that apply] | Other (please specify):<br>All of the above |
| **Q25**<br>Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply] | **Use of GxP compliant platforms,**<br>**GDPR specific checks** |
| **Q26**<br>Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one] | **Yes – very keen** |
| **Q27**<br>What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply] | **Reduced uptake during recruitment,**<br>**Local laws and regulations,**<br>**Return of results** |
| **Q28**<br>Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one] | **Yes, though it is a minor consideration** |
| **Q29**<br>Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one] | **Yes, though it is a minor consideration** |
| **Q30**<br>Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries? | **No** |

**Q31**

Would easier/clearer rules around WES/WGS data collection in trials in a given country/site/jurisdiction increase the likelihood of your company basing a trial there?

**Yes, it would be a lesser factor**

**Q32**

Would your answers have changed if we had asked only about WES or WGS, rather than both? [Free text]

No - though we prefer WGS given limited increase in cost and importance of non-genic regions

**Q33**

Are there any other comments or clarifications you would like to make? [Free text]

**Respondent skipped this question**

# #5

COMPLETE

**Collector:** Email Invitation 1 (Email)
**Started:** Monday, June 06, 2022 1:47:55 PM
**Last Modified:** Tuesday, June 07, 2022 12:57:03 PM
**Time Spent:** 23:09:08
**Email:**
**IP Address:**

Page 1

**Q1**

Please provide your company identifying code provided to you by Julian Arbuckle:

7333

**Q2**

What type of company are you representing? [Multiple choice, one answer]:

**Big pharma (>10,000 employees)**

**Q3**

What is your most common stage of data that you work on within the company? [multiple choice, one answer]

**Clinical research**

**Q4**

In broad terms, what role best describes your position at the company (e.g. statistical geneticist?) [open text]

Biomarker/PGx SME

**Q5**

Is your company currently using (internally or externally sourced) Next Generation Sequencing (NGS) technologies for clinical PGx studies?

**Yes**

**Q6**

How often does your company currently use NGS technologies for clinical PGx studies? [Multiple choice, choose one answer]

**Rarely used**

| | |
|---|---|
| **Q7**<br>For DNA sequencing, what approaches are being used? [Check all that apply] | **Whole Exome Sequencing,**<br>**Targeted panels** |
| **Q8**<br>Which indications are using NGS for clinical PGx studies at your company? [Check all that apply] | **Opt out of answering** |
| **Q9**<br>Which phases of clinical development have utilized NGS technologies at your company? [Check all that apply] | **Preclinical or research focused,**<br>**Phase IIa,**<br>**Phase IIb,**<br>**Phase III,**<br>**Phase IV** |
| **Q10**<br>To what extent are you using WES/WGS in your trials? [Choose one] | **Minority of trials** |
| **Q11**<br>What are your main motivations for generating WES/WGS in trials? [Select all that apply] | **Ability to detect somatic mutations,**<br>**Exploratory research into disease/new targets,**<br>**Expansion opportunities** |
| **Q12**<br>Is WES/WGS data being generated retrospectively in older completed studies? [Choose one] | **Yes, for specific trials when a specific question arises** |
| **Q13**<br>Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one] | **No and never has been** |
| **Q14**<br>If you answered "Yes" to Q13, did mandatory WES/WGS cause a significant challenge to recruitment into trials? (more than any other form of genetic data collection) [Select one option] | **NA** |

**Q15**

In general, when requesting  WES/WGS in trials does it lead to reduced uptake of enrolment in the trial, or other logistical challenges? [Select one option]

**No/Negligible**

**Q16**

To what extent have the American College of Medical Genetics' guidelines for returning genomic results to participants influenced your decision to include WES/WGS in trials? [Select one option]

**To a large extent – decreasing likelihood of WES/WGS use**

**Q17**

Where do you receive the most pushback around inclusion of WES/WGS in trials? [One choice]

**Internal – Operations**

**Q18**

Are there any common pushbacks from patients around WES/WGS? [Free text]

Not of which I am aware

**Q19**

Are there any common pushbacks from sites/IRBs around WES/WGS? [Free text]

Scope of use, patient privacy protection, access to data and how incidental findings would be managed

**Q20**

Are there any particular countries where you have difficulty implementing WES/WGS? [Free text]

Turkey and Canada have both pushed back regarding potential WES/WGS even when optional

**Q21**

Have you identified any particularly successful strategies for increasing patient uptake of WES/WGS? [Multiple choice]

**Engaging PIs**

**Q22**

Which methods do you use for WES/WGS in clinical trials? [Select all that apply]

**Low depth sequencing**

| | |
|---|---|
| **Q23**<br>Do you generate WES/WGS to a CLIA standard or equivalent? [Select one] | **NA** |
| **Q24**<br>Do you generate WES/WGS alongside other data? [select all that apply] | Other (please specify):<br>RNA-seq and proteomics (survey wouldn't let me check the 2 boxes) |
| **Q25**<br>Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply] | **Use of GxP compliant platforms,**<br>**CDISC data formats,**<br>**GDPR specific checks** |
| **Q26**<br>Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one] | **No** |
| **Q27**<br>What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply] | **Cost,**<br>**Local laws and regulations,**<br>**Return of results,**<br>**Insufficient scientific justification,**<br>**Too small a sample size in trials** |
| **Q28**<br>Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one] | **No** |
| **Q29**<br>Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one] | **No** |
| **Q30**<br>Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries? | **No** |

**Q31**

Would easier/clearer rules around WES/WGS data collection in trials in a given country/site/jurisdiction increase the likelihood of your company basing a trial there?

**It might occasionally be a factor**

**Q32**

Would your answers have changed if we had asked only about WES or WGS, rather than both? [Free text]

No, except for perhaps cost, WES and WGS have the same issues for us

**Q33**

Are there any other comments or clarifications you would like to make? [Free text]

WGS has not been used, WES is occasionally used, but rarely and in a research or post-trial research use. Most common use is NGS for targeted applications and we still get pushback from ECs/IRBs lumping "NGS" together regardless if targeted or broad. For question 15, we don't have mandatory inclusion of WES/WGS, but we do have this included as optional testing and so have had no issues impacting enrollment.

# #6

COMPLETE

| | |
|---|---|
| **Collector:** | Email Invitation 1 (Email) |
| **Started:** | Tuesday, June 07, 2022 3:31:01 PM |
| **Last Modified:** | Tuesday, June 07, 2022 5:12:12 PM |
| **Time Spent:** | 01:41:11 |
| **Email:** | |
| **IP Address:** | |

Page 1

**Q1**

Please provide your company identifying code provided to you by Julian Arbuckle:

8008

**Q2**

What type of company are you representing? [Multiple choice, one answer]:

**Big pharma (>10,000 employees)**

**Q3**

What is your most common stage of data that you work on within the company? [multiple choice, one answer]

**Clinical research**

**Q4**

In broad terms, what role best describes your position at the company (e.g. statistical geneticist?) [open text]

Pharmacogenomics head

**Q5**

Is your company currently using (internally or externally sourced) Next Generation Sequencing (NGS) technologies for clinical PGx studies?

**Yes**

**Q6**

How often does your company currently use NGS technologies for clinical PGx studies? [Multiple choice, choose one answer]

**Widely used**

| | |
|---|---|
| **Q7**<br>For DNA sequencing, what approaches are being used? [Check all that apply] | **Whole Exome Sequencing** |
| **Q8**<br>Which indications are using NGS for clinical PGx studies at your company? [Check all that apply] | **Cardiovascular,**<br>**Metabolism,**<br>**Neuroscience,**<br>**Immunology,**<br>**Infectious disease,**<br>**Rare disease,**<br>**Oncology** |
| **Q9**<br>Which phases of clinical development have utilized NGS technologies at your company? [Check all that apply] | **Preclinical or research focused,**<br>**Phase I,**<br>**Phase IIa,**<br>**Phase IIb,**<br>**Phase III,**<br>**Phase IV** |
| **Q10**<br>To what extent are you using WES/WGS in your trials? [Choose one] | **Majority of trials** |
| **Q11**<br>What are your main motivations for generating WES/WGS in trials? [Select all that apply] | **Pharmacogenetics and predicting response,**<br>**Use of genomic variables for stratification/covariates in trial** |
| **Q12**<br>Is WES/WGS data being generated retrospectively in older completed studies? [Choose one] | **Yes, for many trials as part of broader company wide effort** |
| **Q13**<br>Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one] | **Yes, in some trials** |

**Q14**

If you answered "Yes" to Q13, did mandatory WES/WGS cause a significant challenge to recruitment into trials? (more than any other form of genetic data collection) [Select one option]

**Yes, large challenges for recruitment**

**Q15**

In general, when requesting  WES/WGS in trials does it lead to reduced uptake of enrolment in the trial, or other logistical challenges? [Select one option]

**No/Negligible**

**Q16**

To what extent have the American College of Medical Genetics' guidelines for returning genomic results to participants influenced your decision to include WES/WGS in trials? [Select one option]

**Not a factor**

**Q17**

Where do you receive the most pushback around inclusion of WES/WGS in trials? [One choice]

**IRBs,**

**Country specific laws/guidelines**

**Q18**

Are there any common pushbacks from patients around WES/WGS? [Free text]

**Respondent skipped this question**

**Q19**

Are there any common pushbacks from sites/IRBs around WES/WGS? [Free text]

**Respondent skipped this question**

**Q20**

Are there any particular countries where you have difficulty implementing WES/WGS? [Free text]

**Respondent skipped this question**

**Q21**

Have you identified any particularly successful strategies for increasing patient uptake of WES/WGS? [Multiple choice]

**Modifying consent wording to clarify risks/reason for research**

**Q22**

Which methods do you use for WES/WGS in clinical trials? [Select all that apply]

**Deep sequencing**

| | |
|---|---|
| **Q23**<br>Do you generate WES/WGS to a CLIA standard or equivalent? [Select one] | **Never** |
| **Q24**<br>Do you generate WES/WGS alongside other data? [select all that apply] | **Genome-wide genotyping** |
| **Q25**<br>Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply] | **Respondent skipped this question** |
| **Q26**<br>Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one] | **Yes – very keen** |
| **Q27**<br>What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply] | Other (please specify):<br>No hesitation. |
| **Q28**<br>Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one] | **No** |
| **Q29**<br>Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one] | **No** |
| **Q30**<br>Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries? | **Yes, though it is a minor consideration** |
| **Q31**<br>Would easier/clearer rules around WES/WGS data collection in trials in a given country/site/jurisdiction increase the likelihood of your company basing a trial there? | **Yes, it would be a lesser factor** |

**Q32**

Would your answers have changed if we had asked only about WES or WGS, rather than both? [Free text]

no

**Q33**

Are there any other comments or clarifications you would like to make? [Free text]

**Respondent skipped this question**

# #7

COMPLETE

| | |
|---|---|
| **Collector:** | Email Invitation 1 (Email) |
| **Started:** | Friday, June 10, 2022 5:55:52 AM |
| **Last Modified:** | Friday, June 10, 2022 6:12:55 AM |
| **Time Spent:** | 00:17:02 |
| **Email:** | |
| **IP Address:** | |

Page 1

**Q1**

Please provide your company identifying code provided to you by Julian Arbuckle:

7755

**Q2**

What type of company are you representing? [Multiple choice, one answer]:

**Mid to large size biotechnology (>1000 - ≤10,000 employees)**

**Q3**

What is your most common stage of data that you work on within the company? [multiple choice, one answer]

**Preclinical research**

**Q4**

In broad terms, what role best describes your position at the company (e.g. statistical geneticist?) [open text]

Biomarker specialist

**Q5**

Is your company currently using (internally or externally sourced) Next Generation Sequencing (NGS) technologies for clinical PGx studies?

**Yes**

**Q6**

How often does your company currently use NGS technologies for clinical PGx studies? [Multiple choice, choose one answer]

**Widely used**

| | |
|---|---|
| **Q7**<br>For DNA sequencing, what approaches are being used? [Check all that apply] | **Targeted panels** |
| **Q8**<br>Which indications are using NGS for clinical PGx studies at your company? [Check all that apply] | **Oncology** |
| **Q9**<br>Which phases of clinical development have utilized NGS technologies at your company? [Check all that apply] | **Preclinical or research focused,**<br>**Phase I,**<br>**Phase IIa,**<br>**Phase IIb** |
| **Q10**<br>To what extent are you using WES/WGS in your trials? [Choose one] | **None** |
| **Q11**<br>What are your main motivations for generating WES/WGS in trials? [Select all that apply] | Other (please specify):<br>NA |
| **Q12**<br>Is WES/WGS data being generated retrospectively in older completed studies? [Choose one] | **No - it is not a priority** |
| **Q13**<br>Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one] | **No and never has been** |
| **Q14**<br>If you answered "Yes" to Q13, did mandatory WES/WGS cause a significant challenge to recruitment into trials? (more than any other form of genetic data collection) [Select one option] | **Respondent skipped this question** |
| **Q15**<br>In general, when requesting WES/WGS in trials does it lead to reduced uptake of enrolment in the trial, or other logistical challenges? [Select one option] | **NA** |

**Q16**

To what extent have the American College of Medical Genetics' guidelines for returning genomic results to participants influenced your decision to include WES/WGS in trials? [Select one option]

**NA**

**Q17**

Where do you receive the most pushback around inclusion of WES/WGS in trials? [One choice]

**Internal – Scientific rationale**

**Q18**

Are there any common pushbacks from patients around WES/WGS? [Free text]

NA

**Q19**

Are there any common pushbacks from sites/IRBs around WES/WGS? [Free text]

NA

**Q20**

Are there any particular countries where you have difficulty implementing WES/WGS? [Free text]

NA

**Q21**

Have you identified any particularly successful strategies for increasing patient uptake of WES/WGS? [Multiple choice]

Other (please specify):
NA

**Q22**

Which methods do you use for WES/WGS in clinical trials? [Select all that apply]

**Respondent skipped this question**

**Q23**

Do you generate WES/WGS to a CLIA standard or equivalent? [Select one]

**NA**

**Q24**

Do you generate WES/WGS alongside other data? [select all that apply]

Other (please specify):
NA

**Q25**

Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply]

**Respondent skipped this question**

**Q26**

Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one]

**No**

**Q27**

What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply]

**Cost,**

**Insufficient scientific justification**

**Q28**

Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one]

**No**

**Q29**

Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one]

**No**

**Q30**

Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries?

**No**

**Q31**

Would easier/clearer rules around WES/WGS data collection in trials in a given country/site/jurisdiction increase the likelihood of your company basing a trial there?

**No**

**Q32**

Would your answers have changed if we had asked only about WES or WGS, rather than both? [Free text]

No

**Q33**

Are there any other comments or clarifications you would like to make? [Free text]

-

# #8

COMPLETE

**Collector:** Email Invitation 1 (Email)
**Started:** Friday, June 10, 2022 4:25:33 PM
**Last Modified:** Friday, June 10, 2022 4:30:41 PM
**Time Spent:** 00:05:07
**Email:**
**IP Address:**

Page 1

**Q1**

Please provide your company identifying code provided to you by Julian Arbuckle:

2772

**Q2**

What type of company are you representing? [Multiple choice, one answer]:

**Big pharma (>10,000 employees)**

**Q3**

What is your most common stage of data that you work on within the company? [multiple choice, one answer]

**Clinical research**

**Q4**

In broad terms, what role best describes your position at the company (e.g. statistical geneticist?) [open text]

Genetics lab scientist; biomarker lead; biospecimen oversight head; bioinformaticist

**Q5**

Is your company currently using (internally or externally sourced) Next Generation Sequencing (NGS) technologies for clinical PGx studies?

**Yes**

**Q6**

How often does your company currently use NGS technologies for clinical PGx studies? [Multiple choice, choose one answer]

**Occasionally used**

| | |
|---|---|
| **Q7**<br>For DNA sequencing, what approaches are being used? [Check all that apply] | **Whole Genome Sequencing,**<br>**Whole Exome Sequencing,**<br>**Targeted panels** |
| **Q8**<br>Which indications are using NGS for clinical PGx studies at your company? [Check all that apply] | **Metabolism,**<br>**Immunology,**<br>**Infectious disease,**<br>**Rare disease,**<br>**Oncology** |
| **Q9**<br>Which phases of clinical development have utilized NGS technologies at your company? [Check all that apply] | **Preclinical or research focused,**<br>**Phase I,**<br>**Phase IIa,**<br>**Phase IIb,**<br>**Phase III** |
| **Q10**<br>To what extent are you using WES/WGS in your trials? [Choose one] | **Minority of trials** |
| **Q11**<br>What are your main motivations for generating WES/WGS in trials? [Select all that apply] | **Ability to detect somatic mutations,**<br>**Exploratory research into disease/new targets,**<br>**Pharmacogenetics and predicting response,**<br>Other (please specify):<br>Monitoring pharmacodynamic response |
| **Q12**<br>Is WES/WGS data being generated retrospectively in older completed studies? [Choose one] | **Yes, for specific trials when a specific question arises** |
| **Q13**<br>Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one] | **Yes, in some trials** |

**Q14**

If you answered "Yes" to Q13, did mandatory WES/WGS cause a significant challenge to recruitment into trials? (more than any other form of genetic data collection) [Select one option]

**No meaningful impact on recruitment**

**Q15**

In general, when requesting  WES/WGS in trials does it lead to reduced uptake of enrolment in the trial, or other logistical challenges? [Select one option]

**Yes, to a small degree**

**Q16**

To what extent have the American College of Medical Genetics' guidelines for returning genomic results to participants influenced your decision to include WES/WGS in trials? [Select one option]

**Not a factor**

**Q17**

Where do you receive the most pushback around inclusion of WES/WGS in trials? [One choice]

**Country specific laws/guidelines**

**Q18**

Are there any common pushbacks from patients around WES/WGS? [Free text]

No

**Q19**

Are there any common pushbacks from sites/IRBs around WES/WGS? [Free text]

Yes. Pushback due to sensitivity of genetic information.

**Q20**

Are there any particular countries where you have difficulty implementing WES/WGS? [Free text]

Turkey; China

**Q21**

Have you identified any particularly successful strategies for increasing patient uptake of WES/WGS? [Multiple choice]

Other (please specify):
No; patient uptake has not been a big issue for us

| | |
|---|---|
| **Q22**<br>Which methods do you use for WES/WGS in clinical trials? [Select all that apply] | **Deep sequencing** |
| **Q23**<br>Do you generate WES/WGS to a CLIA standard or equivalent? [Select one] | **Sometimes** |
| **Q24**<br>Do you generate WES/WGS alongside other data? [select all that apply] | Other (please specify):<br>Question will not allow multiple choice. Answer is: Targeted panels + RNAseq + Proteomics + Metabolomics |
| **Q25**<br>Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply] | **CDISC data formats** |
| **Q26**<br>Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one] | **Yes – limited enthusiasm for selected projects** |
| **Q27**<br>What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply] | **Cost,**<br>**Local laws and regulations,**<br>**Insufficient scientific justification,**<br>**Too small a sample size in trials** |
| **Q28**<br>Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one] | **No** |
| **Q29**<br>Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one] | **No** |
| **Q30**<br>Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries? | **No** |

**Q31**

Would easier/clearer rules around WES/WGS data collection in trials in a given country/site/jurisdiction increase the likelihood of your company basing a trial there?

**No**

**Q32**

Would your answers have changed if we had asked only about WES or WGS, rather than both? [Free text]

No

**Q33**

Are there any other comments or clarifications you would like to make? [Free text]

**Respondent skipped this question**

# #9

COMPLETE

**Collector:** Email Invitation 1 (Email)
**Started:** Friday, June 10, 2022 5:07:21 PM
**Last Modified:** Friday, June 10, 2022 5:13:24 PM
**Time Spent:** 00:06:03
**Email:**
**IP Address:**

Page 1

**Q1**

Please provide your company identifying code provided to you by Julian Arbuckle:

2999

**Q2**

What type of company are you representing? [Multiple choice, one answer]:

**Big pharma (>10,000 employees)**

**Q3**

What is your most common stage of data that you work on within the company? [multiple choice, one answer]

**Clinical research**

**Q4**

In broad terms, what role best describes your position at the company (e.g. statistical geneticist?) [open text]

supporting inclusion of broad PGx analysis in clinical studies

**Q5**

Is your company currently using (internally or externally sourced) Next Generation Sequencing (NGS) technologies for clinical PGx studies?

**Yes**

**Q6**

How often does your company currently use NGS technologies for clinical PGx studies? [Multiple choice, choose one answer]

**Widely used**

**Q7**

For DNA sequencing, what approaches are being used? [Check all that apply]

**Whole Genome Sequencing,**

**Whole Exome Sequencing,**

**Targeted panels**

**Q8**

Which indications are using NGS for clinical PGx studies at your company? [Check all that apply]

**Cardiovascular,**

**Metabolism,**

**Neuroscience,**

**Immunology,**

**Infectious disease,**

**Rare disease,**

**Oncology**

**Q9**

Which phases of clinical development have utilized NGS technologies at your company? [Check all that apply]

**Preclinical or research focused,**

**Phase I,**

**Phase IIa,**

**Phase IIb,**

**Phase III**

**Q10**

To what extent are you using WES/WGS in your trials? [Choose one]

**Majority of trials**

**Q11**

What are your main motivations for generating WES/WGS in trials? [Select all that apply]

**Exploratory research into disease/new targets,**

**Pharmacogenetics and predicting response,**

**Inclusion/exclusion criteria,**

**Use of genomic variables for stratification/covariates in trial**

**Q12**

Is WES/WGS data being generated retrospectively in older completed studies? [Choose one]

**Yes, for specific trials when a specific question arises**

**Q13**

Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one]

**Respondent skipped this question**

**Q14**

If you answered "Yes" to Q13, did mandatory WES/WGS cause a significant challenge to recruitment into trials? (more than any other form of genetic data collection) [Select one option]

**Respondent skipped this question**

**Q15**

In general, when requesting  WES/WGS in trials does it lead to reduced uptake of enrolment in the trial, or other logistical challenges? [Select one option]

**Respondent skipped this question**

**Q16**

To what extent have the American College of Medical Genetics' guidelines for returning genomic results to participants influenced your decision to include WES/WGS in trials? [Select one option]

**Not a factor**

**Q17**

Where do you receive the most pushback around inclusion of WES/WGS in trials? [One choice]

**IRBs,**

**Country specific laws/guidelines**

**Q18**

Are there any common pushbacks from patients around WES/WGS? [Free text]

**Respondent skipped this question**

**Q19**

Are there any common pushbacks from sites/IRBs around WES/WGS? [Free text]

when considering optional WES/WGS, there are requests to return results of clinical significance

**Q20**

Are there any particular countries where you have difficulty implementing WES/WGS? [Free text]

Excluding countries which require return of results - Taiwan also requires lists of the genes which will be analysed

**Q21**

Have you identified any particularly successful strategies for increasing patient uptake of WES/WGS? [Multiple choice]

Other (please specify):

Multiple choice function not working - Engaging PI, FAQ for IRB and Modifying consent wording

| | |
|---|---|
| **Q22**<br>Which methods do you use for WES/WGS in clinical trials? [Select all that apply] | **Deep sequencing** |
| **Q23**<br>Do you generate WES/WGS to a CLIA standard or equivalent? [Select one] | **Respondent skipped this question** |
| **Q24**<br>Do you generate WES/WGS alongside other data? [select all that apply] | Other (please specify):<br>Multiple choice not working - Targeted panel, RNA-seq and proteomics |
| **Q25**<br>Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply] | **Respondent skipped this question** |
| **Q26**<br>Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one] | **Yes – very keen** |
| **Q27**<br>What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply] | **Respondent skipped this question** |
| **Q28**<br>Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one] | **Respondent skipped this question** |
| **Q29**<br>Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one] | **Respondent skipped this question** |
| **Q30**<br>Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries? | **Respondent skipped this question** |

**Q31**

Would easier/clearer rules around WES/WGS data collection in trials in a given country/site/jurisdiction increase the likelihood of your company basing a trial there?

**Respondent skipped this question**

**Q32**

Would your answers have changed if we had asked only about WES or WGS, rather than both? [Free text]

No

**Q33**

Are there any other comments or clarifications you would like to make? [Free text]

**Respondent skipped this question**

# #10

COMPLETE

**Collector:** Email Invitation 1 (Email)
**Started:** Monday, June 13, 2022 3:04:31 AM
**Last Modified:** Monday, June 13, 2022 3:15:39 AM
**Time Spent:** 00:11:07
**Email:**
**IP Address:**

Page 1

**Q1**

Please provide your company identifying code provided to you by Julian Arbuckle:

8871

**Q2**

What type of company are you representing? [Multiple choice, one answer]:

**Big pharma (>10,000 employees)**

**Q3**

What is your most common stage of data that you work on within the company? [multiple choice, one answer]

**Clinical research**

**Q4**

In broad terms, what role best describes your position at the company (e.g. statistical geneticist?) [open text]

Specimen Management/Informed Consent/Bioinformatics Research

**Q5**

Is your company currently using (internally or externally sourced) Next Generation Sequencing (NGS) technologies for clinical PGx studies?

**Yes**

**Q6**

How often does your company currently use NGS technologies for clinical PGx studies? [Multiple choice, choose one answer]

**Widely used**

| | |
|---|---|
| **Q7**<br>For DNA sequencing, what approaches are being used? [Check all that apply] | **Whole Genome Sequencing,**<br>**Whole Exome Sequencing** |
| **Q8**<br>Which indications are using NGS for clinical PGx studies at your company? [Check all that apply] | **Opt out of answering** |
| **Q9**<br>Which phases of clinical development have utilized NGS technologies at your company? [Check all that apply] | **Preclinical or research focused,**<br>**Phase I,**<br>**Phase IIa,**<br>**Phase IIb,**<br>**Phase III** |
| **Q10**<br>To what extent are you using WES/WGS in your trials? [Choose one] | **Majority of trials** |
| **Q11**<br>What are your main motivations for generating WES/WGS in trials? [Select all that apply] | **Biobanking data that may be hard to retrieve later,**<br>**Ability to detect somatic mutations,**<br>**Exploratory research into disease/new targets,**<br>**Expansion opportunities,**<br>**Pharmacogenetics and predicting response** |
| **Q12**<br>Is WES/WGS data being generated retrospectively in older completed studies? [Choose one] | **Yes, for specific trials when a specific question arises** |
| **Q13**<br>Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one] | **Yes, in some trials** |
| **Q14**<br>If you answered "Yes" to Q13, did mandatory WES/WGS cause a significant challenge to recruitment into trials? (more than any other form of genetic data collection) [Select one option] | **Yes, but minor challenges** |

**Q15**

In general, when requesting WES/WGS in trials does it lead to reduced uptake of enrolment in the trial, or other logistical challenges? [Select one option]

**No/Negligible**

**Q16**

To what extent have the American College of Medical Genetics' guidelines for returning genomic results to participants influenced your decision to include WES/WGS in trials? [Select one option]

**Not a factor**

**Q17**

Where do you receive the most pushback around inclusion of WES/WGS in trials? [One choice]

**IRBs,**

**Country specific laws/guidelines,**

**Internal – Scientific rationale**

**Q18**

Are there any common pushbacks from patients around WES/WGS? [Free text]

None directly from patients

**Q19**

Are there any common pushbacks from sites/IRBs around WES/WGS? [Free text]

**Respondent skipped this question**

**Q20**

Are there any particular countries where you have difficulty implementing WES/WGS? [Free text]

Yes, China, Turkey, Japan, Denmark, Israel.

**Q21**

Have you identified any particularly successful strategies for increasing patient uptake of WES/WGS? [Multiple choice]

Other (please specify):
Both FAQs for IRBs and modifying consent wording

**Q22**

Which methods do you use for WES/WGS in clinical trials? [Select all that apply]

**Deep sequencing**

| | |
|---|---|
| **Q23**<br>Do you generate WES/WGS to a CLIA standard or equivalent? [Select one] | **Never** |
| **Q24**<br>Do you generate WES/WGS alongside other data? [select all that apply] | Other (please specify):<br>All of the above |
| **Q25**<br>Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply] | **GDPR specific checks** |
| **Q26**<br>Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one] | **Respondent skipped this question** |
| **Q27**<br>What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply] | Other (please specify):<br>WES is currently conducted in many trials, but where it is not, a mix of cost, sample size, and scientific justification main considerations |
| **Q28**<br>Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one] | **No** |
| **Q29**<br>Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one] | **No** |
| **Q30**<br>Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries? | **No** |
| **Q31**<br>Would easier/clearer rules around WES/WGS data collection in trials in a given country/site/jurisdiction increase the likelihood of your company basing a trial there? | **It might occasionally be a factor** |

**Q32**

Would your answers have changed if we had asked only about WES or WGS, rather than both? [Free text]

Yes, WES used far more widely than WGS in clinical trials

**Q33**

Are there any other comments or clarifications you would like to make? [Free text]

Answers to many questions somewhat indication-specific, and would vary if asked for a specific indication.

For #22, assume "deep sequencing" means standard depth sequencing

# #11

COMPLETE

**Collector:** Web Link 2 (Web Link)
**Started:** Tuesday, June 14, 2022 10:00:18 PM
**Last Modified:** Tuesday, June 14, 2022 10:06:57 PM
**Time Spent:**
**IP Address:**

Page 1

**Q1**

Please provide your company identifying code provided to you by Julian Arbuckle:

2276

**Q2**

What type of company are you representing? [Multiple choice, one answer]:

**Small biotech (<1000 employees)**

**Q3**

What is your most common stage of data that you work on within the company? [multiple choice, one answer]

**Clinical research**

**Q4**

In broad terms, what role best describes your position at the company (e.g. statistical geneticist?) [open text]

Bridging discovery and preclinical work to ensure clinical readiness of preclinical assets

**Q5**

Is your company currently using (internally or externally sourced) Next Generation Sequencing (NGS) technologies for clinical PGx studies?

**Yes**

**Q6**

How often does your company currently use NGS technologies for clinical PGx studies? [Multiple choice, choose one answer]

**Occasionally used**

| | |
|---|---|
| **Q7**<br>For DNA sequencing, what approaches are being used? [Check all that apply] | **Whole Genome Sequencing,**<br>**Whole Exome Sequencing,**<br>**Targeted panels** |
| **Q8**<br>Which indications are using NGS for clinical PGx studies at your company? [Check all that apply] | **Cardiovascular,**<br>**Metabolism,**<br>**Neuroscience,**<br>**Immunology,**<br>**Rare disease,**<br>**Oncology** |
| **Q9**<br>Which phases of clinical development have utilized NGS technologies at your company? [Check all that apply] | **Preclinical or research focused,**<br>**Phase I,**<br>**Phase IIa,**<br>**Phase IIb,**<br>**Phase III** |
| **Q10**<br>To what extent are you using WES/WGS in your trials? [Choose one] | **Majority of trials** |
| **Q11**<br>What are your main motivations for generating WES/WGS in trials? [Select all that apply] | **Exploratory research into disease/new targets,**<br>**Pharmacogenetics and predicting response,**<br>**Inclusion/exclusion criteria,**<br>**Use of genomic variables for stratification/covariates in trial** |
| **Q12**<br>Is WES/WGS data being generated retrospectively in older completed studies? [Choose one] | **No - insufficient samples/consent etc.** |
| **Q13**<br>Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one] | **Yes, in some trials** |

**Q14**

If you answered "Yes" to Q13, did mandatory WES/WGS cause a significant challenge to recruitment into trials? (more than any other form of genetic data collection) [Select one option]

**NA**

**Q15**

In general, when requesting  WES/WGS in trials does it lead to reduced uptake of enrolment in the trial, or other logistical challenges? [Select one option]

**Yes, to a small degree**

**Q16**

To what extent have the American College of Medical Genetics' guidelines for returning genomic results to participants influenced your decision to include WES/WGS in trials? [Select one option]

**To a large extent – increasing likelihood of WES/WGS use**

**Q17**

Where do you receive the most pushback around inclusion of WES/WGS in trials? [One choice]

**Country specific laws/guidelines,**

**Internal – Operations**

**Q18**

Are there any common pushbacks from patients around WES/WGS? [Free text]

Not aware of any

**Q19**

Are there any common pushbacks from sites/IRBs around WES/WGS? [Free text]

Not so far

**Q20**

Are there any particular countries where you have difficulty implementing WES/WGS? [Free text]

In the process of expanding into Europe i.e. at present no experience outside of North America

**Q21**

Have you identified any particularly successful strategies for increasing patient uptake of WES/WGS? [Multiple choice]

Other (please specify):
Too early to tell

| | |
|---|---|
| **Q22**<br>Which methods do you use for WES/WGS in clinical trials? [Select all that apply] | **Respondent skipped this question** |
| **Q23**<br>Do you generate WES/WGS to a CLIA standard or equivalent? [Select one] | **Always** |
| **Q24**<br>Do you generate WES/WGS alongside other data? [select all that apply] | **Targeted clinical genotyping/gene panels** |
| **Q25**<br>Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply] | **Use of GxP compliant platforms** |
| **Q26**<br>Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one] | **No** |
| **Q27**<br>What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply] | **Local laws and regulations** |
| **Q28**<br>Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one] | **No** |
| **Q29**<br>Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one] | **No** |
| **Q30**<br>Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries? | **No** |

**Q31**

Would easier/clearer rules around WES/WGS data collection in trials in a given country/site/jurisdiction increase the likelihood of your company basing a trial there?

**No**

**Q32**

Would your answers have changed if we had asked only about WES or WGS, rather than both? [Free text]

No

**Q33**

Are there any other comments or clarifications you would like to make? [Free text]

The use of WGS in clinical trials is a very recent development and therefore only very limited experience exists to date