COMPLETE

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

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Page 1

Q1 Respondent skipped this question

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

Q2 Big pharma (>10,000 employees)

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

Q3 Clinical research

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

Q4

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

genomic Operational Expert

Q5 Yes

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

Q6 Rarely used

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]

Opt out of answering

Q9

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

Respondent skipped this question

Q10

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

Minority of trials

Q11

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

Other (please specify):

investigation with multiple scope from the above

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]

No WES/WGS generated

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]

Yes, to a large degree

Q16 Not a factor

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]

Q17 IRBs,

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

Country specific laws/guidelines,

Internal - Finance

Q18 Respondent skipped this question

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

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 Respondent skipped this question

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

Q22 Deep sequencing

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

Q23 NA

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

Q24 Genome-wide genotyping

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

Q25 Respondent skipped this question Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply] **Q26** Respondent skipped this question Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one] **Q27** Local laws and regulations, What are your main hesitations/bottlenecks for doing Insufficient scientific justification WES/WGS? [Select all that apply] **Q28** No Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one] Q29 Yes, though it is a minor consideration Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one] Q30 No Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries? Q31 No 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? **O32** Respondent skipped this question Would your answers have changed if we had asked only about WES or WGS, rather than both? [Free text]

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.

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

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Page 1

Q1

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

3444

Q2 Big pharma (>10,000 employees)

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

Q3 Clinical research

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

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 Yes

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

Q6 Widely used

Q7 Whole Genome Sequencing, For DNA sequencing, what approaches are being used? Whole Exome Sequencing, [Check all that apply] Targeted panels Q8 Neuroscience, Which indications are using NGS for clinical PGx studies Immunology, at your company? [Check all that apply] Infectious disease. Rare disease, Oncology, Other Q9 Preclinical or research focused, Which phases of clinical development have utilized NGS Phase I, technologies at your company? [Check all that apply] Phase IIa, Phase IIb. Phase III Q10

Majority of trials

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

Q11 Ability to detect somatic mutations, What are your main motivations for generating WES/WGS Exploratory research into disease/new targets, in trials? [Select all that apply] Pharmacogenetics and predicting response

Q12 Yes, for many trials as part of broader company wide effort Is WES/WGS data being generated retrospectively in older completed studies? [Choose one]

Q13 Yes, in some trials Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one]

Yes, but minor challenges

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]

Q15

Yes, to a small degree

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]

Q16

Not a factor

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]

Q17

IRBs.

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

Country specific laws/guidelines

Q18

Respondent skipped this question

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

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

Modifying consent wording to clarify risks/reason for research

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

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]	Never
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]	Yes – limited enthusiasm for selected projects
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]	No
Q30 Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries?	No

Q31 No

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?

Q32

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

No

Q33 Respondent skipped this question

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

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

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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 Clinical research

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

Q4

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

Clinical geneticist

Q5 Yes

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

Q6 Widely used

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]

Neuroscience,

Rare disease,

Other

Q9

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

Phase I,

Phase IIa,

Phase IIb,

Phase III,

Phase IV

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]

Biobanking data that may be hard to retrieve later,

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]

Yes, in some trials

No meaningful impact on recruitment

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]

Q15 No/Negligible

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]

Q16 Not a factor

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]

Q17 Country specific laws/guidelines

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

Q18 Respondent skipped this question

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

Q19 Respondent skipped this question

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

O20

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

China, mostly.

Q21 Modifying conse

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

WES/WGS specifically influence the selection of trial

sites/countries?

Q31 Yes, it would be a lesser factor

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?

Q32

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

no

Q33 Respondent skipped this question

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

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

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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 Clinical research

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

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 Yes

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

Q6 Occasionally used

Q7 Whole Genome Sequencing, For DNA sequencing, what approaches are being used? **Targeted panels** [Check all that apply] Q8 Metabolism, Which indications are using NGS for clinical PGx studies Rare disease, at your company? [Check all that apply] Oncology, Other Q9 Preclinical or research focused, Which phases of clinical development have utilized NGS Phase I, technologies at your company? [Check all that apply] Phase IIa, Phase IIb, Phase III Q10 **Majority of trials** To what extent are you using WES/WGS in your trials? [Choose one] Q11 Biobanking data that may be hard to retrieve later, Ability to detect somatic mutations, What are your main motivations for generating WES/WGS in trials? [Select all that apply] Expansion opportunities, Pharmacogenetics and predicting response, Inclusion/exclusion criteria Q12 Yes, for many trials as part of broader company wide effort Is WES/WGS data being generated retrospectively in older completed studies? [Choose one]

Q13

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

No and never has been

Q14 NA

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]

Q15 No/Negligible

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]

Q16 To a small extent – decreasing likelihood of WES/WGS use

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]

Q17 IRBs

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

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 Other (please specify):

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

Engaging PIs, FAQs for IRBs [multiple choice did not work]

Q22 Which methods do you use for WES/WGS in clinical trials? [Select all that apply]	Low depth sequencing
Q23 Do you generate WES/WGS to a CLIA standard or equivalent? [Select one]	Never
Q24 Do you generate WES/WGS alongside other data? [select all that apply]	Other (please specify): All of the above
Q25 Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply]	Use of GxP compliant platforms, GDPR specific checks
Q26 Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one]	Yes – very keen
Q27 What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply]	Reduced uptake during recruitment, Local laws and regulations, Return of results
Q28 Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one]	Yes, though it is a minor consideration
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

Yes, it would be a lesser factor

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?

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

Respondent skipped this question

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

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

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Page 1

Q1

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

7333

Q2 Big pharma (>10,000 employees)

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

Q3 Clinical research

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

Q4

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

Biomarker/PGx SME

Q5 Yes

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

Q6 Rarely used

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

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]

Q15 No/Negligible

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]

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

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]

Q17 Internal – Operations

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

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 Engaging PIs

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

Q22 Low depth sequencing

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

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): RNA-seq and proteomics (survey wouldn't let me check the 2 boxes)
Q25 Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply]	Use of GxP compliant platforms, CDISC data formats, GDPR specific checks
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, Local laws and regulations, Return of results, Insufficient scientific justification, Too small a sample size in trials
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

It might occasionally be a factor

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?

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.

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

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Page 1

Q1

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

8008

Q2 Big pharma (>10,000 employees)

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

Q3 Clinical research

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

Q4

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

Pharmacogenomics head

Q5 Yes

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

Q6 Widely used

Whole Exome Sequencing

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

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,

Phase IV

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]

Pharmacogenetics and predicting response,

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 many trials as part of broader company wide effort

Q13

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

Yes, in some trials

Yes, large challenges for recruitment

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]

Q15 No/Negligible

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]

Q16 Not a factor

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]

Q17 IRBs,

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

Country specific laws/guidelines

Q18 Respondent skipped this question

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

Q19 Respondent skipped this question

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

Q20 Respondent skipped this question

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

Q21 Modifying consent wording to clarify risks/reason for research

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

Q22 Deep sequencing

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

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

WGS in Clinical Trials - BioMarin Company Survey

Q32

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

no

Q33

Respondent skipped this question

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

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

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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 Preclinical research

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

Q4

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

Biomarker specialist

Q5 Yes

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

Q6 Widely used

Q7 Targeted panels For DNA sequencing, what approaches are being used? [Check all that apply] Q8 Oncology Which indications are using NGS for clinical PGx studies at your company? [Check all that apply] Q9 Preclinical or research focused, Which phases of clinical development have utilized NGS Phase I, technologies at your company? [Check all that apply] Phase IIa, Phase IIb Q10 None To what extent are you using WES/WGS in your trials? [Choose one] Q11 Other (please specify): NA What are your main motivations for generating WES/WGS in trials? [Select all that apply] Q12 No - it is not a priority Is WES/WGS data being generated retrospectively in older completed studies? [Choose one] Q13 No and never has been Is taking part in WES/WGS ever mandatory for participant inclusion into a trial? [Choose one] Q14 Respondent skipped this question 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] Q15 NA 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]

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 WE NA	S/WGS? [Free text]
Q19 Are there any common pushbacks from sites/IRBs around V NA	VES/WGS? [Free text]
Q20 Are there any particular countries where you have difficulty in NA	mplementing WES/WGS? [Free text]
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	Respondent skipped this question	
Which data management processes do you include for WES/WGS data from clinical trials? [Select all that apply]		
Q26	No	
Is there appetite to share genomic data from clinical trials as part of cross-industry collaborations? [Select one]		
Q27	Cost,	
What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply]	Insufficient scientific justification	
Q28	No	
Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one]		
Q29	No	
Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one]		
Q30	No	
Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries?		
Q31	No	
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?		
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]		
-		

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: lea.c.harty@pfizer.com

IP Address: 148.168.96.5

Page 1

Q1

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

2772

Q2 Big pharma (>10,000 employees)

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

Q3 Clinical research

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

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 Yes

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

Q6 Occasionally used

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]

Metabolism,

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]

Minority of trials

Q11

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

Ability to detect somatic mutations,

Exploratory research into disease/new targets,

Pharmacogenetics and predicting response,

Other (please specify):

Monitoring pharmacodynamic response

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]

Yes, in some trials

No meaningful impact on recruitment

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]

Q15 Yes, to a small degree

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]

Q16 Not a factor

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]

Q17 Country specific laws/guidelines

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

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

Q31 No

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?

Q32

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

No

Q33 Respondent skipped this question

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

#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: helen.stevens1@astrazeneca.com

IP Address: 147.161.166.179

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Q1

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

2999

Q2 Big pharma (>10,000 employees)

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

Q3 Clinical research

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

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 Yes

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

Q6 Widely used

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

Q7 Whole Genome Sequencing, For DNA sequencing, what approaches are being used? Whole Exome Sequencing, [Check all that apply] Targeted panels Q8 Cardiovascular, Metabolism, Which indications are using NGS for clinical PGx studies at your company? [Check all that apply] Neuroscience, Immunology, Infectious disease, Rare disease. Oncology Q9 Preclinical or research focused, Which phases of clinical development have utilized NGS Phase I, technologies at your company? [Check all that apply] Phase IIa. Phase IIb, Phase III Q10 **Majority of trials** To what extent are you using WES/WGS in your trials? [Choose one] Q11 Exploratory research into disease/new targets, Pharmacogenetics and predicting response, What are your main motivations for generating WES/WGS in trials? [Select all that apply] Inclusion/exclusion criteria, Use of genomic variables for stratification/covariates in trial

Q12

Q13

Is WES/WGS data being generated retrospectively in older

Yes, for specific trials when a specific question arises

completed studies? [Choose one]

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

Respondent skipped this question

Q14

Respondent skipped this question

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]

Q15

Respondent skipped this question

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]

Q16 Not a factor

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]

Q17 IRBs,

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

Country specific laws/guidelines

Q18 Respondent skipped this question

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

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

Q21

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

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 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]	Respondent skipped this question
Q24 Do you generate WES/WGS alongside other data? [select all that apply]	Other (please specify): Multiple choice not working - Targeted panel, RNA-seq and proteomics
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]	Yes – very keen
Q27 What are your main hesitations/bottlenecks for doing WES/WGS? [Select all that apply]	Respondent skipped this question
Q28 Does the ability to collect WES/WGS data influence the selection of trial sites? [Choose one]	Respondent skipped this question
Q29 Does the ability to collect WGS data prevent basing trial sites within specific counties? [Choose one]	Respondent skipped this question
Q30 Do the rules around the return of results around WES/WGS specifically influence the selection of trial sites/countries?	Respondent skipped this question

WGS in Clinical Trials - BioMarin Company Survey

Q31

Respondent skipped this question

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?

Q32

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

No

Q33

Respondent skipped this question

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

#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: Aparna.Chhibber@bms.com

IP Address: 165.89.114.113

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Q1

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

8871

Q2 Big pharma (>10,000 employees)

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

Q3 Clinical research

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

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 Yes

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

Q6 Widely used

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

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

Q14 res, but minor cha

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]

Q15 No/Negligible

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]

Q16 Not a factor

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]

Q17 IRBs,

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

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 Respondent skipped this question

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

Q20

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

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

Q21 Other (please specify):

Both FAQs for IRBs and modifying consent wording

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

Q22 Deep sequencing

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

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

WGS in Clinical Trials - BioMarin Company Survey

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: 00:06:38 **IP Address:** 66.78.209.129

Page 1

Q1

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

2276

Q2 Small biotech (<1000 employees)

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

Q3 Clinical research

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

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 Yes

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

Q6 Occasionally used

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

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

Q13 Yes, in some trials

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

Q14 NA

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]

Q15 Yes, to a small degree

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]

Q16 To a large extent – increasing likelihood of WES/WGS use

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]

Q17 Country specific laws/guidelines,

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 aware of any

019

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 Other (please specify):

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

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

Q31 No

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?

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