

Appendix C

Vendor Interview Guide

Project SAGE: Stakeholders Assessing Genetics with Employers

Project funder: National Human Genome Research Institute

Project lead: Patricia Deverka, MD, Geisinger Research

Purpose of the study: Understand the level of interest, opportunities, challenges and real-world experience associated with implementing non-indication based genetic testing as part of employer-sponsored wellness programs or health insurance. This information will be obtained through semi-structured interviews.

Read the following statement:

Before we proceed with the interview, I want to confirm that you understand the purpose of the research and have an opportunity to ask any questions you may have. You understand that, unless you refuse, your interview will be recorded, and any data collected during the study may be looked at by other researchers or regulatory authorities. However, identifying data, such as your name, your employer, and locations will be removed from transcriptions and notes. Recordings will be kept securely, only accessed by select members of the research team, and destroyed at the conclusion of the analysis. You have the right to leave the interview at any time or refuse to answer any questions. Do I have your permission to proceed with the interview?

Before we proceed with the interview, I'd like to ask you a few demographic questions:

- 1. What is your job title?***
- 2. Time in role?***
- 3. Time at company***

And a few questions about your company:

- 1. Company start date?***
- 2. Time in this market segment?***
- 3. Number of employer clients?***
- 4. National or regional presence?***

Interview questions:

Definition of employee genetic testing:

Voluntary genetic testing in employees with or without a personal or family history of genetic disease. The purpose of testing is to identify inherited risks that are evidence-based and medically actionable. The goals of testing may include employee engagement in their health, greater understanding of how genetics can affect health, enhanced well-being, early identification of health risks, safer and more effective medication use, and potential cost savings from improved preventive care.

- ***Clarify that medically actionable variants includes disease risk and PGx***
- ***Health-related physical and behavioral traits/conditions include nutrition, fitness, sleep, stress***

Please provide your feedback regarding the definition of non-indication based genetic testing for employees. Anything that you would change or add? Why?

1. ***What are the types of genetic tests that you offer to employers?***
2. ***What are the factors that led you to choose these types of tests?***
3. ***Can you provide access to examples of a typical client report (if available)?***
4. ***What types of wrap-around services do you provide in addition to testing?***

Now I'd like to ask you a few questions about who purchases your services and why.

1. ***Why do self-insured employers purchase or otherwise make available genetic testing services for their employees?***
 - *Probe: How does non-indication based genetic testing support health and wellness goals of employers? Of employees?*
2. ***Are there certain types of employers that tend to offer these services to their employees?***
 - *Industry*
 - *Geography*
 - *Self-insured*
3. ***Do any of these factors influence the purchasing decision?***
 - *Internal factors - Employee demand, fit with organizational goals re employee health and wellness, Employer understanding of federal and state-by-state legal requirements related to genetics and wellness programs, corporate decision-making structure*
 - *External factors – market competition for employees, need to retain top talent, state of genetic evidence supporting non-indication based genetic testing, laws governing privacy, laws governing uses of genetic data by state*

- 4. Are there advantages or disadvantages associated with offering these services as part of wellness programs?**
- 5. What is the process for employers to 'purchase' or otherwise make available non-indication based genetic testing services for their employees?**
 - Who are the key employer decision-makers involved in this process?
 - What are their role and title in their organization?
 - How do federal and state laws governing genetic testing and wellness programs influence employer decision-making if at all?

Now I'd like to ask you a few questions about how you demonstrate the value of your services to clients:

- 1. What types of reporting or outcomes do employers tend to ask for to assess the value of offering these services to their employees?**
- 2. Has your company evaluated the impact of these service? What do you typically measure in terms of impact?**
 - For example, the impact on employee health, quality of life, productivity, absenteeism, or health care costs for any of your clients?
 - If yes, can you describe your key findings now?
 - Can you provide access to any written reports?
 - If no, do you have any anecdotal evidence of general findings?
- 3. If feasibility or resources were not an issue, what types of outcomes or reporting or evidence would you like to provide to your clients to support the value proposition of these types of services?**
- 4. What has been the range of uptake of genetic testing by employees?**
 - By uptake, I am referring to a range of potential interactions, e.g., employees may express interest in genetic testing but not follow through with testing; scheduling a test, engaging in pre-and/or post-test counseling; seeking reimbursement for a test
- 5. What have been the lessons learned by your company regarding implementation?**
 - What barriers get in the way of employees taking advantage of these services?
 - What enablers support employees taking advantage of these services?
- 6. Would you be able to provide the names of employer clients that may be willing to be interviewed?**

Thank you for participating in this interview. I'd like to collect some information to ensure that we can send your honorarium promptly:

Name, address for mailing check.

CMO Interview Guide

Project SAGE: Stakeholders Assessing Genetics with Employers

Project Funder: National Human Genome Research Institute

Purpose of the study: Understand the level of interest, opportunities, challenges and real-world experience associated with implementing non-indication based genetic testing as part of employer-sponsored wellness programs or health insurance. This information will be obtained through telephone-based semi-structured interviews with experts such as you. We are asking you to represent your organization's experience in response to the interview questions. In circumstances where your organization has limited or no experience, we ask you to represent your own professional experience.

Employee Genetic Testing: *Voluntary, health-related genetic testing in employees with or without a personal or family history of genetic disease. The purpose of testing is to identify inherited risks that are evidence-based and medically actionable. The hypothesized goals of testing may include employee engagement in their health, greater understanding of how genetics can affect health, enhanced well-being, early identification of health risks, safer and more effective medication use, and potential cost savings from improved preventive care.*

Before we proceed with the interview, I want to confirm that you understand the purpose of the research and have an opportunity to ask any questions you may have. You understand that, unless you refuse, your interview will be recorded and any data collected during the study may be looked at by other researchers or regulatory authorities. However, identifying data, such as your name, your employer, and locations will be removed from transcriptions and notes. Recordings will be kept securely, only accessed by select members of the research team, and destroyed at the conclusion of the analysis no later than the end of August, 2020. You have the right to leave the interview at any time or refuse to answer any questions. Do I have your permission to proceed with the interview?

Job Title:

Job Role:

Years at Company:

Years in Role:

Interview questions:

1. *What is your general experience or familiarity with non-indication based genetic testing for employees at self-insured employers?*
2. *What is your understanding of the evidence supporting a relationship between genetic testing and employee health?*
3. *How does non-indication based genetic testing support the health and wellness goals of employers? Of employees?*
4. *What are the potential benefits of offering non-indication based genetic testing as part of company-sponsored wellness programs?*
5. *What are the potential challenges of offering genetic testing as part of company-sponsored wellness programs?*

Probes for potential benefits/challenges:

- *Type of employer (industry segment)*
- *Type of employee (age, educational background and role in company)*
- *How program is paid for (part of wellness program, part of health insurance benefit, out-of-pocket costs)*
- *How communication about offering genetic testing is conducted*
- *Internal factors - Employee demand, fit with organizational goals re employee health and wellness, CMO understanding of federal and state-by-state legal requirements related to genetics, corporate decision-making structure*
- *External factors - market competition for employees, need to retain top talent, state of genetic evidence supporting non-indication based genetic testing, laws governing privacy, laws governing uses of genetic data by state*
- 6. *What types of outcome measures would be useful to you to inform your assessment of the value of non-indication based genetic testing in wellness programs?*

For CMOs at companies that currently offer non-indication based genetic testing:

1. *If your organization currently offers population genetic testing for your employees, what are the categories of tests that are included?*
2. *What were the factors that led your organization to choose these categories?*
3. *Why do self-insured employers purchase or otherwise make available genetic testing services for their employees?*

- 4. Describe the decision-making process that led to your organization making genetic testing services available to employees?**
 - Who were the decision-makers involved in this process?
- 5. What is your current assessment of the net balance of benefits and challenges affecting implementation of genetic testing for employees?**
 - What are the key factors from your perspective that would affect this balance?
 - What have been the lessons learned regarding implementation?
- 6. What has been the uptake of genetic testing by employees?**
- 7. Are there certain types of employees that seem to be more or less interested in this type of offering?**
- 8. Are you aware of any data regarding the impact of these services on employee health, quality of life, productivity, absenteeism, or health care costs?**
 - If yes, can you share these findings now?
 - Can you provide access to any written reports?
 - If no, do you have any anecdotal evidence of general findings?

Researcher Interview Guide

Project SAGE: Stakeholders Assessing Genetics with Employers

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Purpose of the study: Understand the level of interest, opportunities, challenges and real-world experience associated with implementing and evaluating non-indication based genetic testing as part of employer-sponsored wellness programs. This information will be obtained through telephone-based semi-structured interviews with experts such as you. Given the importance of evaluating the health and economic impact of non-indication based genetic testing for employees, we are interviewing researchers with experience evaluating employee health and wellness programs. We are asking you to represent your experience as a researcher in response to the interview questions.

Definition of non-indication based genetic testing for employees: *Voluntary, health-related genetic testing in employees with or without a personal or family history of genetic disease. The purpose of testing is to identify inherited risks that are evidence-based and medically actionable. The hypothesized goals of testing may include employee engagement in their health, greater understanding of how genetics can affect health, enhanced well-being, early identification of health risks, safer and more effective medication use, and potential cost savings from improved preventive care.*

Before we proceed with the interview, I want to confirm that you understand the purpose of the research and have an opportunity to ask any questions you may have. You understand that, unless you refuse, your interview will be recorded, and any data collected during the study may be looked at by other researchers or regulatory authorities. However, identifying data, such as your name, your employer, and locations will be removed from transcriptions and notes. Recordings will be kept securely, only accessed by select members of the research team, and destroyed at the conclusion of the analysis no later than the end of August, 2020. You have the right to leave the interview at any time or refuse to answer any questions. Do I have your permission to proceed with the interview?

Interview questions:

- 1. Please provide your feedback regarding the definition of non-indication based genetic testing for employees. Anything that you would change or add? Why?**
 - *To let you know, as we have already discussed the 'non-indication based genetic testing' definition together, I will be referring to 'employee genetic testing' as 'genetic testing services' throughout the rest of our discussion.*
- 2. How might genetic testing services support health and wellness goals of employers? Of employees?**

- 3. Are you aware of any wellness program companies that currently include employee genetic testing as part of their program? As a stand-alone intervention?**
- 4. Are you aware of any employers that currently offer these types of testing services to employees?**
 - If yes, have these employers discussed the need for research regarding impact of genetic testing?

The next set of questions relate to your experiences with conducting evaluations of wellness programs with employers.

- 1. What are the main reasons employers pursue evaluations/studies of wellness programs?**
- 2. What are the typical sources of funding for wellness program evaluations? Any sources viewed as more or less desirable from an employer perspective?**
- 3. How feasible is it to conduct wellness program evaluation with a single employer (can have multiple worksites)? Please describe the process you followed to initiate, conduct and publish research on wellness programs with employers.**
- 4. How feasible is randomization?**
- 5. How feasible is it to conduct wellness program evaluations across multiple employers? Please describe any incremental challenges of working with multiple employers**
- 6. What are the wellness program study outcomes of greatest interest to employers (e.g., self-reported health and behaviors, clinical outcomes, healthcare resource utilization and spending, employment outcomes)?**
- 7. Are easy or difficult is it to gain access to the data sources for collecting and evaluating these study measures/outcomes?**
 - What are the employer concerns?
 - What are the employee concerns?
- 8. What have been the biggest challenges of developing a data sharing plan for employer wellness program evaluations?**
- 9. How have you overcome these challenges?**
- 10. Are there best practices?**
- 11. Are all your past wellness program evaluations publicly available? If not, what are the reasons for not sharing the results?**
- 12. Please describe any good governance practices that you have used in conducting research with employers**
- 13. Do you think that genetic data presents additional challenges to wellness program evaluation?**
 - Can you describe any proactive steps that should be taken to mitigate these potential concerns?