

NATIONAL NIPT ADOPTION STRATEGY IN KSA

Discussion Guide

**MAY 30, 2023
PREPARED BY: CAREXSO**

Discussion overview and objectives

Guide Sections	Objectives	Timings
Introduction	<ul style="list-style-type: none"> • Introduction to discussion 	<5 mins
Screener	<ul style="list-style-type: none"> • Screening of relevant stakeholder 	5 mins
Market Overview (Assess NIPT Landscape and Clinical, economic and humanistic burden of aneuploidies)	<ul style="list-style-type: none"> • Understand overall NIPT market • Clinical, economic and humanistic burden of all rare autosomal aneuploidies (RAAs), sex chromosome aneuploidies (SCAs), and partial duplications and deletions ≥ 7 Mb for all autosomes. • Eligibility criteria for NIPT 	10 mins
Stakeholder mapping	<ul style="list-style-type: none"> • Understand Stakeholder role and responsibilities in market access and policy making decision making in NIPT • Understand Stakeholder perception towards NIPT • Validate / assess drivers & behaviours of stakeholders involved pricing, market access and policy framework decision making 	10 mins
Regulatory, access and reimbursement	<ul style="list-style-type: none"> • Understand Regulatory, access and reimbursement • Challenges in NIPT access and reimbursement 	10 mins
Policy landscape	<ul style="list-style-type: none"> • Current policies governing NIPT • Factors determining inclusion criteria 	10 mins
Market Strategy	<ul style="list-style-type: none"> • Understand key market drivers • Perception towards Verifi/VeriSeq • Market share of different tests available 	10 mins
Closing remarks	<ul style="list-style-type: none"> • Gather any additional comments from the participant 	<5mins

Introduction

Moderator Note: *Please introduce yourself, confirm that the respondent has time to speak, then outline the following for the interviewee:*

The discussion will last about 60 minutes. Before we start the discussion, we would like to reiterate that:

- This market research is sponsored by a biotech company
- Your responses will be used by us only.
- Your name and organization will be kept confidential.
- Findings from this discussion will be collated with other respondents and presented to the sponsor in aggregated or anonymous form
- During this interview, you will not be asked to share any information that you are not supposed to share. Please let our moderator know if a question requires you to reveal confidential information

You have the right to withdraw from the interview at any time.

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Are you willing to proceed with the interview?

Discussion objectives

Moderator note: Please briefly outline key discussion objectives to the participant:

Throughout the discussion we would like to cover below main sections specifically related to Aneuploidies and NIPT market dynamics in KSA.

- *Market Overview (Regulatory, pricing, access, reimbursement landscape in KSA)*
- *Screening Programs and Guidelines for managing high-risk pregnancies*
- *Market sizing and population eligibility profile*
- *SWOT analysis of available NIPTs in KSA, physician's and expecting parents' perception and preferences*
- *Competitive landscape and stakeholders' expectations from a screening test*

Do you consent to having the interview recorded for note taking purposes? The interview will remain blinded. [Start recording]

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For Interviewer consideration only

Stakeholders Profile

Entity	Clinician	Geneticists	Payers	Regulatory & Policy officials	Private Insurance	Total
KFSH	3	1	1	1	-	6
MoH	3	1	1	1	-	6
Other Institutions (MODA, NG)	4	1	2	2	-	9
CHI & Private insurers (Bupa, Taawunyah, Medgulf)	3	1	-	2	3	9

Expert profile Screener

Good morning/afternoon, I am calling on behalf of Carexso, a boutique consulting company specialized in transaction advisory and strategy projects focused on Policy shaping, national strategic initiatives and Public Private Partnerships with diverse set of clients and track record of key projects with governments, institutions in addition to a range of other global pharma and med-tech companies. We are conducting a study to understand the '**NATIONAL ADOPTION STRATEGY FOR NON-INVASIVE PRENATAL TESTING, NIPT**' in KSA and would like to speak to you on this subject. May I ask you a few preliminary questions?

S1. [All] What is your profession or primary medical specialty?

Ob/Gynaecologist/ Maternal-foetal Specialist/ prenatalologist	<input type="checkbox"/>	[CONTINUE WITH S2]
Geneticist/Genetic Counsellor	<input type="checkbox"/>	[CONTINUE WITH S2]
Payer	<input type="checkbox"/>	[CONTINUE WITH S2]
Regulatory & Policy official	<input type="checkbox"/>	[CONTINUE WITH S2]
Private Insurance	<input type="checkbox"/>	[CONTINUE WITH S2]

S2. [All] Where do you spend the majority of your professional time? Please select one response only.

KFSH	<input type="checkbox"/>	[CONTINUE WITH S3]
MoH	<input type="checkbox"/>	[CONTINUE WITH S3]
Other Institutions (MODA, NG)	<input type="checkbox"/>	[CONTINUE WITH S3]
CHI & Private insurers (Bupa, Taawunyah, Medgulf)	<input type="checkbox"/>	[CONTINUE WITH S3]
Private Hospital (Saudi-German, Suleiman Habib)	<input type="checkbox"/>	[CONTINUE WITH S3]

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S3. [For Clinicians/Geneticists] What percentage of your medical practice is devoted to direct patient care as opposed to research, teaching or administration?

_____ % of medical practice devoted to direct patient care

(Note: If direct patient care is <70%, thank and terminate. If ≥70%, continue with S5)

S4. [For Clinicians/Geneticists] Are you currently affiliated by a biotech company, healthcare company or government agency?

Yes, full time	<input type="checkbox"/>	[Thank and Terminate]
Yes, closely affiliated	<input type="checkbox"/>	[Thank and Terminate]
No, not affiliated	<input type="checkbox"/>	[CONTINUE WITH S6]

S5. [For Clinicians/Geneticists] On an average, how many pregnant women do you see in your practice in a typical month?

_____ # in a month

S6. [For Clinicians/Geneticists] How do you define high-risk pregnancies? Are you involved in managing any high-risk pregnancies (consanguine marriage, previous pregnancy with aneuploidy/ miscarriage, family history)?

If Yes, then are you prescribing any IPT or NIPT and what is the rationale for prescribing these tests?

If No – **Thank and Terminate**

S7. [For policy makers] Are you involved in any form or capacity in the decision-making regarding policy formulation for National or Sector level prenatal screening or any diagnostic testing?

<input type="radio"/> Yes	CONTINUE TO S11
<input type="radio"/> No	[Thank and Terminate]

S8. [For payers] Are you involved in any form in decision-making regarding reimbursement advanced molecular testing diagnostics or relevant technologies in your sector?

<input type="radio"/> Yes	CONTINUE TO S11
<input type="radio"/> No	[Thank and Terminate]

S9. [For private insurers] Are you involved in any form in decision-making regarding insurance coverage advanced molecular testing or diagnostics in your sector?

<input type="radio"/> Yes	CONTINUE TO S11
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○ No	[Thank and Terminate]
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S10. [For policy makers/payers/private insurers] How many years of experience do you have in managing the policy formulation /reimbursement process related to prenatal screening/any diagnostics?

# of Years		
≥ 5-7 years	<input type="checkbox"/>	CONTINUE
< 5-7 years	<input type="checkbox"/>	[Thank and Terminate]

S11. Please could you briefly describe your role in policy making or reimbursement decisions of diagnostic tests? Can you help us to understand your role in the following activities?

How does your role align with the overall objectives of Policy shaping framework and reimbursement and coverage of advanced molecular testing?

Practice setting	
Policy maker, MOH	<input type="checkbox"/>
Institutions (KFSH, MODA, NG)	<input type="checkbox"/>
Private insurance company	<input type="checkbox"/>

IF RESPONDENT IS ELIGIBLE SAY:

The main purpose of our study is to **discuss and understand the market dynamics of NIPT and current policy landscape for NIPT** in KSA. The discussion will be conducted telephonically or face to face and will last for approximately **60 minutes**. The discussion will be arranged at a time to suit you and we can offer _____ (compensation) in appreciation of your time and participation.

Please let me assure you that this Market Research is sponsored by a healthcare company and is conducted in accordance with International Market Research guidelines. The research is not designed to be promotional in any way – we are not trying to sell you anything. You have a right to withdraw from the interview at any time and withhold information as you see fit. I would like to reassure you that your identity and individual responses will be kept strictly confidential as per international privacy and data security norms. No personal information (including your name, email address and phone number) will be included in any reports provided to the healthcare company sponsoring the research, or to their affiliate companies.

S13. Based on the (above) information, would you be interested in taking part in this market research program?

Yes	<input type="checkbox"/>	[CONTINUE]
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No	<input type="checkbox"/>	[Thank and Terminate]
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It may also be necessary at a future date to re-contact you if we have a query on any of the information you have provided for our analysis.

S14. Do you agree to be re-contacted in case of a query?

Yes	<input type="checkbox"/>	[CONTINUE]
No	<input type="checkbox"/>	[CONTINUE BUT NOTE ON FILE]

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Section A. Market Overview (Clinical, economic and humanistic burden of aneuploidies)

1. Is there any prenatal screening program, focused on Aneuploidies screening and awareness, in your hospital/sector? Please share details.
2. What are the different initiatives done in your sector for Aneuploidies screening and awareness in the community? Please share details.

Initiatives	
Awareness campaigns	q
Genetic diseases Education	q
Identification and targeted awareness programs for high-risk pregnancies	q
Any other	q

3. What is the role of NGO's and civil society if any, in raising awareness against Aneuploidies? Probe: awareness campaigns, caregivers support services, media campaigns, others..
4. According to you, what are the main challenges that are hindering an optimum Aneuploidies prevention plan?

Major challenges	
Access to test/infrastructure	<input type="checkbox"/>
Legal framework for high risk population	<input type="checkbox"/>
Social and cultural stigma	<input type="checkbox"/>
Inability to identify high risk groups for target awareness and implementing measures	<input type="checkbox"/>
Budgetary constraints	<input type="checkbox"/>
Any other	<input type="checkbox"/>

5. Thinking of all the demographic information/ epidemiological data you have in KSA, please give us an estimate of the current prevalence of aneuploidy (Down syndrome, Edward syndrome and Patau syndrome) and the source of your estimation.

Probe: In KSA **prevalence** of Down syndrome is highest among all aneuploidies, 6.6 per 10,000 children [Source: [Frontiers | Next Generation Sequencing Based Non-invasive Prenatal Testing \(NIPT\): First Report From Saudi Arabia \(frontiersin.org\)](https://www.frontiersin.org/articles/10.3389/fgen.2020.00001/full)]

Aneuploidies	# cases per 10,000 live births

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Down Syndrome	
Edward Syndrome	
Patau Syndrome	

6. What is the **incidence** of aneuploidy (Down syndrome, Edward syndrome and Patau syndrome) in your sector? what would the number of new cases be that originated in the last one year in KSA? **[Open Numeric Answer]**

Probe: Rate of Down syndrome, Edward syndrome and Patau syndrome is estimated at 1/800, 1/5000, 1/16000, respectively. [Source: [Frontiers | Next Generation Sequencing Based Non-invasive Prenatal Testing \(NIPT\): First Report From Saudi Arabia \(frontiersin.org\)](https://www.frontiersin.org)]

Aneuploidies	# of New cases in last 1 year
Down Syndrome	
Edward Syndrome	
Patau Syndrome	

7. In your opinion, what is the definition of high-risk pregnancies?

Criteria for high-risk pregnancy	
Consanguine marriages	<input type="checkbox"/>
Maternal Age (35 years or older at the time of delivery)	<input type="checkbox"/>
High-Risk Screen Results from other prenatal screening tests	<input type="checkbox"/>
Previous Pregnancy with Aneuploidy or miscarriage	<input type="checkbox"/>
Family History	<input type="checkbox"/>
Others, please specify _____	<input type="checkbox"/>

8. Do you prescribe Invasive Prenatal Test (IPT) to the pregnant women who are at high risk of aneuploidies?
9. Do you prescribe NIPT to the pregnant women who are at high risk of aneuploidies?
10. If you prescribe both, then what criteria you opt while selecting IPT or NIPT?
11. At what gestational age do you prescribe IPT or NIPT?
12. What are the eligibility criteria from your perspective for NIPT testing amongst the following high-risk group? Please provide a rationale for your rating

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Criteria for high-risk pregnancy	Eligibility criteria	Not a criteria	Rationale for selection
All pregnant women	<input type="checkbox"/>	<input type="checkbox"/>	
Maternal Age (35 years or older at the time of delivery)	<input type="checkbox"/>	<input type="checkbox"/>	
High-Risk Screen Results from other prenatal screening tests (ultrasound)	<input type="checkbox"/>	<input type="checkbox"/>	
Previous Pregnancy with Aneuploidy or miscarriage	<input type="checkbox"/>	<input type="checkbox"/>	
Family History	<input type="checkbox"/>	<input type="checkbox"/>	
Patient Preference	<input type="checkbox"/>	<input type="checkbox"/>	
Consanguine marriages	<input type="checkbox"/>	<input type="checkbox"/>	

13. Can pregnant women request an NIPT testing without the need for prescription?

14. What would be the process for this?

15. Out of 100 Pregnancy you see, how many are considered above 35 years of age?
.....%

16. Out of which, how many are considered high risk (consanguine marriage, previous pregnancy with aneuploidy/ miscarriage, family history)
.....%

17. Of which how many would you consider NIPT for? Is this standard practice according to your experience?
.....%

18. Do you follow any of the following specific guidelines/protocols for NIPT recommendations in pregnant women? Please select what you are following for he below list

Guidelines	
ACOG Guidelines	q
ISPD Guidelines	q
SOGC Guidelines	q
NOCE Guidelines	q
Others, please specify _____	q

19. Apart from international guidelines, do you follow any national society guidelines to inform your prenatal testing decisions? If so, which one?

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- 20.** Do you have protocols for prenatal testing in your own institution that overwrite guidelines and if yes, to which extent do they differ?
- 21.** Many guidelines already include statements on quality parameters for NIPT tests, like reporting of fetal fraction. In your opinion, what should future guidelines in Saudi Arabia consider including with regards to quality standards of NIPT?
- 22.** What is the current process to update guidelines around prenatal care and what kind of evidence and data would be required?
- 23.** What's the medical society's opinion on recommending NIPT for all pregnancies regardless of risk like the American College of Obs/Gyn did?
- 24.** Is prenatal screening currently a part of your hospital/sector programs for screening of Aneuploidies?
If YES:
a. What are the current screening guidelines governing NIPT testing, do you refer to international or local/ sector regulations/ policies? Please share these guidelines
b. Amongst which profiles mentioned in Question 12 is prenatal screening prescribed in your institution?
- 25.** Can you please describe the patient journey in your sector starting from consultation? Who are the stakeholders involved (Probe: For screening of high-risk groups, clinical examination investigations and prescription, follow up)?

Step #	Patient journey	Stakeholders involved	Probe
1	Regular Check-ups	Obs/Gyn	Diagnostic ultrasound, and blood tests
2	Assessment of high-risk patients	Obs/Gyn	Maternal age, family history, others
3	Preliminary Prenatal screening	Obs/Gyn	Gestational age?
4	Prenatal screening through IPT/NIPT	Obs/Gyn/geneticist	Preferences between form IPT and NIPT?
5			
6			
7			
8			
9			
10			
11			
12			

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- a. Could you please elaborate on patient management following positive test results?

	Management	comments
Aneuploidy		
Insertion deletion		
Pathogenic variants (carrier vs affected)		
Other		

- 26.** Are there any barriers that exist in Saudi Arabia to come to an informed patient consent? If yes, what are they?
- 27.** Can you elaborate on any training currently provided in your institution for OB/GYN and geneticists in NIPT?
- 28.** Could you share with us a list of OBGYN/ Geneticist in your sector prescribing NIPTs?
- 29.** Is NIPT a standard screening procedure in your hospital/sector? If Yes, Why?
- a. Could you share the current standard framework if any?
- 30.** If not included, is there a plan in near future to include the same in a program in your sector?
- a. If YES:
- i. When is it likely to be implemented?
 - ii. What guidelines shall be referenced to implement screening?
 - iii. Which high risk groups mentioned before are likely to be benefitted?
 - iv. Which stakeholders will be involved (Probe: For screening of high-risk groups, clinical examination investigations and prescription, follow up, purchasing and reimbursement)?
- b. If NOT
- i. What do you think are major barriers for the implementation of prenatal screening in your sector?
 - A. Legal and regulatory
 - B. Socio-Cultural stigma
 - C. Perception amongst regulators and specialists it may affect emotional behaviour
 - D. Policy makers do not see the value in spending on screening (cost benefit)
 - E. Fragmented systems, clinical and community prevention
 - F. Inadequate epidemiological knowledge to access high risk groups
 - G. Training gaps amongst the healthcare professionals
 - H. Any other
- 31.** Which department in your establishment is responsible for formulary inclusion, reimbursement, policy governance, procurement?

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- 32.** Who are the key stakeholders responsible for reimbursement of diagnostics in your establishment?
- 33.** As a key decision maker beyond your institution that can influence in your opinion the reimbursement and adoption advocacy of NIPT, can you share these entities and stakeholders (SFDA, CHI, National screening program)

Entity	Stakeholder	Role and responsibility

- 34.** Do you refer to other laboratories? Why? Could you share a list of laboratories by name offering NIPT?
- 35.** Are NIPT test done in KSA or sent abroad? Why? If sent abroad, please could you share names of these laboratories?
- 36.** How is NIPT described and explained to the patient?
- 37.** What type of counseling is available to pregnant women and what creative counseling mechanisms would, in your opinion, work best in Saudi Arabic? (In person, tele-counseling, online resources, brochures, none)
- 38.** How do you see the acceptance of NIPT in pregnant women and why?
- 39.** Who delivers the results to the patient? OBGYNs? Geneticists? (Some NIPT tests provide positive or negative insight for the 3 main syndrome others like VeriSeq are more of a genetic report)
- 40.** Which NIPT test is currently available in your institution/ Hospital? Is the test fully covered (probe for % OOP fees born by patient)? Market share per NIPT (should sum up to 100%)

NIPT	Price	Coverage / OOP	Proportion %
Illumina (Verifi)			...
Illumina (VeriSeq™ NIPT Solution)			...
Roche (Harmony)			...
BGI (Nifty)			...
Natera (Panorama)			...

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Labcorp (MaterniT21 Plus)			...
PerkinElmer (Vanadis)			...
Centogene (CentoNIPT)			...
Eurofins (PrenaTest)			...
Others, please specify			...
Total			100%

- 41.** Which NIPT are you currently prescribing? Can you share the price of that test?
- 42.** Can you elaborate on preferences rationale for opting for a specific NIPT test over other options available?
- 43.** Is NIPT in general covered in your sector/hospital? Or a particular NIPT test?
- 44.** Do you believe that the economic burden of aneuploidies in Saudi Arabia leads to financial hardships for affected individuals/families? Why?
- a. Yes
 - b. No
 - c. Not sure
- 45.** In your opinion, are there sufficient social support programs and services available to individuals/families affected by aneuploidies in Saudi Arabia?
- a. Yes, they are sufficient (Please share details, Monthly financial support, Healthcare coverage, etc.)
 - b. No, more support programs and services are needed
 - c. Not
- 46.** In your opinion what type of programs is required to support families with infants with aneuploidies?

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Section B. Stakeholder mapping

47. What is your perception about prenatal screening for pregnant women who are at high risk (consanguine marriage, previous pregnancy with aneuploidy/ miscarriage, family history) as one of the important preventive measures for aneuploidies?

Please provide rating on a scale of 1 to 5 where 1 means 'not at all important' and 5 means 'very important'. Please provide a rationale for your rating.

Not at all important	Not so Important	Neutral	Important	Very important	Rational for rating
1	2	3	4	5	Open Text

48. What is your perception about prenatal screening with special focus on Non-Invasive Prenatal Testing (NIPT) v/s Invasive Prenatal Testing (IPT)?

Probes
Understanding of the differences between NIPT and IPT in terms of their approach and accuracy
Familiarity with the benefits and limitations of NIPT compared to IPT
Any concerns or reservations you have regarding the use of NIPT or IPT in prenatal screening
Accessibility and affordability of NIPT compared to IPT
Any specific reasons why you might prefer NIPT over IPT or vice versa
Personal opinions or beliefs about the significance of NIPT or IPT in prenatal care
NIPT and IPT contribution to the overall quality of prenatal care

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Section C. Regulatory, access and reimbursement

49. Could you walk us through the diagnostics inclusion and reimbursement process in your institution step by step and the stakeholder type by step and their requirements:

- a. Which stakeholders or entities are involved in the process?
- b. What are the timelines for regulatory decisions for diagnostics?
- c. What data is required to make the case for reimbursement of a technology?

50. What are the requirements to include NIPT in a national prenatal screening program?

	Stakeholder	Requirements
Step 1:		
Step 2:		
Step 3:		
Step 4:		

51. Who governs screening and diagnostics regulatory and policy framework in your institution/ sector?

52. Can you share key stakeholders involved in the Regulatory and reimbursement decision making process?

Entity	Stakeholder	Influence (High, Medium, low)

53. Is prenatal screening especially NIPT in general currently reimbursed in your organization? Or a particular test (if yes, which one and why)?

If YES

- a. What is the name of that test?
- b. in which high risk groups it is prescribed?
- c. is it currently included into the reimbursement ambit of your organization?
- d. Which high risk groups are currently reimbursed?
- e. For covered high risk groups, what is the process currently applied for coverage:
- f. Are expats currently reimbursed for NIPT?

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54. On a scale of 1 to 5, **where 1 is not at all willing and 5 is Very much willing**, would you provide full or partial reimbursement for prenatal screening (NIPT)? please state your reason for rating?

Not at all willing				Very much willing	Rational for rating
1	2	3	4	5	Open Text

a. If partially covered, then at what percentage OOP? _____%

55. What would be the key drivers / factors that will determine or drive the inclusion of prenatal screening into the formulary?

Key Drivers	
Test performance	<input type="checkbox"/>
Test quality	<input type="checkbox"/>
Level of clinical evidence on the technology	<input type="checkbox"/>
Technology addresses a significant unmet need	<input type="checkbox"/>
Technology improves healthcare efficiency (e.g. replacement of standard of care, impact on cost of care)	<input type="checkbox"/>
Managed entry agreements	<input type="checkbox"/>
Provision of education or services	<input type="checkbox"/>
Availability of infrastructure	<input type="checkbox"/>
Others, please specify _____	<input type="checkbox"/>

56. If NIPT test is already covered in your institution, could you share in details the access framework adopted for Reimbursement? And for which test? What are the conditions for reimbursement of this test? (probe: what clinical criteria are used for testing selection, timing for testing)

57. What are the barriers challenges when it comes to provision screening through reimbursement?

- a. Absence of Integrated screening program
- b. Legal and culture aspects
- c. Formal policy framework
- d. Perception amongst regulators and specialists that use of screening may increase irresponsible behaviour
- e. Payers do not see the value in spending on screening (cost benefit)
- f. Inadequate epidemiological knowledge to assess high risk groups
- g. Lack of appropriate infrastructure (e.g. counselling services)

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h. Any other

- 58.** What needs to be done to overcome these barriers and facilitate the implementation of screening in your sector? (Probe: awareness campaigns among general population / high risk population, HCP education, Policy maker's education, policy and guidelines developments...) And by type of stakeholders? (Probe Government role, HCP role, NGOs and civil society role, biotech companies' role...)
- 59.** Could you share based on your knowledge key engagement activities of NIPT providers in the Saudi Market.
- 60.** Could you share your perspective on potential strategic initiatives that can be adopted to drive public-private partnerships supporting patients access to NIPT and early screening?
- 61.** What are the expectations from biotech companies that support the inclusion of screening in the reimbursement list? Please elaborate.

PROBE:

- a. Patient access programs
- b. HTA assessments
- c. Innovative contracting models
- d. Net price discounts / rebates
- e. Managed entry agreement with provision of services

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SECTION D: Policy landscape

62. How do you think the regulatory and legal landscape of genetic diseases prevention is evolving? Do you envision any amendments regarding the same e.g. any policy changes for expatriates etc.?

63. What are the requirements to include NIPT in Saudi Screening program?

Key requirements	
Test performance	<input type="checkbox"/>
Test quality	<input type="checkbox"/>
Level of clinical evidence on the technology	<input type="checkbox"/>
Technology addresses a significant unmet need	<input type="checkbox"/>
Technology improves healthcare efficiency (e.g. replacement of standard of care, impact on cost of care)	<input type="checkbox"/>
Managed entry agreements	<input type="checkbox"/>
Provision of education or services	<input type="checkbox"/>
Availability of infrastructure	<input type="checkbox"/>
Affordability	<input type="checkbox"/>
Others, please specify _____	<input type="checkbox"/>

64. What need to be done to overcome any challenges and facilitate the implementation of prenatal screening in your sector? (Probe: awareness campaigns among general population / high risk population, HCP education, Policy maker's education, policy and guidelines developments...) And by which stakeholders? (Probe Government role, HCP role, NGOs and civil society role, biotech companies' role...)

65. How a biotech company can support to facilitate the implementation of prenatal screening program in your sector?

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Section E. Market Strategy

66. In your opinion what are the market drivers for NIPT in Saudi Arabia?

Market driving factors	
High risk of chromosomal abnormalities with increasing maternal age	<input type="checkbox"/>
Rise in demand for early and non-invasive testing procedure	<input type="checkbox"/>
Others, please specify _____	<input type="checkbox"/>

67. Who are the key decision makers in your organizations for access levels/restrictions on prenatal screening? (Probe for involvement of regulator, Obs/Gynae, Geneticists, KOLs etc.). Is there a sequence of stakeholders?

68. Is there any specific stakeholder to engage with from the list of stakeholders mentioned in the previous question? If yes, can you please mention the name of this stakeholder

69. If you are prescribing NIPT what are your preferences for a particular test, do you prescribe a particular NIPT test, if yes, which one and why?

NIPT	Accuracy	Sensitivity/ Specificity	Price & Coverage	Partnership
Illumina (Verifi)				
Illumina (VeriSeq™ NIPT Solution)				
Roche (Harmony)				
BGI (Nifty)				
Natera (Panorama)				
Labcorp (MaterniT21 Plus)				
PerkinElmer (Vanadis)				
Centogene (CentoNIPT)				
Eurofins (PrenaTest)				
Others, please specify				
Total				

70. Do you think currently available tests are capable of addressing unmet need in NIPT market? If so which ones?

71. Do you prescribe Verify/ VeriSeq™ NIPT Solution? What is your perception towards Verify/VeriSeq™ NIPT Solution from Illumina from sensitivity specificity, price, availability, value of test, other outcome measures etc.?

72. What would be the key value drivers to opt for Verify/VeriSeq™ NIPT Solution as your recommendation as NIPT?

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73. Considering the factors of sensitivity and affordability, how likely would you prescribe Verify/VeriSeq™ NIPT Solution to the eligible women. Please rate on a scale of 1-7, where 1 = 'Not at all likely' and 7= 'Extremely likely'.

Not at all likely			Neutral			Extremely likely
1	2	3	4	5	6	7

Please explain the rationale of your assigned score.

74. What is the percent market share of the available tests in your sector?

NIPT	%
Illumina (Verifi)	...
Illumina (VeriSeq™ NIPT Solution)	...
Roche (Harmony)	...
BGI (Nifty)	...
Natera (Panorama)	...
Labcorp (MaterniT21 Plus)	...
PerkinElmer (Vanadis)	...
Centogene (CentoNIPT)	...
Eurofins (PrenaTest)	...
Others, please specify	...
Total	100%

Closing Remarks

- Beyond what we have just discussed, is there any other advice you would offer the company?
- Are there any additional points that we didn't cover, and you think would be beneficial to our study?

Moderator Script: *Thank participant and close interview*