A new narrative on genomic testing value frameworks and partnership models in the UK

Charles River Associates (CRA) has been commissioned by the British In Vitro Diagnostics Association (BIVDA) to develop a new narrative on the UK genomics landscape. The focus is firstly to develop a value framework articulating the benefits of advanced in vitro diagnostics (for patients, healthcare systems, payers, and wider society) and the challenges in the access environment, and secondly to explore how new partnership models can facilitate improved patient access to genomic testing. The aim is to gather views across BIVDA's membership and also to specifically include companies who have been involved in the development of partnerships between industry and the NHS or Genomics England in order to discuss the barriers faced, how these were overcome to enable patient access, and potential best practices.

PART A: The advanced in vitro diagnostics value chain – 15 minutes

1. Could you briefly describe the position of your company's services in the genomic testing value chain? Is this primarily 'front end' (i.e. testing equipment, sequencing hardware) or 'back end' (i.e. data analysis, bioinformatics) or a combination?
    a. How do you work with the NHS or university hospitals? Do you compete with their in-house provision?
2. *CRA to show slide with outline of the value narrative for genomic testing.* By looking at CRA slides on the categories of value of genomic testing (to patients, healthcare systems and society):
    a. Do you feel that this captures the value of your services?
    b. Is this recognised currently by policymakers, regulators, payers, clinicians and patients in the UK? If not, what are the main gaps in understanding?
    c. How involved have charities and patient advocacy organisations been in supporting value recognition in the UK? What has their role been?
3. *CRA to show slide with case studies illustrating the value of genomic testing.* Are you aware of any additional case studies, using your company's technology or that of others, that could be used in the narrative to illustrate the benefits of genomic testing?

PART B: The access environment in the UK – 20 minutes

4. *CRA to show slide with summary of access environment for genomic testing in England.* Is this an accurate reflection of the current patient access environment for advanced in vitro diagnostic tests in England?
5. On a scale of 1-10, where 1 is the most challenging and 10 is optimal access, how would you rate the access environment for genomic testing in England, in terms of ease of patient access to advanced in vitro diagnostic testing?
    a. What are the key strengths in the access environment? What has contributed to those successes (e.g. responsible stakeholders, policy prioritisation, funding…)?
    b. What factors are contributing to the gap between available advanced in vitro diagnostics and what is actually being used in clinical practice in the NHS today?

6. *CRA to show slide with summary of key access challenges in England as identified in the literature review.* Do you disagree with any of the access challenges stated? What else currently limits patient access to testing in the UK?
    a. Have any of these access challenges improved or been resolved over time? If so, what has led to this improvement?
    b. Do different types of diagnostic technology experience different challenges?
7. What changes do you believe are needed in the future to support broader patient access to genomic testing?

PART C1: New partnership models between innovators, payers, and providers (for companies involved in the identified UK partnerships) – 25 minutes

8. *CRA to show slide with high-level information on the partnership model of interest.* Could you please briefly explain how this partnership was designed and implemented, covering the following elements if possible:
    a. Initial dialogue (who was involved, which party was the initiator)
    b. Design of the partnership model (agreements on elements of partnership, timelines, budget decision, reimbursement/payment mechanism)
    c. Process for implementation (any hurdles to overcome)
9. Which of the previously discussed access challenge(s) did this partnership experience or overcome?
    a. What is the benefit to the NHS and to patients?
    b. What is the benefit of such a model to the owner of the technology involved?
    c. How should we position services provided by companies relative to NHS in-house capabilities? How can partnerships be used to support this positioning?
10. What were the key enabling factors that led to successful development and implementation of the partnership model?
    a. What was the role, if any, of non-industry/non-health provider stakeholders in supporting establishment of the partnership (such as charities and patient advocacy organisations)? If none, what do you expect their involvement could have supported with?
11. In your view, is this a model that should be encouraged and replicated more systematically for novel diagnostic technologies going forward? If yes, what would support this (e.g. policy change, establishment of formal pathways)?
    a. What are the disadvantages or caveats of pursuing such an access route (e.g. bureaucracy, delays, temporary nature, conditional access)? Are these challenges that could be overcome, and if so, how?
    b. Does the ideal partnership model depend on the type of diagnostic technology involved? Is there a greater need for new partnership models for specific technologies?

PART C2: New partnership models between innovators, payers, and providers (for companies not involved in any specific novel partnerships in the UK) – 25 minutes

12. *CRA to show summary slide with high-level information on types of partnership models in the UK.* Has your company been involved in a partnership with the NHS or Genomics England (or other similar organisation) that aimed to support patient access to genomic testing and is not listed here?
    a. *If yes, go to C1 section above*
    b. *If no, follow remaining C2 questions below*
13. How are these types of partnership model perceived by other advanced in vitro diagnostic companies in the UK?
    a. Are any specific examples regarded as a "best practice" in terms of successful types of approach or elements involved in the model?
    b. What are the main benefits of these partnerships in terms of:
        i. Benefits to patients, the NHS and the companies involved
        ii. Access challenges they help to overcome
    c. What are the main disadvantages or caveats?
    d. Does the ideal partnership model depend on the type of diagnostic technology involved? Is there a greater need for new partnership model for specific technologies?
14. In your view, are there any types of model that should be encouraged and replicated more systematically for novel diagnostic technologies going forward? If yes, what would support this (e.g. policy change, establishment of formal pathways)?
    a. What are the disadvantages or caveats of pursuing such an access route (e.g. bureaucracy, delays, temporary nature, conditional nature of access)? Are these challenges that could be overcome, and if so, how?
    b. How should we position services provided by companies relative to NHS in-house capabilities? How can partnerships be used to support this positioning?
    c. What are the potential benefits associated with non-industry/non-health provider stakeholders supporting establishment of the partnership (such as charities and patient advocacy organisations)?
        i. Are there any potential drawbacks?
        ii. Are you aware of any examples involving charities or patient advocacy organisations in any capacity?