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UTILISING HEALTH ECONOMICS TO ENABLE OPTIMAL TRANSITION FROM A PLATFORM TECHNOLOGY TO A DEVELOPMENT PROGRAMME AND PRODUCT

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BACKGROUND/INTRODUCTION

- Translation of research, and science into product development is critical in any innovation and breakthrough. Great research doesn't automatically translate to great products [1]. There is a critical phase in a technology company's growth, where with constrained resources, it must focus down on developing one or at most two products (at least to proof of concept).
- A new technology can provide seemingly unlimited potential across many indications, but it is important for companies, patients and health systems that platform technologies are focused in areas of the most unmet need and optimal returns.

  "technologies are not deterministic. We can harness their potential for the common good, and we have an obligation to do so." - *António Guterres UN [2]*
- We take a case study of a platform technology that could reduce costs, and improve the accuracy of diagnostics, potentially changing existing pathways and clinical testing, but also creating new opportunities by producing test results quicker and at point of care. To optimise product development, we need to optimise decision making, selecting the "product" opportunity that represents the best mix of a range of criteria.
- The developed tool is aimed at assessing the ideal positioning for a new technology, and can be applied to multiple therapeutic areas and setting, Effectively a Multi-criteria decision making (MCDM) tool

OBJECTIVES

- To develop a tool to prioritise product development, and support the selection of an optimum 1st target test, indication and therapy area
- For the tool to facilitate internal decision making, and ensure robustness and confidence in the strategy
- To have a tool that can be active and able to adapt to changing environment, for selecting subsequent and other product developments

METHODS

- The process for developing and using the tool incorporated 7 steps, developed through a series of iterative workshops. The steps are listed out below

Scoping – (Step 1)
1. Scoping workshop [Corporate & Technology Strategy, Product Brief , Constraints, Long List Criteria , Desired Outputs]

Criteria development (Step 2-4)
2. Risks, Uncertainties, Impact and Selection of important criteria
3. Full criteria agreed
4. Scoring and weighting of criteria

Landscape assessment (Step 5)
5**.** Landscape analysis of all test applications, and further secondary research. Databases were searched to explore potential applications for the test, including

Scoring (Step 6)
6. Scoring, including revision of scoring through multiple iterations of using the tool. Multiple users scored the same items to validate the tool

Reviewing (Step 7)
7. Review of the scoring. During this step High and low priority opportunities were also grouped

Some of the steps are expanded on below

- **Step 2**: To develop the criteria, first we thought about the go, no-go points that would limit the progress for the company, which were concluded to be technical feasibility and attractiveness of the market
  - Technical feasibility – ability to be used in area, existence of proof of concept (peer reviewed preferable), availability of required components commercially.
  - Attractiveness of the market – Size of the commercial opportunity (as defined by size of addressable market and return on investment). This can be driven by unmet need or ability to deliver significant added value and better use of resources
- **Step 3**: Considering these factors, a five item criteria were developed to be used in the tool, which would be used to assess the technology. The five criteria are listed below. For each criteria we could score a 1-5, and table 1 shows an example of the scoring for a single criterion (**step 4**):

METHODS CONT.

- **Step 3**: agreeing the criteria
  - Clinical validity of existing products
  - Commercial attractiveness of the indication (total addressable market)
  - Clinical value of existing test on disease/treatment pathway,
  - Technical feasibility
  - Opportunity for differentiation.
    - Products could be differentiated by criteria such as time to results, multiplexing, ease of implementation, patient experience, budget or economic impact, competitiveness.
- **Step 5**: To find ways in which the case-studied diagnostic technology could be used, various databases were searched and used to capture a range of diagnostic tests (Evaluate, WHO “essential” diagnostics, and targeted literature review)[3,4].
- **Step 6&7**: Each test was scored during an iterative process and the resulting matrix used to recommend product development targets. This was reviewed so the results could be prioritised to company needs.

Table 1 Example of the scoring system for clinical validity criteria

Criteria	Scoring for criteria	Example of how scored
Clinical validity of existing technology	5 Validated biomarker(s) in routine commercial use (screening) 4 Validated commercial biomarker in limited use (diagnostic) 3 Strong in vivo proof-of-concept data, good precedence for regulatory approval (equivalence claims) 2 Some in vivo proof-of-concept data, good precedence for regulatory approval 1 Some limited validation in tissue samples or in vitro experiments; some regulatory precedence 0 Concept with very limited lab validation; limited regulatory precedence	In order to achieve high scores (4 or 5), the marker must be commercially available and approved for use

RESULTS

- Having developed the MCDM tool with its criteria and weighting, it was used to narrow down a field of 170 test targets, to a shortlist of 14 tests. Each one of the shortlist being a credible and feasible product development target, commercially valuable and clinically needed.
- Potential areas of application were given a colour ranking based on the score to separate to determine where to prioritise efforts.
- The tool was subsequently pressure tested using opportunities already identified by the company, in order to independently assess those applications. The results of that analysis produced similar conclusions than that made by the company

DISCUSSION

- A MCDM process is a useful tool in supporting the transition from technology development to product development
- Such a process does need multiple iterations and should be designed to maximise engagement and discussion. This can then enable decisions to be made, and stuck to, within very complex environments
- It is critical to consider multiple perspectives, such as the patient, the HCP, the payer, the clinical pathway, the lab, pathology services, the health infrastructure as well as the multi faceted challenges of development (regulatory, technical, commercial, and corporate funding). The tool facilitates this thinking and analysis, and the ability for thinking to be transparently challenged
- In this case study, where there was an opportunity for significant impact in radically changing the market (by say bringing the "lab" to the consultation or bedside or enabling more testing to be done due to significantly lower costs or multiplexing) the economic evaluation is made more complex. But even then, the tool could be used to test thinking and analysis
- Multiple iterations built increased confidence across all stakeholders of the appropriateness of the decision making and strategy

CONCLUSIONS

- The scale of opportunity for where to focus a transformational technology can be seemingly overwhelming. All companies are resource constrained and need to make decisions early in making the translation from technology to product development. This is very much an economics problem - ("the study of scarcity and its implications for the use of resources, production of goods and services") and developing a tool based around multiple-criteria decision-making facilitates such complex and high-risk decision making.
- The tool enabled a strong alignment across the management team and confidence in the selections made, through multiple iterations and reviews.

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