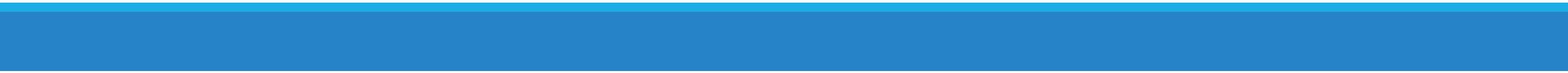


Evaluation of the Commercial Potential of a new Diagnostic Technology

Medical Diagnostics & Devices
Homerton College
University of Cambridge
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DAVID WILSON

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Scenarios

Which university research projects justify the costs of IP protection (e.g. patent applications) in the early stages?

Which university research projects should attract limited commercialisation support funding, either from the university or from external sources (e.g. grants, industry)?

Which are the most commercially viable applications for a platform technology with multi application potential?

Some general considerations

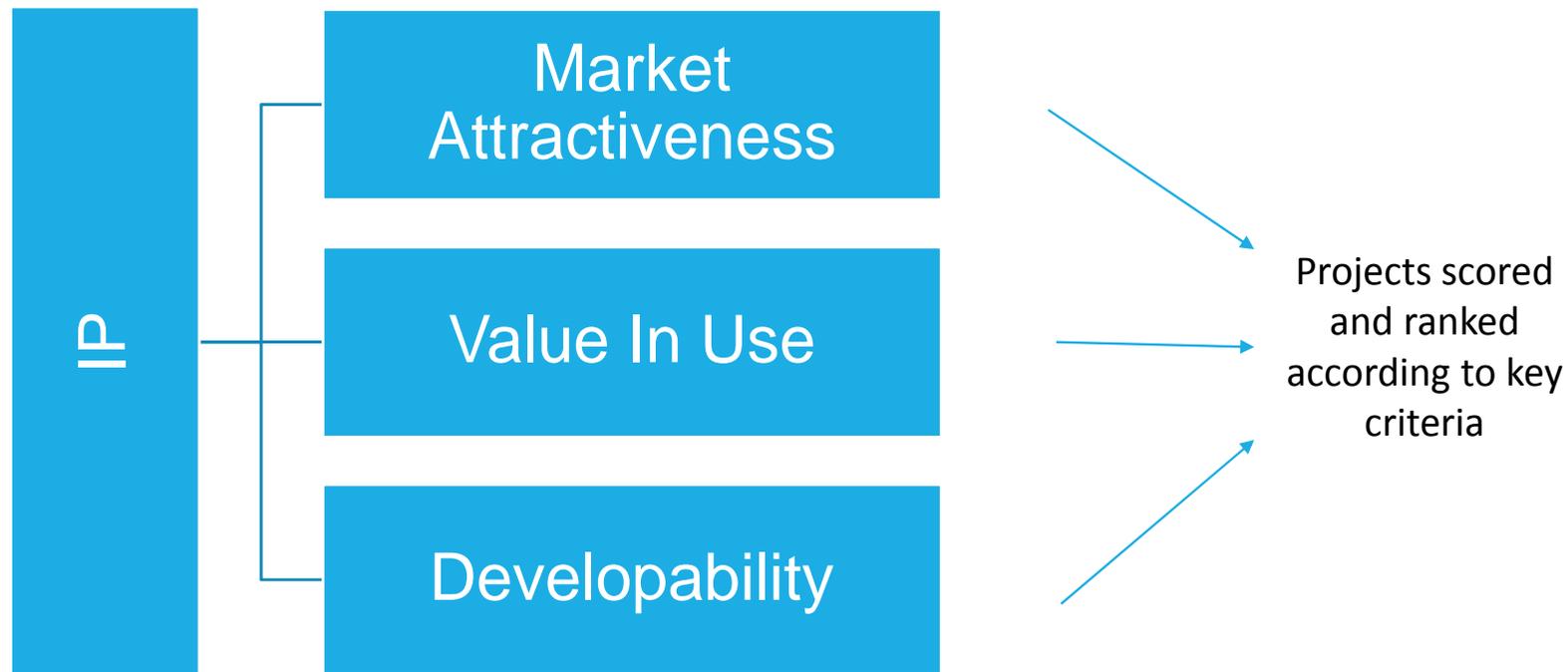
Value is driven by application(s) of the technology where there are buyers that will pay for the benefits derived from technical advantages (i.e. where there are well defined markets for the application(s) where the technology offers competitive advantages)

Don't think of time to market, think of time to adoption. Very different timescales that will influence all valuations

Think of global markets, not just UK (NHS), and not even UK as first or primary market as slow (or no) adoption will lead to commercial failure

Biomarker research projects triaged by Commercial Viability/Potential

Is there a potential Return on Investment?



IP

Is it valuable?

- Is it novel?
 - Is it patentable?
 - Is it policeable?
- 

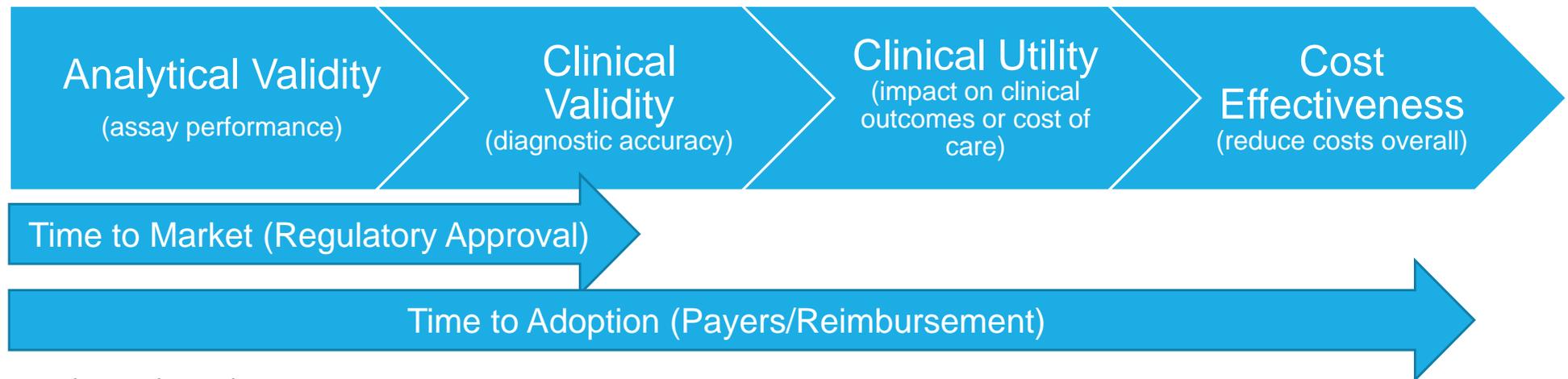
Market Attractiveness

Revenue Potential

- Specific to selected **applications** defined by unmet clinical needs and clinical pathways
- Many possible types of “diagnostic” test and applications, e.g. triage tool, replacing existing diagnostic test, add-on to existing diagnostic pathway, new diagnostic pathway, patient stratification for treatment options, patient stratification for prognosis, marker of treatment response etc
- **Estimating Market Size** - this can be estimated by multiplying the number of target patients per year by the number of tests each patient needs per year and by the price per test. Remember that disease prevalence is not a proxy for patient numbers as many patients will test negative
- **Competitive Landscape/Positioning**
 - are there technical advantages that are relevant (i.e. do they translate into commercial advantages or benefits for which potential buyers can be identified)?
- In the context of the unmet diagnostic need, how high are the **barriers to uptake (adoption)**?
 - Low unmet need
 - Medium unmet need, high barriers to uptake
 - High unmet need, high barriers to uptake
 - Medium unmet need, low barriers to uptake
 - High unmet need, low barriers to uptake
 - Barriers to uptake covers issues such as: does it fit an established platform? is investment in a new device needed? does sample collection or processing need modification? are there significant training needs? how easy is it to integrate into workflow with minimal disruption? how high are the barriers to convince purchasers to pay?

Developability

Cost and Time



Evidence-based

Clinical study design (clinical validity)

How large a prospective trial will be needed to validate at $p=0.05$?

How long would patients need to be followed in a prospective trial?

What parameters confirm the validity of the biomarker (i.e. what end points are needed)? Clinical observation over what time period, reference test (easy or complex)

Study design (clinical utility) – what outcome measures directly impacted by result of test?

Value in Use

- How important is the decision that use of the biomarker informs?
 - Low impact decision in non-critical situation
 - Stratification of patients for prognosis or monitoring
 - High impact decision in non-critical situation
 - Selection of patients for high impact decision
 - Potential life-saving decision
- What is the role of the biomarker?
 - Research tool
 - Aid to diagnosis
 - One of the available tests
 - Part of a definitive panel of tests
 - Definitive test
- What is the potential impact on health resource utilisation across the clinical pathway (Clinical Utility and Cost Effectiveness)?
 - Leads to major increase in resource use
 - Leads to some increase in resource use
 - Neutral impact on resource use
 - Can lead to some reduction in resource use
 - Can lead to major reduction in resource use

Commercial Viability

Key Elements

