THE VALUE-ENGINEERED TRANSLATION (VET) FRAMEWORK

Here, we provide additional description of the VET Framework (Figure 1). We focus on the details of the first of the three phases, headroom analysis. Phases two and three are dependent on more detailed data and evidence generated through early stage clinical trials, ultimately resulting in technologies that are Phase 3 clinical trial-ready, and for which investment is greatly de-risked.

Headroom Analysis

Headroom analysis considers whether there is sufficient unmet need for a candidate technology for a specific indication to support a price consistent with an acceptable return on the investment in clinical translation. In other words, it considers the scope for therapeutic or health system benefits of a technology relative to other technologies on the market or expected to be on the market at the time of product launch. This phase may commence as soon as a technology/indication dyad has been specified. It first assesses the maximum health gain that could be achieved if a new therapy returned affected individuals to full health for someone of their age/gender. If current therapies return patients to something close to full health, then it will be very difficult to justify a premium price for a new therapy on the basis of the health impact delivered.

Fortunately in a value-based decision framework, improvements in the cost of care are also valued, as they reflect potential health gain for other people served by the health system. Thus, the second component of the headroom assessment considers whether the candidate technology could achieve savings elsewhere in the system that would be valued by the budget holders, by releasing resources to provide healthcare to others.

The final component of the headroom assessment explicitly considers whether there are characteristics of the technology, the disease, or the affected population that would modify the value that the decision-maker would attach to either health benefits or resource savings. For example, many jurisdictions incentivize technology development for rare/orphan diseases and for pediatric populations.

The assessment of headroom draws upon insights from clinical and technology landscaping. The former exercise maps how the condition is currently managed in target healthcare systems, representing current headroom. The latter draws upon patent, clinical trials, trade and publications databases to identify potential competitor technologies likely to be on the market at the expected time of product launch, representing the likely headroom at the time of market access. Combined, these analyses determine whether the technology is likely to be a first to market, a fast follower or a me-too, all of which impact upon the ability of a developer to command a premium price.
The final component of the headroom analysis examines the pre-clinical and early clinical data for evidence of publication bias, and uses this as the basis for adjusting expectations about the scope the new technology for ‘over-confidence’ bias. This process combines the methods of evidence synthesis and Bayesian expert elicitation. For further discussion and examples see,¹.

**FIGURE 1: THE VET FRAMEWORK**
Figure 1. The Value-Engineered Technology Framework comprises: Step one, headroom analysis, which integrates considerations of the health and resource impacts of a candidate technology and whether social values may modify our assessments of those impacts. Steps two and three are based on the availability of more specific evidence and comprise increasingly sophisticated economic models to assess the likelihood of clearing market access hurdles and, the value of alternative R&D investments in terms of their impact on that likelihood.