

## **Event**

In the current era of budget constraint, gaining regulatory approval no longer guarantees that a new product will be adopted and reimbursed by healthcare payers. Decisions regarding funding and adoption are only indirectly related to regulatory criteria, as the latter are not indicative of whether a new technology represents a good investment from either a commercial or healthcare system perspective. Given that reimbursement considerations influence all markets, technology developers should plan their research and development (R&D) efforts by explicit consideration of the value of those efforts to healthcare payers. The Value-Engineered Translation (VET) framework<sup>1</sup> offers a new tool to facilitate alignment of R&D activities with health system needs, thus increasing the efficiency and cost-effectiveness of clinical translation.

## **Significance**

Development of novel diagnostic-therapeutic combinations, as well as other innovative personalized medicines, is costly in terms of time, money and research careers invested. These costs are reflected in concomitant high product prices with payers increasingly reluctant to reimburse without a clear indication of value, including cost-effectiveness and population health impact in comparison to the existing standard of care. The VET framework enables technology developers to evaluate early stage candidate diagnostic-therapeutic combinations for their potential to clear value-based reimbursement hurdles and provide a competitive return on investment, decreasing research misfires. The VET framework can also be applied by payers to evaluate an extended range of factors during Health Technology Assessment (HTA)<sup>2</sup>, streamlining coverage decision-making, and decreasing time and cost to patient access.

## **Analysis**

The VET comprises 3 distinct steps along the translational continuum – headroom analysis, macro-analysis and micro-analysis – each providing developers with information at key R&D transition points to inform ‘go-no-go’ and research prioritization decisions. For technologies that clear all three stages, the framework results in a ‘reimbursable evidence dossier’ that can be used to attract further investment and inform design of costly phase 3 trials. This dossier constitutes a starting point for designing the final evidence package to submit to HTA agencies for their reimbursement decisions.

The first phase of the VET framework comprises a headroom assessment, which integrates considerations of the health and resource impact of a candidate technology and whether social values might modify assessments of these impacts. The second and third phases are based on the availability of more detailed evidence generated as the technology progresses through early stage clinical trials, and comprise increasingly sophisticated economic models to assess the likelihood of clearing market access hurdles, along with the value of alternative R&D investments and their impact ([see Brief #3 Supp. Information for diagram and details](#)).

## **Conclusion**

The VET framework is a novel tool designed to foster alignment between stakeholders and activities along the translational pathway, promote investment in technologies with a high likelihood of clinical adoption and reimbursement, and streamline the innovation process. The VET analytical framework is readily adaptable to other personalized medicine therapeutics, biotherapeutics, ‘omics-based diagnostics, combination therapies and codependent technologies with the goal of optimizing efficient and cost-effective clinical translation.

1. Value-engineered translation for regenerative medicine: meeting the needs of health systems. (2013). Bubela T, McCabe C. *Stem Cells Dev.* 22 (supp 1) 89-93. Doi: 10.1089/scd.2013.0398.
2. International Network of Agencies of Health Technology Assessment: INAHTA glossary. [http://www.inahta.org/HTA/Glossary/□\\_Health\\_Technology\\_Assessment](http://www.inahta.org/HTA/Glossary/□_Health_Technology_Assessment)