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Traversing the valley of death

Academic research plays a central role in the translational ecosystem, sitting on one end of the valley of death, that is, the gap between preclinical research and real-world clinical applications. Considering clinical need and applicability early in research and development, and knowing about regulatory and commercialization processes, may help academics push innovations across the valley.

The aim of bioengineering and biomedical research is to ultimately provide new treatments, diagnostics and prevention approaches that reach the patients. However, the huge strides made in the laboratory-scale development of biomedical innovations are not resulting in commensurate gains in new clinically translated solutions, and, even if they enter the market, patient access often remains limited, particularly in low-resource settings. Traversing this so-called valley of death hinges on a connected ecosystem that includes academics, industry, funding agencies, investors and regulatory bodies.

From an academic point-of-view, there are two sides to this problem.

First, to aim for eventual clinical translation of an innovation, one may greatly benefit from knowing about commercialization aspects to understand the requirements further down the translational road, including intellectual property, investigational new drug application, clinical trial design, regulatory pathways and funding options, as Kyriacos A. Athanasiou and colleagues outline in this issue. Knowledge of how a product will be regulated and investigated clinically can guide the directions and priorities of preclinical research, for example, to define the complexity, materials and components of a device or system and to establish scientific support for clinical investigation. Sometimes, a tiered approach, that is, building complexity incrementally, may reduce risks and increase chances of clinical translation. Importantly, academics and developers should consult with key stakeholders, who represent the end users and consumers of the technology, to gain a vision of how a product will be applied clinically, as discussed by Annie Moisan et al. in this issue. Such consultation may reveal other aspects that need to be developed, such as tools for product placement or delivery as well as markers for efficacy evaluation. These considerations shall not prevent curiosity-driven bioengineering research, but the reality of translational pathways should be accounted for to avoid the engineering of solutions that will never leave the lab.

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Second, clinical need and feasibility of deployment across various settings should be identified before diving into the laborious and time-consuming endeavour of developing a new biomedical product for clinical translation. Here, context matters, including systemic, infrastructural, operational and logistical limitations. Often, much effort is invested into optimizing bioengineered tools or systems during development; however, comparatively less attention is paid to factors that contribute to their sustainable implementation. In this issue, Tivani P. Mashamba-Thompson et al. highlight the importance of designing context-specific solutions that consider population variations, the intricacies of the disease profile, affordability, sample collection and transportation logistics, as well as infrastructure and resource availability. Considering all these aspects within the context of an academic research project may seem far-fetched but may ultimately make the difference between a publication and real-world clinical effect across the globe.

A beautiful example of how context-dependent and access-conscious engineering can have a real impact is Rise Bionics, as discussed in this issue by Arun Cherian and Shriya Srinivasan. To increase the accessibility and affordability of prostheses, Rise Bionics was founded in India to produce devices using local materials, sustainable product cycles, a digital fabrication protocol and a human-centred design approach, thereby addressing a key clinical need. However, translating this product was not without challenges, ranging from funding and regulatory frameworks to material availability and pricing. Similarly, in this issue, Anthony Vipin Das and Ranganath Vadapalli highlight the road to translation of the eyeSmart electronic medical record system, an ophthalmic electronic medical record and hospital management system that allows efficient, equitable and decentralized digital eyecare. This project started on the premise of addressing the difficulty of reaching remote patients, not only identifying an important medical need, but also accounting for the logistics of delivering healthcare across India.

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