Perspectives from Invibio

In recent months I have travelled to the US, Europe and Asia and spent time speaking with regulators, medical device companies and surgeons. Although the conversations and topics varied, it was clear that every region focused on the same goal: delivering the best clinical outcomes at the lowest costs. Progress towards this goal is gaining momentum, with different approaches around the world. After speaking with different stakeholders, I have concluded that to achieve our common goal will require significant changes in the behaviors and practices of everyone involved, including Invibio.

Clinical Outcomes

So how do we define "best clinical outcomes"? Outcomes are defined as: interventional patient benefits or harms which can be assessed from different measured perspectives including, patient-reported outcome (PRO), clinician-reported outcome (ClinRO), observer-reported outcome (ObsRO), and performance outcome (PerfO) (Ref. Figure 1). All of these measures contribute to determining the progress and treatment efficacy of the chosen intervention.

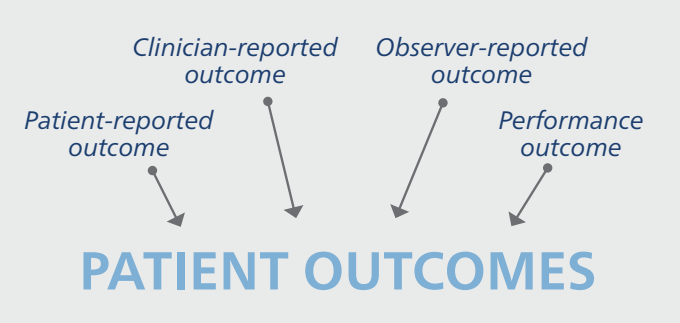


Figure 1

These measures or clinical outcomes are typically obtained through clinical studies, which are expensive and time consuming, and include many operational challenges during execution, to acquire robust clinical evidence. Though approaches vary, each geographic region has taken steps to improve patient outcomes and lower costs.

In the US, the introduction of The Bundled Payments for Care Improvement (BPCI) initiative links payments for multiple services received from providers during an episode of care. Under this initiative, organizations enter into payment arrangements that include financial and performance accountability. It's thought that these models may lead to higher quality and more coordinated care at a lower cost. In knee and hip surgery, for example, hospitals where the surgery took place will be accountable for the quality and costs of care from the start of the surgery through 90 days after discharge. This model focuses resources on the immediate episode of care rather than fee-for-service. However, it does not take into consideration the medium- to long-term issues that may arise. Moreover, it poses the question of how to differentiate between low- and high-risk patient clinical outcomes. Within Europe, the approach to improving patient outcomes and lowering costs even varies by country. For example, in Germany, rising costs are managed with maximum reimbursement levels assigned to each diagnosis-related group (DRG) allowing healthcare professionals (HCPs) to determine which intervention has the potential to provide the best clinical outcome, as long as it fits within the reimbursement framework. Clinical efficacy is aided by disease management programs for common chronic conditions. The programs use evidence-based guidelines to ensure program protocols include the most effective treatments. Despite these measures, Germany struggles to contain healthcare costs.

Although implemented measures throughout Europe have helped, they may also have implications for new product innovation. With reimbursement caps and new Medical Device Regulations (MDR) requiring extensive pre- and post-market surveillance clinical studies, innovation that may improve clinical outcomes may be slow-to-market.

Earlier this year, the Chinese central government took its own measures to lower costs. It issued a notice to deploy a disease-based charge system, similar to DRGs. The government provided a disease reference list from which the regions could then select which diseases to implement. Additionally, the Chinese Tender System (product price proposal) was designed to drive the cost-effectiveness of quality products sold in the market. Consequently, most regional Chinese governments focus on price only and do not emphasize clinical outcome.

In summary, the goal of achieving the best possible clinical outcomes appears consistent worldwide. However, with so much regional variation and an array of different stakeholders requiring different levels of clinical evidence, the medical device industry will have a difficult task of demonstrating that new product innovations are addressing this challenge and, ultimately improving patient care.

Cost Containment

Not only is defining "best clinical outcomes" difficult, but so is delivering healthcare at the lowest cost. The majority of current cost metrics focus on up-front purchasing costs rather than the total cost of care. For example, no standards exist for accurately assessing complication rates, or measuring the cost of revision surgeries, and reflecting these in purchasing decisions. When faced with delivering a consistent, quality of healthcare at the lowest cost, the market has yet to create an environment that encourages more ambitious solutions than simply preserving the status quo at a fractionally reduced price.

Invibio's Contribution

These current healthcare challenges force me to reflect on the changes within our business. Specifically, how can Invibio contribute to the goal of achieving the best possible clinical outcomes and lower costs?

Perhaps the biggest changes have to do with how we establish and maintain clinical efficacy for each of our healthcare solutions. Invibio already focuses on areas (Spine, Trauma, Dental and Orthopedics) where we believe we can deliver the greatest clinical and economic benefit (Ref. Figure 2). To help us raise our own bar for patient care and provide even greater clinical efficacy, we recruited a clinical study manager and are working with HCPs, medical device manufacturers and other stakeholders to determine the clinical and economic impact of our solutions. We have also brought in clinical relations expertise to interact with HCPs, hospitals and payers. Doing so ensures the clinical evidence we develop is not only shared in the marketplace, but accurately supports the benefits our products provide to patients and the entire healthcare community.

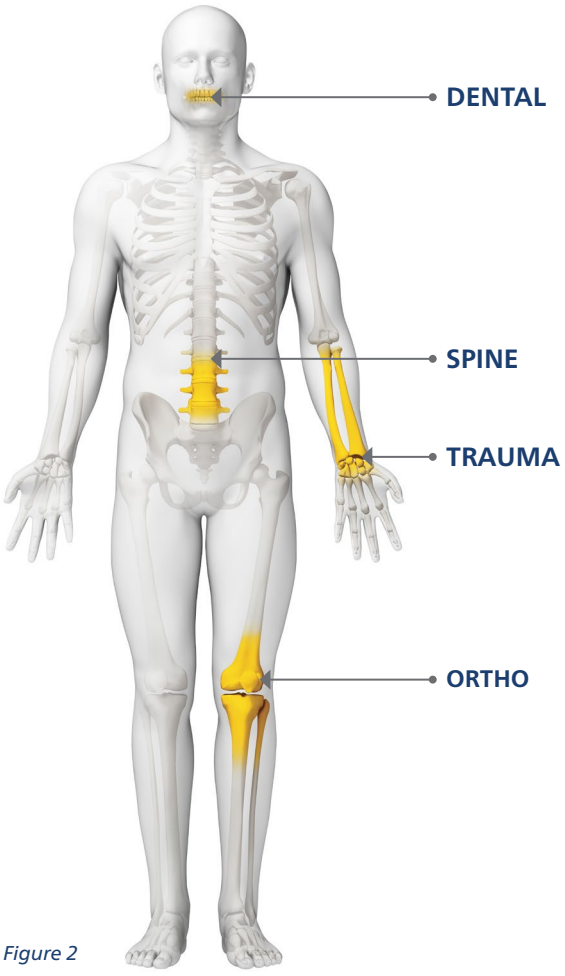


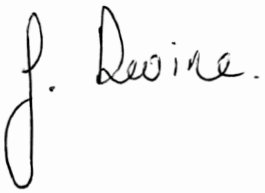
Figure 2

As a result of these enhanced research and clinical data capturing efforts, we have become more certain of the effectiveness of our solutions.

In addition, our investments have made it easier for medical device companies to innovate and change the way they develop new products. Our investment in component manufacturing facilities and component testing, for example, gives us a greater role in the design, development and commercialization of trauma fracture plates. We have also pledged more support to our customers' new product development. We have helped customers worldwide navigate the challenging, regulatory pathway toward product safety and efficacy. It's a win-win for Invibio, our customers, and patients alike.

In This Issue

As you read this issue of Invibio Insider, I hope to provide insight into all of these aspects across our areas of business. Focused topics will provide a greater understanding of the levels of clinical evidence and what that may mean for the patient and clinical outcomes. We will also explore approaches for treating challenging patients, including the HCP's perspective, showcase recent clinical evidence and discuss its potential economic impact. Finally, this issue of the Invibio Insider brings to life some of the investments Invibio has made to help facilitate and accelerate innovation in our key areas of business.



John Devine, PhD
Medical Business Director
Invibio Biomaterial Solutions

Invibio
BIOMATERIAL SOLUTIONS

Invibio Ltd.
Victrex Technology Centre
Hillhouse International
Thornton-Cleveleys
Lancashire
FY5 4QD, UK

Tel: +44 (0) 1253 898 000
FAX: +44 (0) 1253 898 001

Invibio Inc.
300 Conshohocken State Road
West Conshohocken, PA
19428
USA

Toll Free: 866-INVIBIO (468-4246)
Tel: (484) 342-6004
Fax: (484) 342-6005

For further information please email us at info@invibio.com or visit our website at:

Invibio.com