

Innovation within Clinical Development Will Come from New Commercial Models

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It is certainly not a new concept to state that the biopharmaceutical industry is in dire need of transformation, in fact it is a tired concept regularly discussed, but often the pathway to transformation is misunderstood. As shareholder value declines — or remains stagnant at best — and the number of new products introduced continues to hover at modest levels, the industry must transform the basis in which it conducts its research and development processes and think less about clinical strategy and more about a broader concept, what is the best ‘evidence optimization plan.’

By and large, the industry as a whole already knows this and has undertaken several strategies to enhance pipeline productivity. Mergers, acquisitions, partnerships, creative outsourcing arrangements, and even reductions in headcount have all been utilized to some degree in acknowledgement of the changing nature of drug discovery and development and the need to reduce costs and cycle time. Taken collectively, however, these actions are but stop-gap measures only capable of producing nominal, short-term gains and are comparable to the cost savings synergies seen from M&A over the last decade, rather than the transformation of R&D productivity that many of these deals were predicated upon. Notwithstanding the need for grass roots scientific innovation and the elucidation and understanding of disease process, transformation in product development and perceived asset value will also be driven through the deployment of new commercial models that harvest real world outcomes and in a currency and language that resonates with payers, providers and patients.

To truly create an R&D renaissance, biopharma must accept the notion that commercial realities have become part of the key to clinical transformation. To fundamentally alter the manner in which new medicines are developed and brought to market — and further, to verifiably produce positive change in the overall patient experience — seamless, cooperative convergence between the clinical and commercial functions must be acknowledged, acted upon and optimized.

Today’s *New Health* landscape consists of a vast constellation of stakeholders who possess more power than ever before. Physicians, payers, patients and regulators are each now demanding more demonstrable proof of a new product’s benefit, typically measured in real-world patient outcomes. As such, defining and demonstrating true value to these stakeholders is one of the most important charges for the biopharmaceutical industry. But most critically, this effort must be undertaken from the very early stages of a drug candidate’s lifecycle to ensure that data produced throughout development will be adequate to address the needs of all stakeholders. Put another way, biopharma must begin to back into clinical trial design with more emphasis on market access and reimbursement realities, and less on simply obtaining basic regulatory approval. Regulatory approval is only the start of ‘proof of value’ in *The New Health*.

To provide demonstrable proof of a product’s value, biopharma must look to harness and utilize multiple sources of data and then incorporate this knowledge into clinical development plans. First and foremost, there must be a better standard of data analytics in measuring clinical outcomes, clinical performance and the patient experience in healthcare provision. In addition, industry must also develop patient-centric models to enable the collection of real-world patient outcomes — whether from the home, hospital or primary care environment. Although these patient-centric commercialization models may take many forms, these channels must be in place for true clinical

and commercial convergence. From nurse educators to web-based patient communities, the point of these models must be to create a closed-loop model in which information is *pulled* and not simply *pushed*.

Furthermore, information that is gathered and then used to justify value increasingly must be culled from regional populations. Many payers simply do not want data from a global clinical trial, but are demanding localized, real-world data from actual patients within their region and that can be related to local budgetary spend. The value of this data is not just limited to demonstrating the value of existing therapeutics for reimbursement decisions; indeed, the most significant benefit of obtaining and understanding patient-centric data is the insight it provides can then assist in designing better clinical trials. With such real-world insight into patient behavior, quality of life, drug safety and efficacy, biopharma will then have a solid understanding of what the ideal product profile might look like, and thus enabling clinical trials to be designed that specifically speak to multiple stakeholder needs.

Europe, particularly the U.K., has vast experience in conducting health technology assessments on medicinal products for potential formulary placement, and many private payers in the U.S. have developed extensive proprietary formulas as well. But despite differing data tools and methods from one country or payer to the next, all of these assessments typically balance quality of life with cost of treatment. The upcoming changes to the remit of the UK's National Institute for Clinical Excellence (NICE) places more emphasis on patient experience, but NICE's legacy on controlling market access is clear: Payers everywhere are demanding tangible proof of positive patient outcomes from a real-world population and will withhold their reimbursement for products that can't provide this data.

Germany, for example, is now potentially moving into a world that will require a never-before-seen proof of value. A product must show a benefit or it will be deemed as having 'no added benefit' If a biopharmaceutical company cannot provide this, their product will go directly into a reference pricing category. Should proof of value be present, a drug can command a premium price, however, the government payers are reserving the right to demand further real-world outcomes data post launch for biopharma to keep that premium price. This type of environment underscores the need for additional data collection in the form of observational research or other types of patient-centric data. It is precisely this commercialization domain that will drive a revolution in the efficiency and quality of clinical development, as well as the targeting of unmet medical need.

In that sense, market access considerations will not only transform clinical development processes and priorities, but will additionally spur innovation and unlock the latent potential of personalized medicine. Observational research, for example, may highlight a particular subgroup of patients who respond favorably to a drug, thus potentially changing both the coverage dynamic and future research into predictive biomarkers. Further, this coming commercial environment will also increase the use of drugs that are paired with diagnostics. Already a growing field with huge advances in technology, drug/diagnostic combinations narrow down target populations to only the most likely responders and thereby provide payers with precisely the type of individualized information they need to make reimbursement decisions. This is a radical departure from the traditional blockbuster model, but this movement is absolutely necessary as the sphere of stakeholder influence widens. Biopharma is still — and will always remain — an essential component of the global healthcare ecosystem, however the industry must now place more emphasis on cooperation and individualization and retool its processes to better understand the needs of other stakeholders.

Naturally, the key driver behind the changing commercialization dynamic of biopharmaceuticals is cost-containment. But the conversation is shifting from being about cost, to being about value. As part of larger lifecycle management strategy, the industry has been in a pattern of launching marginally differentiated "me-too" drugs that produce minimal benefit in real-world outcomes. So with the market — and all its associated players — demanding more proof and higher quality, the industry has no choice but to respond. Through closed-loop patient-centric commercialization

models, data and insight will be gathered that provide the substrate for smarter clinical trials and will provide payers with the proof they demand, pharma with the price point it needs and patients with the treatments they want.