Besieged by rising R&D costs and sinking returns on investment, the pharmaceutical industry now faces a global healthcare system in which cost containment is imperative. In this value-based world, the value story of a new product must resonate with payers, prescribers, health technology assessment (HTA) boards and patients.

How well this story is told, and how clearly every value attribute links to supporting evidence, is the key to product success, corporate survival and most importantly patient access to life-changing therapies.

The Global Value Dossier (GVD) is the foundation for tailored, country-specific submissions, ensuring consistent execution of global access strategies. Standard GVDs include: an executive summary; the disease and its burden; current therapies and unmet needs; clinical, safety, quality of life and economic data (the evidence base); and frequently asked questions and objections.

However, the current GVD model:
- Is very large. The volume of data can bury the value story; the document becomes difficult to navigate. Bloat creeps in because the GVD is meant to serve global, regional and local users simultaneously.
- Is often prepared just before approval or launch. It gathers data to support a value story that’s already finalized. Therefore, evidence gaps must be filled in hastily.
- Covers a single product in a single indication. GVDs do not connect the value story of a product across multiple indications or to other products in a therapy area.
- Is created on a one-off basis by disparate internal teams or external consultants. Activities that should be linked are conducted independently, potentially leading to misalignment and duplication of effort.
- May not be regularly updated. Chaos can ensue if everyone is not aware of the updates or is working off an outdated iteration.
A GVP IS A LIVING RESOURCE, NOT A STATIC DOCUMENT

Delivered in a responsive, electronic format that mirrors the technologies people use in their everyday lives, a GVP can grow and change over the course of a product’s whole lifecycle.

The central GVP hub will include a GVD-type document, but also provide easy, organized access to slide decks, targeted messaging materials, economic models, payer policies and guidelines, clinical trial results, and publication plans, among other data. User-friendly, the platform promotes utilization.

Recently, PAREXEL used one of the many available platforms (here, Microsoft’s SharePoint) to build a GVP for a client. The SharePoint platform allows system architects to create a matrix into which folders and files can be deposited, organized and saved. Only the latest files reside in the system, so everyone gets an up-to-date version at the same time.

A GVP BEGINS PRESSURE TESTING THE VALUE STORY EARLY IN DEVELOPMENT

Due to the high rate of product failure in Phase I, it’s best to begin building the GVP around Phase II. Unfortunately, GVDs are viewed traditionally as product launch tools and thus begun at Phase III. But when started early, the GVP can have a transformative effect on the drug development process.

An early start focuses developers on the value story as soon as Phase I safety hurdles are cleared, and then directs future work towards supporting that story.

Gaps in evidence, especially payer-targeted evidence, become clear as the story is articulated; relevant data can be generated while there is still time to do so effectively as it is extremely costly to address serious gaps near launch.

PAREXEL currently is engaged in a multi-year GVP partnership with a large, global pharmaceutical company to develop the resource hub for a single product across multiple indications—all in varying stages of Phase II and Phase III clinical development.

We are pressure testing the value story for this client in these indications, considering the payer perspective and analyzing similar prior submissions. Using those findings, we are comparing the available data and current messaging for the new product to what has been successful before. If we see that a trial is missing a key Quality of Life (QoL) parameter or clinical endpoint, or if the duration of an endpoint is not adequate, we deliver that feedback to our client.

Whether or not our client accepts all of our recommendations, it can proceed knowing the potential impact of its development decisions on its product’s value story. The worth of the GVP model is realized in

Other platforms, which PAREXEL is exploring, potentially could make the user experience even more rewarding and interactive.

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the process of studying and understanding payer needs, considering whether the right data are being gathered and making informed decisions about the endpoints, duration and size of clinical trials.

A GVP LINKS THE PRODUCT/INDICATION(S) STORY TO THE PIPELINE AND THE COMPANY

A GVP connects value and evidence for a single product and single indication, but it can also be scaled to align a product’s value story across multiple indications, an entire portfolio, and even link to the overarching corporate strategy through its dynamic matrix form, allowing users to switch from macro (i.e., the corporate value story) to micro (i.e., country-specific outputs from a budget impact model) with a mouse click. And if there are multiple products developed for the same indication, any conflicts in the value stories across indications can be identified early.

A GVP DEMANDS CROSS-DISCIPLINARY EXPERTISE AND COLLABORATION

A GVP involves internal collaboration that engages R&D, medical affairs, marketing, pricing, health economics, and market access functions with consulting and external communications experts.

Rather than a dossier that’s compiled, used intensively for a defined period and then becomes outdated, the GVP process communicates an ongoing value story with multi-disciplinary moving parts. Indeed, the very act of creating the GVP breaks down barriers by encouraging different disciplines to interact earlier in the drug development process and debate issues such as, say, the market access consequences of clinical decisions.

A GVP ENABLES THE VALUE STORY TO SHINE THROUGH

Unlike the GVD, the GVP does not run the risk of becoming a data dump. Rather, the quality of each input is scrutinized and aligned across disciplines by messaging experts, ensuring the relevance and rigor of evidence used to support the value story to regulators, payers, and other stakeholders. In a value-based healthcare market, products must pass through a gauntlet of stakeholders who will challenge the value story at every step. Outdated information, gaps in information and internal conflicts in the value story can all be fatal to market access and product uptake. The GVP, an expanded and enhanced form of the standard GVD, can be a powerful tool upon which companies can rely throughout this process. A dynamic, multi-layered and interactive hub of product intelligence, the GVP can be used from early in development to refine the value story that is essential to achieve market access and success.

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