# Common Misconceptions About the Global Value Dossier

***At Nexus Values we believe that the Global Value Dossier is often misunderstood – and therefore undervalued. Used to its' full potential, the Global Value Dossier can transform your market access outcomes***

## NV Highlights

- **Need**: All products will have a global value story at launch and beyond, and this is most often captured alongside the key supporting evidence in a Global Value Dossier (GVD) for the product.
- **Misconceptions**: Often the GVD is started too late, seen as a tick-box exercise, or used as a data repository for reimbursement submissions meaning that the true purpose cannot be fulfilled and the value of the GVD to your team is reduced.
- **NV Recommendation**: We believe that the GVD should be started early and used to shape the value story and strategy, evolving in alignment with the value story as evidence is generated, and ultimately used as a bespoke, concise tool to internally communicate the value strategy for launch and beyond.

| True purpose | Common mistake |
|---|---|
| Core internal resource | Tick-box afterthought |
| Concise and value-focused | Lengthy data write-ups |
| Aligns global strategy | Attempts to cover all market perspectives |
| Assesses evidence gaps with an evolving mitigation plan | Summarises current evidence only |
| Identifies potential challenges and objections | Disease and product data repository |
| Communicates key strategy & future milestones | Overview of work to date |

## Definition

To understand the purpose of a Global Value Dossier (GVD; also called Core Value Dossier [CVD]) we first need to define value strategy more broadly. We all recognise that every product has a value, and that value is used to convince healthcare providers to pay for the product. Product value includes the specific clinical benefit for the patient, as well as the economic value or impact of reimbursing the product, all within the context of the unmet need in that specific disease and patient population. This value is proactively defined and shaped by the manufacturer, and used as a framework to plan evidence generation activities.

Here is where the GVD is vital – it is an industry-standard tool used to ensure effective internal communication across the manufacturing company of the current value strategy for a product in a specific indication. As almost all products will require a similar framework for their value strategy, the GVD structure has evolved over time to capture both the unmet need story and the product value story, which is summarised at a holistic level in the executive summary as a set of key value messages (KVMs) for the product.

## *Purpose…*

As a product is developed, launched, and maintained, there is a need for **internal understanding** across all functions and teams, global and local, of what the current value strategy is. There is an imbalance in knowledge and awareness that needs to be bridged between global and local teams, and competing priorities that need to be aligned across the company. This is an internal document only and so it is not intended to be used as a copy-paste into local reimbursement submissions, instead providing a global view that requires tailoring within the value strategy framework to the local market conditions.

Secondly, the GVD is not just communication of data in a repository, it is a **strategic guide** to the planned launch messaging. The GVD captures the target product positioning for reimbursement, the value story to achieve that goal, and the key evidence supporting the story. The phrase "key evidence" is vital here as the content should be very **targeted** and present only what is needed to understand the value strategy and be able to implement it.

Although the GVD is typically based upon a similar structure of presenting the unmet need followed by introducing the product as the solution, **each GVD is unique** in terms of the product value story and therefore each one needs careful planning and consideration when developing content. All of the main chapters should be framed by the value story and provide the evidence to support that messaging. While you may have a template to use as a basis and broad section headers may stay the same across projects, the subsections, level of detail in each section, and inclusion/exclusion of subsections is dependent on product value and the competitive landscape.

Finally, it is important to note that the value strategy evolves over time, and as such the GVD should also **evolve and be updated** as new data are available, as the positioning becomes clearer, or other strategic decisions are made. It is not a static resource that is developed once and never changed. All products should have a GVD that clearly and concisely captures the value strategy for the product in a particular patient population, and this should be regularly updated at key timepoints in the product lifecycle.

## *Common mistakes…*

*Treating the GVD as a **direct source for HTA and reimbursement submissions**, which is not a feasible goal – the GVD is global, the reimbursement submission is local. Trying to achieve both goals in one document will only lead to a long, confusing, and potentially ambiguous document that is difficult to navigate and contains extraneous information not relevant to most users.*

*Writing up content in a GVD as a **factual repository**, with extensive detail on disease and the clinical trial program beyond what is needed to understand the value strategy. This approach leads to an excessively long document that is closer to a data repository than a strategic tool.*

*Using a **set template** without deviation, completing all sections with content irrespective of the relevance to the product value story – and missing adding different sections that may not be standard but could be very important in a specific scenario. This approach misses the purpose of the GVD and leads to a dry, factual document that does not achieve the main objective – internal communication of the value strategy.*

*Developing the GVD **content once** and never revisiting it. Given the constantly changing competitive landscape and ongoing evidence generation, this rapidly leads to an out of date and irrelevant GVD. This creates a missed opportunity for internal alignment and clarity, and often occurs where GVD development is seen as a tick-box exercise only.*

## What this Means for You

This true purpose has several implications for your GVD preparations:

- **Timing**: a GVD should be initially created at the point that a product is considered a viable launch asset – this can be as early as Phase 1b/2 interim data analysis for an innovative oncology agent, or can be closer to Phase 3 read-out in other areas.
- **Focus**: the GVD should be framed around the global value strategy – beginning with aspirational messaging and transitioning to draft and then final value messaging as the evidence strengthens.
- **Content**: the GVD should contain key data that support the global value messaging – local data required for HTA submissions should be avoided unless relevant to several important markets and related directly to the value strategy.
- **Updates**: the GVD is not a static resource and instead should be regularly updated and evolved in alignment with the evolving product value strategy. The optimal approach is to start by developing an early disease dossier that evolves into a product dossier, with each iteration supporting a clearer and more specific value strategy for the product.

***For a discussion of your Global Value Dossier needs please contact Ebony at ebony.samuels@nexusvalues.com or Michael at michael.tang@nexusvalues.com***

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