



How can the Value Story be used to optimize the AMCP Dossier?

At Nexus Values we believe that the content of the AMCP dossier should be firmly rooted in the value story to ensure it remains clear, concise, and relevant to the end users to achieve desired positioning and maximize uptake

NV Highlights

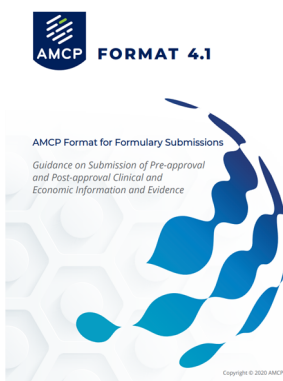
- **Situation:** the manufacturer-developed AMCP dossier provides US health care decision makers with the information needed to determine use of a product and typically follows the AMCP Format structure
- **Challenge:** the information suggested for inclusion by the Format can quickly become unfocused and dense if completed as a check-box exercise without the guidance of an overarching product-specific framework
- **Solution:** the value story should guide the development of the AMCP dossier to bring the relevant content to the health care decision makers to meet their decision-making requirements: a clear unmet need, with a concise summary of relevant clinical evidence, and easy to follow cost implications that provides the manufacturer-suggested positioning for optimal patient benefit

The Situation

Although an AMCP dossier is not a mandated document for launch, it is commonly used to provide US health care decision makers (HCDM) with the information needed to determine use of a product for a specific patient population. While it is an externally-facing document and should present the evidence in a clear balanced way, HCDM are assessing from the perspective of relative value beyond existing standard of care; a clear value-focused dossier can therefore make a difference in uptake compared with a long data repository that is poorly structured and developed.

The Challenge

The current AMCP Format (v4.1, 2020) provides a useful template that clarifies the information needed by HCDM to assess the product. However, the information suggested for inclusion by the Format can quickly become unfocused and dense if completed as a check-box exercise without an overarching product-specific framework to guide the overall flow.



Unfocused selection of available evidence to populate the template

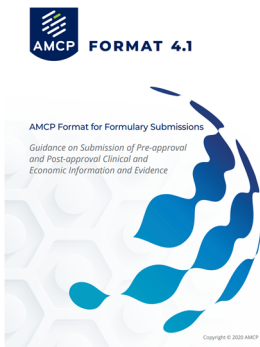


- Ambiguous
- Encyclopedic
- Confusing
- Lack of flow
- Vague product value
- Uncertain unmet need
- Unconvincing
- Resource-intensive to develop and update

The result is an unclear, lengthy dossier with unnecessary detail and evidence that is difficult to navigate and ultimately not used for decision making

The Solution

To optimize the content in an AMCP dossier, the value story for the product and indication should be used in combination with the Format as an overarching framework to guide inclusion/exclusion of content, as well as used to optimize the format and flow of the evidence presented.



**Value-story
driven selection
of evidence to
support
decision-making**



- Clear
- Concise
- Relevant
- Strong product value
- Definite unmet need
- Convincing
- User-focused
- Resource-efficient to develop and update

The result is a clear, concise dossier focused on relevant evidence that is easy to navigate and helps the HCDM understand the need and positioning for the product

With a clear value story in place ahead of starting content development, the AMCP dossier becomes clear, concise, and user-focused:

- A clear value story ensures **optimal flow of information** that is easy to follow and understand; there is clarity on unmet need, current landscape, and product benefits
- The underlying value story is **evidence-based**, avoiding any risk of promotional-sounding content; risk of bias is avoided with transparent narrative on the information presented
- Adherence to **AMCP Format page limits** is more easily achieved; a clear value story ensures concise presentation of information and ensures only **relevant information for the end-user** is included, avoiding lengthy, dense text
- The dossier is **more likely to be read and used**; the content required to support decision-making is easily identified and therefore directly benefits patient access
- The **need for an update** is easier to identify, with the removal of information more simply determined; it is clear when new data impacts the value story and therefore requires a dossier update (including both addition of data as well as content removal), versus when new data can wait for annual refresh for inclusion

What this Means for You

- **Remember the purpose** – use the value story to help define what the HCDM needs to know and ensure the dossier content meets those needs in a user-friendly, easy to navigate format
- **Keep a clear focus** – use the value story to consistently determine evidence inclusion/exclusion without bias and avoid the creation of a dense disease or product encyclopedia; early aspirational messages can be used ahead of clinical data availability to plan the content and identify key gaps for evidence generation activities
- **Stay relevant** – use the value story to trigger dossier updates in between the annual refresh, as well as determine what content to remove in future updates to keep the content relevant and focused for HCDM needs
- **Achieve your desired positioning and maximize uptake** – a good AMCP dossier has a direct impact on HCDM decision-making, effectively communicating the manufacturer-suggested positioning to ultimately achieve optimal patient benefit

**For more on how to improve AMCP dossier development and best practice please contact
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