

Compendia Strategy for a New Oncology Product.



How Xcenda developed a compendia strategy for a client new to the oncology market.

The Need

Our client was a mid-sized pharmaceutical manufacturer planning for phase 3 clinical trials for its 2 pipeline products. In a crowded therapeutic area, the challenge was to create a strategy that would enhance the opportunities for successful and timely compendia listings for its new products in the oncology space, specifically by evaluating needed study parameters for its anticipated indications and sub-indications.

The Xcenda Solution

Using our team of compendia experts, Xcenda evaluated compendia listings in the therapeutic area for selected comparator products in each of the 4 Medicare-approved compendia, and benchmarked the level of data provided. Specifically, our approach included

Identifying Proxy Products	Developing Evidence Tables	Developing a Compendia Landscape Strategy for the Client's New Oncology Products
<ul style="list-style-type: none">• Identified products that had non-labeled compendia listings for the therapeutic area• Selected products most relevant in comparison to the client's products, as well as those with the most recent studies included in compendia decisions	<ul style="list-style-type: none">• Reviewed studies referenced in the respective non-labeled compendia listings for each proxy product• Compiled information on key studies and assessed the strength of evidence for each	<ul style="list-style-type: none">• Summarized research to prepare for analysis• Reviewed the current compendia landscape and individual publications to create a compendia strategy for the client's products, including specific details on the strength of evidence, study size, and endpoint criteria needed by compendium in the therapeutic class the client was seeking indications and sub-indications• Evaluated the likelihood of successful submission for each compendium

The Outcome

Given the outcome of the compendia strategy, the client also pursued a gap analysis, in order to conduct a thorough review of the clinical trial literature for its own products, and to identify development gaps for additional data needed. In addition, the client utilized the findings from the compendia strategy to plan for phase 3 clinical trials.

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