FACT SHEET

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5 Considerations to Help Differentiate Your Oncology Drug

An increasing number of oncology drugs are putting PROs on their label. Since 2012, 13 oncology drug labels have PRO data.

Regulatory authorities now encourage sponsors to capture data on how their drug makes the patient feel and how it affects their quality of life. For example, in 2020 the FDA launched Project Patient Voice. Being able to demonstrate a reduction in symptoms, potentially leading to improved quality of life will help your cancer treatment stand out in a highly competitive market. This will provide Healthcare Authorities, clinicians and patients with the information they need to make decisions on which drug to use:

1. **Capture data which is specific to your indication by using indication-specific questionnaires.** Using a standard oncology PRO form may not capture symptoms that are specific to the indication a sponsor is targeting and won't therefore produce the data that is needed for differentiation. Often eCOA providers will recommend generic oncology questionnaires, such as the EORTC-QLQ-C30 or FACT-G.

   By using more indication specific questionnaires sponsors are able to correlate symptom reduction to improved Quality of Life (QOL). **Ensure your questionnaires allow you to demonstrate how a reduction in symptoms impacts patients' quality of life** and capture QOL aspects that are important to your patients:

   For example, a reduction in the frequency of diarrhea may increase a patient's ability to be active, to take part in family and social activities which they may report as being important to their quality of life.

2. **Realize the full impact of your drug on a patient's life by collecting PRO data at the right frequency.**

   Collect symptom data in between site visits to enable:

   - Additional data to be collected: using a provisioned handheld, the patient's own device and connected devices
   - Improved accuracy of data by allowing patients to log Adverse Events (AEs) and symptoms as and when they happen (ie not just at site where there will be recall bias)

   Capturing data frequently will enable patients to more accurately:

   - Report on events such as headaches, diarrhea
   - Capture frequency of events (e.g. number of headaches each week)
   - Capture severity of events (e.g. intensity of headaches)
   - Capture duration of events (e.g. length of headache)

   All of these data points are key to demonstrating the whole impact of your drug on a patient's life.

3. **Ensure you are asking the right questions to capture the data you need to differentiate.** Too often not enough emphasis is placed on this. There are 13 Oncology drug labels with PRO data from 2012-2022. 9 of these are efficacy-related PRO data. Well-thought out and written questions will help evidence your drug's superiority. Work with eCOA scientists to design the questions around your specific study needs to ensure it will show differentiation to competitor drugs that are already available.

4. **Develop your eCOA strategy early in the drug development program.** Explore potential PRO endpoints in PI and PII so when you get to PIII your PRO strategy is fully defined.

   For example, a study in myeloma may use the PRO-CTCAE and discover patients have impaired vision as an Adverse Event. Focus could then be put on developing a PRO strategy that properly measures the severity of the impaired vision and how it impacts their patients' quality of life at frequent time intervals. Although the drug may show it impairs vision, the duration may only be short-term and not impact patient quality of life.

5. **Consider how to collect this additional data.**

   - Patients are able to **collect data more frequently, remotely** in between site visits using a provisioned handheld, their own smartphone, tablet, web and various connected devices. Your eCOA provider and eCOA Science teams will be able to advise on the most appropriate solution for your patient population and study.
   - Additionally objective data is vital to help with differentiation and provide regulators, Healthcare Authorities and patients with more powerful data on your drug. These will provide you with important quality of life data on how your drug is affecting, for example, activity levels, impact on sleep.
   - Sourcing connected devices from a single eCOA provider will simplify the patient, site and sponsor experience. From faster set-up times, being simpler to use for the patient, to reporting on all eCOA data being in one portal.

Speak to a Scientist
For a free consultation on how to differentiate your oncology drug for an upcoming trial, email science@clario.com

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