eCOA Best Practices for CDAI and mMS Scoring in Crohn's Disease and Ulcerative Colitis Clinical Trials

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Crohn's Disease (CD) and Ulcerative Colitis (UC) are global inflammatory bowel diseases that significantly affect these patients' lives[1]. Every year since 2017, around 200 clinical trials (phase I-IV) have started to explore treatments for these conditions[2]. To measure the success of these treatments, clinical trials utilize tools such as the Crohn's Disease Activity Index (CDAI) for CD and the Modified Mayo Score (mMS) for UC, measuring achievement of clinical remission, as a primary endpoint of these trials[3,4]. The CDAI and mMS are both composite scores consisting of different subcomponents.

When implementing these composite scores/calculations into an electronic clinical outcome assessment (eCOA) system, several aspects should be taken into consideration. These include:

Key Considerations for CDAI in CD

1. Symptom Tracking via Electronic Diary (eDiary) Completion
   The CDAI (and mMS) includes patient-reported components, in which patients capture their symptoms such as stool frequency in an eDiary. Within the CDAI, the stool frequency subscore specifically assesses the number of liquid or soft stools that were passed in a day. To assist patients in tracking this, the Bristol Stool Chart can be included in the eDiary, providing a reference image (copyright approval may be required). Additional patient training materials on how to use the eDiary can also be created by Signant Health to improve accuracy and adherence.
2. Hematocrit Values for CDAI Calculation
   Another subcomponent of the CDAI is the patient's hematocrit value which is derived from central labs. There are different options to input this value into the eCOA system for CDAI calculations at specified visits. Clinical study teams should decide whether to input the hematocrit value from the previous visit or to wait until the current visit's results are available. This decision can impact the timing of CDAI calculations and should be planned carefully.

Key Considerations for mMS in UC

1. Capturing Reference Stool Frequency
   Within the mMS, the stool frequency subscore compares the patient's daily stool frequency to their normal daily stool frequency (when the patient was in remission from UC or before the patient started showing UC signs and symptoms[3]). Patients may find it challenging to consistently recall their usual daily stool frequency and subtract it from their current number of stools each day. Therefore, it's recommended to capture this reference frequency in the eCOA system, to automate the subscore calculation. Different options to capture this data can be discussed during the design and setup of the eCOA solution.

Considerations for both CD and UC Trials

1. eDiary Data for Subscore Calculations
   When calculating subscores derived from eDiary data, the FDA recommends having at least 3 consecutive or 4 nonconsecutive days of eDiary entries leading up to the study visit where the CDAI or mMS will be calculated[3,4]. However, the FDA has no recommendation on the cadence of eDiary completion. This is another aspect that can be discussed during the design phase - whether to open the eDiary for 7 days before the specified visits, or to have the eDiary completed daily throughout the duration of the trial.
2. Handling Bowel Prep and Endoscopy Days
   Endoscopy is essential for calculating the mMS (endoscopy subscore) and it's also performed in CD trials to evaluate mucosal inflammation. Because of this, the FDA recommends that the bowel preparation and endoscopy days are considered invalid when performing the subscore calculations derived from eDiary data[3,4]. Study teams have many options as to how to capture these relevant dates in eCOA systems. For example, an eCOA solution can prompt sites to input the day(s) of bowel preparation, or the bowel preparation days can automatically be captured based on the date of endoscopy.

Conclusion

Implementing the CDAI and mMS in eCOA systems can be complex due to the numerous components involved. It is important to consult with an experienced clinical and digital health sciences partner that can help provide a solution that is easy to use for sponsors, sites, and patients. Signant Health has dozens of years of experience supporting CD and UC trials – our team of eCOA scientists and clinicians are happy to support your team in setting up the eCOA solution design and create participant and site training materials to ensure a successful trial.

EXPLORE SIGNANT'S SOLUTIONS FOR INFLAMMATORY BOWEL DISEASE CLINICAL TRIALS.

References

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