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It's time to measure what matters in inflammatory bowel disease

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Dear editor,

A Core Outcome Set (COS) is a standardized group of outcomes that should be assessed and reported in all randomized controlled trials (RCTs) within a specific medical or health-related field. These outcomes are selected based on their relevance to key stakeholders, including patients and healthcare providers. Additionally, COS help improve the synthesis of evidence by reducing variability in reported outcomes across RCTs (1).

Three years ago, the CORE-IBD Collaborators published the first COS for inflammatory bowel disease (IBD) to be used in RCTs (2), developed with input from both patients and clinical experts (table 1). However, conducting an RCT is not always feasible due to financial, ethical, or logistical constraints. In such cases, observational studies may be the only viable approach to analyzing various aspects of a disease. Recognizing this need, in

2022, researchers from the European Crohn's and Colitis Organisation (ECCO) developed a COS for real-world data in IBD (3). This COS covers nine study domains: a) disease activity, b) patient-reported outcomes, c) disease complications, d) specific symptoms, e) medical therapy, f) medical therapy-related safety, g) surgical intervention, h) surgical intervention-related safety, and i) healthcare utilization.

Additionally, emerging outcomes, such as cross-sectional imaging techniques (computed tomography enterography, magnetic resonance enterography, and intestinal ultrasound), are gaining prominence in IBD research (4). It is likely that new COS will be developed in the coming years to integrate these advancements.

These milestones mark a significant step toward a more standardized, evidence-based, and patient-centered approach to IBD research and care. We encourage researchers and readers of *Revista Española de Enfermedades Digestivas* to integrate these COS into their work, fostering more consistent and impactful research in IBD.

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Table 1. Core Outcomes set in IBD Randomized Controlled Trials (2)

Domain	Crohn's Disease	Ulcerative Colitis
PROs, symptom-based measures, and composite indices	PRO: stool frequency and abdominal pain Composite: CDAI composite outcome measure Clinical response should be defined by CDAI reduction >100 points compared with baseline	PRO for UC should include rectal bleeding, stool frequency, and fecal urgency The adapted 9-point MCS (including rectal bleeding, stool frequency, and mMES) should be used in UC trials Symptomatic remission should be defined by rectal bleeding subscore ¼ 0 and stool frequency subscore 1
Endoscopic Outcomes	Endoscopic outcomes should be assessed using the SES-CD. Endoscopic response is defined as a >50% SES-CD reduction from baseline, while remission is the absence of ulcerations in all segments (SES-CD 2 for isolated ileal CD). Missing segments should be reported at baseline and post-treatment. Response should be evaluated in induction trials,	Endoscopic outcomes should be assessed by flexible sigmoidoscopy in UC trials Scoring should be based on the most affected segment Endoscopic remission should be defined as mMES ¼ 0 Endoscopic response should be defined by reduction in mMES 1 from baseline Endoscopic response and remission should be measured in UC induction trials at 9–12 week Endoscopic response and remission should be measured in UC maintenance trials at 52 weeks

	and both endoscopic remission and response in maintenance trials at 1 year.	
Histopathology	Not included as a core domain.	Histopathology should be scored using the RHI Histologic remission should be defined by RHI <3 with absence of neutrophils (or Geboes Score <3.0with no neutrophilic inflammation in the epithelium) Histologic remission should be measured in induction and maintenance trials
Biomarker Outcomes	CRP & fecal calprotectin for induction & maintenance. - Remission: CRP <5 mg/L. - Response: >50% reduction in CRP & fecal calprotectin if elevated at baseline	Fecal calprotectin for induction & maintenance. Remission: CRP <5 mg/L or fecal calprotectin <150 µg/g. Response: >50% fecal calprotectin reduction if elevated at baseline.

Abbreviatures: PRO, patient-reported outcomes; CDAI, Crohn's Disease Activity Index; SES-CD, Simple Endoscopic Score for Crohn's Disease; mMES, modified Mayo Endoscopic Subscore; CRP, C-reactive protein; CD, Crohn's disease; UC, Ulcerative colitis; RHI, Robarts Histopathology Index