EXPERT CONSENSUS TO STANDARDISE TRANSCRIPTOME ANALYSIS IN INFLAMMATORY BOWEL DISEASE CLINICAL TRIALS

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UEG Week Copenhagen 2023 | Poster

IBD

October 15, 2023

A two-part study combining systematic review and expert consensus developed recommendations to standardise transcriptomic analysis methods in multicentre inflammatory bowel disease clinical trials, addressing substantial methodological heterogeneity that limits data interpretation and generalisability.

KEY POINTS

- Systematic review of 22 clinical trials (13 ulcerative colitis, 6 Crohn's disease, 3 both) published primarily between 2017 and 2021 revealed persistent methodological heterogeneity in transcriptomic analyses.
- A panel of 16 IBD translational researchers rated 305 statements across four topic areas using modified RAM methodology, reaching consensus that 75% were appropriate, 1% inappropriate, and 24% uncertain.
- Transcriptomic analysis using mucosal biopsy or blood samples was considered appropriate at all phases of clinical development in patients with active disease for multiple research objectives.
- Validation of results with external datasets or orthogonal methods and complete reporting of individual patient metadata (demographics, disease/treatment history, sample location, local disease activity) were deemed appropriate and critical for data utility.
- The study provides an initial expert framework to overcome methodological discrepancies and increase the value of transcriptomic research in IBD clinical development.

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