

Computer-vision assessment of endoscopic disease severity in subjects with and without prior exposure to advanced therapies across adult and pediatric ulcerative colitis clinical trials

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Key takeaway



A computer-vision based continuous endoscopic score provides an objective assessment of disease activity in both adult and pediatric UC trials, capturing healing patterns in ADT-naïve and ADT-exposed subgroups.

Conclusions



ARGES-UC CMES and UCEIS_{ARGES} measures show consistent improvement across trial visits in UNIFI and UNIFI-Jr, supporting extrapolation of novel AI scoring systems towards regulatory and clinical decision-making.



In both adult and pediatric populations, CMES and UCEIS_{ARGES} detected greater endoscopic improvement in ADT-naïve compared to ADT-exposed subjects.



Data suggests that ARGES-UC can be generalizable across UC populations and advanced therapy exposure subgroups, showing potential to support smaller trials through more precise treatment effect detection.

Disclosures

All authors are employed by Johnson & Johnson. All AI model development and analysis presented in this poster has been conducted internally within Johnson & Johnson Innovative Medicine.

References

- Damasceno, Pablo F., et al. "ARGES: AN AI-CENTRIC TOOLBOX FOR IBD CLINICAL TRIAL RESEARCH AND DEVELOPMENT.", *Gastroenterology* 166.5 (2024): S-178.
- Mobadersany, Pooya, et al. "ARGESMAP: AN AI-DRIVEN MODEL TO ENHANCE ANATOMIC SEGMENT CLASSIFICATION OF GASTROINTESTINAL ENDOSCOPY VIDEOS IN CROHN'S DISEASE.", *Gastroenterology* 166.5 (2024): S-1483.
- Chaitanya, Krishna, et al. "Tu1992 ARGES-CMES: A NOVEL, CONTINUOUS SCORING FOR ULCERATIVE COLITIS DISEASE SEVERITY: ASSOCIATION WITH CLINICAL MEASURES AND TREATMENT RESPONSE VARIABLES." *Gastroenterology* 166.5 (2024): S-1482.
- Scherer, Emily, et al. "544 ARGES-CMES: A NOVEL, CONTINUOUS SCORING FOR ULCERATIVE COLITIS DISEASE SEVERITY: PREDICTION AND SENSITIVITY IN ASSESSING TREATMENT RESPONSE." *Gastroenterology* 166.5 (2024): S-125

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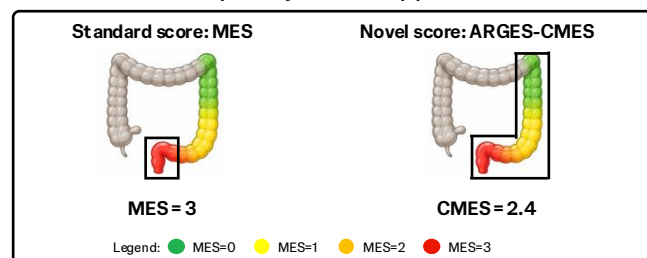
Background

- Adult and pediatric inflammatory bowel disease (IBD) studies consistently demonstrate greater treatment response rates in subjects without prior exposure to advanced therapies (ADT-naïve).
- Endoscopic endpoints** are considered objective measures of improvement. However, standard scoring systems like the Mayo Endoscopic Scoring (MES) and the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) are **coarse**, present **high inter-reader variability**, and have **limited sensitivity**.
- Artificial Intelligence** can standardize and enhance endoscopic scoring through comprehensive **computer vision** analysis of endoscopic videos. However, validation in pediatric populations is needed to support extrapolation and regulatory decision-making.
- We compared two **ARGES-UC** computer vision-derived endoscopic severity measures, **CMES** and **UCEIS_{ARGES}**, across **adult and pediatric trials** to characterize treatment response stratified by prior **ADT exposure**.

Methods

- Subjects from the **UNIFI (NCT02407236)** and **UNIFI-Jr (NCT04630028)** phase 3 trials assessing ustekinumab (UST) in adult and pediatric UC, respectively, were included. Adult placebo subjects were excluded from the analysis.
- The **ARGES-UC pipeline** [1-2], previously trained and validated on adult UC colonoscopy videos, was applied without further parameter tuning to compute **continuous endoscopic severity scores (CMES)** and ordinal scores for each of the UCEIS components (**UCEIS_{ARGES}**: bleeding 0–3, vascularity 0–2, erosion 0–3) [3-4] in endoscopy videos from both trials.
- CMES** quantifies disease activity across the descending colon, sigmoid colon, and rectum using a **continuous scale**, in contrast with the standard categorical MES (discrete 0–3 scoring) (Figure 1).

FIGURE 1: CMES computed by ARGES-UC pipeline vs traditional MES.



Results

- In total, 561 UNIFI participants and 70 UNIFI-Jr participants were included in the analysis.
- Across adult and pediatric populations, the computer-vision CMES score detected greater endoscopic improvement (lower CMES scores) over time in ADT-naïve compared with ADT-exposed subjects (Figure 2).
- CMES and UCEIS_{ARGES} reflected ongoing endoscopic improvement in ADT-exposed subjects during induction and maintenance therapy, demonstrated by the decreasing of CMES scores and progressive shift of UCEIS components towards lower categorical scores over screening, week 8, and week 52 visits (Figures 2/3).
- UCEIS_{ARGES} scores indicate that the differences in treatment response profiles observed in the UNIFI-JR CMES trajectories were primarily driven by improved vascularity and erosion in the ADT-naïve compared to ADT-exposed subjects, whereas bleeding scores distributions in each visit were more consistent across both groups (Figure 3).

FIGURE 2. CMES trends across trial visits (screening, week 8 and week 52 q8w/q12w) for UNIFI (A) and UNIFI-JR (B) stratified by previous exposure to advanced therapy (ADT-naïve vs ADT-exposed).

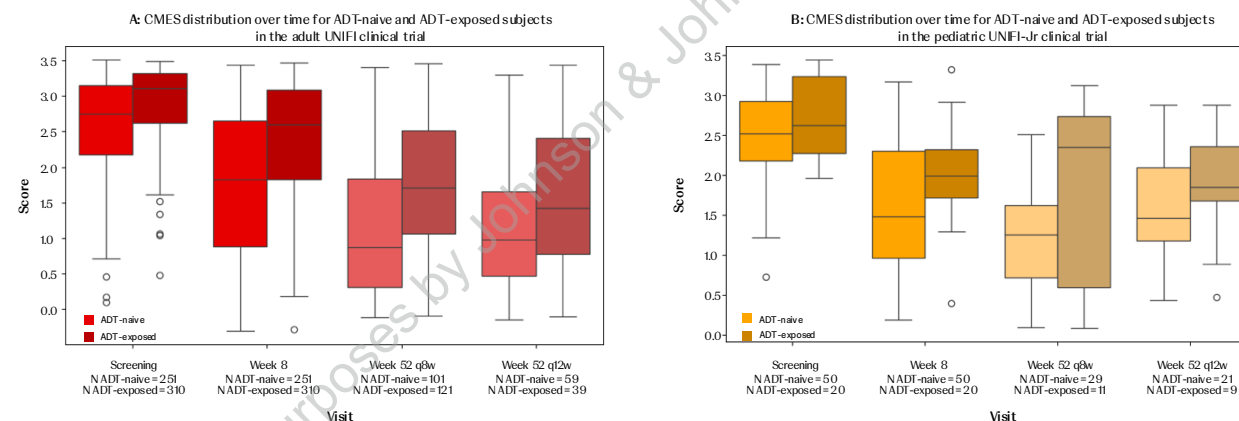


FIGURE 3. UCEIS_{ARGES} trends across trial visits (screening, week 8 and week 52 q8w/q12w) for UNIFI (A) and UNIFI-JR (B) stratified by previous exposure to advanced therapy (ADT-naïve: top vs ADT-exposed: bottom).

