

DDW 2026.
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Chicago, IL



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ARGES-UC

AI-BASED CONTINUOUS SCORING FOR DISEASE SEVERITY IN ULCERATIVE COLITIS
ENHANCES DETECTION OF TREATMENT EFFECTS AND REDUCES SAMPLE SIZE REQUIREMENTS IN CLINICAL TRIALS FOR
MEASURING ENDOSCOPIC TREATMENT DIFFERENCES

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Disclosure information

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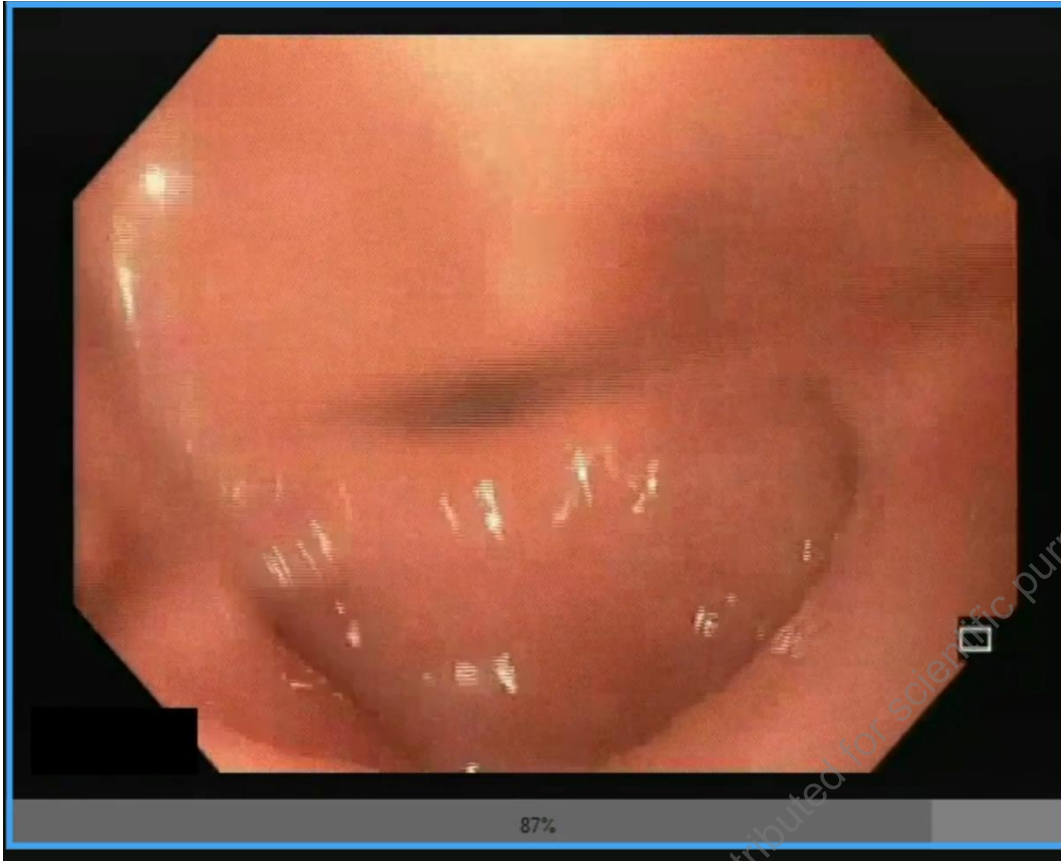
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The problem

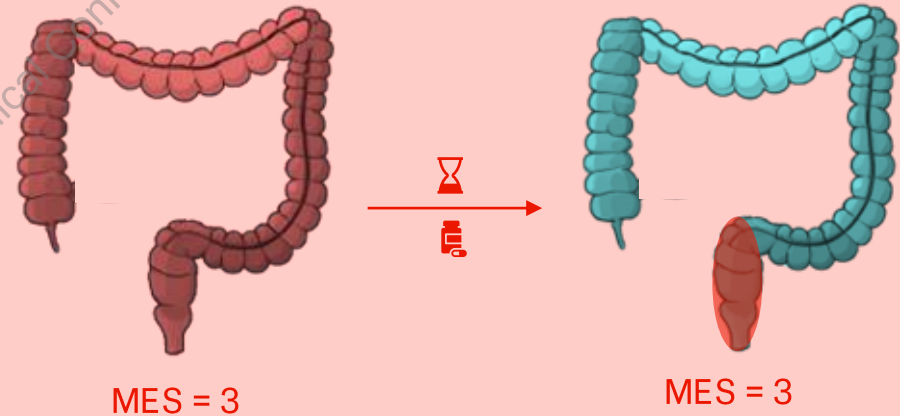
Need for more sensitive endoscopic disease measures



- Video from Ulcerative Colitis clinical trial.
- Total length: ~ 10 minutes (**5 Billion pixels**)
- MES: 3/3

J&J

Ulcerative Colitis Trial Endoscopic Endpoint



- ❖ Endpoint lacks sensitivity;
- ❖ Endpoint has high inter / intra-reader variability;
- ❖ Endpoint scoring is time-consuming;

The opportunity

Wealth of meticulously curated and annotated clinical trial data

Study	GALAXI CNT01959CRD3001 ¹		GRAVITI CNT01959CRD3004 ²		QUASAR CNT01959UCO3001 ³		ASTRO CNT01959UCO3004 ⁴		DUET-CD 78934804-CD2001 ⁵		DUET-UC 78934804-UCO2001 ⁶		FUZION-CD CNT01959CRD3005 ⁷		ANTHEM-UC ⁸ 77242113UCO2001 ¹	
	CD	CD	UC	UC	CD	UC	CD	UC	CD	UC	CD	UC	CD	UC		
Phase	III	III	III	III	Ib	Ib	Ib	Ib	III	III	III	III	Ib	Ib		
Drug	Guselkumab	Guselkumab	Guselkumab	Guselkumab	JNJ-78934804	JNJ-78934804	Guselkumab	Guselkumab	JNJ-78934804	JNJ-78934804	Guselkumab	Guselkumab	Oral IL-23 receptor antagonist	Oral IL-23 receptor antagonist		
Route	SC, IV	IV	SC, IV	IV	IV	IV	IV	IV	IV	IV	SC, IV	SC, IV	Oral	Oral		
Target	IL-23	IL-23	IL-23	IL-23	IL-17/Fc α	IL-17/Fc α	IL-23	IL-23	IL-17/Fc α	IL-17/Fc α	IL-23	IL-23	IL-23	IL-23		
Treatment period	48 weeks	24 weeks	56 weeks	24 weeks	48 weeks	48 weeks	48 weeks	48 weeks	48 weeks	48 weeks	48 weeks	48 weeks	48 weeks	28 weeks		
Placebo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
LTE (duration)	✓ (4 years)	✓ (72 weeks)	✓ (4 years)	✓ (72 weeks)	✓ (4 years)	✓ (4 years)	✓ (4 years)	✓ (4 years)	✓ (4 years)	✓ (4 years)	✓ (48 weeks)	✓ (48 weeks)	✓ (48 weeks)	✓ (48 weeks)		
Population	Mod-Sev CD	Mod-Sev CD	Mod-Sev UC	Mod-Sev UC	Mod-Sev CD	Mod-Sev UC	Mod-Sev CD	Mod-Sev UC	Mod-Sev CD	Mod-Sev UC	Fistulizing, perianal CD	Fistulizing, perianal CD	Mod-Sev UC	Mod-Sev UC		
Bio-naïve	✓	✓	✓	✓	None	None	None	None	None	None	✓	✓	None	None		
ADT-naïve	✓	✓	✓	✓	None	None	None	None	None	None	✓	✓	None	None		
ADT-IR (min %)	50%	35-65%	40-50%	40-50%	100%	100%	100%	100%	100%	100%	✓	✓	40-60%	40-60%		
No. of visits	13	13	13	13	14	14	14	14	14	14	13	13	13	8		
Trial specs	Enrollment complete	Enrollment complete	Enrollment complete	Enrollment complete	Actively recruiting	Actively recruiting	Actively recruiting	Actively recruiting	Actively recruiting	Actively recruiting	Actively recruiting	Actively recruiting	Actively recruiting	Actively recruiting		

Key to route icons



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Abbreviations

ADT = Advanced Therapy
ADT-IR = Advanced Therapy Inadequate Response
IBD = Inflammatory Bowel Disease
IL = Interleukin
IV = Intravenous

ITE = long-term Extension
Mod = Moderate
SC = Subcutaneous
Sev = Severe
Th1a = T-helper 1a

Footnote

¹The oral IL-23 receptor antagonist study in patients with Crohn's disease is now projected to begin in 2025. The study design is currently being revised, and will be informed by the results of the ANTHEM UC study. Further information will be shared once this has been finalized.

References

1. [ClinicalTrials.gov: NCT03460441](https://clinicaltrials.gov/ct2/show/study/NCT03460441). Accessed October 11, 2022.
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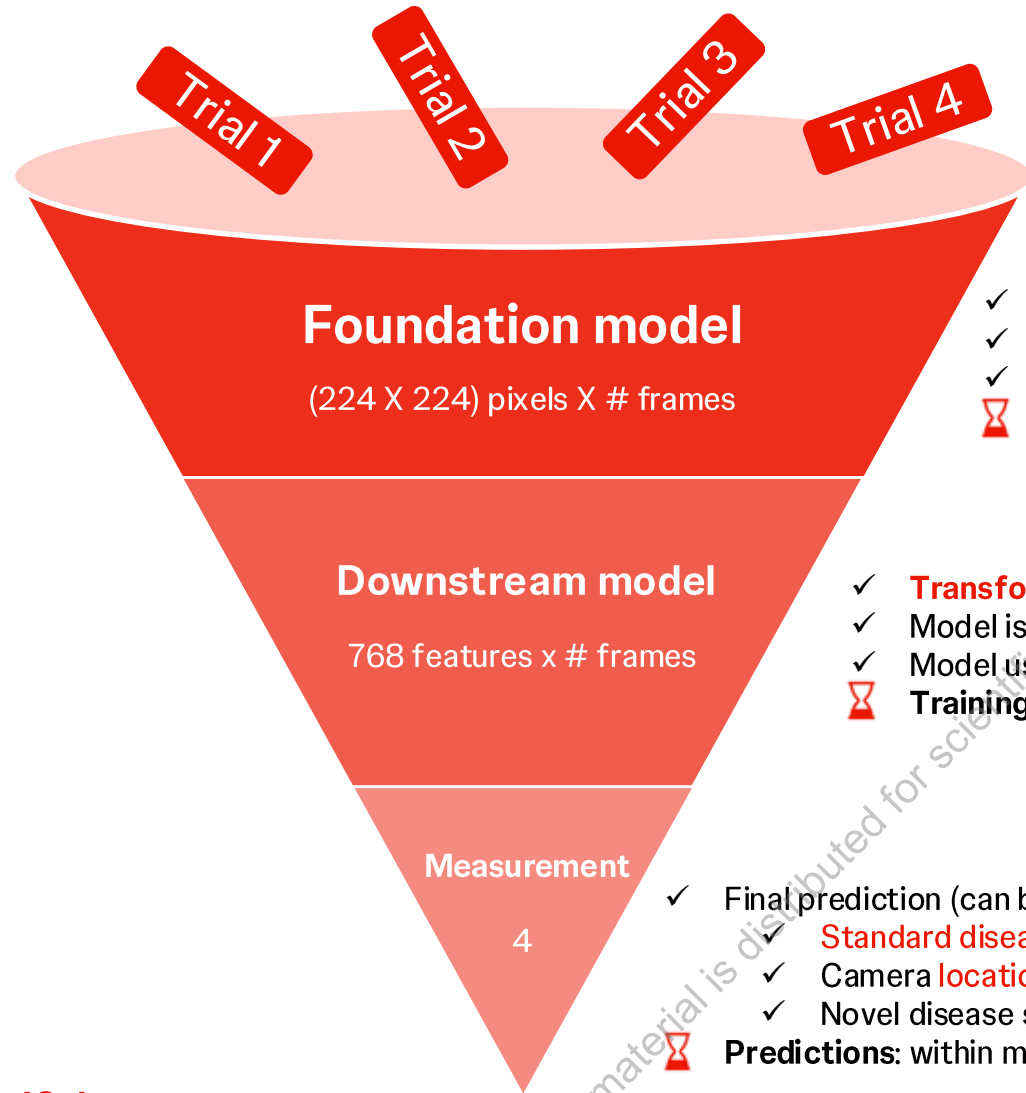
Study specifications may change. Date of preparation: February 2024.

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The Solution: ARGES

Video understanding models for colon characterization



- ✓ 4 IBD clinical trials (**60M frames, 3T pixels**);
- ✓ Annotations included MES, UCEIS, colon segment;

- ✓ **Vision encoder: 50K pixels to 768 features** per frame;
- ✓ Model is **unsupervised** (learns from *data*, not *annotations*);
- ✓ Model is **disease and task agnostic**;
- ⌚ **Training: days to weeks**;

- ✓ **Transformer encoder: 768 features to < 6 predictions**;
- ✓ Model is **supervised** (learns from *annotations*);
- ✓ Model uses spatio-temporal information for predictions;
- ⌚ **Training: hours to minutes**;

- ✓ Final prediction (can be a *class, integer value, or continuous value*);
- ✓ **Standard disease severity** (MES, UCEIS)
- ✓ Camera **location** (e.g. Ileum)
- ✓ Novel disease severity (**Continuous MES -- CMES**)
- ⌚ **Predictions: within minutes from video ingestion**;

*Arges (Greek: Ἄργης) was one of the three Hesiodic Cyclopes in Greek mythology. His name means "bright" and represents the brightness from lightning.

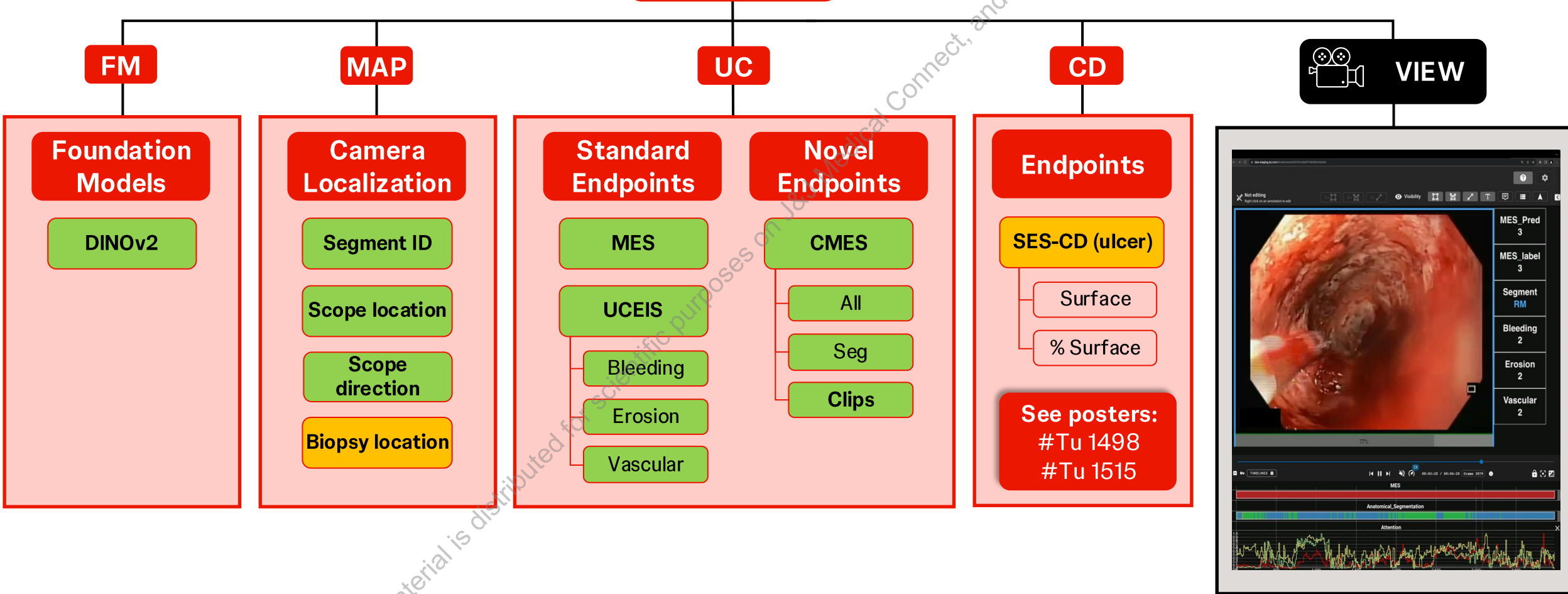
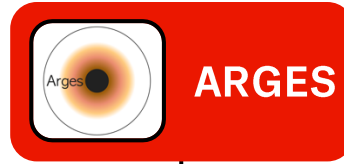
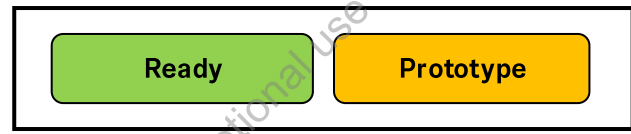


For details, see posters:
 #Tu 1498 : ARGES-Ulcer-CD
 #Tu 1515: ARGES-Ulcer-score
 May 5, 12:30 to 1.30pm

See also oral presentations:
 #88 #169 #Sp837

ARGES

A toolbox for detailed characterization of the colon health.

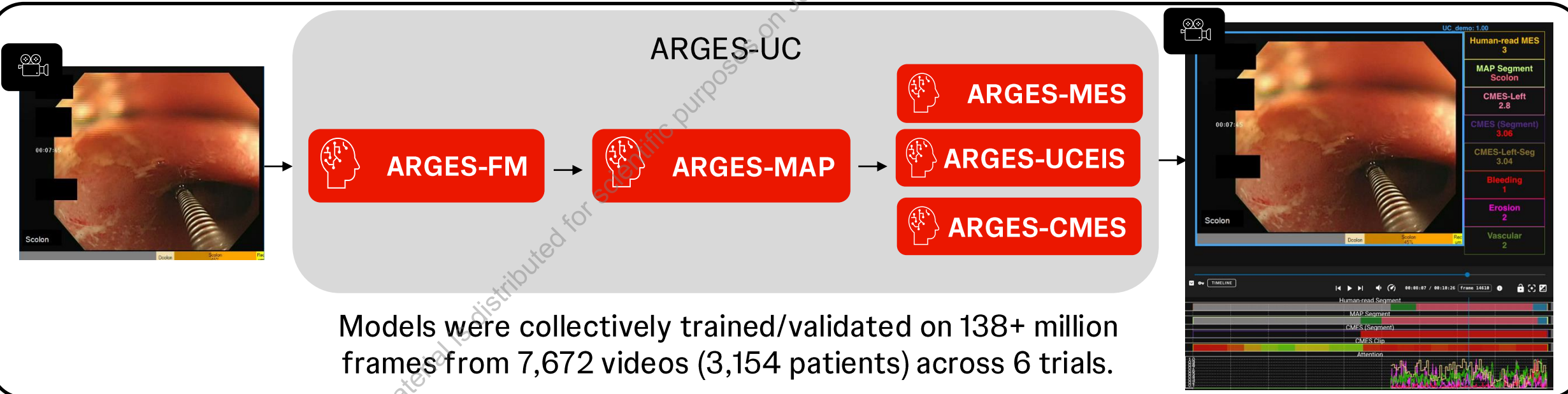


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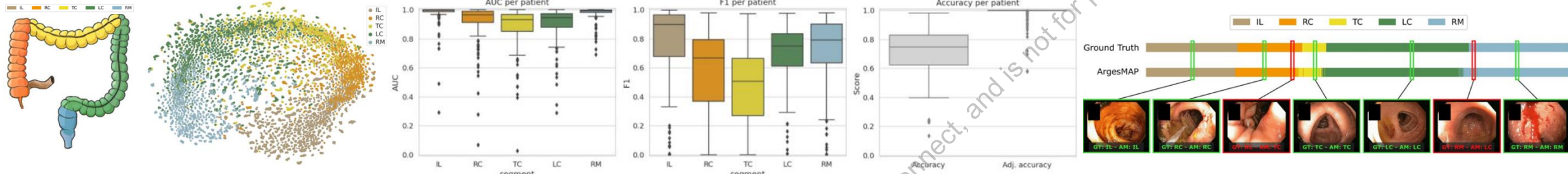
ARGES-UC

ARGES-UC integrates five components:

- **ARGES-FM**: a ViT-based foundation model pre-trained with self-supervised learning on UC and Crohn's disease clinical-trial endoscopy frames to create rich feature embeddings
- **ARGES-MAP**: camera-localization transformer identifying left-side distal colon and its **anatomic segments**
- **ARGES-MES** and **ARGES UCEIS**: transformer-based disease severity estimation modules that mimic **standard MES and UCEIS sores**
- **ARGES-CMES**: transformer-based continuous scoring estimating **mean between local and central reader scores**



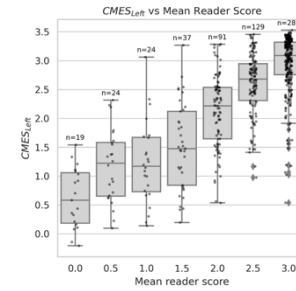
ARGES Modules are validated on different trials (UC + CD)



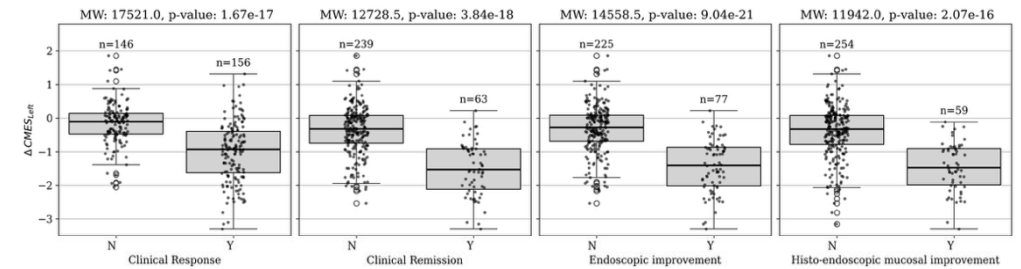
Target UCEIS score	Method	ARGES-UCEIS		
		Test Set (UNIFI)	Test Set (JAKUC)	Prospective data (QUASAR)
Bleeding	WSL[19] CNNs	0.434 ± 0.04	0.334 ± 0.04	0.444 ± 0.03
	Arges	0.624 ± 0.02*	0.525 ± 0.03*	0.384 ± 0.01
Erosion	WSL[19] CNNs	0.545 ± 0.01	0.488 ± 0.04	0.437 ± 0.02
	Arges	0.611 ± 0.02*	0.637 ± 0.01*	0.446 ± 0.02*
Vascular pattern	WSL[19] CNNs	0.693 ± 0.02	0.602 ± 0.04	0.704 ± 0.02
	Arges	0.731 ± 0.01*	0.635 ± 0.05*	0.723 ± 0.01*

Full colon or left-colon segments	ARGES-MES		
	QUASAR (locked model & prospective data)		
	AUC	Accuracy	F1
Full colon	0.810	0.687	0.693
Descending colon	0.774	0.531	0.544
Sigmoid colon	0.796	0.642	0.641
Rectum	0.764	0.640	0.633

➤ ARGES can recapitulate standard endpoints (MES / UCEIS).



Clinical measures	CMES _{left}	Human-read MES
Histological measures		
Total Geboes score (GS)	0.48	0.44
Robarts Histological Index (RHI)	0.48	0.43
Nancy Histological Index (NHI)	0.47	0.47
Disease severity measures		
Mayo score and its subscores:	0.59	0.73
Stool frequency	0.45	0.45
Rectal Bleeding	0.43	0.43
Physician global assessment	0.50	0.52
Biomarkers		
Fecal Calprotectin (FCP)	0.49	0.46



➤ Novel endpoint (CMES) is analytically and clinically meaningful.

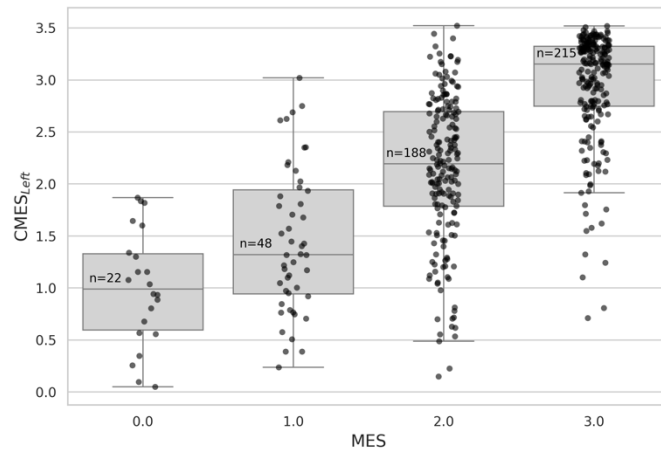
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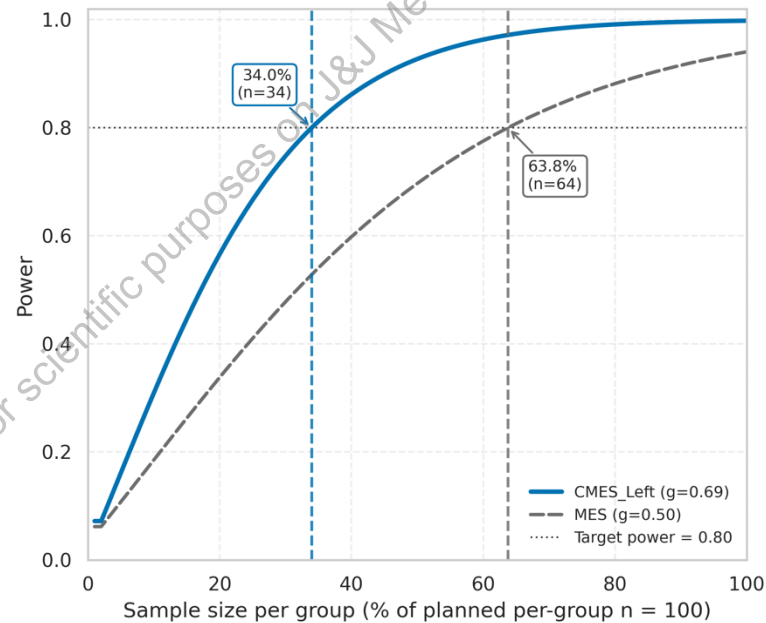
ARGES-UC validation on ANTHEM-UC

CMES increases sensitivity and reduces sample size required to measure endoscopic treatment differences

- Models locked prior to analysis
- Power analysis: Change from baseline → Week 12
- Icotrokinra 200 mg vs placebo



ICO 200 mg QD vs Placebo			
	Hedges' g	95% CI	p-value
CMES _{Left}	-0.69	-1.06, -0.32	<0.05
MES	-0.50	-0.86, -0.13	<0.05




Key results

- Up to ~47% fewer subjects needed to reach 80% power ($\alpha = 0.05$) compared with MES
- Larger effect sizes (Hedges' g) with CMES, indicating improved sensitivity

ARGES-VIEW

Screening



AI 1/60
HNS 0

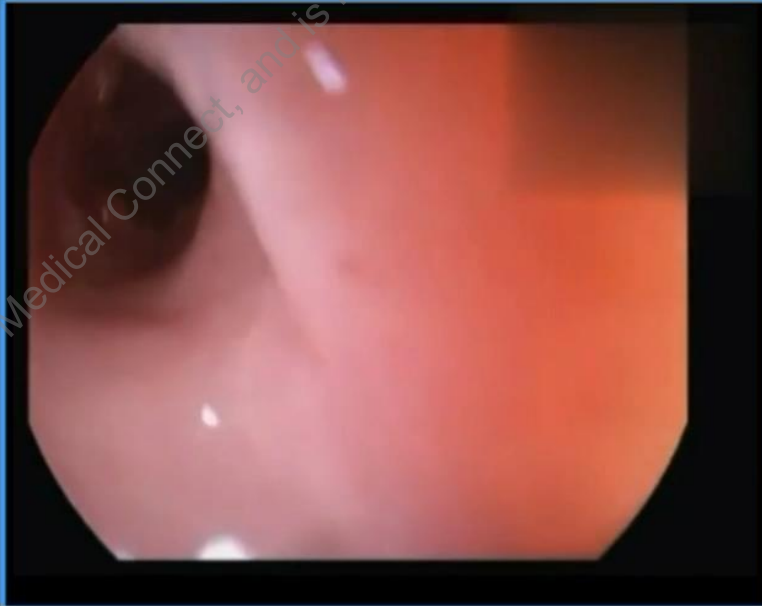
CMES Left	1.722
CMES Left Seg	1.667
CMES Segment	2.727
Current F/B	backward
Current L/R	left
Current Segment	sigmoid
Human-read MES	2

TIMELINE 00:01:16 / 00:03:06 frame 1921

1. Fwd/Bwd Direction
2. Left/Right Direction
3. Anatomical Segments

CMES Attention

Week 12



CMES Left	0.227
CMES Left Seg	0.569
CMES Segment	0.699
Current F/B	backward
Current L/R	left
Current Segment	sigmoid
Human-read MES	2

TIMELINE 00:02:54 / 00:06:33 frame 4359

1. Fwd/Bwd Direction
2. Left/Right Direction
3. Anatomical Segments

CMES Attention

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Take-aways

 **ARGES-UC:** a collection of AI models for spatial UC disease severity characterization from colonoscopies to estimate

- Camera location,
- MES,
- UCEIS,
- Novel measures (CMES)

 **CMES:** AI-generated Continuous MES (trained on average MES across 2 readers)

- Correlates to human ground truth data;
- Correlates to other clinical measures of disease;
- Is more sensitive at detecting treatment effects compared to standard MES.

References & Acknowledgements

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[6] Agbelese, Damola, *et al.* "MEGAN: Mixture of Experts for Robust Uncertainty Estimation in Endoscopy Videos." **MICCAI workshop (2025)**.