2nd Annual
GI ReConnect

June 10-11, 2022
HILTON SANTA FE BUFFALO THUNDER
SANTA FE, NEW MEXICO

Disclosure Statement

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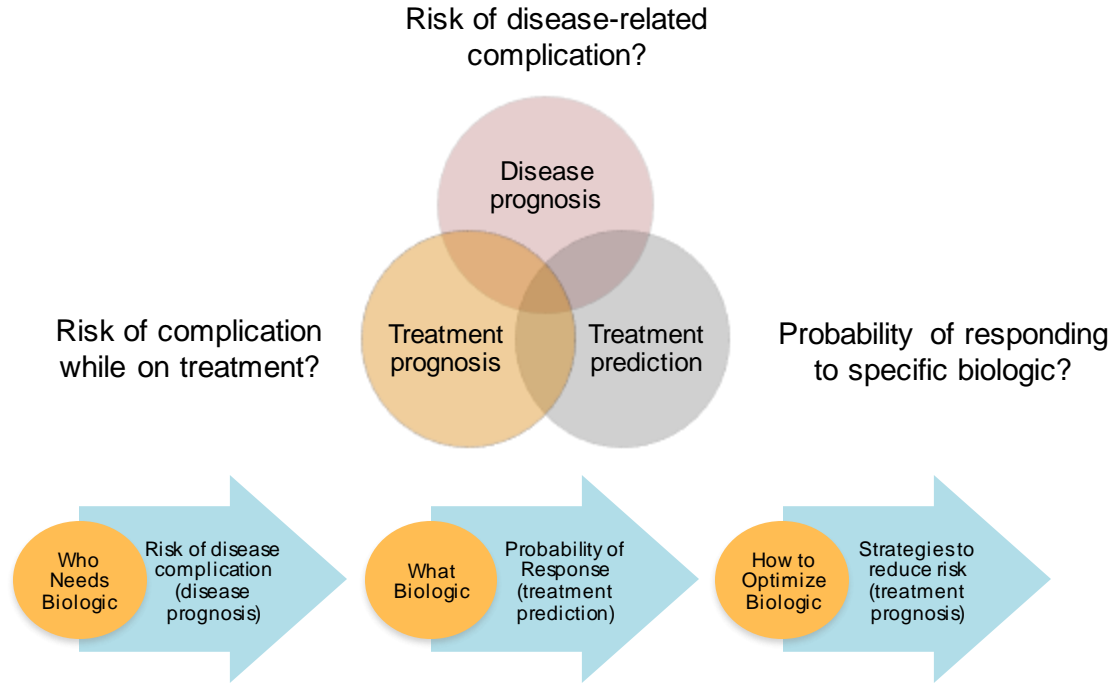
All additional planning committee members, the University of Cincinnati staff and the Gi Health Foundation staff have no relationships to disclose.

Disclosures

- Research Support: Takeda, Pfizer,

- Consulting: Johnson and Johnson, Gilead, Lily, BMS, Novartis, Pfizer, Takeda

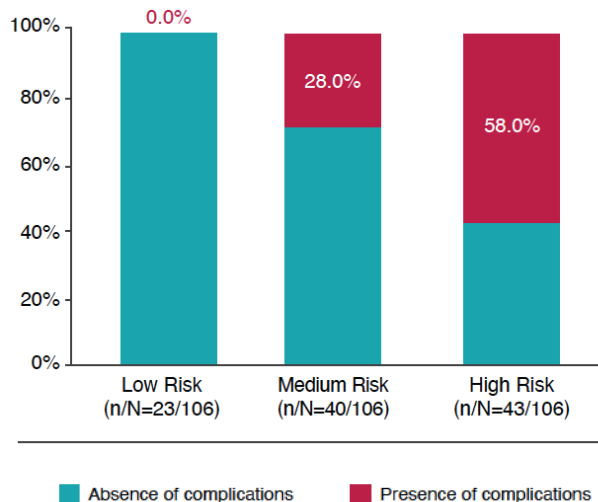- Stock options: DigbiHealth

- Licensing Royalties: PreciDiag

What Is the Ideal Decision Support Tool? Individualized Prognosis and Goals

CDPATH – Prediction of Disease Risk

CDPATH performance characteristics

- Absence of complications
- Presence of complications

Practice Implications: Point of care decision support tool available to identify Crohn's patients at greatest risk for disease complications within first 3 years of diagnosis, guiding use of biologic therapy

Siegel CA et al. ACG 2020. Available at: cdpath.com.

Blood Protein Panel for Anti-TNF in Early CD

RISK COHORT
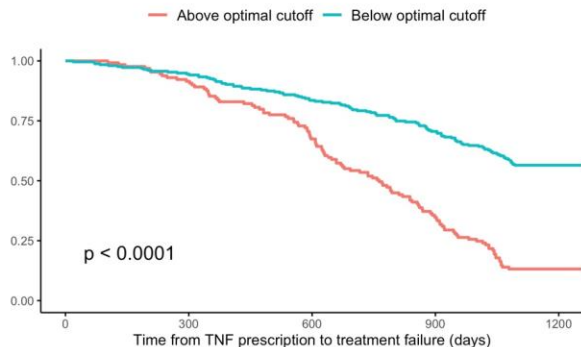
OSCCAR COHORT
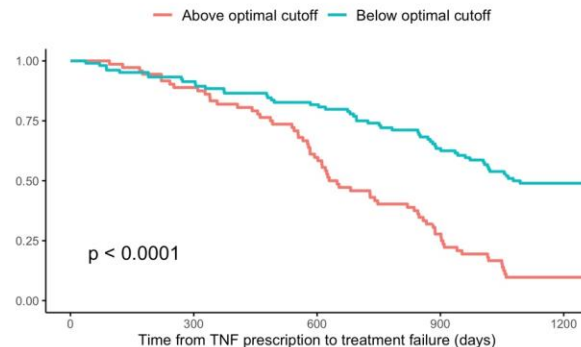
Practice Implications: Blood biomarker panel identifies CD patients likely to benefit from antiTNF therapy and could be paired with CD-PATH to guide combined disease risk and treatment response prediction in early CD

Ungaro RC et al. DDW 2022.

Crohn's Disease Vedolizumab Clinical Decision Support Tool

No prior bowel surgery	No prior TNFα-antagonist	No prior fistulizing disease	Baseline albumin	Baseline CRP
+ 2 points	+ 3 points	+ 2 points	+ 0.4 points per unit (g/L)	- 0.5 points if 3.0-10.0 mg/L - 3.0 points if > 10 mg/L

Probability of Response to VDZ
- Low (≤ 13 points)
- Intermediate (> 13 and ≤ 19 points)
- High (> 19 points)
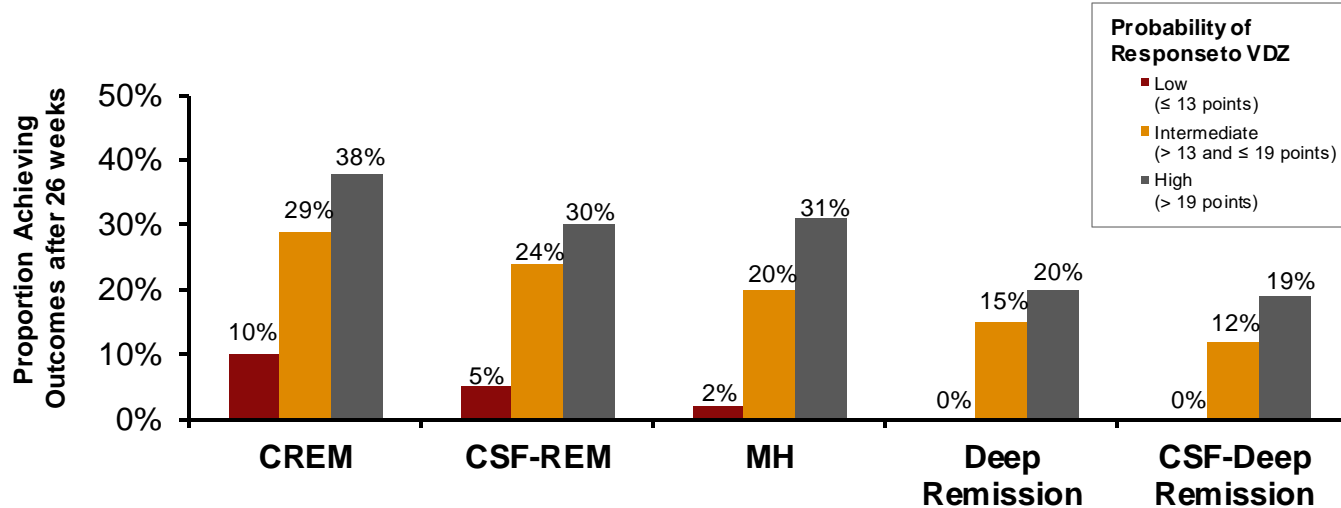
Practice Implications: Point of care decision support tool identifies patients not likely to responds to Vedolizumab

Dulai PS et al. *Gastroenterology.* 2018.

Peripheral Blood DNA Methylation Biomarkers Accurately Predict Clinical – And Endoscopic Response to Vedolizumab in a Real-Life Cohort of CD Patients

Study aims to identify epigenetic markers in CD patients and to develop and validate predictive algorithms using these markers

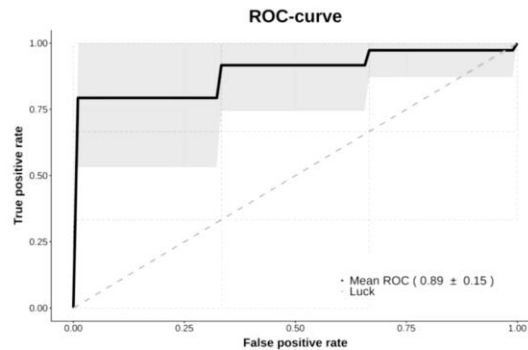Combination of **22 CpG-markers** predict **response** to vedolizumab with **high** (AUC 0.89) performance upon validation
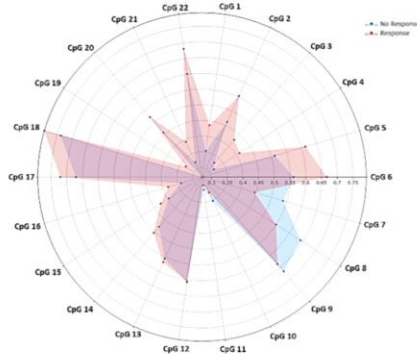
Deep response

A combination of **23 CpG-markers** predicted **deep response** with **high** (F1-score 0.8) performance upon validation

Multiple CpGs associate with **Ly6G5C gene:**
- Member of Ly-6 family
- Reported to be involved in T-cell activation[1]
- LY-6C shown to signal integrin activation needed for CD8+ T-cell homing to lymph nodes *in vivo*[2]
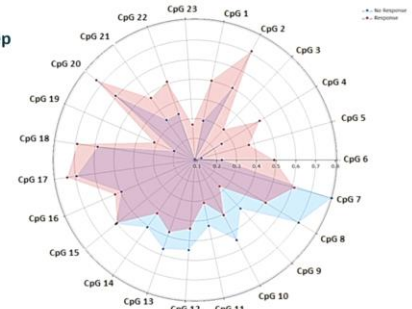
Practice Implications: Novel biomarker panels accurately predict response or deep remission to vedolizumab respectively and could be added to already available decision support tools.

Joustra V et al. DDW 2022.

Ustekinumab Crohn's Model

Variable Included in the CDST

- **No prior TNF-antagonist exposure (+ 2 points)**
- **No prior bowel surgery (+ 2 points)**
- **No active fistulizing disease at baseline (+ 1 point)**
- **No current or prior smoking history (+ 1 point)**
- **Baseline albumin:**

- 3 pts: ≤ 25 g/L
- 1 pts: > 25 to ≤ 32 g/L
  0 pts: > 32 to ≤ 39 g/L
+ 1 pts: > 39 to ≤ 43 g/L
+ 3 pts: > 43 g/L

Low probability responders (≤1 points)

Intermediate probability responders (2-4 points)

High probability responders (≥5 points)

$P<0.01$ for all comparisons of low vs. high and medium vs. high at all follow-up time points

$P<0.05$ for comparisons of low vs. medium groups from Week 6 to Week 16

Proportion of Patients (%)

High Probability Responders: 22.0, 34.0, 34.0, 57.0
Intermediate Probability Responders: 12.0, 19.0, 20.0, 34.0
Low Probability Responders: 9.0, 12.0, 12.0, 21.0

Maintenance Week: 3, 6, 8, 16

- Low Probability Responders
- Intermediate Probability Responders
- High Probability Responders

Practice Implications: Point of care decision support tool identifies patients likely to responds to Ustekinumab

Dulai PS et al. ACG 2019.

Biomarker Predictor of Ustekinumab

The cumulative persistence rate of ustekinumab :
MCP-1 low group vs MCP-1 high group
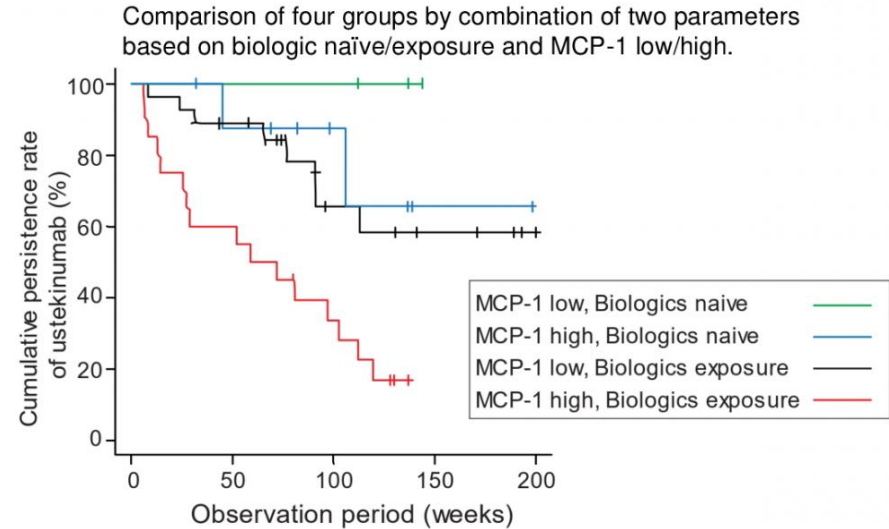
The cutoff value of MCP-1,
29.45 pg/mL, was obtained
from ROC

MCP-1 low ≦ 29.45pg/ml
MCP-1 high > 29.45pg/ml

Comparison of four groups by combination of two parameters
based on biologic naïve/exposure and MCP-1 low/high.

MCP-1 low, Biologics naive
MCP-1 high, Biologics naive
MCP-1 low, Biologics exposure
MCP-1 high, Biologics exposure

Practice Implications: Single serum biomarker could be added to already available decision support tools to optimize prediction of response to Ustekinumab in Crohn's disease.

Okuda H et al. DDW 2022.

CME Platform for Decision Support

US IBD Health Outcomes Consortium CME Initiatives

Educational Reach

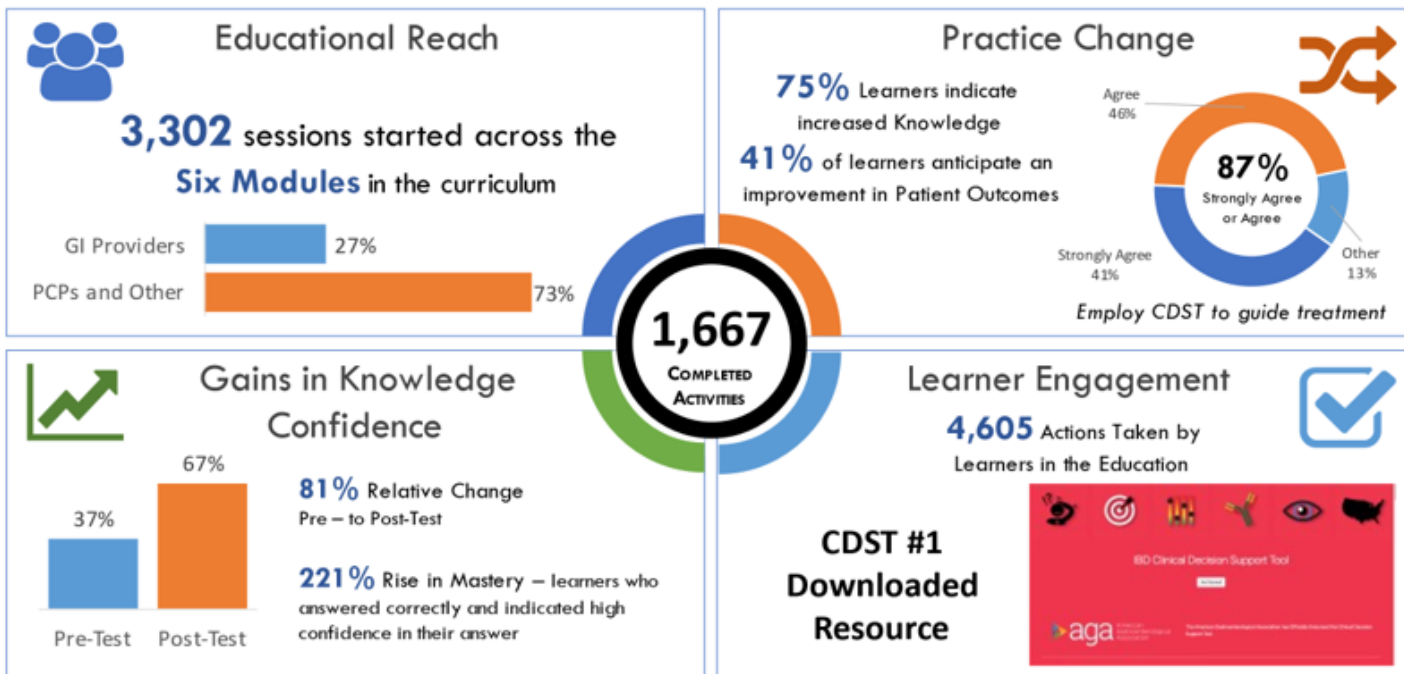**3,302** sessions started across the **Six Modules** in the curriculum

GI Providers — 27%
PCPs and Other — 73%

Practice Change

75% Learners indicate increased Knowledge

41% of learners anticipate an improvement in Patient Outcomes

87% Strongly Agree or Agree

Agree 46%
Strongly Agree 41%
Other 13%

Employ CDST to guide treatment

1,667 COMPLETED ACTIVITIES

Gains in Knowledge Confidence

37% Pre-Test
67% Post-Test

81% Relative Change Pre – to Post-Test

221% Rise in Mastery – learners who answered correctly and indicated high confidence in their answer

Learner Engagement

4,605 Actions Taken by Learners in the Education

CDST #1 Downloaded Resource

Practice Implications

Easy-to-use clinical decision support tools available to guide biologic choice

Web platform improves decision making

Emerging biomarker panels may further augment personalized care in IBD