A VALIDATED PERSONALIZED PROGNOSTIC TOOL

CDPATH™ is a validated prognostic tool that uses a blood test* to evaluate an adult Crohn's disease (CD) patient's potential risk for developing serious complications† within 3 years and can help facilitate shared decision-making.[1,2]

Healthcare professionals should not rely primarily on the risk predictions from CDPATH to make a clinical diagnosis or treatment decision regarding an individual patient.

CDPATH development and validation

① Defining the Model Through a Calibration Cohort in an Independent Clinical Study[1]

ANALYSIS → **RESULTS**

PATIENT COHORT
Adult Crohn's disease patients* (N=243)

INPUTS
- Patient characteristics
- Blood sample

ANALYSIS
Cox proportional univariate + multivariate analyses

STATISTICALLY SIGNIFICANT INDEPENDENT VARIABLES

Patient Characteristics:
- Date of diagnosis
- Disease location

Serologic:
- ASCA IgG
- ASCA IgA
- pANCA
- Anti-CBir1 IgG

Genetic:
- *NOD2* SNP13

DEPENDENT VARIABLE
Time from DIAGNOSIS to first serious COMPLICATION within 3 years†

*Patients were excluded if they had a complication at the time of diagnosis.

†Serious complications are defined as bowel strictures, internal penetrating disease, or non-perianal surgery (bowel resection or stricturoplasty).

② Establishing Clinical Relevance Through a Validation Cohort in an Independent Clinical Study[1,2]

VALIDATION COHORT
Adult Crohn's disease patients (N=109)

CLINICAL VALIDATION
Harrell's C-statistic=0.73; *P*<0.001

INPUTS[1]
- Date of diagnosis
- Disease location
- Serologic factors
- Genetic factor

③ Developing and Validating the Laboratory Developed Test(LDT)[2]

CALIBRATION COHORT
Adult Crohn's disease patients (N=106)

PERFORMANCE CHARACTERISTICS MODEL VALIDATION
Harrell's C-statistic=0.73; *P*<0.001

VALIDATION COHORT
Adult Crohn's disease patients (N=32)

CLINICAL VALIDATION
Harrell's C-statistic=0.70; *P*=0.015

INPUTS[1]
- Date of diagnosis
- Disease location
- Serologic factors
- Genetic factor

*The CDPATH risk assessment tool was developed and validated by Prometheus Laboratories Inc., a partner of Takeda. Test results are provided via Prometheus Laboratories Inc. to physicians.[2]

ASCA=anti-*Saccharomyces cerevisiae* antibodies; CBir1=anti-flagellin; IgA=immunoglobulin A; IgG=immunoglobulin G; *NOD2*=nucleotide-binding oligomerization domain 2; pANCA=perinuclear anti-neutrophil antibody; SNP=single nucleotide polymorphism.

1. Siegel CA, Horton H, Siegel LS, et al. *Aliment Pharmacol Ther.* 2016;43(2):262-271.
2. Data on file. Takeda Pharmaceuticals.

CDPATH™

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