A NON-INTERVENTIONAL CHART REVIEW STUDY OF INFLIXIMAB PRECISION-GUIDED DOSING TOOL'S CLINICAL EXPERIENCE PROGRAM: INTERIM ANALYSIS OF REAL-WORLD HEALTH OUTCOMES AND EXTRAPOLATED COST SAVINGS

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Objective

Evaluate 12-month clinical care outcomes and potential cost savings in a real-world setting before and after inflammatory bowel disease (IBD) patients underwent precision-guided dosing testing utilizing **PredictrPK® IFX.**

Background

Infliximab (IFX) is recognized as standard-of-treatment for IBD. IFX levels and clearance (CL) are influenced by various factors (e.g., anti-drug antibodies, metabolism, inflammation, body weight).

Precision Guiding Dosing utilizes Bayesian pharmacokinetic models, with patient-specific inputs, to predict optimal IFX dose and interval. CL is determined using nonlinear mixed effect models.

EMPOWER IFX: A 2022 clinical experience program (CEP) evaluated how community and academic gastroenterologists, treating patients with IBD, incorporated precision-guided dosing into their routine clinical practice.[1]

Benefits of Precision-guided dosing: Enhances IBD treatment outcomes by optimizing dosing and may reduce healthcare expenditures.

Methods

Study Design: Multisite, retrospective chart review of adult and pediatric random cases from the EMPOWER IFX CEP.
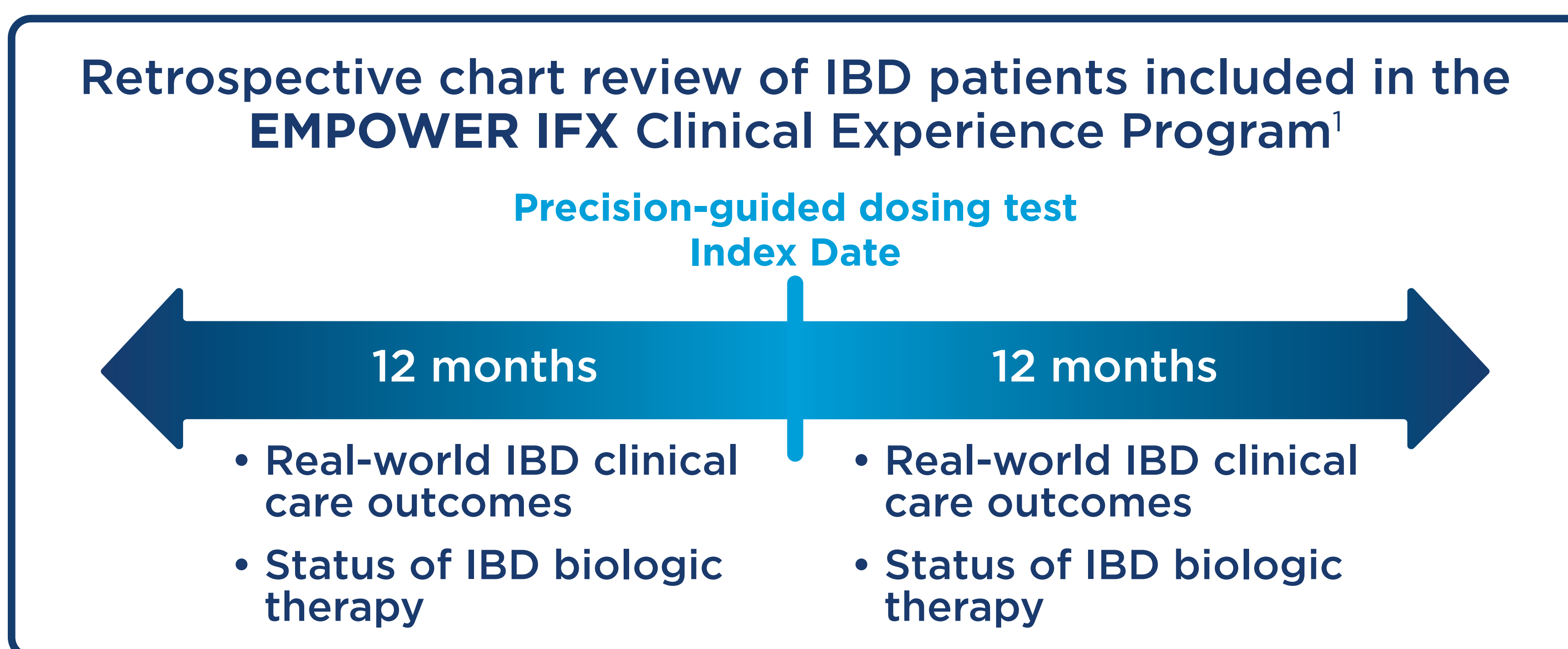
Case report forms included anonymized data on:
- IBD patient treatment disposition
- PredictrPK IFX results
- Real-world outcomes (RWO) before and after precision-guided dosing (index date).

Clinical Care Outcome Analysis: performed a permutation test, paired t-test, Cohen's d, and Wilcoxon signed-rank test.

Cost Impact Assessment extrapolated using 2020 US-Healthcare Cost and Utilization Project (HCUP) figures from **ahrq.gov.**

Results

Retrospective chart review of IBD patients included in the EMPOWER IFX Clinical Experience Program[1]

Precision-guided dosing test Index Date

← 12 months | 12 months →

- Real-world IBD clinical care outcomes
- Status of IBD biologic therapy

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Table 1. Demographics

Characteristics	Overall (n=44)
Male, n (%)	26 (59)
Age, Median years [IQR]	45 [21-56]
White race, n (%)	35 (80)
IBD type, n (%)	
Crohn's disease	30 (68)
Indeterminate colitis	1 (2)
Ulcerative colitis	13 (30)
Disease duration (years), Median [IQR]	10 [5-22]
Measured IFX at index date (µg/mL), Median [IQR]	15.5 [8.6-20.2]
Predicted IFX at index date (µg/mL), Median [IQR]	14 [7.5-22.0]

Table 2. Clinical Care Outcomes Analysis

IBD-related Category	Observed Difference (Comparison Before & After Test)	p-value
Hospital Duration	**0.318**	**0.009**
Office Visits	0.364	0.591
ER Visits	0.068	0.443
Surgeries	0.159	0.077
Colonoscopies	0.045	0.839
MRI	0.136	0.120
Albumin	0.664	0.411
PGA	0.310	0.099

Permutation test. Significant results in bold.

Table 3. Cost Impact Extrapolation Using US-HCUP

Diagnosis/ Procedures	Year 2020, Avg. Length of Stay (days)	Avg. Hospital Costs/Stay (US$ in 2020)	Avg. Hospital Costs/Day (US$ in 2020)	Inflation Adjusted (US$ in 2023)	Estimated Cost Savings (1.4 Days)	Estimated Cost Savings (7.75 Days)
Gastritis & duodenitis (DIG007)	3.8	$10,526	$2,770	$3,261	$4,565	$25,273
Intestinal obstruction & ileus (DIG012)	5.1	$13,378	$2,623	$3,088	$4,323	$23,932
Noninfectious gastroenteritis (DIG022)	3.7	$9,160	$2,476	$2,914	$4,080	$22,584

44 cases included across six CEP centers. (Table 1)

- **Clinical Care Outcomes Analysis:** Hospitalization duration before/after the PredictrPK IFX testing was significant (paired t-test and Wilcoxon signed-rank) with a mean difference of **1.4 days** (Cohen's d=0.435).
  - **Prior hospitalizations subgroup (n=8):** Mean difference was more pronounced; **7.75 days** (paired t-test) and the effect size (Cohen's d=1.574) was larger, indicating a substantial impact of the precision-guided dosing in this specific group.

- **Extrapolated cost impact** estimation using US-HCUP after adjusting for inflation was calculated to range from **$4,080 to $4,565** (*average length of stay/cost per stay for DIG007-gastritis & duodenitis 3.8/$10,526; DIG012-intestinal obstruction & ileus 5.1/$13,378; DIG022-noninfectious gastroenteritis 3.7/$9,160*).
  - **Prior hospitalizations subgroup (n=8):** estimated savings increased significantly, ranging from **$22,584 to $25,273.** (Table 3)

- **Other parameters:** Surgeries and physicians' global assessment score showed a significant trend. Clinic visits, IBD-related ER visits, imaging, and laboratory testing changes in these parameters before and after treatment showed a positive trend before and after precision-guided dosing but did not meet significance in this interim analysis. (Table 2)

Conclusions

Interim analysis indicates that **precision-guided dosing utilizing PredictrPK IFX significantly shortens hospital stays**, particularly for patients with a history of hospitalization.

The economic benefits of the PredictrPK® IFX test are attributed to its ability to accurately individualize infliximab dosing.

Reference

1. Abraham et al. *Am J Manag Care.* 2023;29:S227-S235.