

# Treatment-Free Interval (TFI): A Novel Approach to Assessing Real-World Treatment Effectiveness Among Patients with Irritable Bowel Syndrome with Diarrhea (IBS-D) Treated with Rifaximin or Eluxadoline

BE Lacy<sup>1</sup>, P Gagnon-Sanschagrin<sup>2</sup>, Z Heimanson<sup>3</sup>, R Bungay<sup>2</sup>, R Bellefleur<sup>2</sup>, A Guérin<sup>2</sup>, B Bumpass<sup>4</sup>, D Borroto<sup>4</sup>, G Joseph<sup>4,5</sup>, AA Dashputre<sup>4</sup>

<sup>1</sup> Mayo Clinic, Jacksonville, FL; <sup>2</sup> Analysis Group, Inc., Montréal, QC; <sup>3</sup> Salix Pharmaceuticals, Bridgewater Township, NJ; <sup>4</sup> Bausch Health, Bridgewater Township, NJ; <sup>5</sup> Now with BioNTech US Inc.

## BACKGROUND

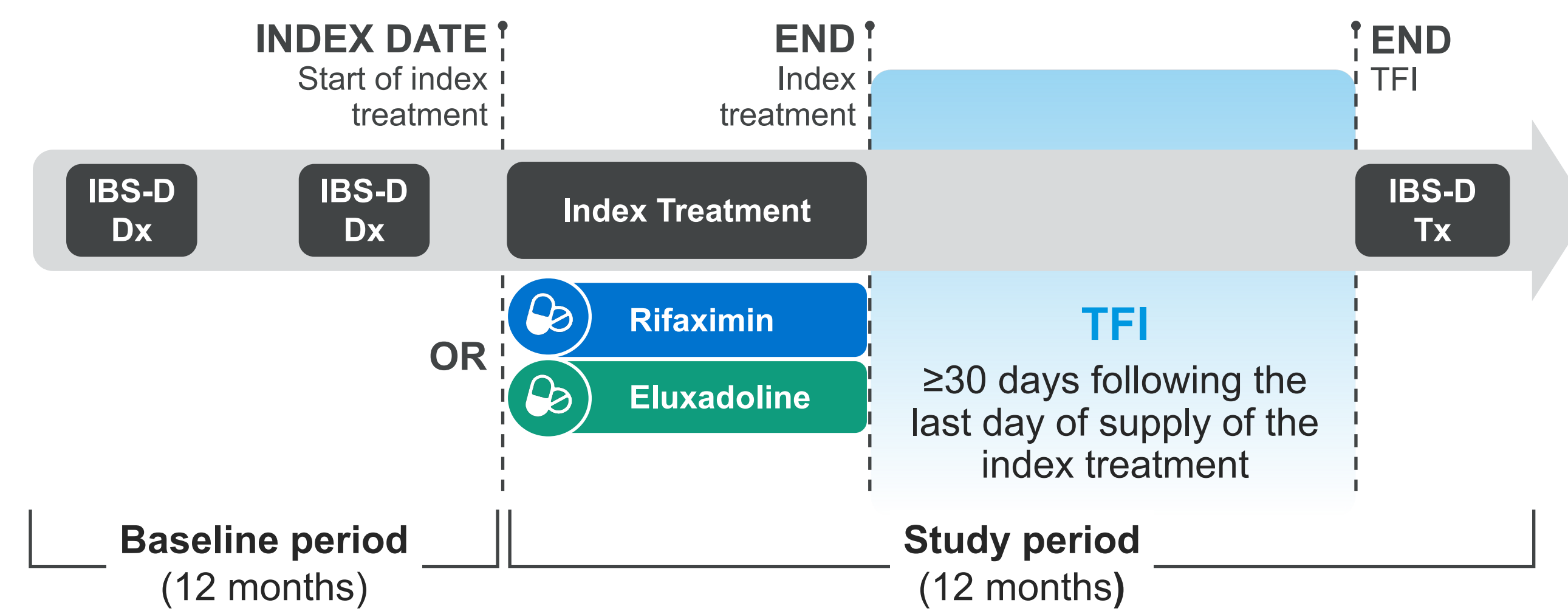
Irritable bowel syndrome (IBS) with diarrhea (IBS-D) is a chronic disorder characterized by bowel urgency, loose stools, bloating, and abdominal pain<sup>1,2</sup>. IBS is highly prevalent, affecting 7.4% of adults in the United States (US), of which 29.6% have IBS-D<sup>3</sup>. The variability in symptoms complicates clinical management of IBS-D, creating a need for real-world treatment comparisons.

## OBJECTIVE

To describe and compare treatment-free intervals (TFIs) and healthcare costs among commercially insured adults with IBS-D in the US treated with either **rifaximin** or **eluxadoline**.

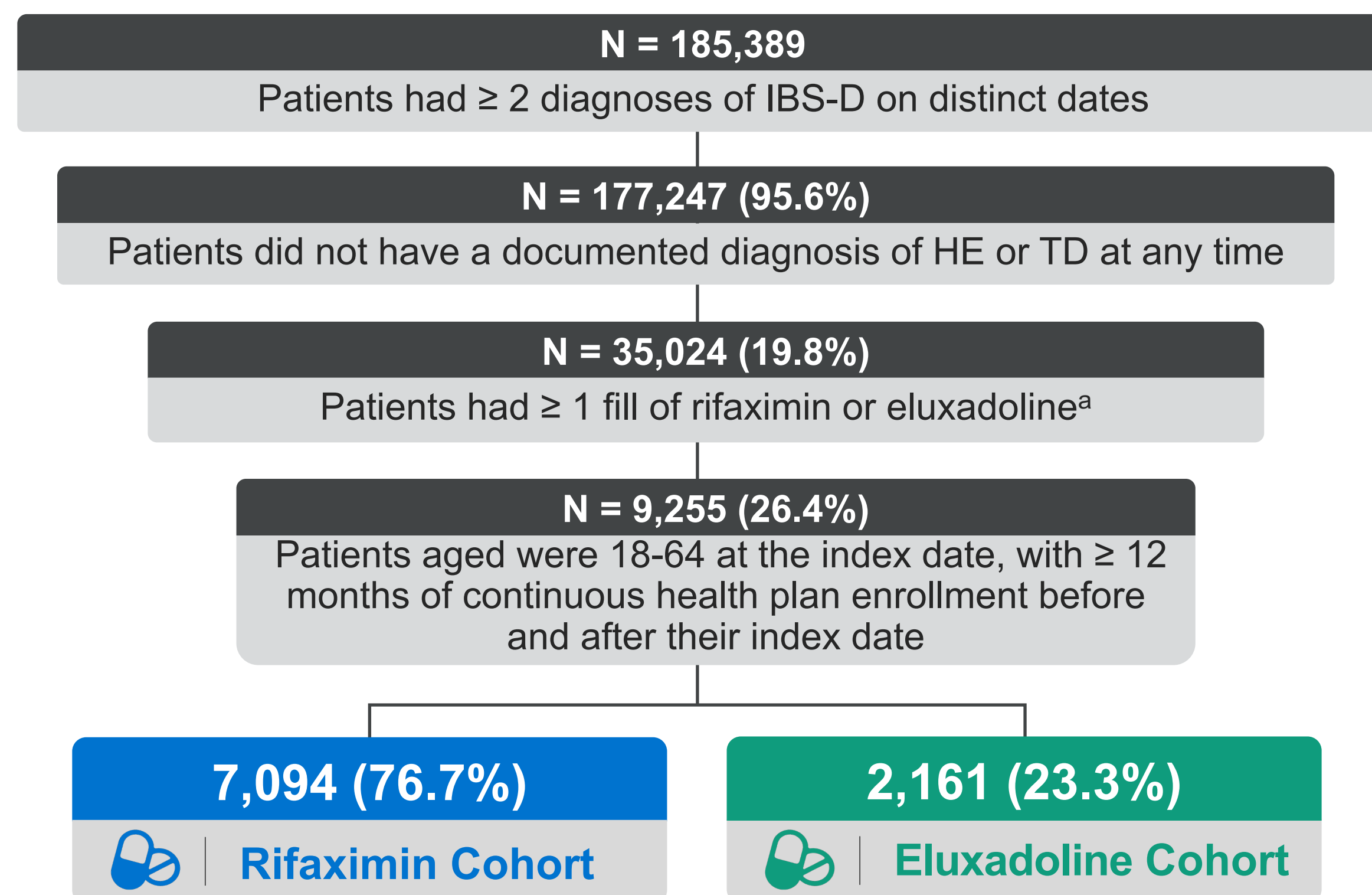
## METHODS

- Data source:** IQVIA PharMetrics® Plus Commercial Claims (2015-2021)
- Adult patients (18-64 years) with ≥2 diagnoses of IBS-D were classified into two mutually exclusive cohorts based on the first fill of **rifaximin** or **eluxadoline**.



- Entropy balancing** was used to balance baseline demographics, provider type, gastroenterology (GI)-related and mental health-related diagnoses, and IBS-D treatments between cohorts.
- Outcomes** included index treatment characteristics, TFI characteristics, and healthcare costs (payer's perspective; 2021 USD) during the study period.
  - Healthcare costs were compared between cohorts using weighted generalized linear regression models (GLM) with a Gamma distribution and log link.

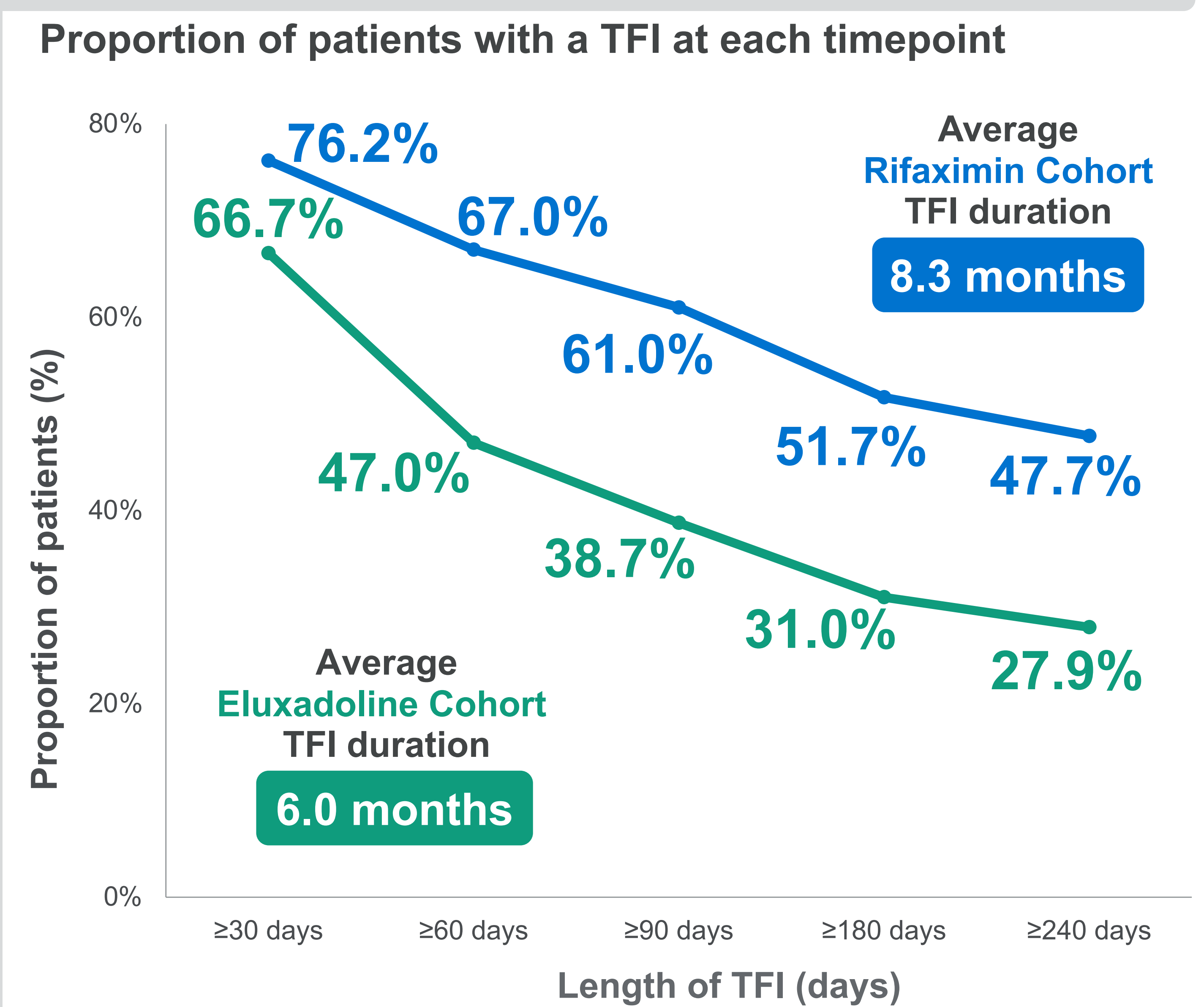
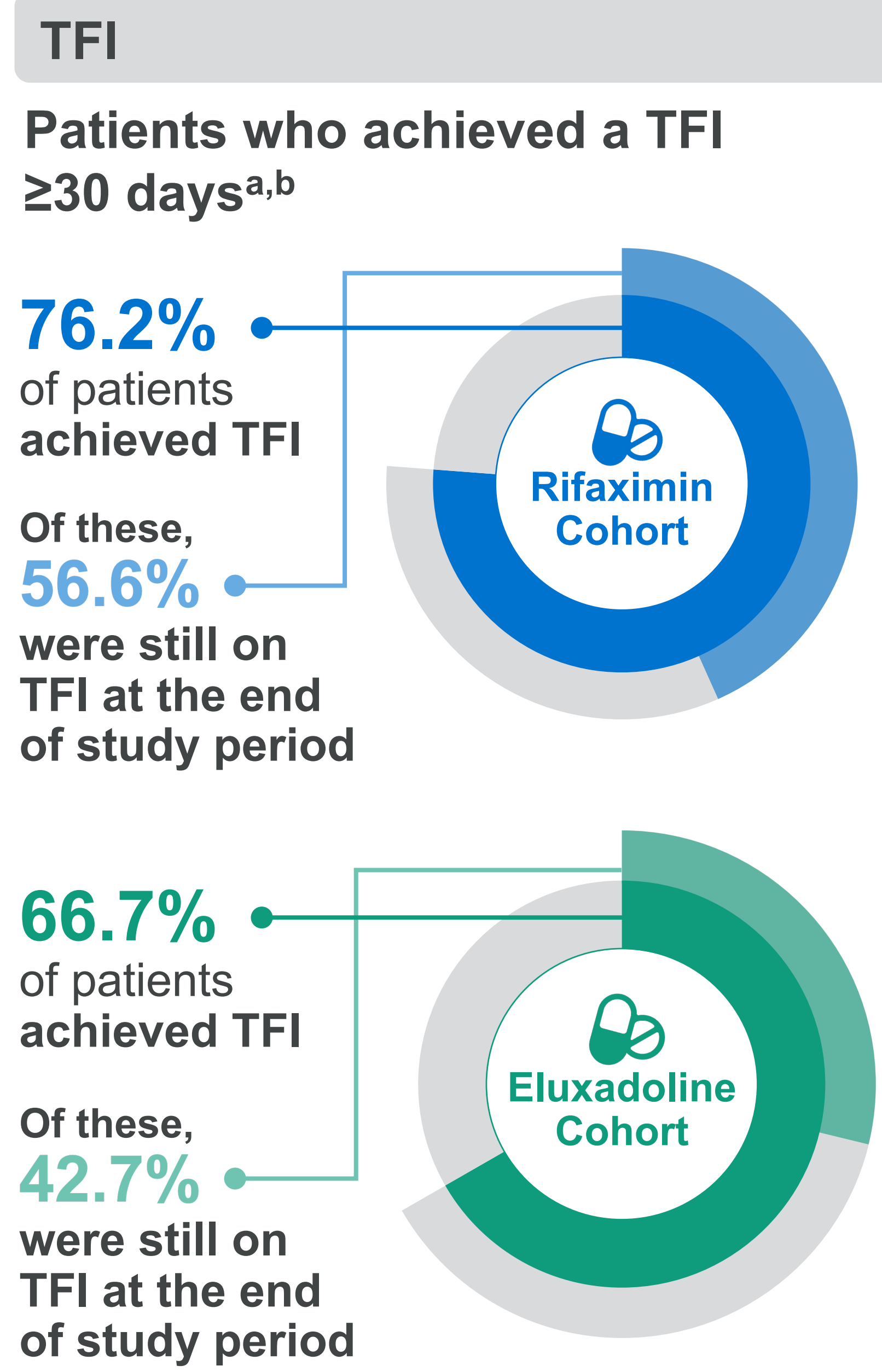
## Sample Selection



a. Patients with first fill for both treatments on the same day were excluded. HE: hepatic encephalopathy; TD: traveler's diarrhea

## RESULTS among balanced cohorts

Baseline characteristics	Rifaximin Cohort N = 7,904	Eluxadoline Cohort N = 2,161
Age (mean, years)	44.1	44.1
Female	72.4%	72.4%
Were seen by a GI specialist	54.4%	54.3%
Index treatment characteristics		
Number of fills (mean)	1.2	2.9
Number of days of supply (mean)	16.2	101.4

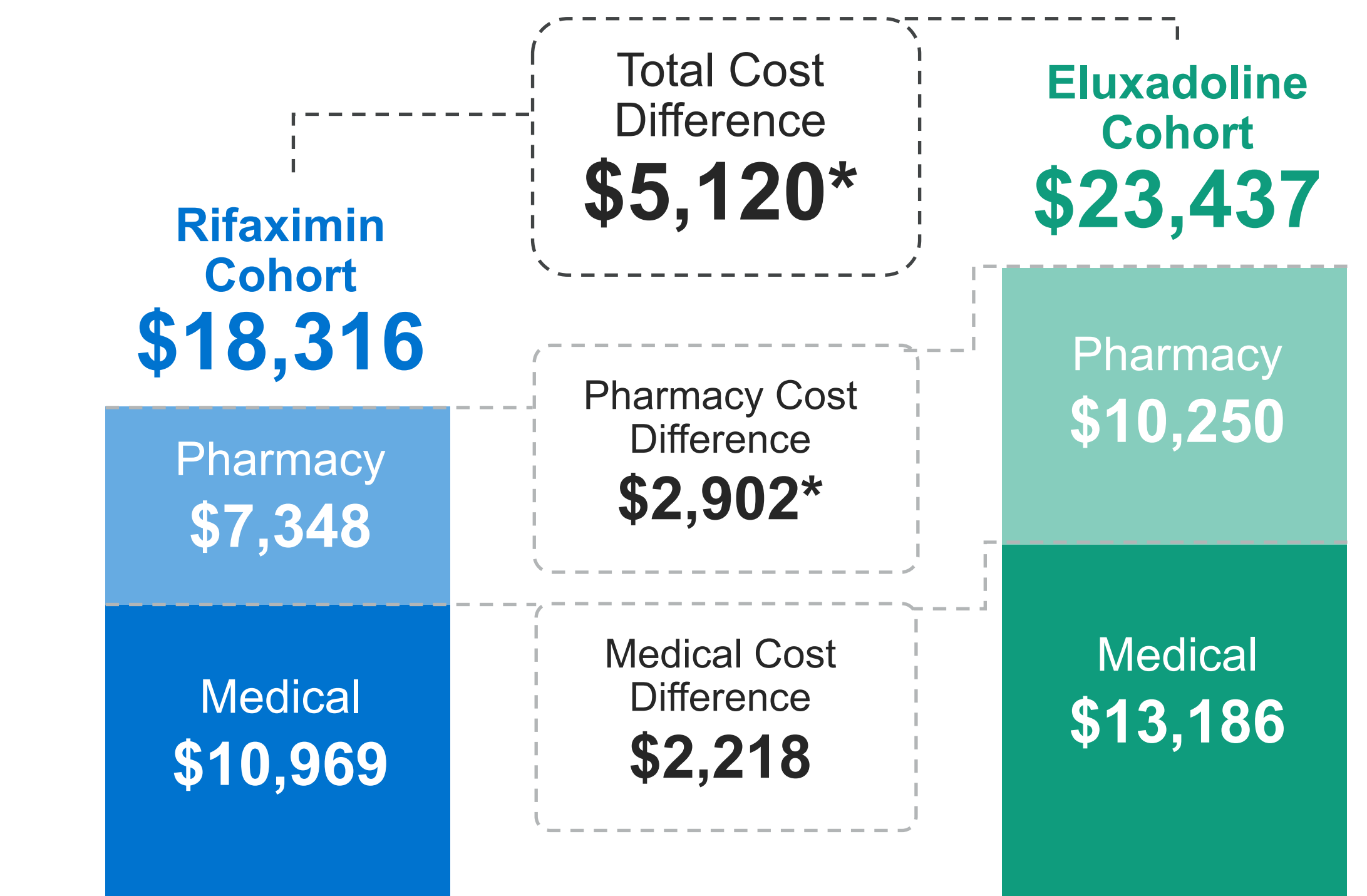


More patients treated with **rifaximin** versus **eluxadoline** achieved a TFI of ≥90 days (61.0% vs 38.7%) and ≥240 days (47.7% vs 27.9%).

a. In the Rifaximin Cohort, 43% of TFIs were broken by treatments in the study period: Rifaximin (19%), antispasmodics (13%), bile acid sequestrants (4%), tricyclic agents (4%), eluxadoline (2%), antiperistaltics (2%), alosetron (0%).  
b. In the Eluxadoline Cohort, 57% of TFIs were broken by treatments in the study period: Eluxadoline (39%), antispasmodics (10%), rifaximin (3%), antiperistaltics (2%), tricyclic agents (2%), bile acid sequestrants (2%), alosetron (1%).

## Healthcare Costs 2021 USD

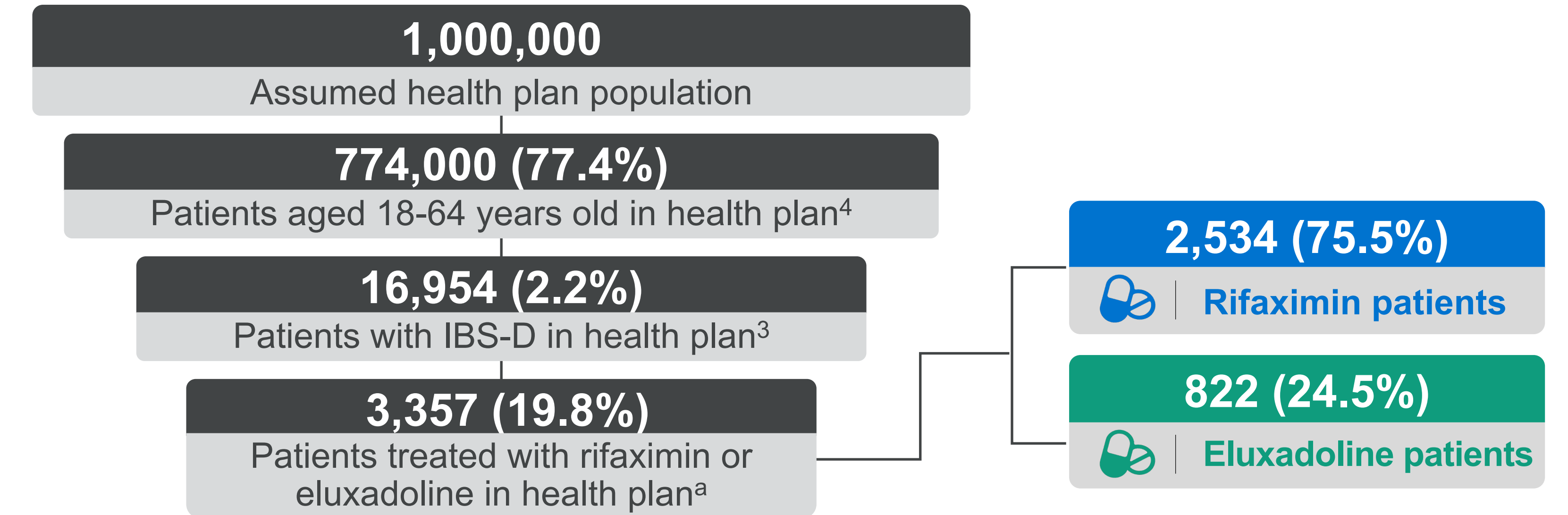
**Annual healthcare cost differences per-patient-per-year (mean)**



\*Indicates significance at P<0.01

Patients in the **Rifaximin Cohort** had \$5,120 lower healthcare costs than the **Eluxadoline Cohort**.

**Simulated impact of initiating rifaximin instead of eluxadoline in a typical Commercial health plan**



If payers and physicians ensured that **50%** of treated patients with IBS-D were initiated on **rifaximin** instead of **eluxadoline**:



a. Proportions were applied based on analyses in IQVIA claims data.  
b. Calculated as 411 patients multiplied by the \$5,120 cost difference.

## CONCLUSIONS

Initiation of **rifaximin** in patients with IBS-D led to shorter treatment duration and extended TFIs.

Over one year, nearly half of **rifaximin** patients achieved a TFI of ≥240 days, compared to less than a third of **eluxadoline** patients.

Patients with IBS-D who were treated with **rifaximin** had lower total healthcare costs compared to those who were treated with **eluxadoline**.

## LIMITATIONS

- This claim-based study is subject to common limitations including billing inaccuracies and missing data.
- Results pertain to a commercially insured population and may not be representative of the US adults with public or no health insurance.

## REFERENCES

- Moshiree B, Heidelbaugh JJ, Sayuk GS. A Narrative Review of Irritable Bowel Syndrome with Diarrhea: A Primer for Primary Care Providers. *Adv Ther.* 2022;39(9):4003-20.
- Lacy BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *Am J Gastroenterol.* 2021;116(1):17-44.
- Almario et al., 2021. Prevalence and burden of illness of Rome IV irritable bowel syndrome in the U.S. *Gastroenterology.* 2021, 160(6):S-610; Available at [https://www.gastrojournal.org/article/S0016-5085\(21\)02161-2/pdf](https://www.gastrojournal.org/article/S0016-5085(21)02161-2/pdf); Accessed on 15 Mar, 2023.
- U.S. Census Bureau, 2021 American Community Survey (ACS), Table H105\_ACS. Health Insurance Coverage Status and Type of Coverage by State and Age for All Persons 2021; Available at <https://www.census.gov/data/tables/time-series/demo/health-insurance/acs-hi.html>; Accessed on 15 Mar, 2023. The proportion is calculated based on the total number of individuals that are only covered by private health insurance. Individuals that are covered by both private health insurance and public health insurance (i.e., Medicare and/or Medicaid) are excluded.

## SPONSORSHIP

Design, study conduct, and financial support for the study were provided by Bausch Health Companies, Inc.; Bausch Health Companies, Inc. participated in the interpretation of data and production of the abstract; all authors contributed to the development of the publication and maintained control over the final content.

## DISCLOSURE

BEL has received consulting fees from Bausch Health Companies, Inc. PGS, RB, RB, and AG are employees of Analysis Group, Inc., a consulting company that has provided paid consulting services to Bausch Health Companies, Inc., which funded the development and conduct of this study. AAD and BB are employees of Bausch Health Companies, Inc. ZH is an employee of Salix Pharmaceuticals. GJ was an employee of Bausch Health US LLC at the time the study was conducted and is currently employed with BioNTech US Inc. DB is a postdoctoral fellow with Rutgers Pharmaceutical Industry Fellowship Program.