

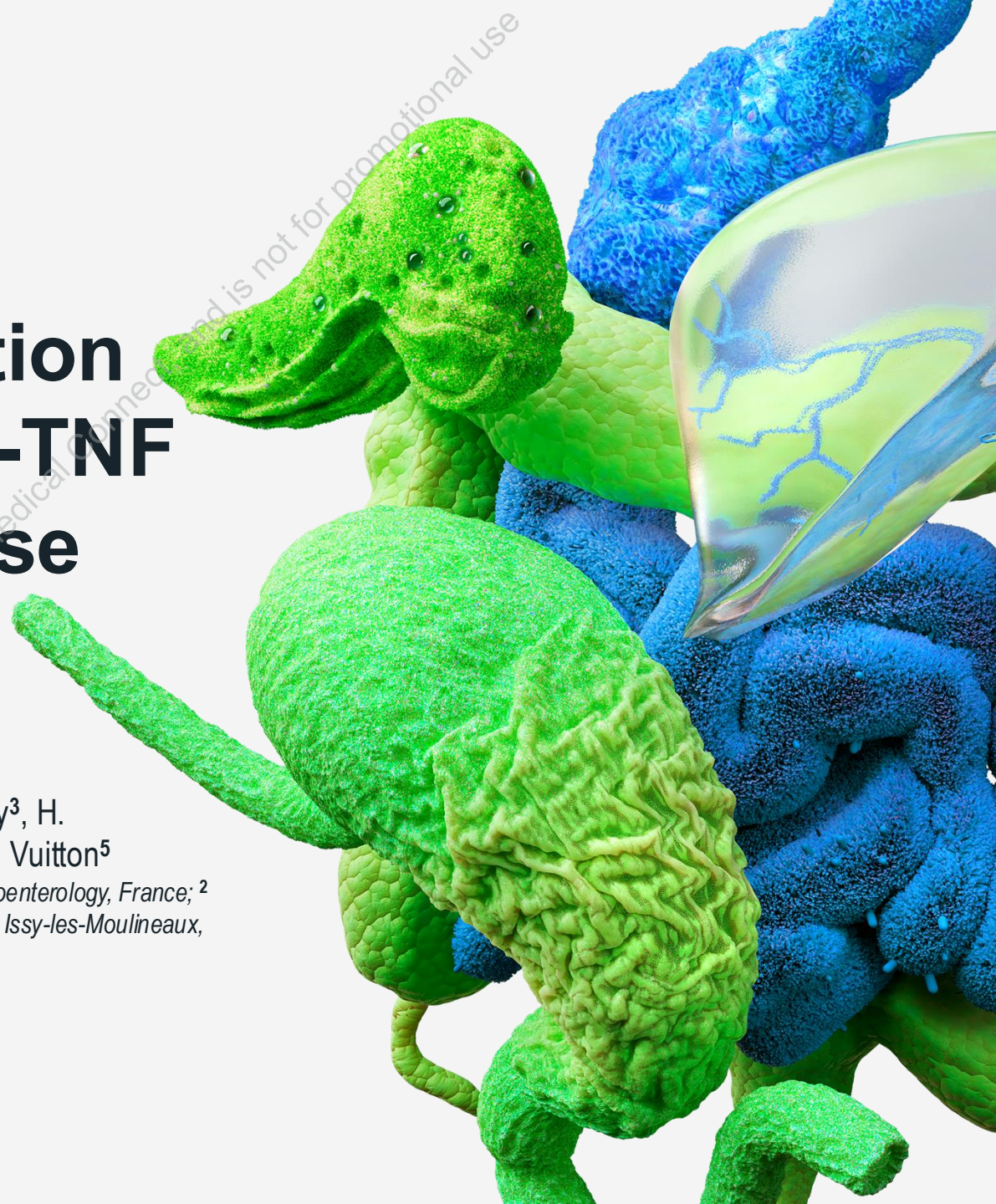
# Therapeutic and hospitalisation outcomes after first line anti-TNF in inflammatory bowel disease

EPITHERA study

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## Disclosure of Conflicts of Interest

I, Julien Kirchgerner, herewith declare the following paid or unpaid consultancies, business interests, or sources of honoraria payments for the past three years, and anything else which could potentially be viewed as a conflict of interest from Johnson&Johnson, Takeda, Lilly, Abbvie, Pfizer, Tillots, Amgen, Celltrion, Roche, Gilead, Galapagos.

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# Background & Aim of the study

With many advanced therapies currently available, treatment choice is crucial for optimizing the therapeutic management of patients with Crohn's Disease (CD) and Ulcerative Colitis (UC).

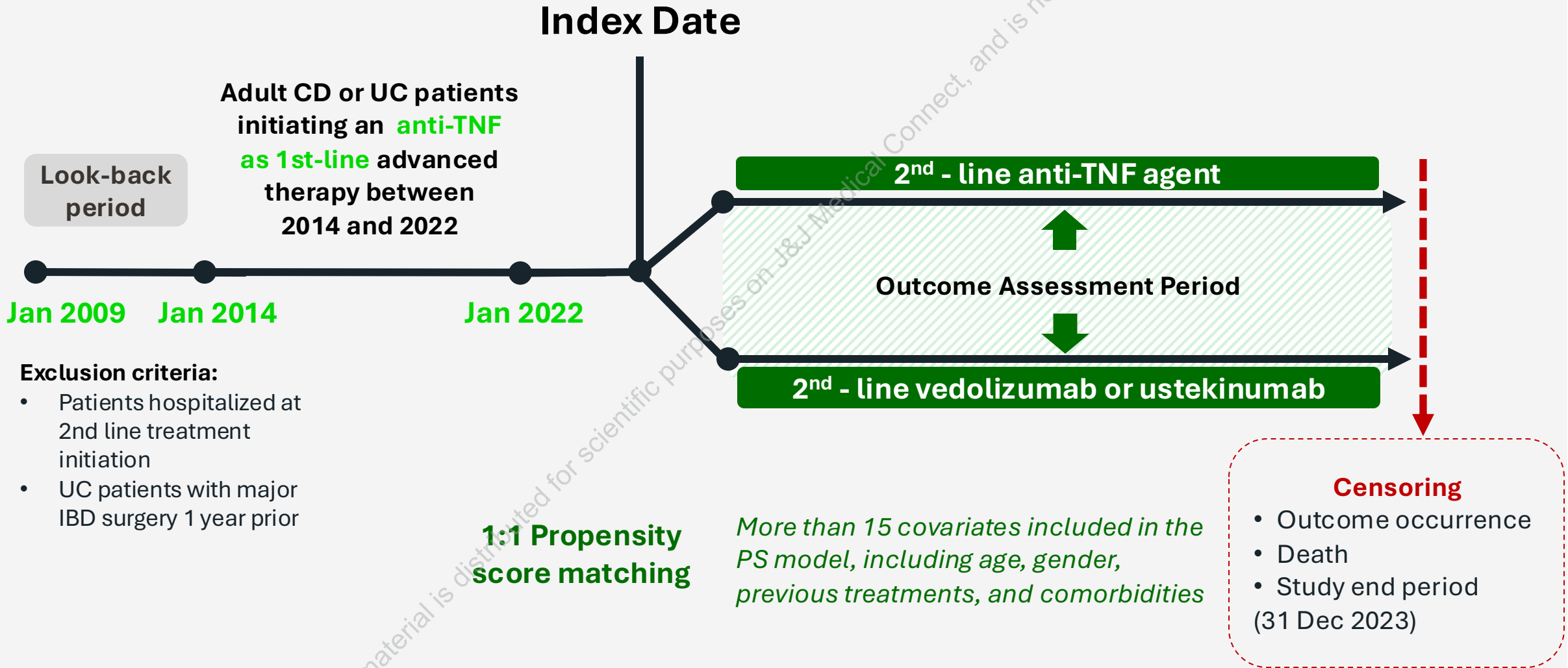


To assess the **impact of the 2<sup>nd</sup> line advanced therapy** following 1<sup>st</sup> line anti-TNF in CD and UC



**Study based on the French administrative healthcare database 2009-2023**  
(Entire French population)

# Study design



# Outcome – Occurrence of events

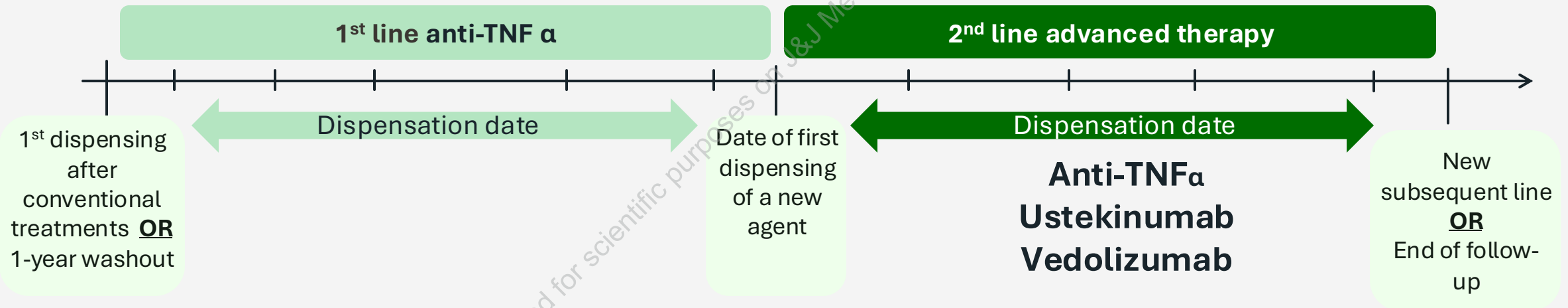
Within 1 year

- Treatment discontinuation
    - Short-term
    - Long-term (within 5 years)
  - Corticosteroid introduction
- IBD-related hospitalisation
  - All-cause hospitalisation
  - Major IBD-related surgery\*
  - Hospitalisations for serious infections

*\*colectomy, intestinal resection*

# Method for identifying treatment sequences of advanced therapies

Definition of treatment sequences: a new line was initiated when a new treatment was dispensed



Theoretical coverage periods were estimated based on dispensation data and for each dispensing were gathered with a grace period (3 months for all treatments)

# Characteristics of CD patients after PS matching

At 2<sup>nd</sup> line initiation date

## 2<sup>nd</sup> line vedolizumab

N=1,963

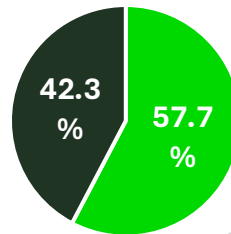
### Mean (SD) age

40.3 (15.5) years old

### Median (Q1-Q3) disease duration

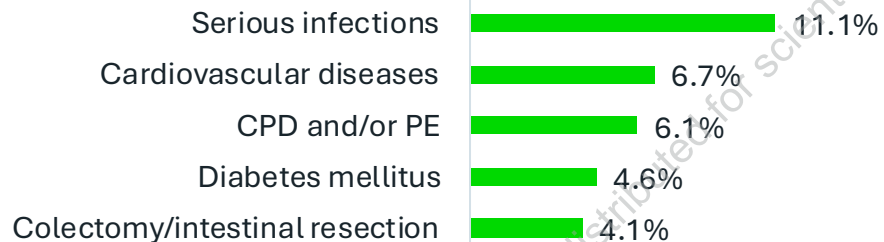
6.5 (2.8-9.7) years

### Gender



■ Female ■ Male

### Medical history and comorbidities



## 2<sup>nd</sup> line anti-TNF $\alpha$

N=1,963

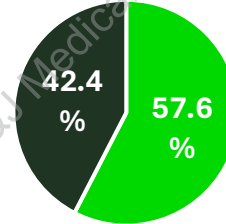
### Mean (SD) age

40.1 (14.9) years old

### Median (Q1-Q3) disease duration

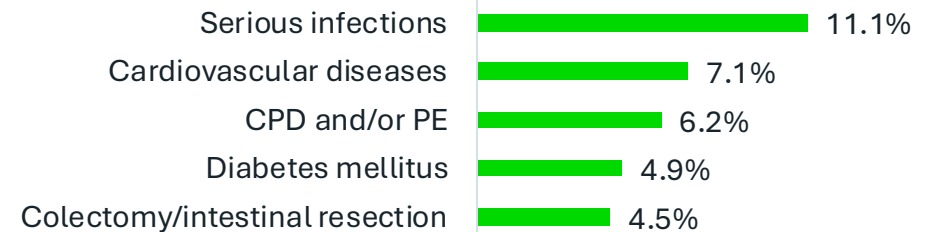
6.5 (2.8-9.6) years

### Gender



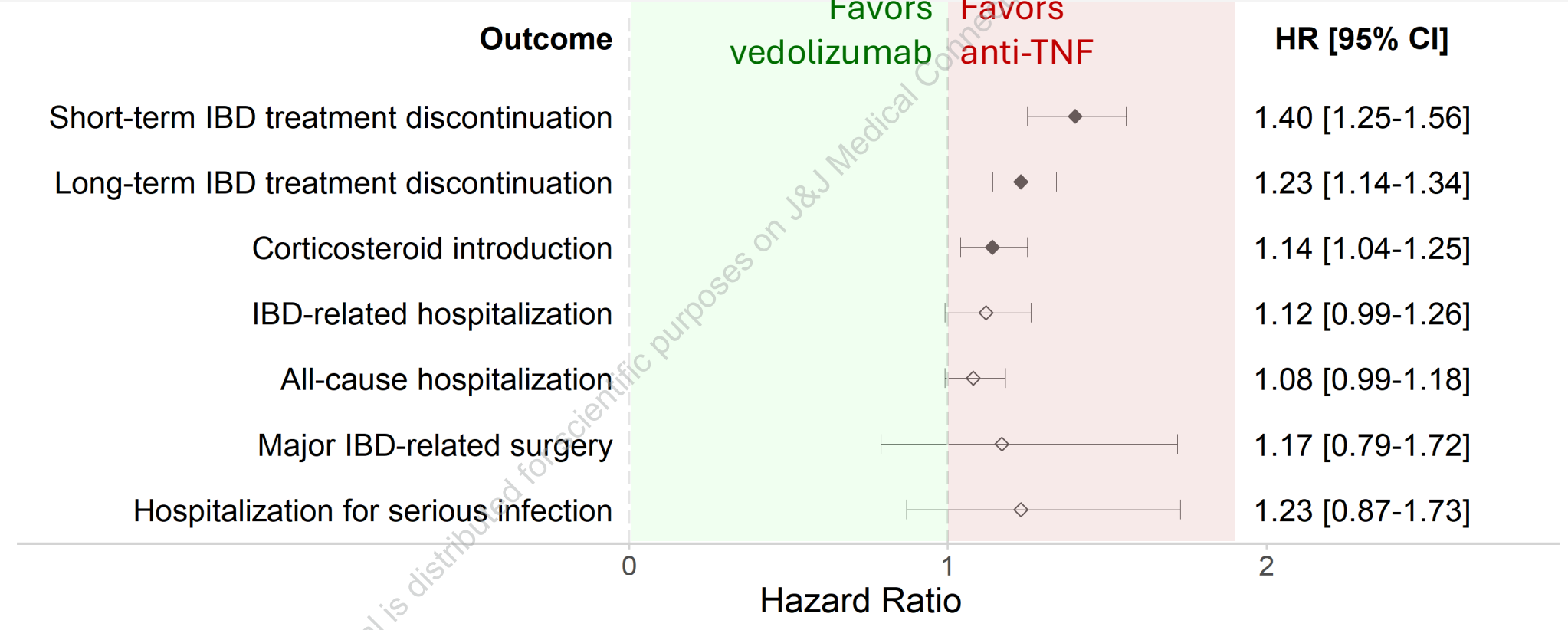
■ Female ■ Male

### Medical history and comorbidities



CPD: Chronic Pulmonary Disease, PE: Pulmonary embolism

# Risk of event occurrence with vedolizumab versus anti-TNF - CD patients



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# Characteristics of CD patients after PS matching

At 2<sup>nd</sup> line initiation date

## 2<sup>nd</sup> line ustekinumab

N=4,532

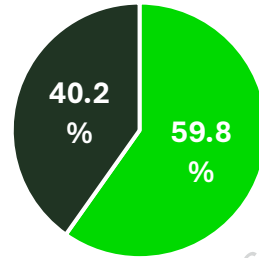
### Mean (SD) age

38.3 (14.6) years old

### Median (Q1-Q3) disease duration

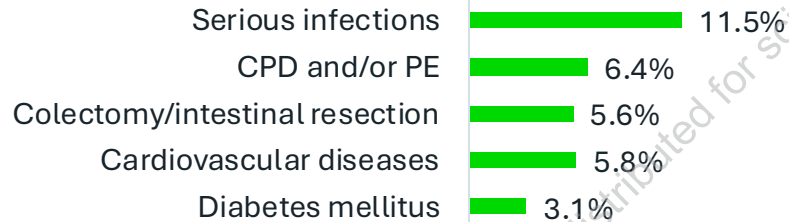
6.5 (2.5-10.1) years

### Gender



■ Female ■ Male

### Medical history and comorbidities



## 2<sup>nd</sup> line anti-TNF $\alpha$

N= 4,532

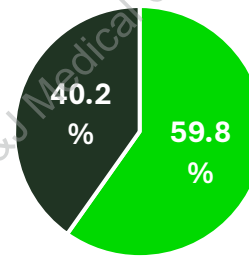
### Mean (SD) age

37.6 (14.1) years old

### Median (Q1-Q3) disease duration

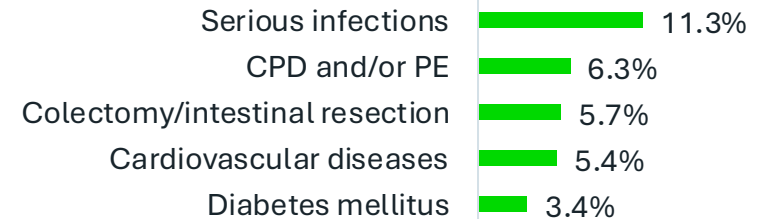
6.0 (2.3-9.7) years

### Gender



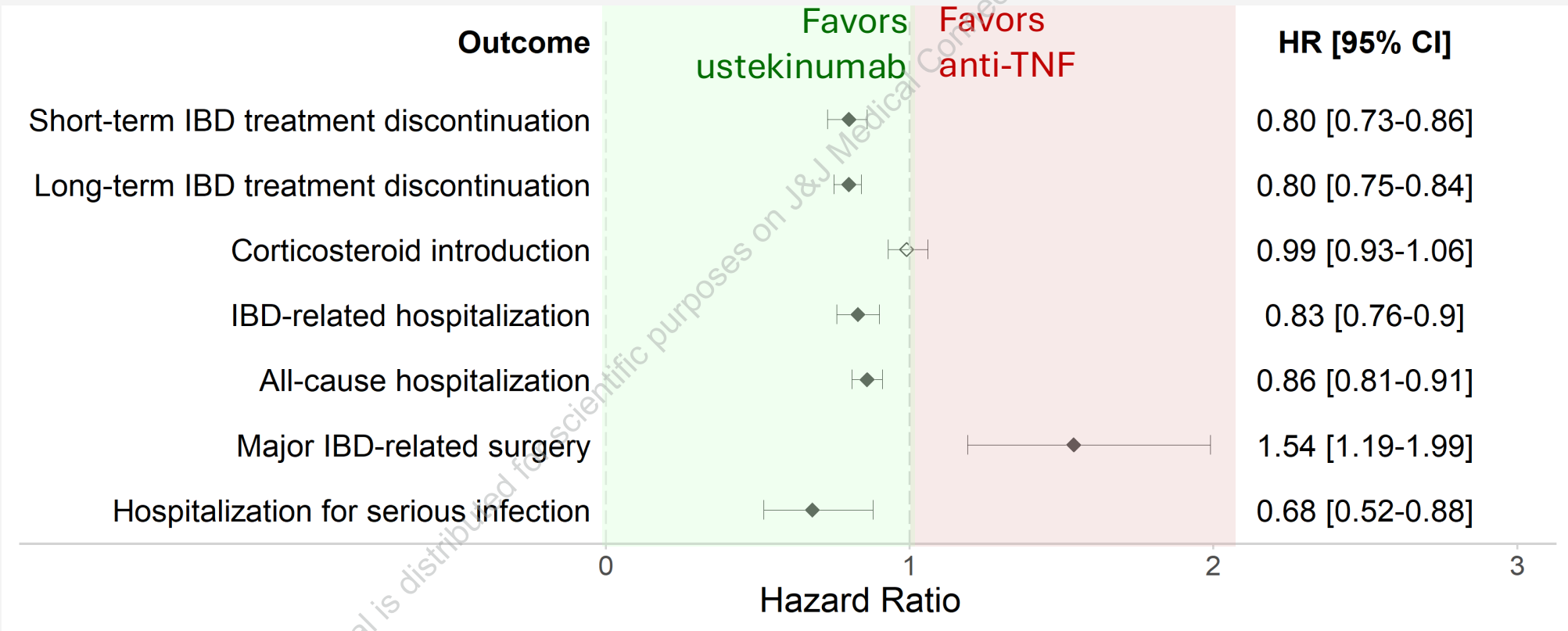
■ Female ■ Male

### Medical history and comorbidities



CPD: Chronic Pulmonary Disease, PE: Pulmonary embolism

# Risk of event occurrence with ustekinumab versus anti-TNF - CD patients



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# Characteristics of UC patients after PS matching

At 2<sup>nd</sup> line initiation date

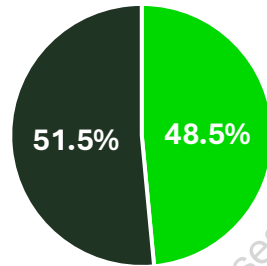
## 2<sup>nd</sup> line vedolizumab

N=2,907

**Mean (SD) age**  
41.9 (15.6) years old

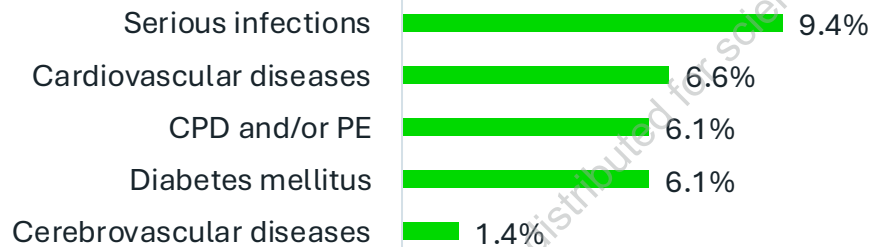
**Median (Q1-Q3) disease duration**  
5.1 (2.1-8.8) years

### Gender



■ Female ■ Male

### Medical history and comorbidities



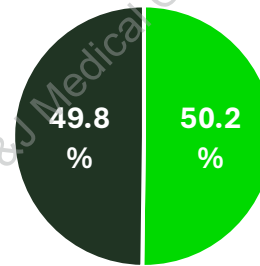
## 2<sup>nd</sup> line anti-TNF $\alpha$

N=2,907

**Mean (SD) age**  
41.5 (15.1) years old

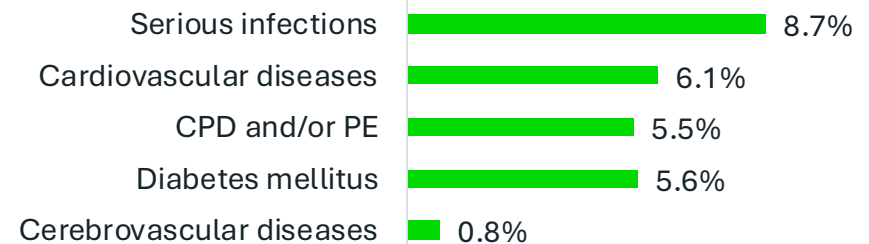
**Median (Q1-Q3) disease duration**  
5.1 (2.2-8.7) years

### Gender



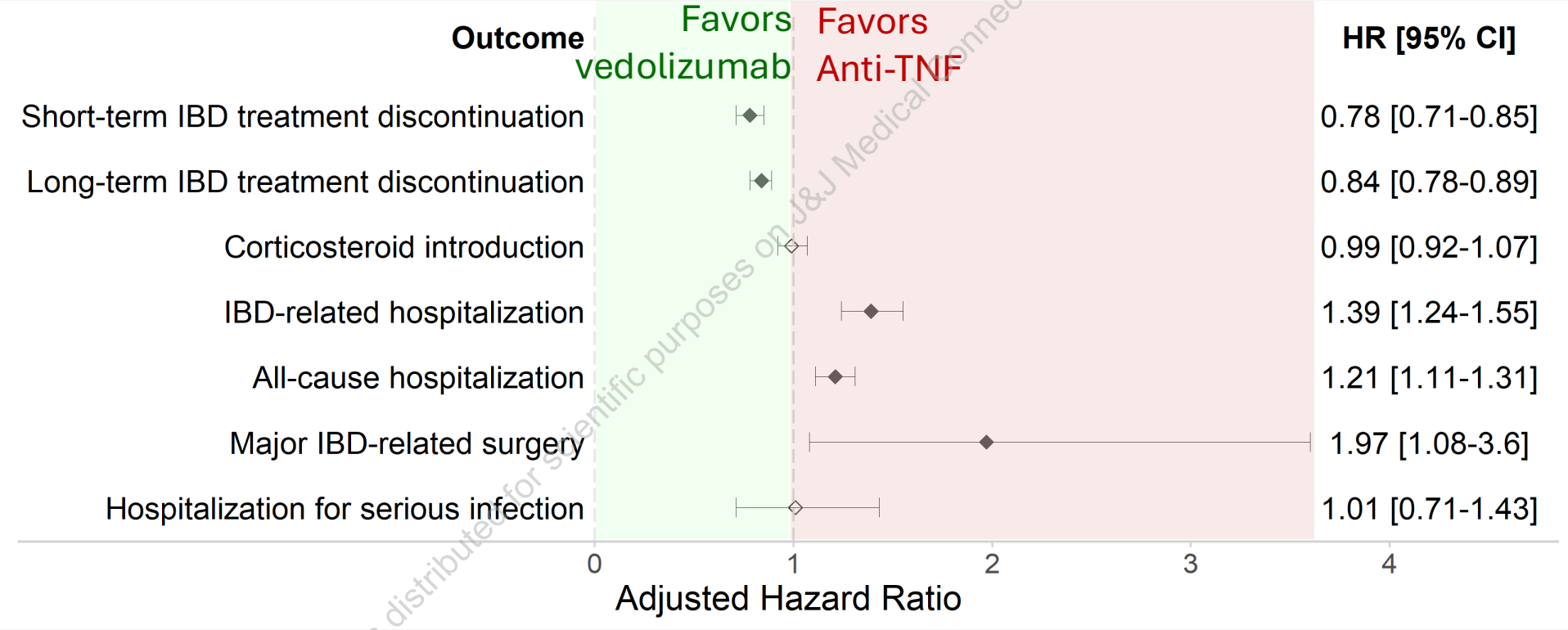
■ Female ■ Male

### Medical history and comorbidities



CPD: Chronic Pulmonary Disease, PE: Pulmonary embolism

# Risk of event occurrence with vedolizumab versus anti-TNF - UC patients



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# Characteristics of UC patients after PS matching

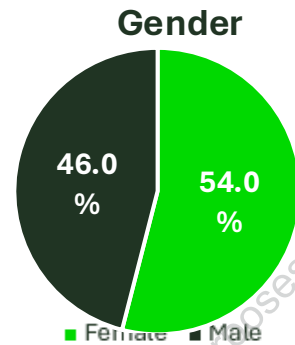
At 2<sup>nd</sup> line initiation date

## 2<sup>nd</sup> line ustekinumab

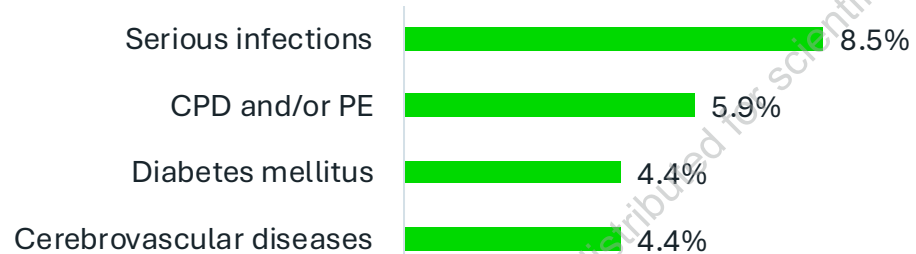
N=768

**Mean (SD) age**  
40.0 (14.5) years old

**Median (Q1-Q3) disease duration**  
5.4 (1.9-10.7) years



### Medical history and comorbidities

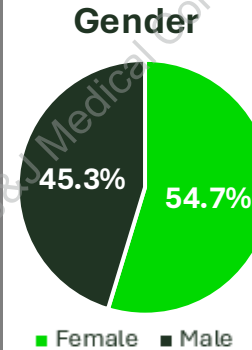


## 2<sup>nd</sup> line anti-TNF $\alpha$

N=768

**Mean (SD) age**  
40.4 (15.2) years old

**Mean (Q1-Q3) disease duration**  
5.4 (2.0-10.5) years

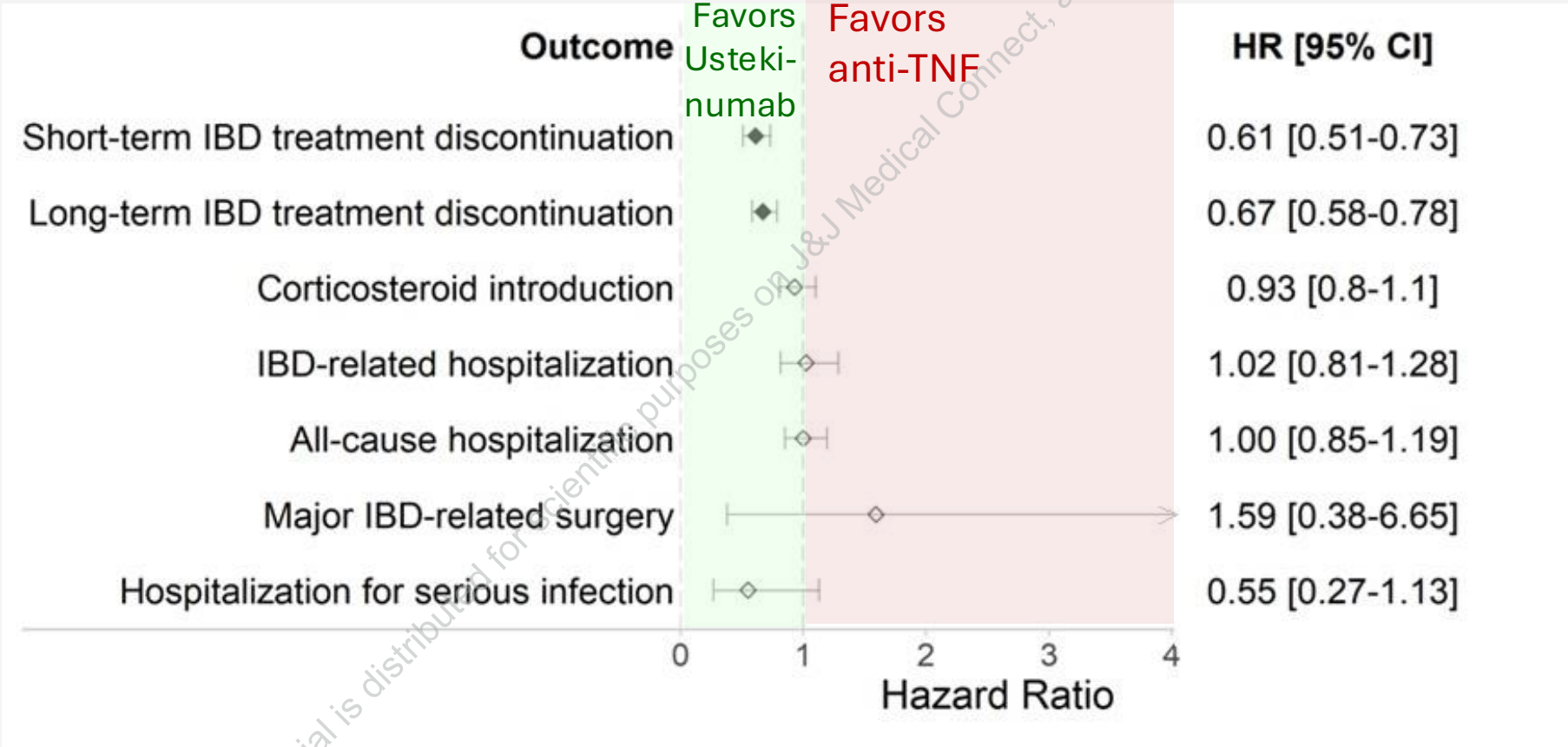


### Medical history and comorbidities



CPD: Chronic Pulmonary Disease, PE: Pulmonary embolism

# Risk of event occurrence with ustekinumab versus anti-TNF - UC patients



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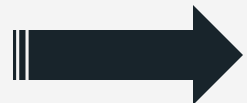
# Discussion

## Strengths

- ✓ **Population-based design:** Enables inclusion of a large, representative sample, reducing selection bias and allowing for generalizability.
- ✓ **Control of confounding factors:** The exhaustive database allows for adjustment of key demographic and clinical variables.

## Limitations

- ✗ **Use of proxies:** Certain outcomes or exposures are inferred indirectly (e.g., medication use as a proxy for diagnosis), which may affect accuracy.
- ✗ **Lack of clinical data:** Claims databases do not include detailed clinical parameters (e.g., lab results, disease severity), limiting the depth of analysis.



**Study Extension:** Inclusion of additional years including recently approved IBD treatments

# Conclusion

**CD**

Compared to a 2<sup>nd</sup> line anti TNF agent

**2<sup>nd</sup> line vedolizumab was associated with:**

**X** *Increased treatment discontinuation and corticosteroids introduction*

**2<sup>nd</sup> line ustekinumab was associated with:**

- ✓ *Fewer treatment discontinuation*
- ✓ *Fewer IBD-related hospitalisations*
- ✓ *Fewer hospitalisations for serious infections*

**X** *Increased major IBD-related surgeries*

**UC**

Compared to a 2<sup>nd</sup> line anti TNF agent

**2<sup>nd</sup> line vedolizumab was associated with:**

- ✓ *Less treatment discontinuation*
- X** *Increased major IBD-related surgeries and IBD-related hospitalisations*

**2<sup>nd</sup> line ustekinumab was associated with:**

- ✓ *Less treatment discontinuation*



**This evidence could help guide clinical practice for improved management of IBD**

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Thank you

Johnson & Johnson



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# *Supplementary Data and Insights*

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# PS matching with vedolizumab versus anti-TNF CD patients

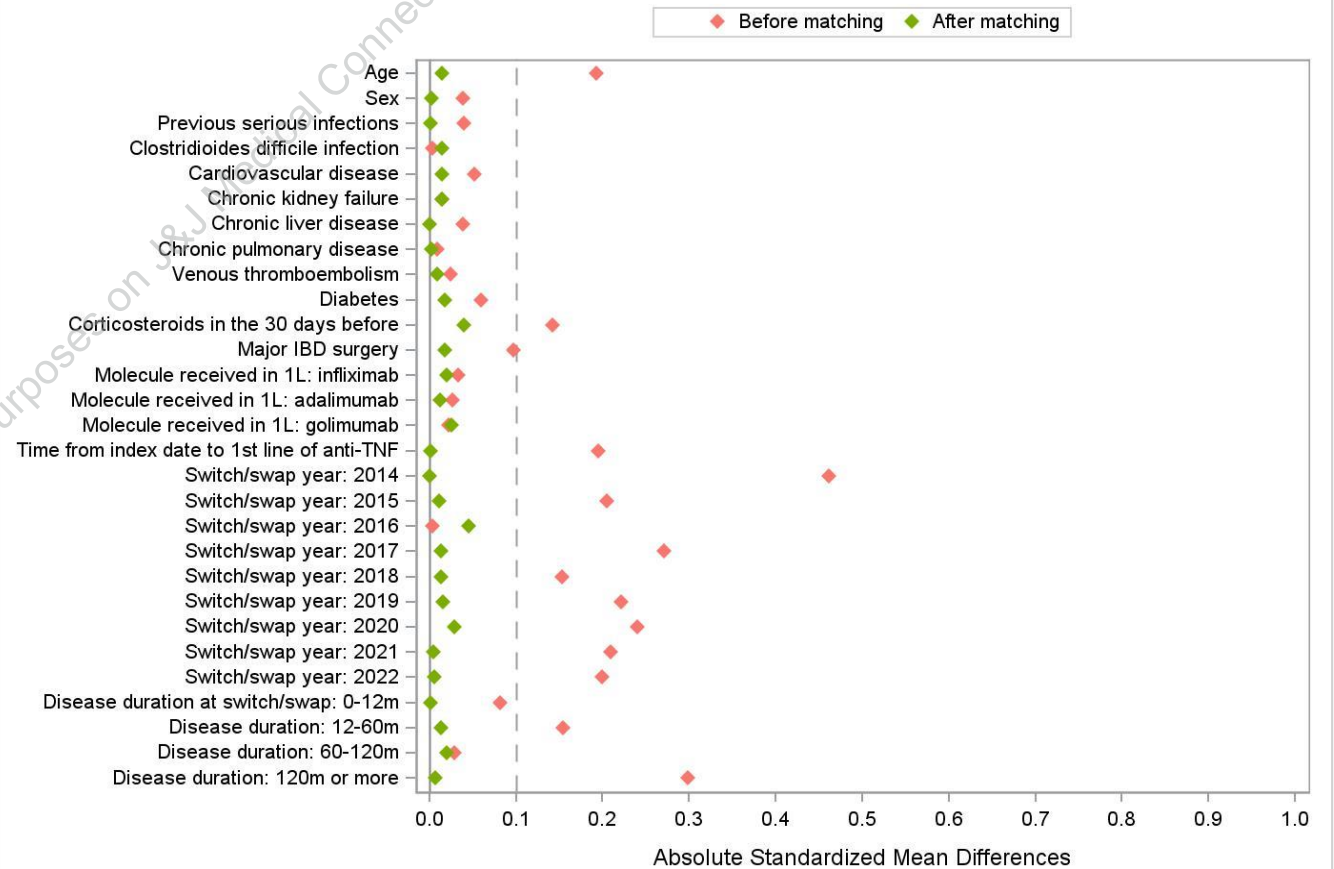
## BEFORE PS matching

- 2<sup>nd</sup> line vedolizumab  
N=1,963
- 2<sup>nd</sup> line anti-TNF  
N=8,988

## AFTER PS matching (ratio 1:1)

- 2<sup>nd</sup> line vedolizumab  
N=1,963
- 2<sup>nd</sup> line anti-TNF  
N=1,963

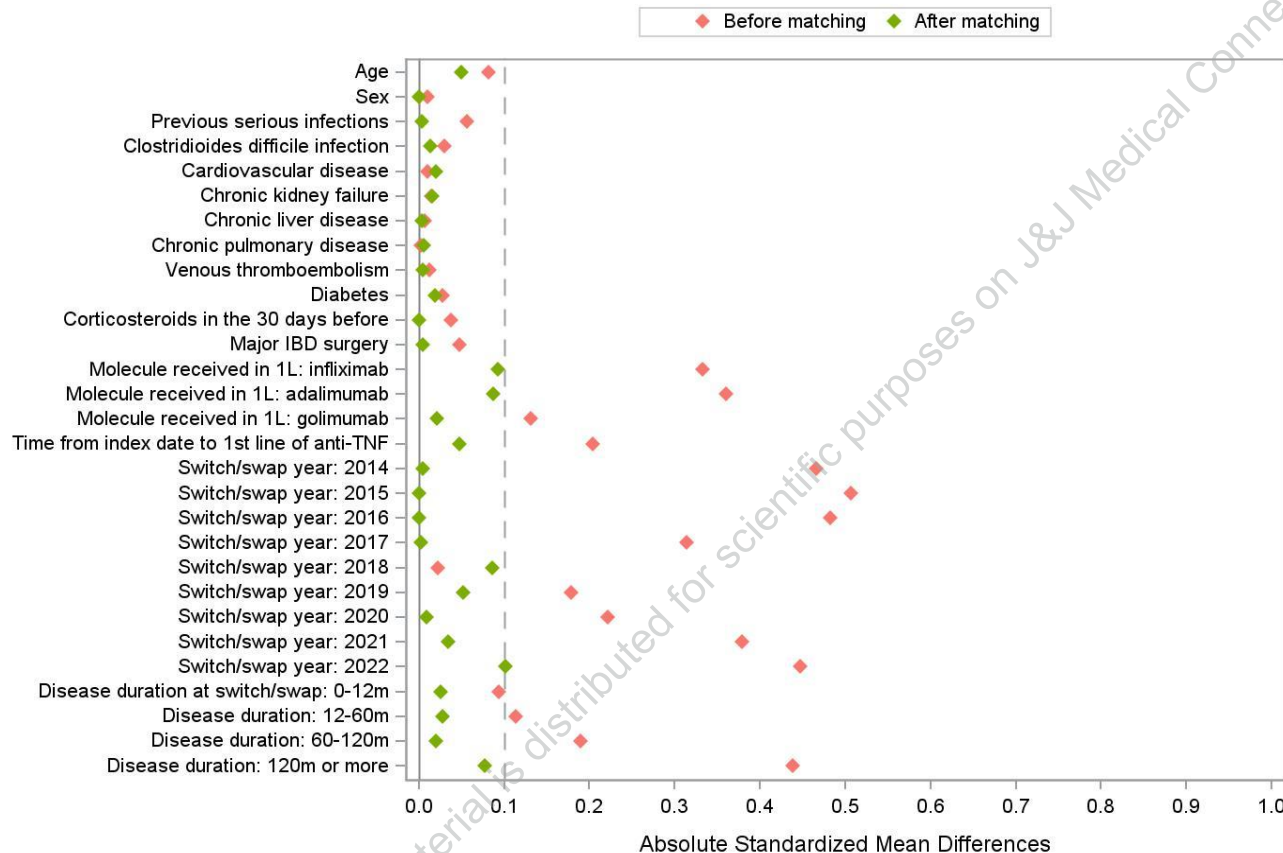
Figure A6. Propensity score matching - Balance diagnostic of covariates included in the propensity score - Absolute standardized mean differences between groups (swap to vedolizumab/switch) - CD population



After matching, SMD < 0.1 for all covariates indicating sufficient balance on these covariates.

# PS matching with ustekinumab versus anti-TNF CD patients

Figure A7. Propensity score matching - Balance diagnostic of covariates included in the propensity score - Absolute standardized mean differences between groups (swap to ustekinumab/switch) - CD population



## BEFORE PS matching

- 2<sup>nd</sup> line ustekinumab  
N=5,987
- 2<sup>nd</sup> line anti-TNF  
N=8,988

## AFTER PS matching (ratio 1:1)

- 2<sup>nd</sup> line ustekinumab
- 2<sup>nd</sup> line anti-TNF  
N=4,532

After matching, SMD < 0.1 for all covariates indicating sufficient balance on these covariates.

# PS matching with vedolizumab versus anti-TNF UC patients

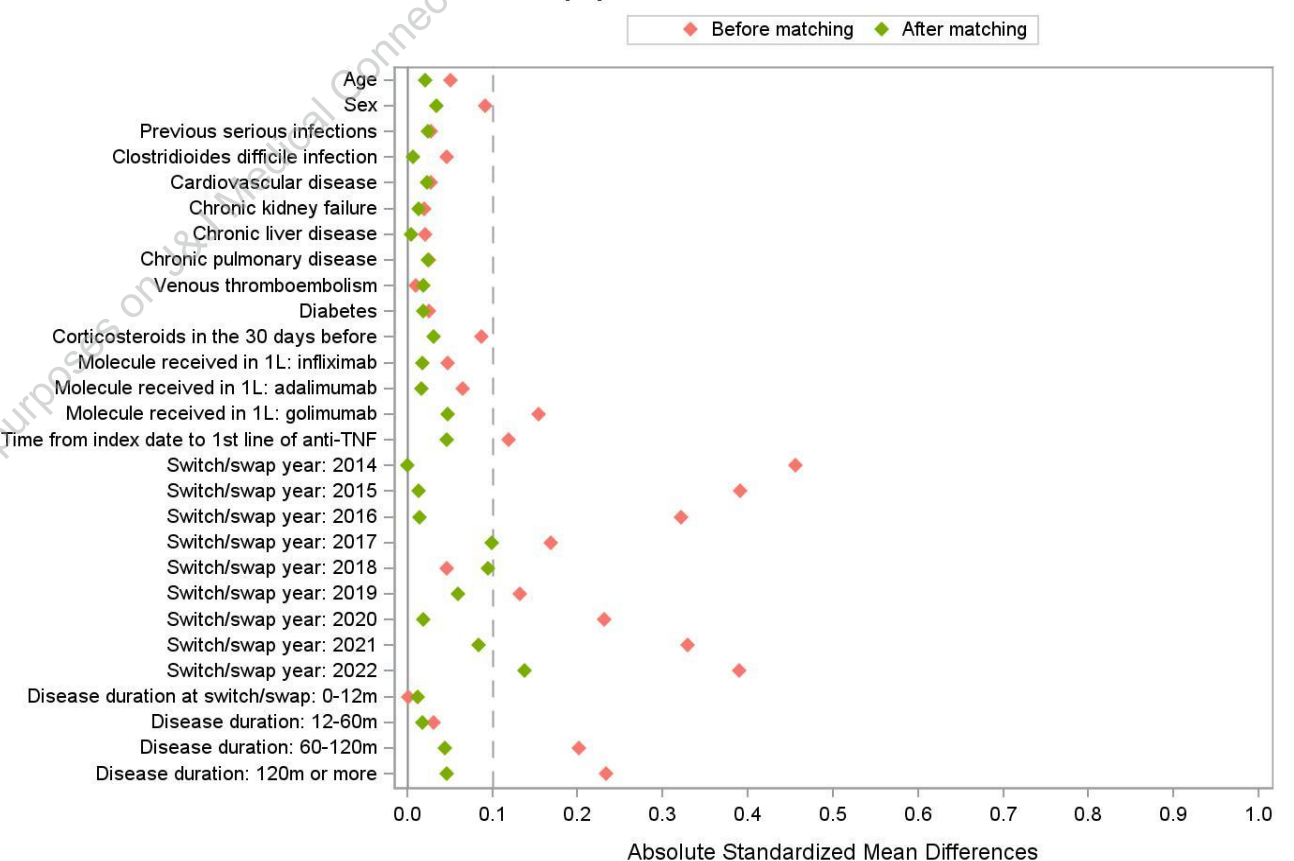
## BEFORE PS matching

- 2<sup>nd</sup> line vedolizumab  
N=4,145
- 2<sup>nd</sup> line anti-TNF  
N=4,634

## AFTER PS matching (ratio 1:1)

- 2<sup>nd</sup> line vedolizumab  
N=2,907
- 2<sup>nd</sup> line anti-TNF  
N=2,907

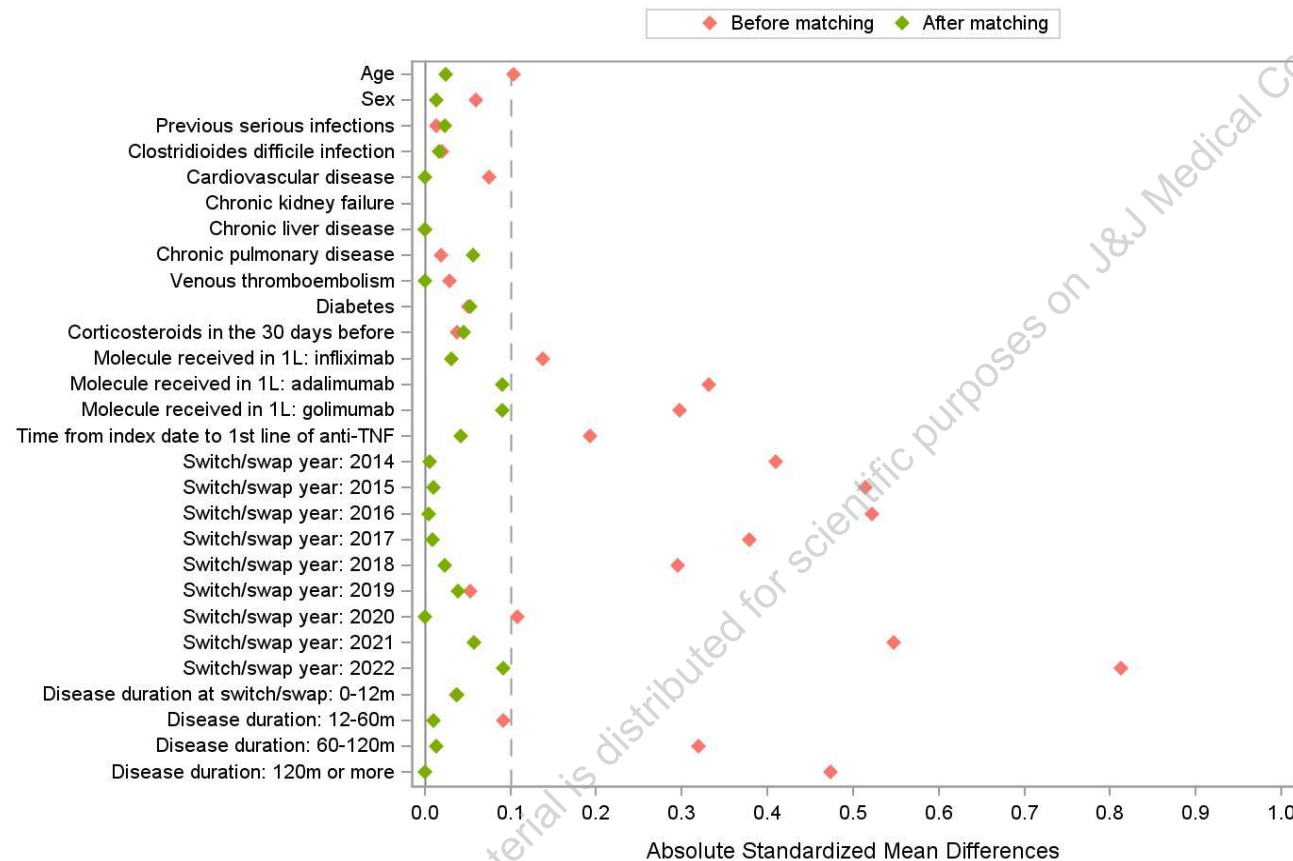
Figure B6. Propensity score matching - Balance diagnostic of covariates included in the propensity score - Absolute standardized mean differences between groups (swap to vedolizumab/switch) - UC population



After matching, SMD < 0.1 for all covariates indicating sufficient balance on these covariates.

# PS matching with ustekinumab versus anti-TNF UC patients

**Figure B7. Propensity score matching - Balance diagnostic of covariates included in the propensity score - Absolute standardized mean differences between groups (swap to ustekinumab/switch) - UC population**



## BEFORE PS matching

- 2<sup>nd</sup> line ustekinumab  
N=773
- 2<sup>nd</sup> line anti-TNF  
N=4,634

## AFTER PS matching (ratio 1:1)

- 2<sup>nd</sup> line ustekinumab
- 2<sup>nd</sup> line anti-TNF  
N=768

After matching, SMD < 0.1 for all covariates indicating sufficient balance on these covariates.

# Event occurrence with vedolizumab versus anti-TNF - CD patients

	CD patients			
	2 <sup>nd</sup> line vedolizumab (N=1,963)		2 <sup>nd</sup> line anti-TNF (N=1,963)	
	N	% [95% CI]	N	% [95% CI]
<b>Short-term: discontinuation within 1 year<sup>1</sup></b>	734	37.5%[35.4-39.7]	556	28.6%[26.6-30.7]
<b>Long-term: discontinuation within 5 years*</b>	494	76.5%[73-79.7]	464	71.4%[67.7-74.8]
<b>Corticosteroid introduction<sup>1</sup></b>	914	46.6%[44.3-48.8]	876	44.6%[42.4-46.9]
<b>IBD-related hospitalization<sup>1</sup></b>	569	29.0%[27-31]	536	27.3%[25.3-29.3]
<b>All-cause hospitalization<sup>1</sup></b>	914	46.6%[44.3-48.8]	893	45.5%[43.3-47.7]
<b>Major IBD-related surgery<sup>1</sup></b>	53	2.7%[2-3.5]	48	2.4%[1.8-3.2]
<b>Hospitalizations for serious infections<sup>1</sup></b>	71	3.6%[2.8-4.5]	61	3.1%[2.4-4]

<sup>1</sup>Outcomes assessment period: up to 365 days after switch/swap index date or until occurrence of a censoring event.

\* Persistence among patients with at least 5 years follow-up

# Event occurrence with ustekinumab versus anti-TNF - CD patients

	CD patients			
	2 <sup>nd</sup> line ustekinumab (N=4,532)		2 <sup>nd</sup> line anti-TNF (N=4,532)	
	N	% [95% CI]	N	% [95% CI]
<b>Short-term: discontinuation within 1 year<sup>1</sup></b>	1107	24.5%[23.3-25.8]	1336	29.7%[28.3-31]
<b>Long-term: discontinuation within 5 years*</b>	691	61.3%[58.4-64.2]	848	68.4%[65.7-71]
<b>Corticosteroid introduction<sup>1</sup></b>	1698	37.5%[36.1-38.9]	1792	39.5%[38.1-41]
<b>IBD-related hospitalization<sup>1</sup></b>	1077	23.8%[22.5-25]	1212	26.7%[25.5-28.1]
<b>All-cause hospitalization<sup>1</sup></b>	1837	40.5%[39.1-42]	1986	43.8%[42.4-45.3]
<b>Major IBD-related surgery<sup>1</sup></b>	149	3.3%[2.8-3.8]	94	2.1%[1.7-2.5]
<b>Hospitalizations for serious infections<sup>1</sup></b>	97	2.1%[1.7-2.6]	140	3.1%[2.6-3.6]

<sup>1</sup>Outcomes assessment period: up to 365 days after switch/swap index date or until occurrence of a censoring event.

\* Persistence among patients with at least 5 years follow-up

# Event occurrence with vedolizumab versus anti-TNF - UC patients

	UC patients			
	2 <sup>nd</sup> line vedolizumab (N=2,907)		2 <sup>nd</sup> line anti-TNF (N=2,907)	
	N	% [95% CI]	N	% [95% CI]
<b>Short-term: discontinuation within 1 year<sup>1</sup></b>	881	30.5%[28.8-32.2]	1071	37.0%[35.3-38.8]
<b>Long-term: discontinuation within 5 years*</b>	688	66.5%[63.6-69.4]	860	70.8%[68.2-73.4]
<b>Corticosteroid introduction<sup>1</sup></b>	1388	47.7%[45.9-49.6]	1426	49.1%[47.2-50.9]
<b>IBD-related hospitalization<sup>1</sup></b>	749	25.8%[24.2-27.4]	539	18.5%[17.1-20]
<b>All-cause hospitalization<sup>1</sup></b>	1214	41.8%[40-43.6]	1006	34.6%[32.9-36.4]
<b>Major IBD-related surgery<sup>1</sup></b>	32	1.1%[0.8-1.6]	16	0.6%[0.3-0.9]
<b>Hospitalizations for serious infections<sup>1</sup></b>	65	2.2%[1.7-2.8]	62	2.1%[1.6-2.7]

<sup>1</sup>Outcomes assessment period: up to 365 days after switch/swap index date or until occurrence of a censoring event.

\* Persistence among patients with at least 5 years follow-up

# Event occurrence with ustekinumab versus anti-TNF - UC patients

	UC patients			
	2 <sup>nd</sup> line ustekinumab (N=768)		2 <sup>nd</sup> line anti-TNF (N=768)	
	N	% [95% CI]	N	% [95% CI]
<b>Short-term: discontinuation within 1 year<sup>1</sup></b>	187	24.5%[21.5-27.7]	279	36.5%[33.1-40]
<b>Long-term: discontinuation within 5 years*</b>	54	70.1%[58.6-80]	54	72.0%[60.4-81.8]
<b>Corticosteroid introduction<sup>1</sup></b>	290	37.8%[34.3-41.3]	315	41.0%[37.5-44.6]
<b>IBD-related hospitalization<sup>1</sup></b>	155	20.2%[17.4-23.2]	141	18.4%[15.7-21.3]
<b>All-cause hospitalization<sup>1</sup></b>	284	37.0%[33.6-40.5]	263	34.2%[30.9-37.7]
<b>Major IBD-related surgery<sup>1</sup></b>	≤10	NR	≤10	NR
<b>Hospitalizations for serious infections<sup>1</sup></b>	12	1.6%[0.8-2.7]	20	2.6%[1.6-4]

<sup>1</sup>Outcomes assessment period: up to 365 days after switch/swap index date or until occurrence of a censoring event.

\* Persistence among patients with at least 5 years follow-up

NR: not reported due to insufficient number of patients (n≤10)