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Supplementary Table 2. Incidence of Adverse Drug Reactions by Background Factors (Safety Analysis Population)

Characteristics		No.	ADR, No. (%)	95% CI
No. of cases analyzed		633	27 (4.3)	2.95–6.13
Sex	Male	340	13 (3.8)	2.25–6.43
	Female	293	14 (4.8)	2.87–7.86
	(Pregnancy; yes)[a]	2	0	0.00–65.76
Age (yr)	< 15	3	0	0.00–56.15
	15–64	542	24 (4.4)	2.99–6.50
	≥ 65	88	3 (3.4)	1.17–9.55
Body mass index (kg/m^2)	< 18.5	60	3 (5.0)	1.71–13.70
	≥ 18.5 and < 25.0	343	15 (4.4)	2.67–7.09
	≥ 25.0	106	8 (7.6)	3.87–14.19
Patient setting	Outpatient	611	26 (4.3)	2.92–6.16
	Inpatient	22	1 (4.6)	0.81–21.80
Duration of disease (yr)	< 1	116	3 (2.6)	0.88–7.33
	≥ 1 and < 5	189	7 (3.7)	1.81–7.45
	≥ 5 and < 10	143	8 (5.6)	2.86–10.65
	≥ 10 and < 20	134	6 (4.5)	2.07–9.42
	≥ 20	48	3 (6.3)	2.15–16.84
	Unknown	3	0 (0.0)	0.00–56.15
Disease phenotype	Pancolitis	245	12 (4.9)	2.82–8.36
	Left-sided colitis	250	9 (3.6)	1.91–6.70
	Proctitis	138	6 (4.4)	2.01–9.16
Disease severity	Mild	196	11 (5.6)	3.16–9.77
	Moderate	426	16 (3.8)	2.32–6.01
	Unknown[b]	11	0	0.00–25.88
Clinical course	First onset	94	4 (4.3)	1.67–10.44
	Relapsing–remitting	433	19 (4.4)	2.83–6.75
	Chronic continuous	106	4 (3.8)	1.48–9.30
Smoking[c]	Current smoker	569	24 (4.2)	2.85–6.20
	Non-smoker	62	2 (3.2)	0.89–11.02
Complications	No	422	12 (2.8)	1.63–4.90
	Yes	211	15 (7.1)	4.36–11.40
Complications (hepatic dysfunction)	No	623	26 (4.2)	2.86–6.04
	Yes	10	1 (10.0)	1.79–40.42
Complications (renal dysfunction)	No	629	27 (4.3)	2.97–6.17
	Yes	4	0	0.00–48.99

[a]The denominator was the number of female cases.
[b]Cases with missing severity data were counted as "other."
[c]Cases with unknown presence/absence were not included in the tally.
ADR, adverse drug reaction; CI, confidence interval.

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