

Table I. *Demographics.*

Variable	All cohorts (261 cohorts)	Placebo monotherapy (127 cohorts)	Placebo monotherapy with diarrhea data (95 cohorts)
Number of patients	220 (5-2,256) (n=261)	192 (10-2,253) (n=127)	194.7 (10-2,253) (n=95)
Year of publication	2018 (2009-2021) (n=261)	2018 (2009-2021) (n=127)	2018 (2009-2021) (n=95)
Median age	57.0 (7.1-74.5) (n=250)	57.4 (7.1-74) (n=122)	57.5 (7.1-74) (n=91)
% male	54 (0-100) (n=243)	54 (0-100) (n=118)	54.8 (0-100) (n=87)
% ECOG 0	56.5 (0-100) (n=181)	55.4 (0-100) (n=88)	55.8 (5.2-100) (n=67)
% Phase 1/2/3	4.6/29.1/66.3 (n=261)	3.1/29.1/67.7 (n=127)	3.2/25.3/71.6 (n=95)
Median line of previous Tx	0.9 (1.0, 0-4) (n=181)	0.9 (0-4) (n=87)	1 (0-4) (n=65)
Cancer diagnosis by organ system			
Liver	9.2% (24)	9.4% (12)	10.5% (10)
Hem	12.3% (32)	12.6% (16)	15.8% (15)
Breast	8.4% (22)	7.9% (10)	7.4% (7)
Lung	8.4% (22)	8.7% (11)	8.4% (8)
Colorectal	13.8% (36)	14.2% (18)	10.5% (10)
Ovary	6.9% (18)	7.1% (9)	6.3% (6)
Skin	4.6% (12)	4.7% (6)	5.3% (5)
No organ system	4.6% (12)	3.1% (4)	3.2% (3)
Kidney	4.2% (11)	3.9% (5)	4.2% (4)
Prostate	6.1% (16)	6.3% (8)	7.4% (7)
Soft tissue	5.4% (14)	5.5% (7)	6.3% (6)
Gastric	2.3% (6)	2.4% (3)	3.2% (3)
Uterus	1.5% (4)	1.6% (2)	-- (0)
Pancreas	1.5% (4)	1.6% (2)	2.1% (2)
Eligibility criteria: Tumor status			
No measurable cancer	29.5% (77)	28.3% (36)	26.3% (25)
Measurable	35.2% (92)	36.2% (46)	35.8% (34)
Mixed tumor status	33.7% (88)	34.6% (44)	36.8% (35)
Newly diagnosed	39.5% (103)	39.4% (50)	34.7% (33)
R/R	44.4% (116)	45.7% (58)	49.5% (47)
Mixed new-R/R	9.2% (24)	9.4% (12)	11.6% (11)
Healthy V.	5.4% (14)	3.9% (5)	3.2% (3)
Prevention	1.5% (4)	1.6% (2)	1.1% (1)
Route of treatment			
PO	75.5 (197)	76.4% (97)	76.8% (73)
IV	16.1% (42)	15% (19)	15.8% (15)
SC	4.6% (12)	4.7% (6)	5.3% (5)
IM	1.5% (4)	1.6% (2)	1.1% (1)
ID	1.5% (4)	1.6% (2)	1.1% (1)
IV + SC	0.8% (2)	0.8% (1)	0

Columns: “All Cohorts” includes all lines of data regardless of treatment or availability of diarrhea data; “Placebo Monotherapy” includes all cohorts treated with placebo monotherapy regardless availability of diarrhea data; “Placebo Monotherapy with Diarrhea Data” includes the core data of this analysis: Placebo cohorts that had diarrhea data. Rows: hem: Hematology cancer studies – leukemia/lymphoma; No organ system: studies enrolling regardless of cancer diagnosis and studies with health volunteers; No measurable cancer: studies enrolling only patients in remission; Measurable: studies enrolling only patients with measurable disease; mixed status: studies enrolling patients regardless of remission status; R/R: relapsed or refractory malignancy; mixed new-R/R: studies enrolling both newly diagnosed and relapsed or refractory disease; Healthy V.: Healthy Volunteers; Prevention: cancer prevention studies enrolling patients at risk but without cancer diagnosis. Cells: quantitative variables are provided as average (range: minimum – maximum) (n=number of available values) categorical variables are provided as % (n).