Table 14.1.2.1: Demographic and Baseline Characteristics
Full Analysis Set

	Characteristics	Treatment A (N=xxx)	Treatment B (N=xxx)	Total (N=xxx)
	Ethnicity [for US studies only]			
	Hispanic/Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Non-Hispanic/Non-Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)
Height (cm)				
n		xx	xx	xx
Mean		xxx.xx	xxx.xx	xxx.xx
Standard Deviation		xxx.xxx	xxx.xxx	xxx.xxx
Median		xxx.xx	xxx.xx	xxx.xx
Min, Max		xxx, xxx	xxx, xxx	xxx, xxx
Weight (kg)				
n		xx	xx	xx
Mean		xxx.xx	xxx.xx	xxx.xx
Standard Deviation		xxx.xxx	xxx.xxx	xxx.xxx
Median		xxx.xx	xxx.xx	xxx.xx
Min, Max		xxx, xxx	xxx, xxx	xxx, xxx
Body Mass Index (kg/m2)				
	n	xx	xx	xx
	Mean	xxx.xx	xxx.xx	xxx.xx
	Standard Deviation	xxx.xxx	xxx.xxx	xxx.xxx
	Median	xxx.xx	xxx.xx	xxx.xx
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx

Body Surface Area (m2)			
n	xx	xx	xx
Mean	xxx.xx	xxx.xx	xxx.xx
Standard Deviation	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xx	xxx.xx	xxx.xx
Min, Max	xxx, xxx	xxx, xxx	xxx, xxx

Notes: The baseline value is defined as the last non-missing value before initial administration of study drug.
[a] Age in years is calculated using the date of birth and date of informed consent.
Source Data: adam.adsl; Listing 16.2.4.x.x.
. Table 14.1.2.1: Demographic and Baseline Characteristics
Full Analysis Set

Characteristics	Treatment A (N=xxx)	Treatment B (N=xxx)	Total (N=xxx)
Stratification Factor 1 (EDC)			
Level 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Level 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Stratification Factor 1 (IXRS)			
Level 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Level 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
ECOG Performance Status			
0 - Fully Active	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 - Restricted in Physically Strenuous Activity	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 - Ambulatory and Capable of All Self-Care	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 – Capable of only limited self-care	xx (xx.x)	xx (xx.x)	xx (xx.x)
4 – Completely disabled	xx (xx.x)	xx (xx.x)	xx (xx.x)

12-Lead ECG			
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal, Not Clinically Significant	xx (xx.x)	xx (xx.x)	xx (xx.x)
Clinically significant findings	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Performed	xx (xx.x)	xx (xx.x)	xx (xx.x)
Baseline/Biomarker Subgroups			
Category 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Smoking Status			
Never	xx (xx.x)	xx (xx.x)	xx (xx.x)
Former	xx (xx.x)	xx (xx.x)	xx (xx.x)
Current	xx (xx.x)	xx (xx.x)	xx (xx.x)

Notes: The baseline value is defined as the last non-missing value before initial administration of study drug.
[a] Age in years is calculated using the date of birth and date of informed consent.
Source Data: adam.adsl; Listing 16.2.4.x.x.
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Table 14.1.2.1: Demographic and Baseline Characteristics
Full Analysis Set

	Characteristics	Treatment A (N=xxx)	Treatment B (N=xxx)	Total (N=xxx)
	Bone marrow/aspirate blast count at baseline	xx xx.x	xx xx.x	xx xx.x

n Mean Median Standard Deviation Min, Max <Median >=Median	xx.x xx.xx xx.x, xx.x xx (xx.x) xx (xx.x)	xx.x xx.xx xx.x, xx.x xx (xx.x) xx (xx.x)	xx.x xx.xx xx.x, xx.x xx (xx.x) xx (xx.x)
Region/Country of Enrollment			
North America	xx (xx.x)	xx (xx.x)	xx (xx.x)
Country 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asia	xx (xx.x)	xx (xx.x)	xx (xx.x)
Country 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Europe (required to list all countries)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Country 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Country 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Country n	xx (xx.x)	xx (xx.x)	xx (xx.x)
Rest of World	xx (xx.x)	xx (xx.x)	xx (xx.x)
Country 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Country 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Country n	xx (xx.x)	xx (xx.x)	xx (xx.x)

Notes: The baseline value is defined as the last non-missing value before initial administration of study drug.
[a] Age in years is calculated using the date of birth and date of informed consent.
Source Data: adam.adsl; Listing 16.2.4.x.x.

Table 14.1.3.1: Prior [xxxxx] Cancer History [for Solid Tumor]

Full Analysis Set

[The shell below uses lung cancer as an example, for breast cancer, gastric cancer, etc., refer to study CRFs for modification]

Parameter	Treatment A (N=xxx)	Treatment B (N=xxx)	Total (N=xxx)
Time from Initial Histologic Diagnosis to Randomization (days)			
n	xx	xx	xx
Mean	xxx.x	xxx.x	xxx.x
Standard Deviation	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min, Max	xxx, xxx	xxx, xxx	xxx, xxx
Histology			
Adenocarcinoma	xx (xx.x)	xx (xx.x)	xx (xx.x)
Squamous	xx (xx.x)	xx (xx.x)	xx (xx.x)
Large Cell	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Done	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Tumor Stage at Initial Diagnosis			
0	xx (xx.x)	xx (xx.x)	xx (xx.x)
I	xx (xx.x)	xx (xx.x)	xx (xx.x)
IA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IB	xx (xx.x)	xx (xx.x)	xx (xx.x)
II	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIB	xx (xx.x)	xx (xx.x)	xx (xx.x)
III	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIIA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIIB	xx (xx.x)	xx (xx.x)	xx (xx.x)

IIIC	xx (xx.x)	xx (xx.x)	xx (xx.x)
IV	xx (xx.x)	xx (xx.x)	xx (xx.x)
IVA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IVB	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown			
Tumor Stage at Study Entry			
0	xx (xx.x)	xx (xx.x)	xx (xx.x)
I	xx (xx.x)	xx (xx.x)	xx (xx.x)
IA	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source Data: adam.adsl; Listing16.2.x.x.x.

Table 14.1.3.1: Prior [xxxxx] Cancer History [*for Solid Tumor*]
Full Analysis Set

Parameter	Treatment A (N=xxx)	Treatment B (N=xxx)	Total (N=xxx)
Tumor Stage at Study Entry			
IB	xx (xx.x)	xx (xx.x)	xx (xx.x)
II	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIB	xx (xx.x)	xx (xx.x)	xx (xx.x)
III	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIIA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIIB	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIIC	xx (xx.x)	xx (xx.x)	xx (xx.x)
IV	xx (xx.x)	xx (xx.x)	xx (xx.x)
IVA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IVB	xx (xx.x)	xx (xx.x)	xx (xx.x)
TNM Stage at Study Entry (T)			
TX	xx (xx.x)	xx (xx.x)	xx (xx.x)
T0	xx (xx.x)	xx (xx.x)	xx (xx.x)
Tis	xx (xx.x)	xx (xx.x)	xx (xx.x)
T1	xx (xx.x)	xx (xx.x)	xx (xx.x)
T1a	xx (xx.x)	xx (xx.x)	xx (xx.x)
T1b	xx (xx.x)	xx (xx.x)	xx (xx.x)
T2	xx (xx.x)	xx (xx.x)	xx (xx.x)
T3	xx (xx.x)	xx (xx.x)	xx (xx.x)

T4	xx (xx.x)	xx (xx.x)	xx (xx.x)
T4a	xx (xx.x)	xx (xx.x)	xx (xx.x)
T4b	xx (xx.x)	xx (xx.x)	xx (xx.x)
TNM Stage at Study Entry (N)			
NX	xx (xx.x)	xx (xx.x)	xx (xx.x)
N0	xx (xx.x)	xx (xx.x)	xx (xx.x)
N1	xx (xx.x)	xx (xx.x)	xx (xx.x)
N2	xx (xx.x)	xx (xx.x)	xx (xx.x)
N3	xx (xx.x)	xx (xx.x)	xx (xx.x)
N3a	xx (xx.x)	xx (xx.x)	xx (xx.x)
N3b	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source Data: adam.adsl; Listing 16.2.x.x.x.

Table 14.1.3.1: Prior [xxxxx] Cancer History [*for Solid Tumor*]
Full Analysis Set

Parameter	Treatment A (N=xxx)	Treatment B (N=xxx)	
TNM Stage at Study Entry (M)			
M0	xx (xx.x)	xx (xx.x)	xx
M1	xx (xx.x)	xx (xx.x)	xx
Histologic Grade			
Well Differentiated	xx (xx.x)	xx (xx.x)	xx
Moderately Differentiated	xx (xx.x)	xx (xx.x)	xx
Poorly Differentiated	xx (xx.x)	xx (xx.x)	xx
Undifferentiated	xx (xx.x)	xx (xx.x)	xx
Unknown	xx (xx.x)	xx (xx.x)	xx
History of Brain Metastasis			
Yes	xx (xx.x)	xx (xx.x)	xx
No	xx (xx.x)	xx (xx.x)	xx
History of Other Metastasis			
Yes	xx (xx.x)	xx (xx.x)	xx
No	xx (xx.x)	xx (xx.x)	xx
Location of Metastasis [*in a descending # order*]			
CNS (brain)	xx (xx.x)	xx (xx.x)	xx
Bone	xx (xx.x)	xx (xx.x)	xx
Adrenal Glands	xx (xx.x)	xx (xx.x)	xx
Lung	xx (xx.x)	xx (xx.x)	xx

Liver	xx (xx.x)	xx (xx.x)	xx
Pericardium	xx (xx.x)	xx (xx.x)	xx
Kidneys	xx (xx.x)	xx (xx.x)	xx
Other	xx (xx.x)	xx (xx.x)	xx

Source Data: adam.adsl; Listing 16.2.x.x.x.

Table 14.1.3.2: Prior Cancer Therapy [for Solid Tumor]
Full Analysis Set

Parameter	Treatment A (N=xxx)	Treatment B (N=xxx)	Total (N=xxx)
Any Prior Systemic Cancer Therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subclass 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Drug 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Drug 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lines of Prior Systemic Cancer Therapy for Relapsed or Metastatic Disease			
1	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)
4+	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Regimens of Prior Systemic Cancer Therapy			
1	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)
4+	xx (xx.x)	xx (xx.x)	xx (xx.x)
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Min. Max	xx, xx	xx, xx	xx, xx
Number of Prior Cancer Chemotherapy			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Intent of Prior Cancer Chemotherapy Regimens			
Neo-Adjuvant	xx (xx.x)	xx (xx.x)	xx (xx.x)

Local Advanced	xx (xx.x)	xx (xx.x)	xx (xx.x)
Metastatic	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preventive	xx (xx.x)	xx (xx.x)	xx (xx.x)
Maintenance	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: If a subject had more than one agent within the same regimen, the subject was counted at each relevant agent.
Source Data: adam.adsl; Listing 16.2.x.x.

Table 14.1.3.2: Prior Cancer Therapy [for Solid Tumor]
Full Analysis Set

Parameter	Treatment A (N=xxx)	Treatment B (N=xxx)	Total (N=xxx)
Best Response to [Prior or Most Recent] Therapy			
Complete Response (CR)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Partial Response (PR)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Stable Disease (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Progressive Disease (PD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown (UNK)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Applicable (NA)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason for Discontinuation of Prior Therapy			
Disease Progression	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed Therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)

Investigator Decision	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cost	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient Choice	xx (xx.x)	xx (xx.x)	xx (xx.x)
Regimen Availability	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: If a subject had more than one agent within the same regimen, the subject was counted at each relevant agent.
Source Data: adam.adsl; Listing 16.2.x.x.

Table 14.1.3.2: Prior Cancer Therapy [*for Solid Tumor*]
Full Analysis Set

Parameter	Treatment A (N=xxx)	Treatment B (N=xxx)	Total (N=xxx)
Prior Radiation Therapy			
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type of Prior Radiation Therapy			
Cranial	xx (xx.x)	xx (xx.x)	xx (xx.x)
Stereotactic	xx (xx.x)	xx (xx.x)	xx (xx.x)
Genral	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prior Cancer Surgery			
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prior Cancer Biopsy			
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with any prior anti-cancer therapy n (%)			
Agent Name 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Agent Name 2	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: If a subject had more than one agent within the same regimen, the subject was counted at each relevant agent.
Source Data: adam.adsl; Listing 16.2.x.x.

Table 14.1.3.3: Medical History
Full /Safety Analysis Set

System Organ Class Preferred Term	Treatment A (N=xxx) n (%)	Treatment B (N=xxx) n (%)	Total (N=xxx) n (%)
Subjects with any Report	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term n	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term n	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class n	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term n	xx (xx.x)	xx (xx.x)	xx (xx.x)

Notes: All investigator reported terms were coded using MedDRA dictionary version xx.x.
If a subject had more than one event per system organ class or preferred term, the subject is counted once at each level of summation.
Source Data: adam.admh; Listing 16.2.x.x

Programming Note: display both Preferred Term and System Organ Class in alphabetical order