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  n  Mean  Median  Standard Deviation  Min, Max  <Median  >=Median | xx  xx.x  xx.x  xx.xx  xx.x, xx.x  xx (xx.x)  xx (xx.x) | xx  xx.x  xx.x  xx.xx  xx.x, xx.x  xx (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  Tumor Stage at Initial Diagnosis  0  I  IA  IB  II  IIA  IIB  III  IIIA  IIIB  IIIC  IV  IVA  IVB  Unknown | | xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x) | xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x) | xx (xx.x)    xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x) |
|  | |  |  |  |
| 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  II | xx (xx.x)  xx (xx.x) | | | xx (xx.x)  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) | Total  (N=xxx) | |
| --- | --- | --- | --- | --- | --- | --- |
|  | |  |  |  |  |
| TNM Stage at Study Entry (M) | |  |  |  |  |
| M0 | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| M1 | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
|  | |  |  |  |  |
| Histologic Grade | |  |  |  |  |
| Well Differentiated | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| Moderately Differentiated | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| Poorly Differentiated | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| Undifferentiated | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| Unknown | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
|  | |  |  |  |  |
| History of Brain Metastasis | |  |  |  |  |
| Yes | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| No | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
|  | |  |  |  |  |
| History of Other Metastasis | |  |  |  |  |
| Yes | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| No | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
|  | |  |  |  |  |
| Location of Metastasis [*in a descending # order*] | |  |  |  |  |
| CNS (brain) | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| Bone | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| Adrenal Glands | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| Lung | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| Liver | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| Pericardium | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| Kidneys | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
| Other | |  | xx (xx.x) | xx (xx.x) | xx (xx.x) |
|  | |  |  |  |  |
|  | |  |  |  |  |
|  | |  |  |  |  |

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  4+ | | | xx (xx.x)  xx (xx.x) | | xx (xx.x)  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  4+ | | | xx (xx.x)  xx (xx.x) | | xx (xx.x)  xx (xx.x) | | | | xx (xx.x)  xx (xx.x) | |
|  | n  Mean  Median  Min. Max  Number of Prior Cancer Chemotherapy  n  Mean  Median  Min, Max | | | xx  xx.x  xx.x  xx, xx  xx  xx.x  xx.x  xx, xx | | xx  xx.x  xx.x  xx, xx  xx  xx.x  xx.x  xx, xx | | | | xx  xx.x  xx.x  xx, xx  xx  xx.x  xx.x  xx, xx | |
|  | Intent of Prior Cancer Chemotherapy Regimens | | |  | |  | | | |  | |
|  | Neo-Adjuvant | | | xx (xx.x) | | xx (xx.x) | | | | | xx (xx.x) |
|  | Local Advanced  Metastatic  Preventive | | | xx (xx.x)  xx (xx.x)  xx (xx.x) | | xx (xx.x)  xx (xx.x)  xx (xx.x) | | | | | 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  Missing | | xx (xx.x)  xx (xx.x) | xx (xx.x)  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  No  Subjects with any prior anti-cancer therapy n (%)  Agent Name 1  Agent Name 2 | | xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x) | xx (xx.x)  xx (xx.x)  xx (xx.x)  xx (xx.x) | | | xx (xx.x)  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*