1.1.1.

1.1.2. Demographic and Baseline Characteristics

Demographics

Demographics including e.g. age, sex, race, ethnicity, height, baseline weight and ECOG PS at screening, and country will be summarized and listed for full analysis set (FAS). This table will be repeated for the Safety Analysis Set if it differs from FAS.

Prior Cancer Therapies

Prior cancer therapy information such as lines of prior regimens, prior treatment type, best response to prior anti-cancer systemic treatment, prior radiation and prior surgery will be summarized and listed for FAS. This table will be repeated for the Safety Analysis Set if it differs from FAS.

Medical History

Medical/surgical history will be coded using the current version Medical Dictionary for Drug Regulatory Activities (MedDRA) at database lock and summarized by system organ class (SOC) and preferred term (PT). This table will be repeated for the Safety Analysis Set if it differs from FAS.

Individual subject listings of the above will be provided for FAS.

Stratification Factors

Cross tabulation between randomization stratification information (obtained from IXRS) and strata derived based on baseline factors collected on eCRFs will be tabulated and listed.

Diagnosis and Extent of Cancer

Summary statistics will be tabulated for diagnosis and extent of cancer for FAS. This analysis may include the following: histological grade, stage at initial diagnosis, stage at study entry, time since initial diagnosis, presence/absence of target and non-target lesions. A listing will also be provided. This table will be repeated for the Safety Analysis Set if it differs from FAS.