

Table 8.12.6i Reason for screen failure for patients not randomized but met eligibility criteria for 68-PSMA-11 scan (PSMA-11 safety analysis set)

	Overall (N=1003) n (%)
Screen failures in patients receiving 68Ga-PSMA-11 ^a , n	39
Reason for screen failure:	
Eligibility criteria not fulfilled	34 (87.2)
Adverse event	2 (5.1)
Withdrew consent (protocol)	1 (2.6)
Progression disease	1 (2.6)
Death	1 (2.6)
Subject lost to follow-up	0
Investigator decision	0
Other	0

^a Patients that received 68Ga-PSMA-11 but not randomized

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Data Cutoff Date: 27JAN2021