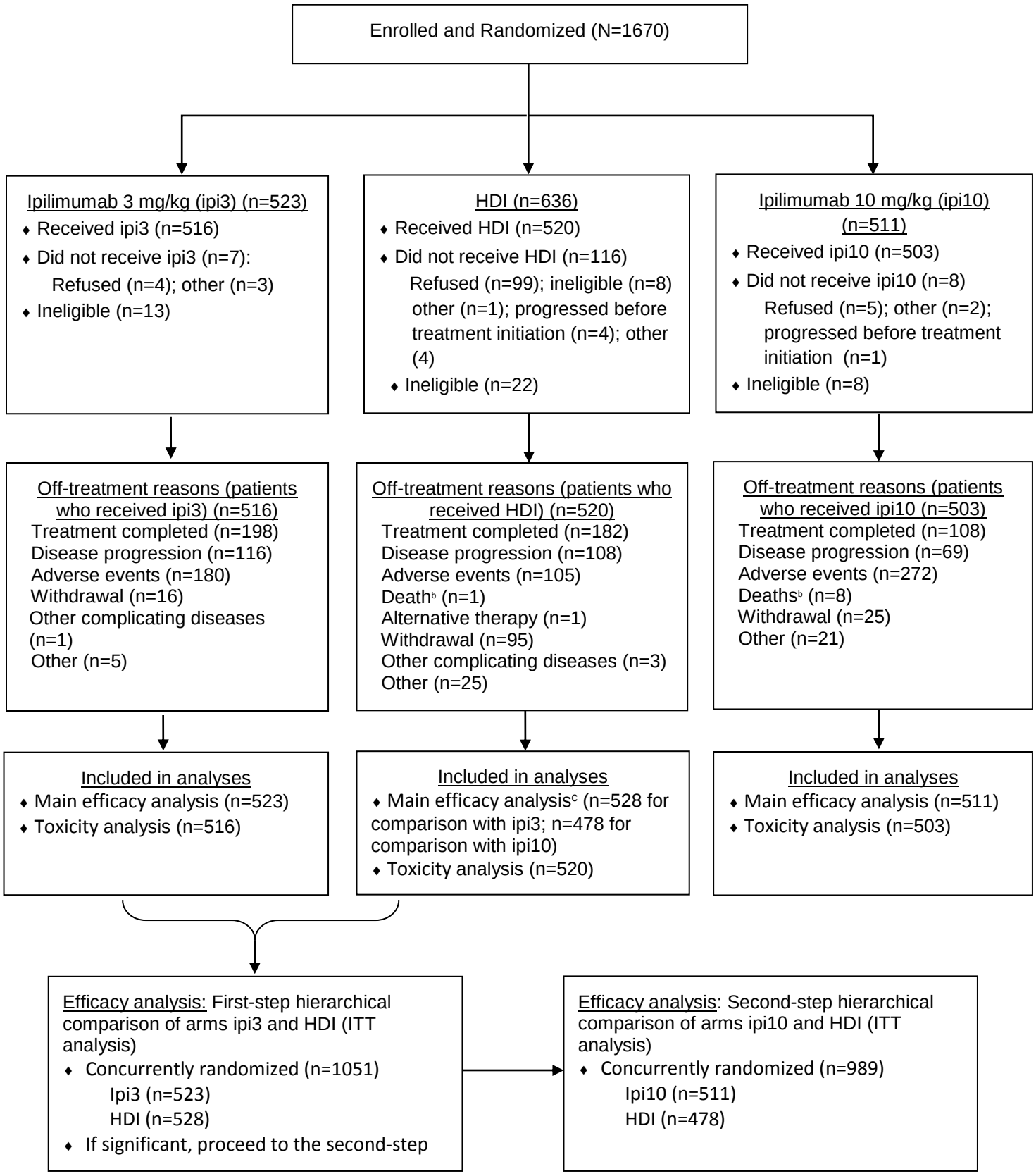
Enrolled and Randomized (N=1670)
Ipilimumab 3 mg/kg (ipi3) (n=523)
Received ipi3 (n=516)
Did not receive ipi3 (n=7):
Refused (n=4); other (n=3)
Ineligible (n=13)
HDI (n=636)
Received HDI (n=520)
Did not receive HDI (n=116)
Refused (n=99); ineligible (n=8) other (n=1); progressed before treatment initiation (n=4); other (4)
Ineligible (n=22)
Ipilimumab 10 mg/kg (ipi10) (n=511)
Received ipi10 (n=503)
Did not receive ipi10 (n=8)
Refused (n=5); other (n=2); progressed before treatment initiation (n=1)
Ineligible (n=8)
Off-treatment reasons (patients who received ipi3) (n=516)
Treatment completed (n=198)
Disease progression (n=116)
Adverse events (n=180)
Withdrawal (n=16)
Other complicating diseases (n=1)
Other (n=5)
Off-treatment reasons (patients who received HDI) (n=520)
Treatment completed (n=182)
Disease progression (n=108)
Adverse events (n=105)
Death[b] (n=1)
Alternative therapy (n=1)
Withdrawal (n=95)
Other complicating diseases (n=3)
Other (n=25)
Off-treatment reasons (patients who received ipi10 (n=503)
Treatment completed (n=108)
Disease progression (n=69)
Adverse events (n=272)
Deaths[b] (n=8)
Withdrawal (n=25)
Other (n=21)
Included in analyses
Main efficacy analysis (n=523)
Toxicity analysis (n=516)
Included in analyses
Main efficacy analysis[c] (n=528 for comparison with ipi3; n=478 for comparison with ipi10)
Toxicity analysis (n=520)
Included in analyses
Main efficacy analysis (n=511)
Toxicity analysis (n=503)
Efficacy analysis: First-step hierarchical comparison of arms ipi3 and HDI (ITT analysis)
Concurrently randomized (n=1051)
Ipi3 (n=523)
HDI (n=528)
If significant, proceed to the second-step
Efficacy analysis: Second-step hierarchical comparison of arms ipi10 and HDI (ITT analysis)
Concurrently randomized (n=989)
Ipi10 (n=511)
HDI (n=478)