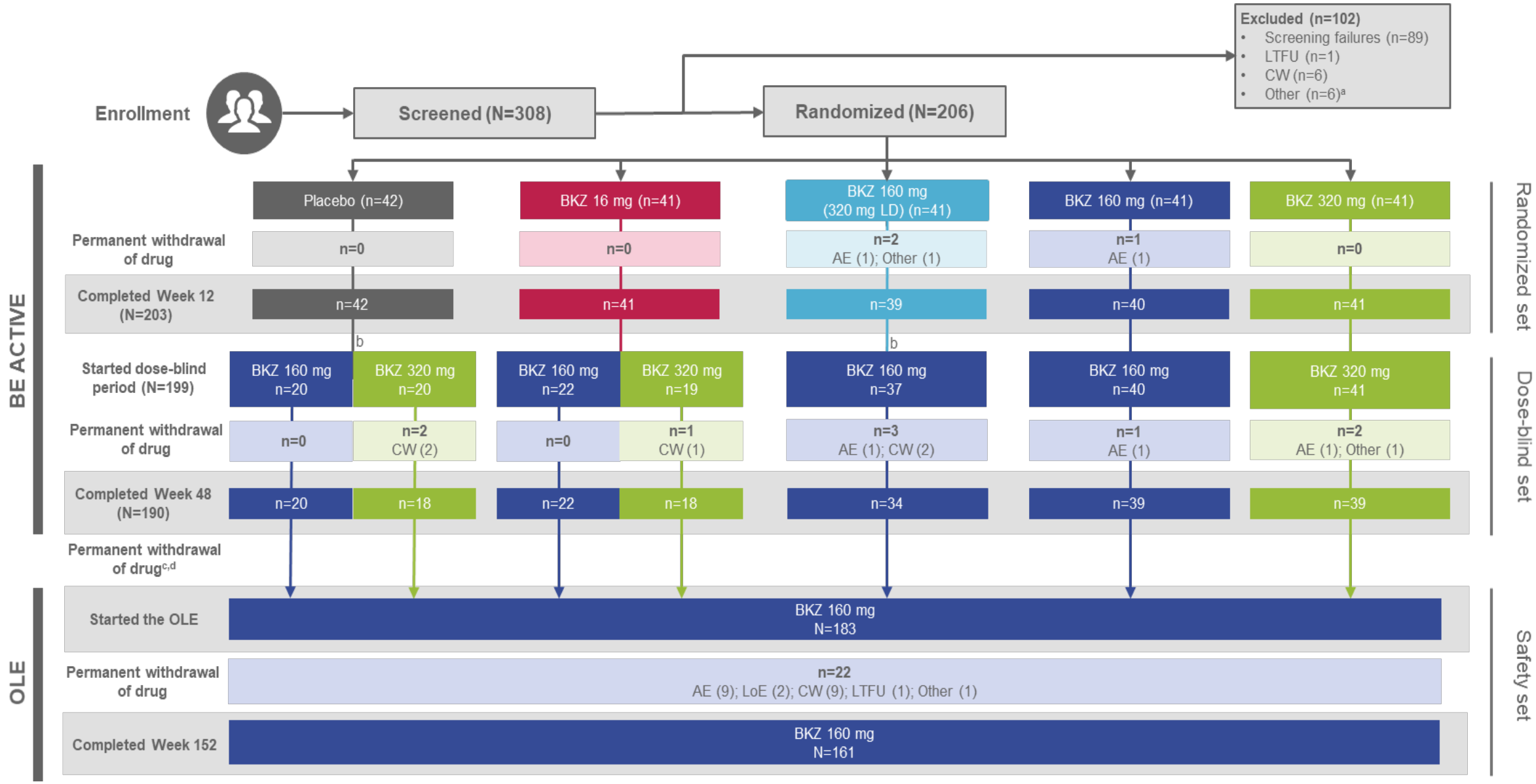
Excluded (n=102)
• Screening failures (n=89)
• LTFU (n=1)
• CW (n=6)
• Other (n=6)a
Enrollment
Screened (N=308)
Randomized (N=206)
BE ACTIVE
Placebo (n=42)
BKZ 16 mg (n=41)
BKZ 160 mg (320 mg LD) (n=41)
BKZ 160 mg (n=41)
BKZ 320 mg (n=41)
Permanent withdrawal of drug
n=0
n=0
n=2 AE (1); Other (1)
n=1 AE (1)
n=0
Completed Week 12 (N=203)
n=42
n=41
n=39
n=40
n=41
b
b
Started dose-blind period (N=199)
BKZ 160 mg n=20
BKZ 320 mg n=20
BKZ 160 mg n=22
BKZ 320 mg n=19
BKZ 160 mg n=37
BKZ 160 mg n=40
BKZ 320 mg n=41
Permanent withdrawal of drug
n=0
n=2 CW (2)
n=0
n=1 CW (1)
n=3 AE (1); CW (2)
n=1 AE (1)
n=2 AE (1); Other (1)
Completed Week 48 (N=190)
n=20
n=18
n=22
n=18
n=34
n=39
n=39
Permanent withdrawal of drugc,d
OLE
Started the OLE
BKZ 160 mg N=183
Permanent withdrawal of drug
n=22 AE (9); LoE (2); CW (9); LTFU (1); Other (1)
Completed Week 152
BKZ 160 mg N=161
Randomized set
Dose-blind set
Safety set