a

Screened
n = 4542

Tofacitinib 5 mg BID
n = 1123

Tofacitinib 10 mg BID
n = 3358

All tofacitinib
n = 4481

Discontinued
n = 639

- Death n = 25
- Did not meet entrance criteria n = 2
- Insufficient clinical response n = 59
- Lost to follow-up n = 31
- Medication error without associated AE n = 0
- No longer willing to participate n = 67
- Other n = 67
- Protocol violation n = 38
- Withdrawn due to pregnancy n = 10
- AE related to study drug n = 178
- AE not related to study drug n = 113

Completed
n = 484

Safety analysis set^a n = 1123
Efficacy analysis set n = 1123

Discontinued^a
n = 1701

- Death n = 30
- Did not meet entrance criteria n = 2
- Insufficient clinical response n = 115
- Lost to follow-up n = 101
- Medication error without associated AE n = 1
- No longer willing to participate n = 211
- Other n = 89
- Protocol violation n = 89
- Withdrawn due to pregnancy n = 8
- AE related to study drug n = 527
- AE not related to study drug n = 248
- Study terminated by sponsor n = 1

Completed
n = 2137

Safety analysis set^a n = 3356^c
Efficacy analysis set n = 3350

Discontinued
n = 2340

- Death n = 55
- Did not meet entrance criteria n = 4
- Insufficient clinical response n = 174
- Lost to follow-up n = 132
- Medication error without associated AE n = 1
- No longer willing to participate n = 484
- Other n = 278
- Protocol violation n = 127
- Withdrawn due to pregnancy n = 18
- AE related to study drug n = 705
- AE not related to study drug n = 361
- Study terminated by sponsor n = 1

Discontinued^a
n = 1701

- Death n = 55
- Did not meet entrance criteria n = 4
- Insufficient clinical response n = 174
- Lost to follow-up n = 132
- Medication error without associated AE n = 1
- No longer willing to participate n = 484
- Other n = 278
- Protocol violation n = 127
- Withdrawn due to pregnancy n = 18
- AE related to study drug n = 705
- AE not related to study drug n = 361
- Study terminated by sponsor n = 1

Study terminated by sponsor n = 1


b

Survival distribution

Months

Tofacitinib 5 mg BID
Tofacitinib 10 mg BID
All tofacitinib