

Enrolled: 7658
Year 1: 3514
Year 2: 4144

Active Safety Set: 3783
(analyzed as treated)
Year 1: 1734
no misdosing
Year 2: 2049
- 1 misdosed w/ placebo
+ 2 placebo misdosed w/ active

Randomized to Active and Treated: 3782
Year 1: 1734
Year 2: 2048

Randomized to Placebo and Treated: 3829
Year 1: 1756
Year 2: 2073

Placebo Safety Set: 3828
(analyzed as treated)
Year 1: 1756
no misdosing
Year 2: 2072
- 2 misdosed w/ active
+ 1 active misdosed w/ placebo

Active Intent to Immunize: 3754
(analyzed as randomized)
Year 1: 1715
- 19 withdrew consent, or no contact post day 21
Year 2: 2039
- 9 withdrew consent, or no contact post Day 21

Placebo Intent to Immunize: 3800
(analyzed as randomized)
Year 1: 1736
- 20 withdrew consent, or no contact post Day 21
Year 2: 2064
- 9 withdrew consent, or no contact post Day 21

Per Protocol Immunogenicity: 1298
Year 1: 891
Year 2: 407

Active Per Protocol: 3714
Year 1: 1703
- 8 prohibited medications
- 3 violated eligibility criteria
- 1 partial dose
Year 2: 2011
- 15 prohibited medications
- 4 violated eligibility criteria
- 8 test article exposed to elevated temperature
- 1 misdosed with placebo

Placebo Per Protocol: 3768
Year 1: 1725
- 9 prohibited medications
- 1 potential unblinding
- 1 case records lost
Year 2: 2043
- 8 prohibited medications
- 2 violated eligibility criteria
- 8 test article exposed to elevated temperature
- 1 case records lost
- 2 misdosed with active

Per Protocol Immunogenicity: 216
Year 1: 136
Year 2: 80