Enrolled: 7658  
Year 1: 3514  
Year 2: 4144

Active Safety Set: 3783  
(analyzed as treated)  
Year 1: 1734  
- 1 misdosed w/ placebo  
+ 2 placebo misdosed w/ active  
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  
- 2 misdosed w/ active  
+ 1 active misdosed w/ placebo  
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

- 8 prohibited medications  
- 9 prohibited medications  
- 2 violated eligibility criteria  
- 2 test article exposed to elevated temperature  
- 2 case records lost  
- 1 case records lost  
- 1 case records lost  
- 2 misdosed with active  
- 2 misdosed with active