

# Observed Mediastinitis Rates

- Control rate  $1/69 = 1.4\%$
- REPEL-CV rate  $4/73 = 5.5\%$
- difference =  $4.1\%$ , 95% CI= $(-3\%, 12\%)$

# Power to detect a difference

- alpha=5%, two-sided, test for superiority
- 80% power
- t-test

Control Rate	Treatment Rate	Total Sample Size
2%	4%	2282
2%	6%	762
2%	8%	412

# Power to demonstrate non-inferiority

- alpha=5%, one-sided
- 80% power
- non-inferiority margin = 4%

Control and Treatment Rate	Non-inferiority margin	Total Sample Size
2%, 2%	4%	414
2%, 2%	6%	218
2%, 2%	8%	140
2%, 2%	10%	102