Statistical Assumptions for TREAT Pilot Roll Out

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Event Rates and Sample Size Assumptions

- Femoral bleeding rates will be roughly 2.5% depending on the study population and the bleeding definition
- Preliminary data would suggest that a decrease of 50+% is plausible
- As is often the case, the maximum feasible sample size is partly determined by non-statistical issues such as budget, number of enrolling sites, equipoise, etc.

Simplified Sample Size Calculation

- In the simplest case, we would be designing a 2-arm RCT with randomization at the patient level
- Suppose we set the allocation ratio to 1:1 and Type I error at 0.05 (two-sided)
- Event Rates: 1.0% for radial vs. 2.5% for femoral
- Testing the hypothesis of equality of proportions in two groups

Simplified Sample Size Calculation

- For 85% power, we would need 1502 patients per group (total N of 3004)
- For 90% power, we would need 1735 patients per group (total N of 3470)
- This study is likely to be observational rather than randomized, so these calculations should be viewed as approximations to be modified depending on the study design
- In a propensity score matched design we would want > 1500 matched pairs of radial with (concurrent) femoral controls

Additional Considerations

- These calculations do not account for missing data or cross-overs
- Low number of expected events: 2000 radial cases would be expected to result in 20 bleeding events
- Clearly subgroups will be underpowered for interaction tests
- If randomized, at what level?
  Patient, interventionalist, site, other
- Clusters may be unwilling to randomize