

NIH StrokeNet Guidance for Managing Competing Trials

Purpose: To provide guidance to StrokeNet Performance Sites (PS) and Satellite Sites (SS) on creating a locally defined process for managing enrollment in competing trials. It is an expectation that StrokeNet PS and SS give enrollment priority to NIH-funded trials.

The StrokeNet Executive and Steering Committees have identified several options that sites can consider when two or more trials may have an overlapping eligible patient population. They are listed in order by what some Regional Coordinating Centers (RCCs) have indicated have worked well. Any are acceptable but each site should indicate which of the following, or another method, is their chosen approach.

Competing Trials Management Options:

1. Rolling Prioritization Enrollment Grid: Trials are placed in order from first to last in which they would be offered to an eligible patient. When an enrollment in one trial occurs, the next trial on the list then assumes the first position. One may decide to place trials with narrower eligibility criteria first.
2. Equal Opportunity Enrollment Grid: Develop a time-based enrollment grid where each trial is given equal opportunity for enrollment. If there are two trials, perhaps one trial is offered first on odd days, and one is offered first on even days.
3. Prioritize Laggards: Put the trial lagging in recruitment at the top of the enrollment grid to maximize recruitment. Once no longer lagging, the order can be modified.
4. Maximize Patient Autonomy: Offer all trials that a patient is eligible for and let them choose. Please note that this approach can be overwhelming to stroke patients and their families and requires very knowledgeable coordinators/investigators with excellent communication skills. This option is more appropriate in the subacute and recovery settings.
5. Minimize Trial Participation: Some sites in an RCC may do just a single trial, avoiding the issue of competing trials altogether and allowing for simpler site management. However, it is the collective experience of StrokeNet that sites tend to improve recruitment when there are more trials due to increased attention on screening. Additionally, participating in more trials allows for more income for research infrastructure (coordinators) which can be an important consideration.

Dual Enrollment in StrokeNet Trials: It may be feasible to enroll one participant into more than one StrokeNet trial. Clinical, statistical and ethical considerations need to be discussed by the each StrokeNet trial Principal Investigator (PI) team. PS and SS should reach out to trial leadership for guidance on whether dual enrollment is allowed for each specific trial.