

October 11, 2007 Meeting of the Circulatory System Devices Advisory Panel

Questions to the Panel

Randomized, controlled trials (RCTs) comparing the safety and effectiveness of carotid artery stenting to carotid endarterectomy in patients who are not at high risk for adverse events from surgical revascularization are ongoing. While it is clear that there are many advantages to the RCT design, enrollment in carotid RCT studies may not result in timely study completion. In addition, it is not clear that an RCT is the only acceptable way to sufficiently evaluate the risks and benefits of carotid artery stenting in this patient population.

Therefore, we are requesting input from the Circulatory System Devices Panel on the design of clinical trials for non-high-risk populations with carotid artery disease.

1. Can acceptable non-RCT trial designs that compare carotid artery stenting to carotid endarterectomy in patients who are not at high risk for adverse events from surgical revascularization be developed? If so, please provide recommendations regarding choice of control, subject eligibility criteria, endpoints, and selection of methodologies for minimizing bias and confounding.
- 2(a) Does sufficient clinical equipoise still exist so that the performance of an RCT to evaluate CAS is scientifically and ethically valid? If so, what are the current barriers to enrollment in RCTs involving carotid revascularization?
- 2(b) What, if any, study parameters can be modified to facilitate enrollment in the RCTs without unduly compromising the validity of the resulting data? Examples of study characteristics that may affect enrollment are subject eligibility criteria, follow-up type and duration, and subject recruitment methods.
3. If the proof of concept of carotid stenting in non-high risk patients is successfully demonstrated, would your study design recommendations change? If so, in what way? For example, would you recommend a non-inferiority RCT comparing two carotid stent systems?
4. What other recommendations do you have that may facilitate initiation, enrollment, completion, and interpretability of clinical trials for this indication?