POINT ANCILLARY BIOMARKERS STUDY SUMMARY

Title:	**Platelet-Oriented Inhibition in New TIA and minor ischemic stroke (POINT) Trial - Ancillary Biomarkers Study**
Objective:	To determine whether clopidogrel resistant genotypes in POINT Trial subjects modify the stroke prevention response in high-risk TIA and minor ischemic stroke patients.
Study design:	A prospective, randomized, double-blind, multicenter trial with the primary null hypothesis that, in patients with TIA or minor ischemic stroke treated with aspirin 50-325 mg/day, there is no difference in the event-free survival at 90 days in those treated with clopidogrel (600 mg loading dose then 75 mg/day) compared to placebo when subjects are randomized within 12 hours of time last known free of new ischemic symptoms. The ancillary study will consent and collect blood specimens from patients who have enrolled in POINT. DNA or DNA and plasma will be extracted for analysis.
Number of centers:	Up to 210 domestic and international investigational sites in partnership with the NINDS Neurological Emergencies Treatment Trials (NETT) Network and the POINT Clinical Research Collaboration (CRC).
Sample size:	Target sample size for the ancillary study is 1,800 subjects.
Patient population:	Patients 18 years of age or older with high-risk TIA (defined as an $ABCD^2$ score $\geq$ 4) or minor ischemic stroke (with NIHSS $\leq$ 3) who can be randomized within 12 hours of time last known free of new ischemic symptoms will be enrolled. Those patients who meet the eligibility criteria and enroll in POINT will be asked to consent to the Ancillary Biomarkers Study.
Inclusion/Exclusion criteria:	Must be enrolled in POINT Trial to be eligible for the ancillary biomarkers study and provide written, dated and signed consent.
Time point:	One-time venous blood sample of approximately 10 mL, collected at the time of enrollment in the trial.
Primary outcome:	Relative risk of vascular outcome events for carriers (of specific ABCB1 and CYP2C19 genotypes) versus non-carriers amongst patients receiving clopidogrel.
Secondary outcome:	A subgroup analysis by the enrolling/index event type (either TIA or minor ischemic stroke) performed separately for the TIA cohort and the minor ischemic stroke cohort.
Study duration for each subject:	One-time blood draw at time of enrollment in the trial; no follow up will be conducted. The ancillary study will be completed in 3 years. The stored samples will be a resource for future studies for 20 years.