Definitions: A "Biomarker" is a "defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how an individual feels, functions, or survives." (Biomarkers, EndpointS and other Tools (BEST) glossary). For the purpose of this table, biomarker "Discovery" includes identification and initial measurement and demonstration that the candidate biomarker is associated with the concept/outcome(s) of interest; "Validation" referrers to studies that seek to demonstrate that an identified biomarker can be reliability and predictably used to indicate the concept/outcomes of interest. "Validation" may refer to analytical or clinical validation (validation of the detection method or validation of the biomarker's clinical utility, respectively).								
Funding opportunities for clinical biomarker discovery and/or validation studies	**Research Project Grants (Parent R01s)**	**Development of Biomarkers and Biomarker Signatures for Neurological and Neuromuscular Disorders**	**Analytical Validation of Candidate Biomarkers for Neurological or Neuromuscular DIsorders (U01, U44)**	**Clinical Validation of Candidate Biomarkers for Neurological or Neuromuscular DIsorders (U01, U44)**	**EPPIC-Net**	**Rare Disease Clinical Trial Readiness**	**NeuroNEXT**	**StrokeNET**
Allows Biomarker Discovery?	Yes	Yes	No	No	No	No	No	No
Disease/Conditions allowed?	Within NINDS Mission	Within NINDS Mission	Within NINDS Mission	Within NINDS Mission	Pain Conditions (all NIH ICs)	Rare Neurological & Neuromuscular Diseases within NINDS Mission	Within NINDS Mission	Stroke
Prior-approval required?	No (unless >$500K DC/yr)	No (unless >$500K DC/yr)	No (unless >$500K DC/yr)*	No (unless >$500K DC/yr)*	Yes	No*	Yes	Yes
Multisite design required?	Not required	Not required	Yes (some exemptions allowed)	Yes (some exemptions allowed)	Yes	Yes	Yes	Yes
Uses existing clinical site infrastructure?	No	No	No	No	Yes	No	Yes	Yes
Allows early feasibility studies (EFS), safety, or efficacy outcomes as primary objective?	not specified	No	No	No	Yes	No	Yes	Yes
Expected end goals?	not specified	Ready for Definitive Analytical or Clinical Validation	Ready for Definitive Clinical Validation	Ready for use in Phase 2 CTs or for FDA Biomarker Qualification Program package	Validated target engagement or therapeutic "proof-of-principle"	Ready for use in specified CT	Ready for use Phase 2 CTs	Ready for use Phase 2 CTs
Milestone driven?	No	Milestones for transition between R61 and R33 Phase	Yes	Yes	Yes	Yes	Yes	Yes
SBIR option?	https://sbir.nih.gov/funding	No	Yes	Yes	Yes	No	Yes	Yes
FOA/Program Contact	Find Your Program Director	Carol Taylor-Burds, PhD	Carol Taylor-Burds, PhD	Carol Taylor-Burds, PhD	Barbara Karp, MD	Glen Nuckolls, PhD	Codrin Lungu, MD	Scott Janis, PhD
Notes:			*Not applicable to SBIRs (U44) - U44 Budget information: Phase 1: up to $700k (TC); Phase 2: up to $3 mil (TC) across 3 years can be requested	*Not applicable to SBIRs (U44) - U44 Budget information: Phase 1: up to $700k (TC); Phase 2: up to $3 mil (TC) across 3 years can be requested		Budgets must be under $650K DC		