## Overview of the Stroke Outcomes and End Points Recommendations

The Outcomes and End Points Subgroup’s recommendations are categorized into seven domains. The following are the list of domains with the corresponding instrument recommendations. Please note that the Pediatric recommendations are grouped as a separate category.

### Neurological Impairment:

National Institutes of Health Stroke Scale (NIHSS)\*

### Activities of Daily Living (ADL)/ Functional Status:

Barthel Index\*;

Functional Independence Measure (FIM);

Glasgow Outcomes Scale (GOS) and Glasgow Outcomes Scale Extended (GOS-E)

Modified Rankin Scale (mRS)\*

Quality of Life in Neurological Disorders (Neuro-QOL) - Adult Mobility, Adult Upper Extremities, and Adult Assistive Devices Item Banks^;

National Institutes of Health (NIH) Toolbox^;

Post Acute Care Admission Continuity Assessment Record and Evaluation (PAC Admission CARE) Tool^;

PROMIS Physical Function^

### Emotional and Cognitive Status:

* + - Short Battery- Center for Epidemiologic Studies Depression Scale (CES-D)\*; Montreal Cognitive Assessment (MoCA)\*; Trail Making Test Parts A&B\*
		- Long Battery- Short Battery plus: Digit Symbol subtest (WAIS-III); Symbol Search subtest (WAIS-III); Stroop Test; Hopkins Verbal Learning Test – Revised (HVLT-R); Rey-Osterrieth Complex Figure Copy and Delay; Controlled Oral Word Association Test (COWAT); Boston Naming Test (BNT) 30-item version and Recognition; Informant Questionnaire for Cognitive Decline in the Elderly (IQCODE); Neuropsychiatric Inventory (NPI)
		- Additional Instruments- Telephone Interview for Cognitive Status (TICS)

### Participation/Quality of Life:

EuroQOL (EQ-5D)\*; Short Form 36 Health Survey (SF-36); Stroke Impact Scale (SIS); Stroke Specific Quality of Life Scale (SS-QOL)

### Performance Measures:

Canadian Occupational Performance Measure (COPM); Walking Speed\*

### Clinical Event End Points:

 Stroke Adjudication Worksheet; Questionnaire for Verifying Stroke-Free Status (QVSFS); Artherosclerosis Risk in Communities (ARIC) TIA/Stroke Form

### Pediatric:

Bayley Scales of Infant Development (BSID); King’s Outcome Scale for Childhood Head Injury (KOSCHI); National Institutes of Health Stroke Scale (NIHSS)^; Perceived Efficacy and Goal Setting System (PEGS); Pediatric Stroke Outcomes Measure (PSOM)\*

*\*Proposed “Core/Primary” instrument*

*^ Recommended “Exploratory” instrument – Instrument requires validation but may fill gaps in currently validated instruments and/or substitute for recommended instruments once validation is complete.*

These recommendations are also presented in the table on the following page.

Table Representing the Outcomes and End Points Subgroup’s Recommendations

| Intentionally left blank | Neurological Impairment | ADL/ Functional Status | Emotional and Cognitive Status | Participation/ QOL | Performance | Clinical Event End Points | Pediatric |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Core/ Primary: | \* NIHSS  | \* Barthel Index\* mRS  | \* CES-D\* MoCA \* Trail Making A&B  | \* EuroQOL  |  \*Walking Speed |  Intentionally left blank | \* PSOM  |
| Supplemental/Secondary: |  Intentionally left blank | \* FIM\* GOS and GOS-E  | \*Digit Symbol\* Symbol Search \*Stroop Test\* HVLT-R\* Rey-Osterrieth Complex Figure\* COWAT\* BNT\* IQCODE\* NPI\* TICS | \* SF-36\* Stroke Impact Scale\* Stroke Specific QOL | \* COPM | \*REGARDS Stroke Adjudication Form\* QVSFS\* ARIC TIA/Stroke Form | \* BSID\* KOSCHI\* PEGS  |
| Exploratory/ Future: |  Intentionally left blank | \* Neuro-QOL (3 item banks)\* NIH Toolbox \* PAC Admission CARE Tool\* PROMIS (Physical Function)  |  Intentionally left blank |  Intentionally left blank |  Intentionally left blank |  Intentionally left blank | \* NIHSS  |

### Timing **of Outcome Assessments**

Acute stroke studies intended to demonstrate durable clinical benefit should assess outcome using a clinically meaningful measure of stroke disability at 90 days. Evaluation of clinical outcomes beyond 90 days is encouraged. Sub-acute or chronic stroke studies should demonstrate durable clinical benefit by evaluation at six month to one year follow-ups.