SCOPE OF WORK 2020-3

THE VALUE OF BIOMARKERS FOR SCI CLINICAL TRIALS

1. Introduction/Background

One of the greatest risks in undertaking the evaluation of a neuroprotective intervention for acute Spinal Cord Injury (SCI) is the inability to recruit enough acute SCI patients, in a timely manner, to address the research question. High variability in spontaneous neurologic recovery in acute SCI patients requires large numbers of patients to detect a therapeutic effect.

- Precision of early physical exams (International Standards for Neurological Classification of SCI or ISNCSCI) has been questioned
- The ability to complete an ISNCSCI immediately after injury can be challenging and may not be valid due to issues such as drug and alcohol use, other injuries (e.g. head trauma) and language barriers
- Variability within each AIS grade – AIS grade have heterogeneity and variable spontaneous recovery – not all AIS Bs are the same

2. Economics Research Questions

What is the value of biomarkers in spinal cord injury?

Cost/savings/benefits considerations

a) If the biomarkers increase available participants for a clinical trial, what are the cost/savings/ benefits?
b) If the biomarkers allow for a reduction in sample sizes for a trial, what are the cost/ savings/ benefits?
c) How much would a study cost as a result of using biomarkers?
d) How much does it cost to 'run' the biomarker analysis?

3. Population, Setting, Intervention and Control/Comparison Group

Possible data sources for questions a) and b) above:

- Data from previous CAMPER study
  - Biomarker expression
  - ISNCSCI – level and severity and motor score
  - Change in motor score/AIS conversion
- Data from RHSCIR and published literature
  - Estimate number or % not able to have neurologic exam that are being excluded from trials

Biomarker costing analysis for questions c) and d) above:

- Can be done retrospectively with what we know about biomarkers from previous CAMPER study and applying to previous trials.
- Considerations for the prospective collection of any data needed to conduct future health economic analysis.

4. Outcomes

Praxis is requesting a prospective analysis (forecast).

5. Time Frame and Budget

Study activities are planned in 2020/21. The table below shows the proposed tasks/activities. All project deliverables will be provided to Praxis in English.

The budget for this analysis is CDN $9,000 to $18,000.

	Schedule
TASKS	**TBD**
Request Proposals/Review/Select and Set Up Contract	
Start Up Meeting/Confirm Scope of Work	
Develop Analysis Plan	
Conduct Analyses	
Summarize Results	
Draft/Final Report	