Clinical Outcome Assessments (COA) Qualification Program
pDDT COA #2019-01: PostopQRS
Letter of Intent

Administrative Structure:

Description of the submitter including, but not limited to, principal investigator(s), working group member(s), institutions, and contact information not contained within the cover letter.

Postoperative Quality of Recovery Scale (PostopQRS™) originated in cross university collaboration and has now been spun out as a company (PostopQRS Ltd) and incorporated in England and Wales.
It has three Executive Directors:
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Two advisors to the Board:
Mr Alex Denoon, Lawyer, Partner. (Regulatory, IP and Commercial)
Mr Tony Dolan, Vice President of IP (Medical Devices, IP and Commercial)
It has a Scientific Advisors who work in the field and are consulted on an ad hoc basis.

Concept(s) of Interest (COI) for Meaningful Treatment Benefit:

A description of the meaningful aspect of patient experience that will represent the intended benefit of treatment (e.g., presence/severity of symptoms, limitations in performance of daily activities).

The Postoperative Quality of Recovery Scale (PostopQRS™) is a generic digital health assessment tool that captures in a comprehensive fashion the extent of recovery of patients from all forms of surgery and anaesthesia. It covers both clinician-reported data and patient-reported information to capture the recovery in detail from the patient's perspective as well as the clinician perspective soon after surgery and. Areas include pain, nausea, mood, cognition, activities of daily living and overall satisfaction with

surgery and anaesthesia. It is a tool that can track patients from immediately after surgery through to their long-term recovery when they have returned home as it is standardised to be used over the telephone at late stage recovery. In this way it can measure generic as well as specific areas of patient recovery from surgery and anaesthesia. Assessment of recovery in real time can provide feedback to the patient about their progress, thereby helping to engage them in their own recovery journey; and provides early warning of poor recovery to the treating health care team, allowing opportunity for therapeutic intervention.

Provide a conceptual framework for the COA(s).

Patient recovery from surgery and anaesthesia is multifactorial where in the early stages some emphasis is placed on physiological measures such as temperature and heart rate and pain management. Prior to discharge focus include patients' symptoms, ambulatory state as well as their cognitive abilities. Late stage recovery include those assessed at prior to discharge as well as activities of daily living. PostopQRS™ covers all these stages of recovery.

COU for COA Qualification:

Targeted study population including a definition of the disease and selection criteria for clinical trials (e.g., baseline symptom severity, patient demographics, comorbidities, language/culture groups)

PostopQRS™ is a generic tool and is applicable to all patients, whether day surgery or in hospital surgery, having elective surgery. The key criteria is that the prospective patient is able to have a pre-surgery assessment. This makes the tool not applicable to emergency cases. Other exclusions include major co-existing psychiatric disease or other conditions making it not possible to record patient responses.

It has been used with many forms of surgery including Orthopaedic, ENT cardiac surgery, general surgery, gynaecological and urological surgery and endoscopy such as colonoscopy and gastroscopy.

Criteria for clinical trials (e.g., baseline symptom severity, patient demographics,

At baseline patients need to be able to respond verbally to questions asked. PostopQRS™ can and has been used with patients of all ages from 6 to years old to elderly patients and has been translated into numerous languages.

***Targeted study design and statistical analysis plan (includes the role of the planned COA in future drug development clinical trials, including the planned set of primary and secondary endpoints with hierarchy, if appropriate*)**

PostopQRS™ provides an overall score for recovery which is most suited as a Primary outcome. Secondary Outcomes include the subdomains of the PostopQRS™ physiologic, nociceptive, functional, cognitive, emotional recovery domains assessed as well as overall patient perspective of their surgery and anaesthesia.

The patients act as their own control using a repeated measures design with the pre-surgery surgery being the reference to assess full recovery. Rates of recovery can also be assessed by examining the slope of change on the full score as well as the domain scores.

Applicable study settings for future clinical trials

- ***Geographic location with language/culture groups***

PostopQRS™ has been translated from English, French, German, Spanish (USA), Portuguese, Mandarin, Japanese, Greek, Arabic, Malaysian and Korean. It has been used and is applicable in all geographic locations.

- ***Other study setting specifics (e.g., inpatient versus outpatient)***

PostopQRS™ is of use to both in and outpatients undergoing elective surgery or investigations.

<u>COA Type:</u> Patient-Reported Outcome, Performance Outcome, Clinician Reported Outcome (PRO, PerfO, ClinRO)