

# Developing and validating a pituitary-specific, patient reported outcome measure across the United Kingdom and Ireland



## Patient-Reported Outcome Measures in Endonasal Skull base Surgery (PROMESS)— Prospective Multi Centre Validation Study

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### BACKGROUND

- Pituitary adenomas are common benign brain tumors that **impact quality of life (QoL)** through ophthalmic and endocrine sequelae.
- Transsphenoidal surgery is the primary treatment for large non-functioning and select functioning adenomas.
- No specific **Patient Reported Outcome Measure (PROM)** exists for QoL changes after pituitary surgery.
- The **Pituitary Outcome Score (POS)** was developed to assess overall, ophthalmic, endocrine, and nasal QoL.
- This study aims to:
  - 1) Validate POS in the UK and Ireland.
  - 2). Assess factors influencing POS changes, including:
    - Surgical approach & skull base repair
    - Complications (e.g., CSF rhinorrhoea)
    - Endocrine outcomes (e.g., remission)

### PRELIMINARY RESULTS

- **Number of recruiting centres:** 8
- **Total participants enrolled:** 92 (52% Male)
- **Baseline participant demographics:**
  - 32% visually impaired, 0% blind
  - 58% Non-functioning, 15% Acromegaly, 14% Cushing's, 4% Prolactinoma, 3% TSHoma
  - 84% Macroadenoma
  - 29% glucocorticoid dependent, 4% DDAVP dependent
  - 16% Previously undergone surgery
- **Operative details:**
  - 96% transsphenoidal approach, 4% extended transsphenoidal approach
  - 5% involved an ear nose and throat surgeon
- **Inpatient complications**
  - 1 CSF leak, treated by lumbar drainage, 0% mortality
  - 21% hyponatraemia, 7% hypernatraemia
  - 61% discharged on glucocorticoids, 5% discharged on DDAVP,

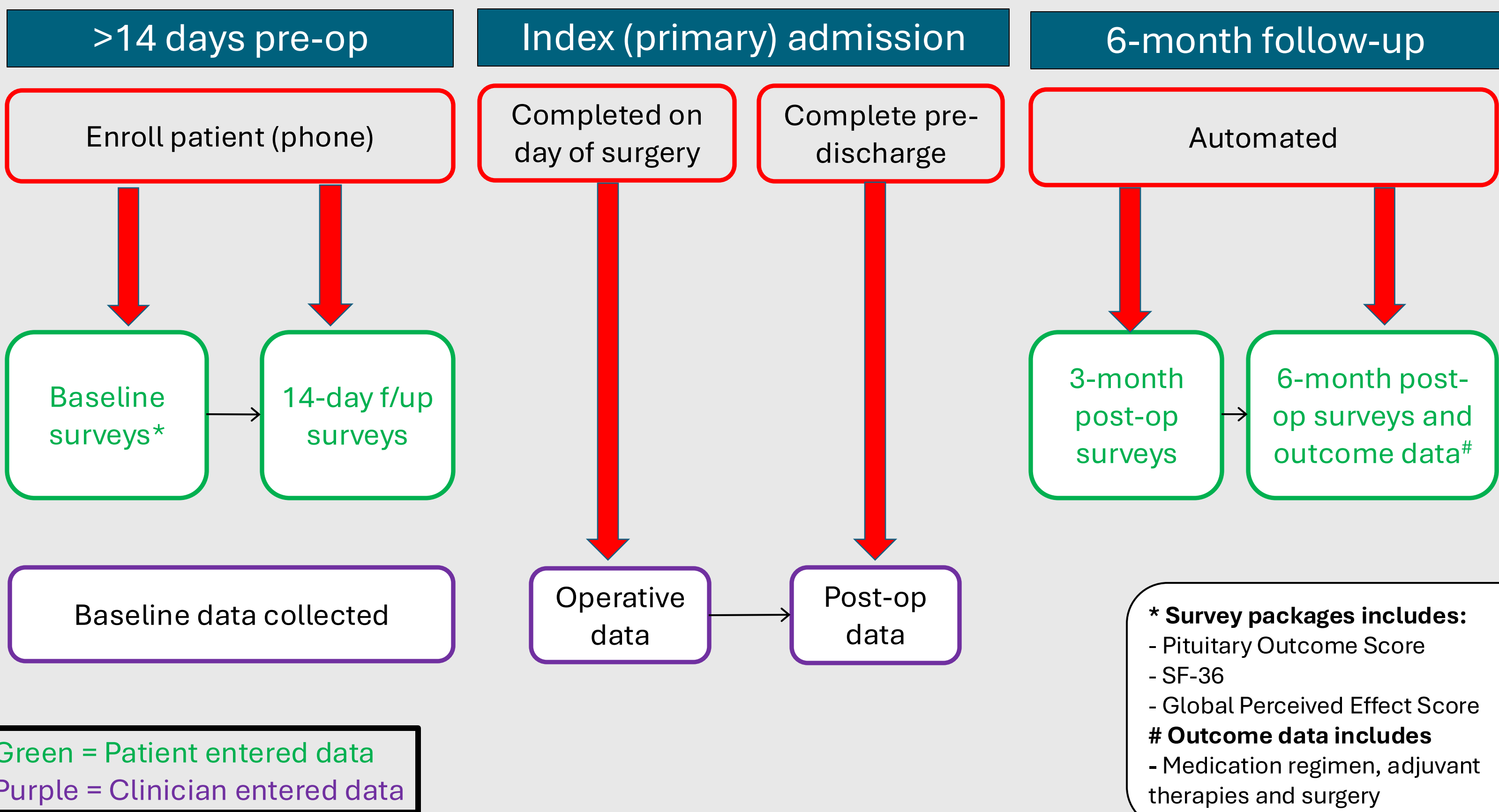
**Methodological learnings:**

- Collaborative research models power the validation of PROMS through enablement of socio-demographic heterogeneity
- Patients are motivated to inform the development of patient centered outcome measures
- Involvement of neurosurgery, endocrinology, ophthalmology, and patients has been key to establishing robust questionnaire construct validity.

### METHODS

- **Design:** Two-phase prospective study. Pilot phase at tertiary neurosurgical unit. Multi-centre phase across UK and Ireland
- **Sample & Data Collection:**
  - Patient demographics, tumour characteristics, operative details, inpatient and six-month outcomes.
  - POS, SF36, and GPE surveys at four time points: twice pre-op, 3 month post-op and 6 month post-op
- **Analysis:**
  - Descriptive: Patient/tumour characteristics, operative details, inpatient complications, outcomes.
  - POS validation: 1) Reliability 2) Validity 3) Responsiveness
  - Comparative: QoL outcomes vs. surgical approach, repair methods, complications, resection extent, endocrine outcomes.

### WORKFLOW



View the Pituitary Outcome Score

