# Protocol safety and efficacy assessment template - Clinical trial application

PSEAT-CTA v3.0

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| 1. Introduction | | |
| **A. Summary of product information** | | |
| Proprietary name of drug product: | | |
| Non-proprietary or common name of drug substance: | | |
| Sponsor: | | |
| Dosage form(s): | | |
| Strength(s): | | |
| Route of administration: | | |
| Proposed indication(s): | | |
| **B. Investigator’s brochure (if applicable)** | | |
| Date: | version/edition number: | |
| Cut-off date for data included in this version/edition of the investigator’s brochure: | | |
| **C. Contact information** | | |
| Contact person/name: | | |
| Telephone: | | Fax: |
| Email address: | | |
| 2. Protocol summary | | |
| Trial Title and Protocol Number/Code: | | |
| Background and Rationale: | | |
| Trial Objectives: | | |
| Study Design and Duration: | | |
| Total Number of Sites and Number of Canadian Sites: | | |
| List of Investigators: | | |
| Sample Size: | | |
| Patient Population: | | |
| Inclusion Criteria: | | |
| Exclusion Criteria: | | |
| Drug Formulation: | | |
| Dosage Regimen: | | |
| Washout Period: | | |
| Pre-study Screening and Baseline Evaluation: | | |
| Treatment / Assessment Visits: | | |
| Concomitant Medication: | | |
| Rescue Medication & Risk Management: | | |
| Premature Withdrawal / Discontinuation Criteria: | | |
| Efficacy Variables and Analysis: | | |
| Safety Variables and Analysis: | | |
| Statistical Analysis: | | |