# 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: |