# Clinical Data Checklist

**Drug Product Name:**

**Manufacturer:**

Please answer each of the questions below and provide references for the responses, including the name of the document(s) in the submission from which the answer came and the relevant page number(s).

## Drug Product

1. What is the pharmacological mechanism of the drug?
2. What are the drug's Health Canada approved indications?
3. What is the recommended dose range and duration of therapy? (Please include relevant patient populations - e.g., the elderly)
4. What Formulary/CDI listing status is proposed by the manufacturer?

## Clinical Evidence

1. What are the conclusions of randomized controlled trials supporting the <u>efficacy</u> (i.e., when used under optimal circumstances) of the product?  Are trials published in peer-reviewed journals?

2. What are the key comparators for this drug product? Which ones are listed in the Formulary/CDI?

3. What are the results of randomized trials comparing the product to listed alternatives on the Formulary/CDI? Are there randomized trials comparing the product to the least costly and most widely used alternative products listed in the Formulary/CDI?

Ontario

4. What are the conclusions of randomized controlled trials supporting the <u>effectiveness</u> (i.e., when used under usual, real world circumstances) of the product? Are trials published in peer-reviewed journals?

5. Do the randomized trials use the most clinically relevant outcome measures, or do they use the surrogate outcomes requiring extrapolation to the relevant outcome? Are the end-point(s) sufficiently justified?

6. Were any clinical studies conducted in the elderly, women and children? If not, why not?

7. Were any of the clinical trials conducted in Canada?

8. Are there ongoing trials that would provide additional information on the product?

9. What are the contraindications for the product?

10. What are the side effects of the drug product?

11. Are there particular safety issues of concern to recipients of the ODB program (e.g., safety in the elderly, women and children)?

12. If the product contains a combination of drugs, is there a pharmacologic and pharmacokinetic rationale for the combination? Specifically, does each component of the combination make a contribution to the claimed effect(s)? Is the dose of each component appropriate for the elderly and/or children? Is the effect of either component modified (synergistically or antagonistically) by the addition of the other component?

Ontario

**Drug Utilization**

1. What are the Health Canada approved patient population group(s) for the drug?

2. Will clinicians be able to easily and precisely determine which patients should be treated with this drug? Please explain.

3. Are there other clinical uses or trials for non-approved Health Canada indications?

4. Is it likely that clinicians will expand the use of the product for conditions not approved by Health Canada? If not, what is the evidence to support this position?

5. What is the projected number of patients in Ontario covered by ODB who will use the product in a year?

6. Are there utilization data for the drug product in other jurisdictions? If so, please discuss the possible utilization impact for ODB.

Ontario