

External Submission Format

Evaluation document or files submitted by external stakeholders should include the below documents and follow the below sequence;

1. Executive Summary: Therapeutic and Pharmacoeconomic Value of the Intervention
 - 1.1. Therapeutic benefits
 - 1.2. Pharmacoeconomic Benefits
 - 1.3. Summary
2. Description of Intervention and Target Disease
 - 2.1. Description of Intervention
 - 2.2. Placement of Intervention in Therapy of Target Disease
 - 2.2.1. Target Disease Description
 - 2.2.2. Treatment Approach
 - 2.2.3. Society Clinical guideline supporting their role in the indication (National and International)
3. Supporting Clinical Evidence
 - 3.1. Summary of Key Clinical Studies
 - 3.1.1. All Relevant Support Data for Labelled Indications with a copy of published evidence
 - 3.1.2. All Relevant Support Data for Off-Label Indications with a copy of published evidence
 - 3.1.3. Clinical Evidence Spreadsheet
 - 3.1.4. Non company sponsored supporting evidence
 - 3.1.5. Secondary Source Evidence Summary
4. Pharmacoeconomic Value Report
 - 4.1. Model Overview
 - 4.1.1. Modeling for Decision Making
 - 4.1.2. Model Types
 - 4.1.3. Additional Details
 - 4.2. Modeling Methodology and Rationale
 - 4.2.1. Rationale and Framework
 - Guidelines
 - Analysis Framework
 - Modeling Methodology
 - Payer Perspective and Timeframe
 - 4.2.2. Data Sources
 - Effectiveness & Efficacy
 - Expert Opinion
 - Safety Data
 - Economic Data
 - Utilities
 - Surrogate Markers
 - Expected Demographics and Projected Practice Pattern
 - 4.2.3. Analysis
 - 4.3. Interactive Modelling and Modeling Report

- 4.3.1. Transparency Statement
- 4.3.2. Reporting Format
- 4.3.3. Interactive Model
- 4.4. Other Supporting Evidence
 - 4.4.1. SFDA registration certificate
 - 4.4.2. Saudi Arabia and non-Saudi Arabia reimbursement status
 - 4.4.3. Pricing
 - 4.4.4. Others
- 4.5. Supporting Data (References, Appendices, Models Etc.)

For further clarification to the file specification kindly IDF IDF@chi.gov.sa