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NOTICE

Release of Protocol Safety and Efficacy Assessment Template-Clinical Trial Application (PSEAT-CTA)

Our file number: 08-101654-925

The final version of the Therapeutic Products Directorate (TPD) and Biologic and Genetic Therapies Directorate (BGTD) *Protocol Safety and Efficacy Assessment Template-Clinical Trial Application (PSEAT-CTA)* is now available. Comments and suggestions received from the consultation on the draft version of the template, then referred to as the Pharmaceutical Safety and Efficacy Assessment Template (PSEAT), were reviewed and considered in the finalization of this document. The effective date for this document is April 1, 2008

The PSEAT-CTA is used by the clinical reviewer during the review process in order to create the final evaluation report. Therefore, the intent is for the PSEAT-CTA to be a brief document that is akin to a protocol synopsis and must be fully editable. In addition, while the PSEAT-CTA is used in conjunction with the protocol, it should not be used to replace the protocol.

The final template provides guidance to sponsors on how to complete the PSEAT-CTA and takes into account the comments received from stakeholders. In particular, the following key revisions were made:

- Guidance notes have been included that provide the requirements for each section;
- The PSEAT-CTA only has information that is required to be completed by the sponsor; and
- Additional guidance related to ‘new’ sections that were not part of the former template (i.e. the Preclinical and Clinical Evaluation Report Template (PCERT)) is also provided.

The proposed PSEAT-CTA for amendments has been removed. However, sponsors are requested to include the following information in the cover-letter that accompanies the amendment, if applicable:

- The date and version number of the current IB; and
- The cut-off date for the data included in this version of the IB.

The PSEAT-CTA will replace the Pre-clinical and Clinical Evaluation Report Template (PCERT), Protocol Synopsis & Evaluation module of the PCERT, and the Manufacturer’s Brief Summary. **Therefore, applicants are invited to use these templates immediately instead of the PCERT.**

The templates are available in both Corel® WordPerfect and Microsoft® Word, and sponsors may submit completed templates in either format.

Comments or questions related to this template may be directed to:

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