



Be Ready...


A Pilot Program to Provide Changes in Updated Package Inserts

Be ready for a Pilot Program from DAIDS, DAIDS RSC and HANC to help clinical research sites identify changes in updated Package Inserts (PIs). The program will begin on February 1, 2012, and will continue for a 3-month period. The DAIDS RSC will contact the pharmaceutical company to provide the changes. When the document is not available from the pharmaceutical company the DAIDS RSC will prepare a document of the changes as noted below in item #2.

1. Goals of the Pilot Program

- Provide PI changes in an easy to read and informative way
- Notify clinical sites of PI changes by sending a PDF attachment by e-mail notification
- Pinpoint where changes have been made to PIs in the PDF document
- Encourage feedback on the usefulness of this Pilot Program

2. Format of Identified Changes

- **Inserted** text is underlined.
- **Replaced** text (text was deleted and text was added) is **highlighted**. Replacements are also annotated with a number that corresponds with a note on the comment list in the PDF document.
- **Deleted** text is indicated with a . The number corresponds with a comment on the comment list in the PDF document.

NOTE: This document is intended for use as a tool to assist clinical sites in evaluating changes between the current version and prior version of the PI. The most recently approved PI, rather than this document, should be referred to when making any healthcare decisions, and primary investigators and other clinical site healthcare providers (not DAIDS/DAIDS RSC) continue to be responsible for having up-to-date knowledge of the approved PIs for therapies that they administer.

3. How to Provide Feedback

- During this Pilot Program, please send any comments, suggestions, or questions to the DAIDS RSC Safety Information Center at RIC@tech-res.com.
- Clinical research sites can also do their own comparisons between two versions of PIs by referring to the following website:

http://help.adobe.com/en_US/Acrobat/9.0/Professional/WS09D04D24-A9FA-416b-9FBC-6188AC2160FF.w.html