Nonclinical Working Group Industry Discussion Group

Project Overview

Welcome to the Nonclinical Project - Industry Discussion Group

In 2014, this group was created to collaborate across pharma and partner industries to promote our common interest relating to nonclinical standardized data and to communicate with FDA in a collective manner as experts in the field. This page was set up to collect comments regarding the FDA Draft Guidance documents related to electronic submissions of non-clinical data. This team will re-convene as needed in the future for similar needs.

The documents reviewed in 2014 were the following:

Providing Submissions in Electronic Format -- Standardized Study Data (PDF - 231KB)

Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act (PDF - 176KB)

Study Data Technical Conformance Guide

As Nonclinical project members we had unique insights, experience and knowledge in the submission of standardized study data. We used this page to share our thoughts and comments regarding the draft FDA guidance and to engage in discussions that highlight areas were these documents can be improved. From this we brought forward significant comments that were submitted to FDA, on behalf of the discussion group, for consideration as changes to the draft guidance documents.

In addition to this page the group held several web conferences to collect input and formulate our comments. This page was updated regularly with the output from those conferences. If you have not already received an invitation and would like to participate in these web conferences, please email *gerard.randolph@roche.com*.

The deadline for public comment was May 07, 2104. Any entries to this page after May 02, 2014 may not be included in the comments submitted to FDA. Comments were submitted on behalf of the CSS Nonclinical Working Group - Industry Discussion Group at regulations.gov

Comments submitted by this discussion group were not attributed to any individual or corporation. Participation in this group did not preclude participants from submitting comments separately on their own behalf or the behalf of their employers.

This discussion group is open to **all industry members** of the CSS, FDA members are not permitted to participate in the public comments.