



AHWP TC WG 02 Proposed Working Plan

1. Maintenance of SADS
2. Propose harmonized Post-market Surveillance and Vigilance Requirements
3. Develop Safety Alert Assessment Guideline for Regulatory Authorities

New Items

1. Prepare PMS Harmonization Chart
2. Propose harmonized ADR reporting form
3. Develop PMS trainings tools



2007 2008 **2009** 2010 2011 **2012**




WG02

Review AHWP members current Requirements on Post-market Surveillance

Develop a simple alert system for exchange of high risk reports between regulatory authorities (SADS)

Propose harmonized post-market surveillance and vigilance definitions and requirements

Develop Safety Alert Assessment Guideline for Regulatory Authorities

-  Preparation
-  Intense
-  Maintenance