Work Group 2

Post-Market Surveillance and Vigilance

Work Plan 2012-14 Update

16th AHWPTC Meeting

Nov 2, 2012

WG2 – Post Market Surveillance

Chair: Yorkie Chow

Co-Chair: Kulwant S Saini

Senior Advisor: Jorge Garcia

Update

- No. of WG members:
  - Need to update the AHWP website (40+ members)
  - New Members
    - **Jackeline Chan, Jeneva Tang, Carrie Li, Jocelyn Yen**
  - New Membership list (20+ members)

- Progress update since Manila Meeting
  - Organized 3 telecons among members (June, July September)
  - Separately 3 between chair and co-chair (June, October x2).

Status of Previous WG Items

No.	Previous Work Item	Status
1	No open item	All previous items closed
2		
3		
4		

Number of documents/forms on the AHWP website

- SADS
- FSCA
- AE

Work Plan 2012 – 2014 : Update

Work Item *Output*	Status
Harmonized definitions PMS Terms i.e. AE, PMS etc, (N 54) ***Guidance document***	•**Guidance Doc : Definition & Classification of Field Corrective Actions** •**Carrie Li + Terrenz Leung**: Project Leaders •Review of the GHTF docs : Completed •Review of the draft by Chair/Co-chair : Completed •Circulate to WG2 members, feedback : Completed •Finalization of the DRAFT document : Completed •Finalization of document : Annual AHWP Meeting 2012
Electronic AE reporting forms in Acrobat ***Electronic System***	•**Guidance Doc: Adverse Event Reporting Form** •**Geneva Tang** : Project Leader •Review the current document: Completed •Review by chair/Co-chair : Completed •Circulate to the WG2 members, feedback : Completed •Finalization of the DRAFT document : Completed •Finalization of Proposed/Proposed Final document : Annual AHWP Meeting 2012. •Electronic form will be available by end 2012.
Implement adoption AE & FSCA forms across AHWP member economies. ***Adoption***	•AE form has been reviewed and to be finalized (Nov 2012) •WG Chair to work with TC Chair to promote the use of the AE form by member economies.

Work Plan 2012 – 2014 : Update

Work Item *Output*	Status
Upgrade the SADS secretariat (Attach with WG02 Chair) ***Secure SADS system***	•WG2 Chair/AHWP Secretariat discussions •Secretariat confirmed : 1. Encryption of the document with password protection or 2. Set up an ID and password for each regulator • Finally decided to go for option 2 • Trial version to be ready by end 2012
Develop AE reporting requirements and Timelines for all stakeholders Mfgrers, HCPs, Distributors ***Guidance Document***	Review GHTF documents Gap assessment Adoption/Acceptance Draft in progress / Group discussion in Nov 2012
Adopt new GHTF FSCA guidance documentation ***Guidance Document***	Review GHTF/IMDRF document Gap assessment Adoption/Acceptance Mid 2013

Work Plan 2012 – 2014 : Update

Work Item ***Output***	**Status**
Developing Guidance Doc for proper disposal of MDs ***Guidance Document***	Gap analysis Review/update/adopt. End 2013
Formal training of SG02 /WG2 guidance document ***Awareness, Implementation***	•Training needs finalized : May 2012 •Training for the software validation (US FDA) •Training on PMS, laying the roadmap (GHTF SG 2) •Training on WG2 output implementation on AE/FSCA (WG6, WG2, IT) •Communicated to WG6 : May 2012

Thank you

Proposed /Final docs

- Proposed docs
- SG2(PD)/N111R9 Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non Safety related Field Corrective Actions [Word] [PDF] 19 December 2011 19 April 2012 Isabelle Demade
- SG2&5(PD1)/N05R10 Reportable Events During Pre-Market Clinical Investigations [Word] [PDF] 10 June 2011 10 December 2011 Greg LeBlanc
- Final docs
- SG2/N38R19
  PDF Word Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program 16 September 2009 9 pages Isabelle Demade
- SG2-N79R11:2009
  PDF Word Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form 17 July 2009 13 pages
- SG2-N54R8:2006
  PDF Word Medical DevicesPost Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices 18 December 2006 37 pages Isabelle Demade
- SG2-N57R8:2006
  PDF Word Medical Devices Post Market Surveillance: Content of Field Safety Notices 31 August 2006 6 pages
- SG2/N47R4:
  2005
  PDF Word Review of Current Requirements on Postmarket Surveillance 01 February 2006 10 pages
- SG2-N8R4
  PDF Word Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices 16 February 2000 *Reposted: 25 October 2000 6 pages, 47Kb-PDF 69Kb-Word
- SG2-N16R5
  PDF Word Charge & Mission Statement 16 February 2000 *Reposted: 25 October 2000 3 pages, 40Kb-PDF 62Kb-ord

AHWP/WG2/SADS/002 AHWP/WG2/PMS/003	GHTF/SG2/N57R8:2006
Field Safety Corrective Action (FSCA) A field safety corrective action **is any remedial action, including preventive and corrective**, taken by a manufacturer for reducing the risk of death or serious deterioration in the state of health associated with the use of the medical device. **The action includes product recalls, device modification, implant alert, device precaution and user warming.**	**Field Safety Corrective Action (FSCA)** A field safety corrective action (FSCA) is **an action** taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device.