



TC WG05 Work Plan 2009-2011

2008-12-20, Shenzhen China

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- Work items
- Tasks & Strategies
- Work Group meetings

Work Items:

1. Start up WG05 & finalize work plan '09-'11
2. Comparative study of Clinical Trials regulations & related guidances on Clinical Safety/Performance in AHWP member economies
3. Establish WG05 representation at GHTF SG5 & participate in the development of SG5 guidance documents
4. Review SG5 & other relevant guidance documents and make recommendations to AHWP member economies on the feasibility of adoption
5. Training to promote Good Clinical Practice, Declaration of Helsinki & ISO 14155 governing clinical investigations
6. Partner with other TC Work Groups' initiatives to provide expertise & input relating to clinical safety/performance eg. WG01 regarding CSDT's section on clinical evidence



Work Item 1- Team Setup

Tasks/Strategies

- Invitation to AHWP member economies for nomination
- Confirm WG05 membership list
- Finalize work plan '09-'11

Timeline: Q1, 2009



Work Item 2 - Comparative study

Tasks/Strategies

Best practice sharing of regulations/status on Clinical Evidence/Clinical Trials in each economy

- Questionnaire and survey
- Deviation of harmonization from GHTF principles
- Analysis & recommendations

Timeline: whole 2009



Work Item 3- Liaison of SG5

Tasks/Strategies –

- Communication & network with SG5 Chair – done
- Establish membership & participation in SG5 initiatives – Q1 ‘09
- Establish mechanism to effectively disseminate SG5 information & guidance documents amongst WG05 & AHWP member economies
- Establish mechanism to build consensus amongst AHWP member economies for feedback to SG5 initiatives/guidance documents

2009~2011



Work Item 4- WG5 deliverables

Tasks/Strategies

- Review relevant guidance documents
- make to AHWP member economies on the feasibility of adoption – ongoing Where necessary
- develop AHWP guidance documents with Asia perspectives in consultation with SG5
- Identify area of focus eg. Clinical Evidence; Clinical Investigation; MEDDEV.2.7.1 guidance document on Evaluation of Clinical Data etc.

2009~2011



Work Item 5- Training

Tasks/Strategies

- Good Clinical Practice
- ISO 14155 governing clinical investigations
- Declaration of Helsinki

2009~2011



Work Item 6 - Partnership with other Groups

Tasks/Strategies –

- provide expertise & input relating to clinical safety/performance
- Identify area of focus eg. WG01 regarding CSDT's section on clinical evidence

2009~2011



WG5 meetings

- Face to face or Teleconference
- Review & update work progress
- Timeline:
 - Quarterly
 - Target: 1~2 face-to-face meetings in 2009



Thank you!

