FORMAT FOR GHTF NEW WORK ITEM PROPOSALS (NWIP) **NWIP shall be submitted to the GHTF Secretariat at least six weeks prior to the upcoming Steering Committee Meeting to allow the Secretariat to propose the NWIP to the Steering Committee for approval**	
Proposed title of the project	Post-Market Clinical Follow-Up for Medical Devices
Initiator	Study Group 5
Purpose and rationale (including a reference to one or more of the goals the GHTF Strategic Direction)	As a follow-on to existing SG5 Clinical Evaluation document as it pertains to medical devices, to provide guidance on how and under what circumstances post-market clinical studies should be carried out in order to fulfil post-market obligations, particularly for those devices where identification of possible emerging risks and the evaluation of long-term safety and performance are critical. While clinical evidence is an essential of the pre-market conformity assessment process, it is important to recognise the limitations inherent in pre-market clinical investigations. The extent of the data that can be gathered in the pre-market phase does not enable the manufacturer to detect infrequent complications or problems only apparent after widespread use or long-term performance issues.
Scope (including outline of issues to be addressed and opportunities for regulatory convergence)	Guidance on post-market clinical follow-up requirements as they pertain to medical devices.
General Work Plan and timelines	• Review existing documents including documents from SG2 (Q2/2007). • Drafting of document (Q3/2007). • Circulation for comment and presentation to Steering Committee (Q4/2007).
Proposed project leader	Study Group 5 Chair
Proposed sources of necessary expertise	SG5
Relevant existing documents at GHTF and national level, as well as in international bodies.	• SG5 clinical evaluation document. • Directive 93/42/EED: Medical Devices Directive. • MEDDEV 2.12-2: Guidelines on Post-Market Clinical Follow-Up.