



# ***GHTF Study Group 5***

***Presented by Kimber Richter  
on behalf of  
Graeme Harris  
Chair GHTF Study Group 5***



## BACKGROUND

- SG5 established at June 2004 GHTF Steering Committee
  - principally on the recommendation of GHTF ad hoc working group on Clinical Evidence
  - with expectation that convergence of clinical evidence requirements should yield 'data' that would be 'common data' for the purposes of mutual acceptance by global regulators
- First new GHTF Study Group in 10yrs
  - finite life (18 months for first phase ToRs)



## STUDY GROUP 5 Assignments

### First phase:

- harmonise clinical definitions;
- review existing GHTF documents and applicable ISO/ICH documents, to assure terminology is consistent and interfaces are clear;
- Develop guidance on how to conduct and document the clinical evaluation; and
- harmonise the content and format for clinical investigation reports.

### Second phase:

- harmonised principles to determine when clinical investigation, as opposed to other forms of clinical evidence, is necessary

# SG5 MEMBERSHIP



Graeme Harris, Therapeutic Goods Administration, AUSTRALIA

Johan Brinch, MIAA, AUSTRALIA

Masaaki Tsukano, Ministry of Health, Labour and Welfare, JAPAN

Kazuhiro Sase, National Cardiovascular Centre, JAPAN

Yoshihiro Noda, JFMDA, JAPAN

Susanne Ludgate, MHRA, UK

Wolfgang Ecker, Federal Ministry of Health and Women, AUSTRIA

Maria Teresa de Martin, AEMPS, Ministry of Health and Consumer Affairs, SPAIN

Peter Rattke, COCIR, AUSTRIA

Klaus-Dieter Willamowski, EDMA, GERMANY

Christophe Bailleul, EUCOMED, BELGIUM

Eric Mann, Food and Drug Administration, USA (replaced Celia Witten after Meeting 1)

Kimber Richter, Food and Drug Administration, USA

Gregory Campbell, Food and Drug Administration, USA

Joanne Less, Food and Drug Administration, USA

Mitchell Krucoff, Duke University Medical Centre, USA

Patricia Garvey, AdvaMed, USA

Mary Anne Hinkson, NEMA, USA

Keith Butler, Health Canada, CANADA

Greg LeBlanc, MEDEC, CANADA



## SUMMARY OF ACHIEVEMENTS TO DATE

- Three meetings
  - Canberra, Australia January 2005
  - London, UK May 2005
  - Gaithersburg, US September 2005
- Established work plan
- Drafts of two documents
  - Definitions and Concepts document
  - Guidance on clinical evaluation
- Developed a proposal to establish MoU with ISO/TC 194



## MEETING 1 OUTCOMES

Determined that need for clinical investigations could be incorporated into guidance on clinical evaluation in future

Guidance on Clinical Investigation Reports requires close liaison with ISO/TC 194

- Harmonised guidance exists (ISO 14155)
- No need for GHTF guidance if ISO 14155 meets our collective regulatory needs
- Proposed revision of ISO 14155
- Members in common with ISO/TC 194 WG4



## MEETING 2 OUTCOMES

- Report on existing documents from other sources
- Continued work on harmonised definitions
- Started work on guidance on clinical evaluation
- Agreed to wording of MoU
- Liaison with other GHTF SGs

# MEETING 3 OUTCOMES

- Edited Definitions Document
- Identified Key Issues To Clarify Clinical Evaluation Process and Complete Guidance
- Updated structure of Clinical Evaluation Guidance and began editing
- Discussed possible future work items suggested by ISO
- Nominated Vice Chair





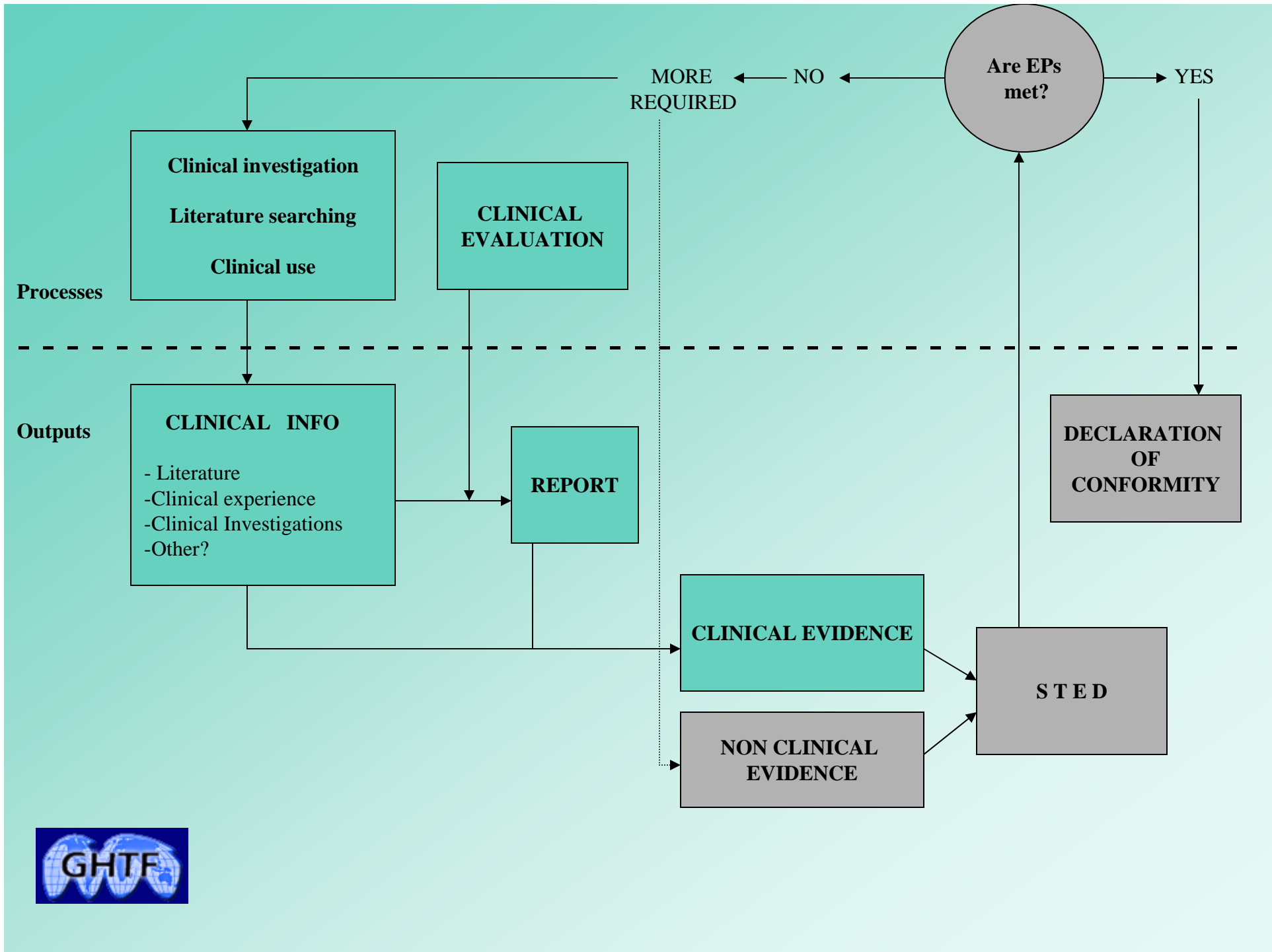
# CLINICAL EVALUATION

- Process for assessing clinical information known about a device to determine whether the relevant Essential Principles for safety and performance have been satisfied
  - Includes scientific literature
  - Clinical Experience  
(Such as market experience, adverse event reports, anecdotal cases)
  - Clinical Investigations



## CLINICAL EVALUATION PROCESS

- Is a critical appraisal of available information
- To determine if a favourable benefit to risk ratio exists for the device
- Nature and amount of information needed will vary with the type of device, conditions of use, and experience with similar devices



# Definitions Document

- Focuses on Key Definitions Related to Clinical Investigations and the Clinical Evaluation Process
- Will be circulated within SG 5 for final comments
- Should be ready for Steering Committee review before / after next meeting

# Status of Clinical Evaluation Guidance

- Some Key Decisions Remaining
- Issues are Under Discussion
- Outline of the Document is Evolving
- Initial Draft Drawn from EU Activities
- Some Editing Has Been Done

# Key Concepts with Clinical Evaluation Proposal

- Each Device Will be Assessed Individually
- No Guidance for Class of Devices
- Builds off Knowledge of Similar Devices, Published Literature, Market Experience
- Risk Assessment will have Key Role
- Expected to be an Ongoing Process as new information emerges (pre and post market)

# More Key Concepts

- All the Clinical Evidence becomes part of the technical documentation maintained by the manufacturer
- Clinical Evaluation Report becomes part of STED, to be held or submitted to Regulatory Authorities as appropriate

# Contents of the Guidance

- Sources of information for clinical evaluation
- How to conduct and document literature reviews
- How to use other information sources in clinical evaluation
- How to report the clinical evaluation



# Remaining Issues

- Is a Clinical Evaluation required for every device? Most devices? Only certain high risk devices?
- Is there a role for Pre-Clinical (bench and animal testing) data in the Clinical Evaluation process? Or is that considered only separately through the STED ?

# Meeting with Study Group 1

- How will the Clinical Evaluation Report be integrated into the STED process?
- Should we try to develop some guidance for clinical evaluation criteria by class of device? How does our current approach relate to the Classification and Conformity Assessment Documents of SG 1?



# SG5 Work plan

<b>WORK ITEM</b>	<b>REF</b>	<b>STATUS</b>	<b>PRIORITY</b>	<b>COMPLETION TARGET</b>
Harmonisation of definitions	SG5/N1R2	Internal working draft	1	Q4/2005
Harmonised guidance on clinical evaluation	SG5/N2R1	Internal working draft	2	Q1/2006
Harmonised content and format for clinical investigation reports	NA	Establishing formal working liaison with ISO/TC 194 WG4	1	Q3/2005 (MoU) ? (revised ISO Standard 14155)

# Future Activities

- Guidance on when clinical investigation is needed
- Regulation of human subject protections
  - IRB / Ethics Committee Requirements
  - Informed Consent
  - Follow up after clinical investigations

Next Meeting January 2006