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Global Harmonization Task Force Study Group #5

Greg LeBlanc

Vice-Chair, GHTF SG5

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Background

- SG5 was established at the June 2004 meeting of the GHTF Steering Committee
- First meeting was January 2005
- Mandate: to work towards convergence of clinical evidence requirements which should yield common data for the purpose of mutual acceptance by global regulators

“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 evaluation reports.
- **Second phase:**
 - harmonise principles to determine when clinical investigation, as opposed to other forms of clinical evidence, is necessary

Current Status

- So far, we have held 6 meetings:
 - Canberra, Australia – January 2005
 - London, UK – May 2005
 - Gaithersburgh, MD – September 2005
 - Sydney, Australia – January 2006
 - Irvine, CA – April 2006
 - Lübeck, Germany – June 2006

Current Status

- Two documents actively in progress:
 - Definitions and Concepts document
 - Guidance on Clinical Evaluation
 - These were approved for release as Proposed Documents by the Steering Committee (SG5(PD)/N1R7 and SG5(PD)/N2R7)
- Memorandum of Understanding with ISO TC 194 (responsible for ISO 14155) – close liaison necessary to avoid overlap

Definitions and Concepts Document

- Focuses on key definitions related to clinical investigations and the clinical evaluation process only
- Defines:
 - Clinical Investigation
 - Clinical Evaluation
 - Clinical Data
 - Clinical Evidence

Definitions

- Clinical Investigation
 - “Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device”

Definitions

- Clinical Data
 - “Safety and/or performance information that are generated from the clinical use of a medical device”

Definitions

- Clinical Evaluation
 - “The assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.”

Definitions

- Clinical Evidence
 - “The clinical data and the clinical evaluation report pertaining to a medical device.”

Clinical Evaluation – What Is It?

- Process for assessing the 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
 - e.g. market experience, adverse event reports
 - Clinical Investigations

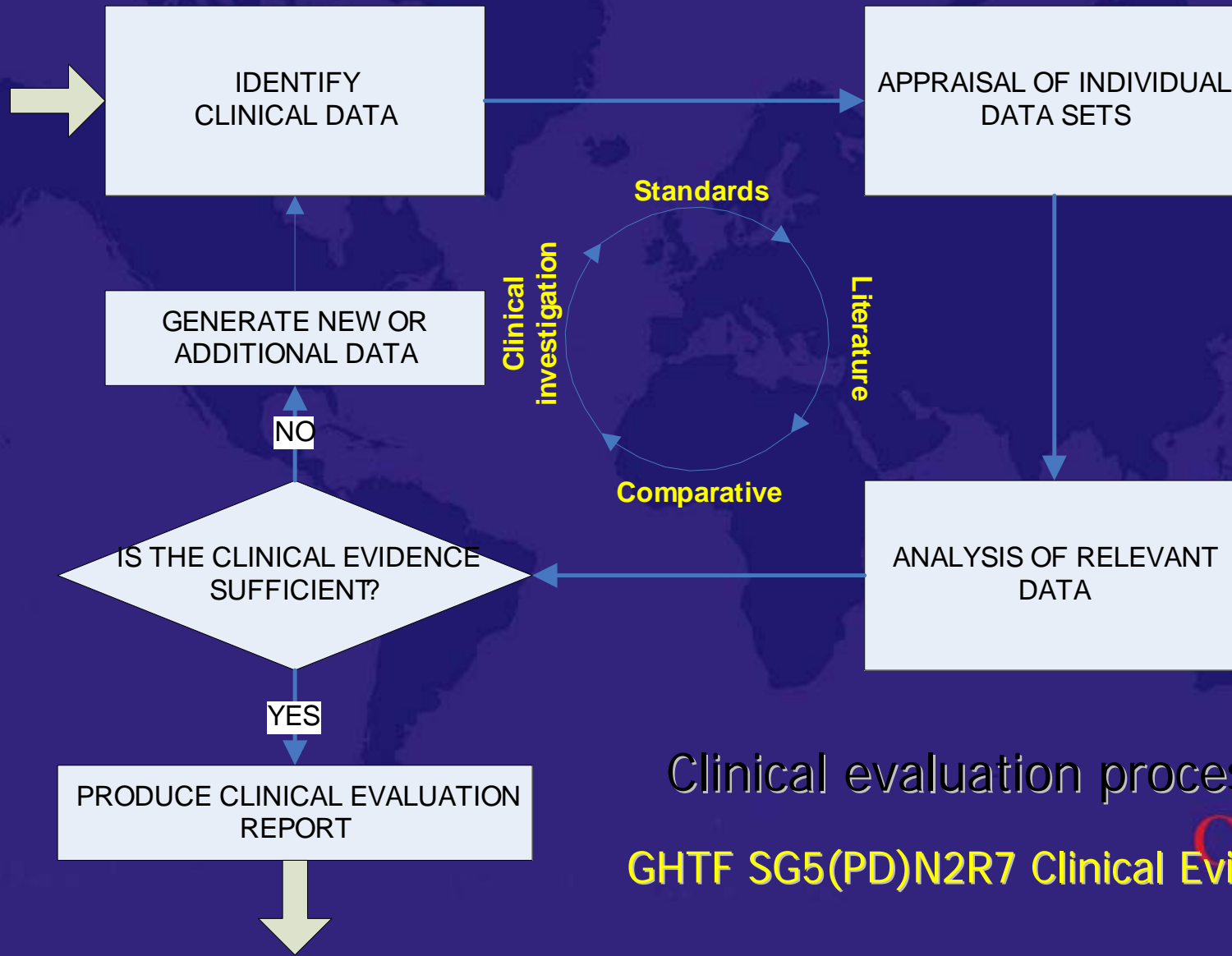
Clinical Evaluation – What Is It?

- a critical appraisal of available clinical 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, along with other available data (e.g. preclinical/bench-top)

Clinical Evaluation – What Is It?

- Each device assessed individually, but builds off of knowledge obtained from similar devices
- Context of Risk Assessment is critical
- Ongoing process as new information emerges (e.g. post-market)

STED & clinical evidence



Clinical evaluation process

GHTF SG5(PD)N2R7 Clinical Evidence **COOK**

Then What?

- Contents of Clinical Evaluation Report and Clinical Data constitute Clinical Evidence
- Used as part of technical documentation (may be submitted for review as part of STED) to support market authorization

Contents of Clinical Evaluation Guidance

- Sources of information
- How to conduct and document literature reviews
- How to incorporate various information sources
- How to report the clinical evaluation

Future Tasks

- Incorporate public comments on Definitions (N1) and Clinical Evaluation (N2) documents
- Continue liaison with ISO TC 194 to examine areas of mutual interest
- Adapt Clinical Evaluation document to address IVDs
- Start consideration of issue of “when is a clinical investigation necessary?”

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THANKS!

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