Clinical Evidence

GHTF Study Group 5

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Asia-Pacific Economic Cooperation

GHTF SG5 – Clinical Evidence

- Background
  - The need to address clinical evidence specifically
  - The mandate of Study Group 5
- Study Group 5
  - Objectives
  - Status

Medical Device

Medical device' means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES

- Medical devices should not compromise clinical condition or safety
- The risk should be acceptable compared to potential benefits
- The benefits must be determined to outweigh any undesirable side-effects for the performances intended.

Demonstration of Clinical safety and Effectiveness

- Where conformity with these Essential Principles should be based on clinical evaluation data, such data should be established in accordance with the relevant requirements applicable in each jurisdiction.
- Clinical investigations on human subjects should be carried out in accordance with the Helsinki Declaration
- (NOTE: Specific guidance on clinical evaluation may be developed in the future)

Demonstration of Clinical safety and Effectiveness

- The STED shows how the Essential Principles are met, including clinical evaluation as appropriate.
- The evaluation may take the form of
  - a systematic review of existing bibliography, clinical experience with the same or similar devices, or
  - by clinical investigation.
- Clinical investigation is most likely to be needed for higher risk class devices, or for devices where there is little or no clinical experience .

GHTF ad hoc WG on Clinical Evidence

Paris March 2004

Statement of problem

- Lack of consistency in guidance between regulators/regulatory systems
- Lack of consistency in clinical evidence requirements in standards
- Inconsistent treatment of competitors with similar products
- Manufacturer's local representative may not have access to adequate clinical evidence

GHTF ad hoc WG on Clinical Evidence

Paris March 2004

Statement of problem

- Lack of consistency in format and content of presentation of clinical evidence
- Inconsistency in clinical study design
- Inconsistency in balance of evidence between requirements pre- and post-market (disconnected study designs)
- Un-harmonised requirements for clinical evidence in smaller markets may discourage product introduction

GHTF ad hoc WG on Clinical Evidence

Paris March 2004

Statement of problem

- Lack of consistency may cause regulators and manufacturers to divert scarce resources to unnecessary duplication of efforts
- Lack of consistency in clinical evidence requirements for ‘emerging technologies’

GHTF ad hoc WG on Clinical Evidence

Paris March 2004

Study Group work products endorsed by GHTF Steering Committee in June 2004.

- Harmonised definition of terms
- Review of existing GHTF, ICH, and ISO documents for relevant guidance
- Harmonised guidance on how to conduct and document clinical evaluation
- Harmonised content and format for clinical investigation reports

SG5 Canberra 17 Jan 2005

- Inaugural meeting
  - Context given by Ad-hoc Working Group
- Work Plan
- Definition of terms
- Evaluation of Data

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WORK ITEM	REF.	STATUS	PRI.	TARGET Date
Harmonisation of definitions	SG5/N1R1	Internal working draft. Further work to include review of existing GHTF, ISO, ICH and jurisdictional documents	1	Q4/2005
Harmonised Guidance on Clinical Evaluation	SG5/N2R0	First working draft to be considered at May 2005 meeting	2	Q1/2006
Harmonised content and format for clinical investigation reports	NA	Establishing formal working liaison with ISO TC 194 WG4 – will include a proposal for an MoU.	1	Q3/2005

Technical Documentation

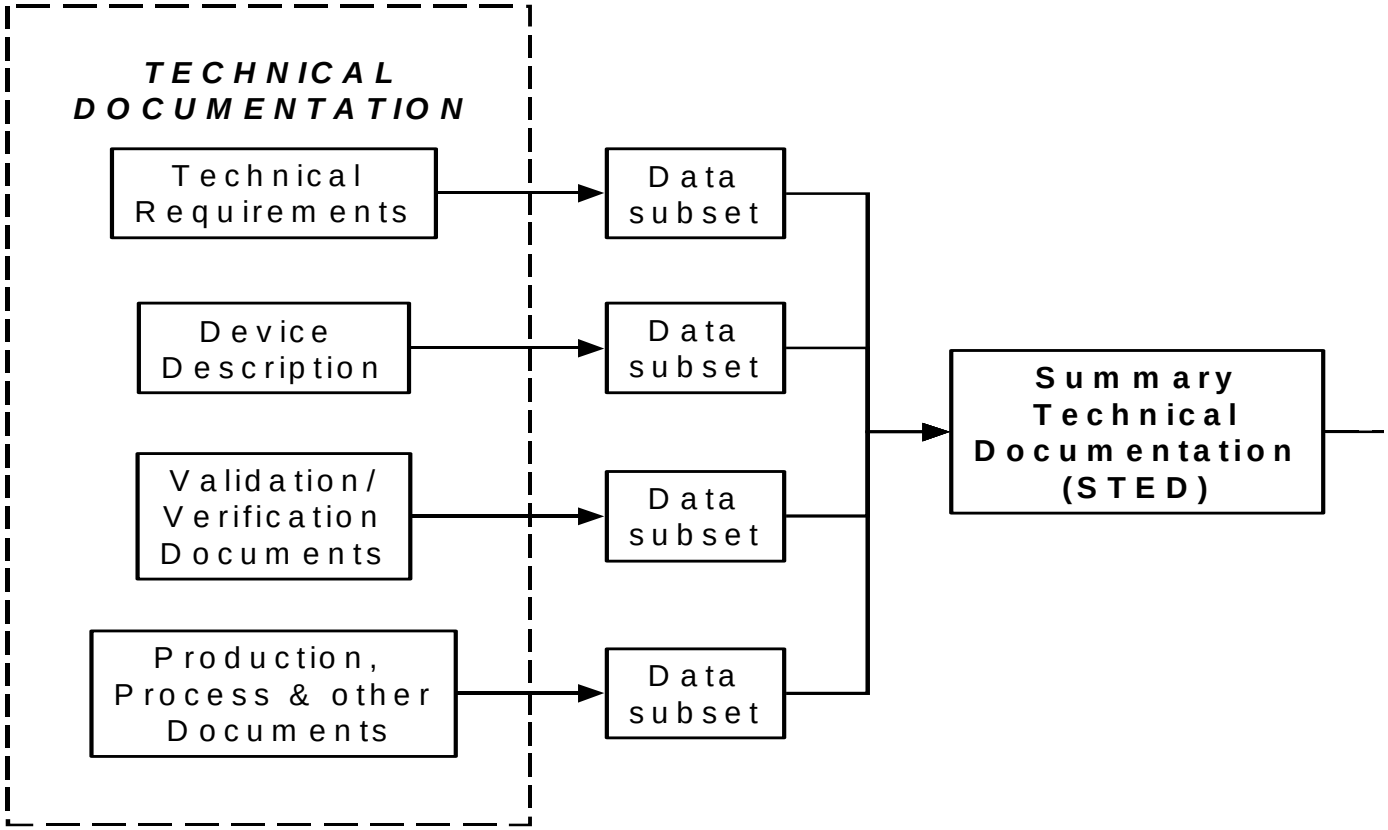

FIGURE 1: SOURCE AND APPLICATIC

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Technical Documentation

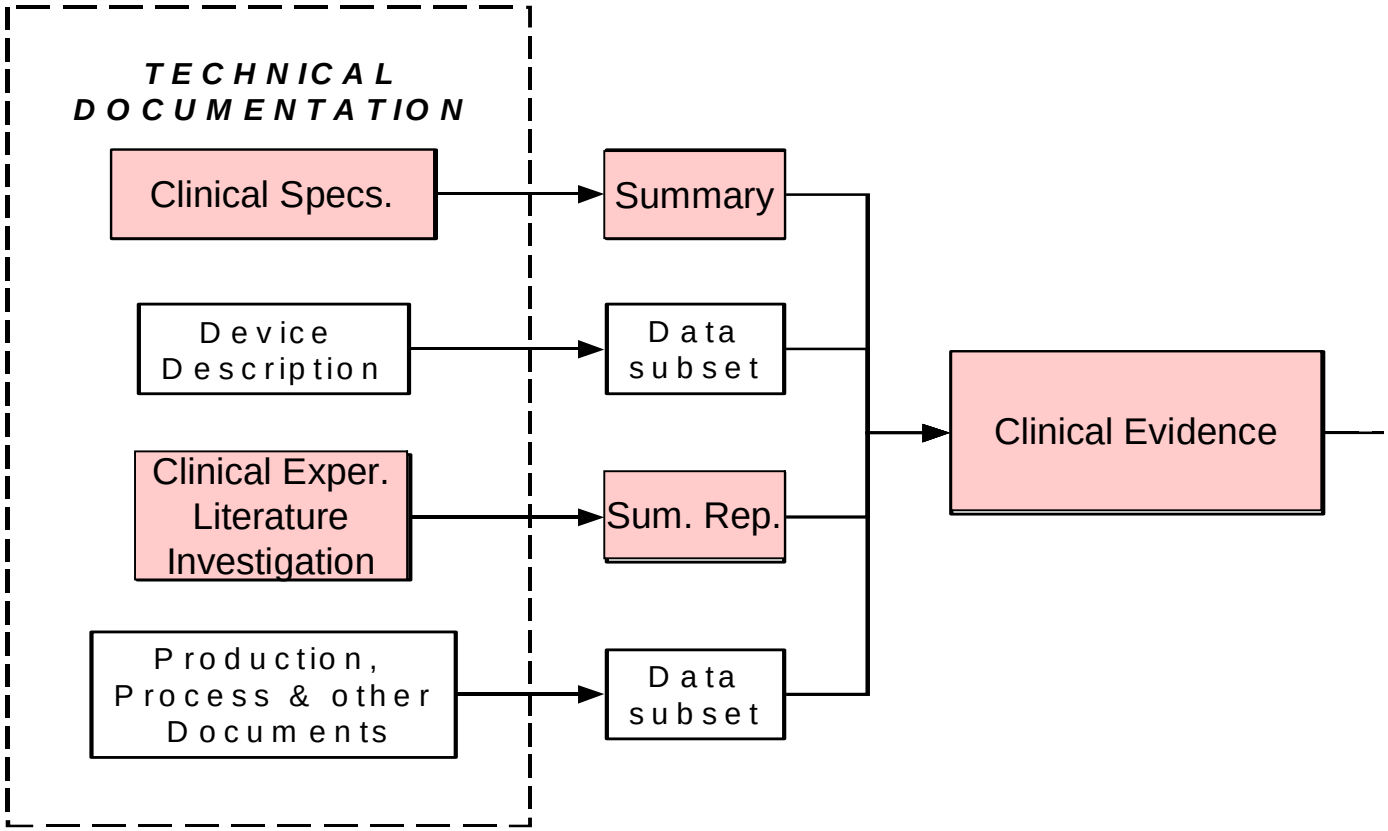
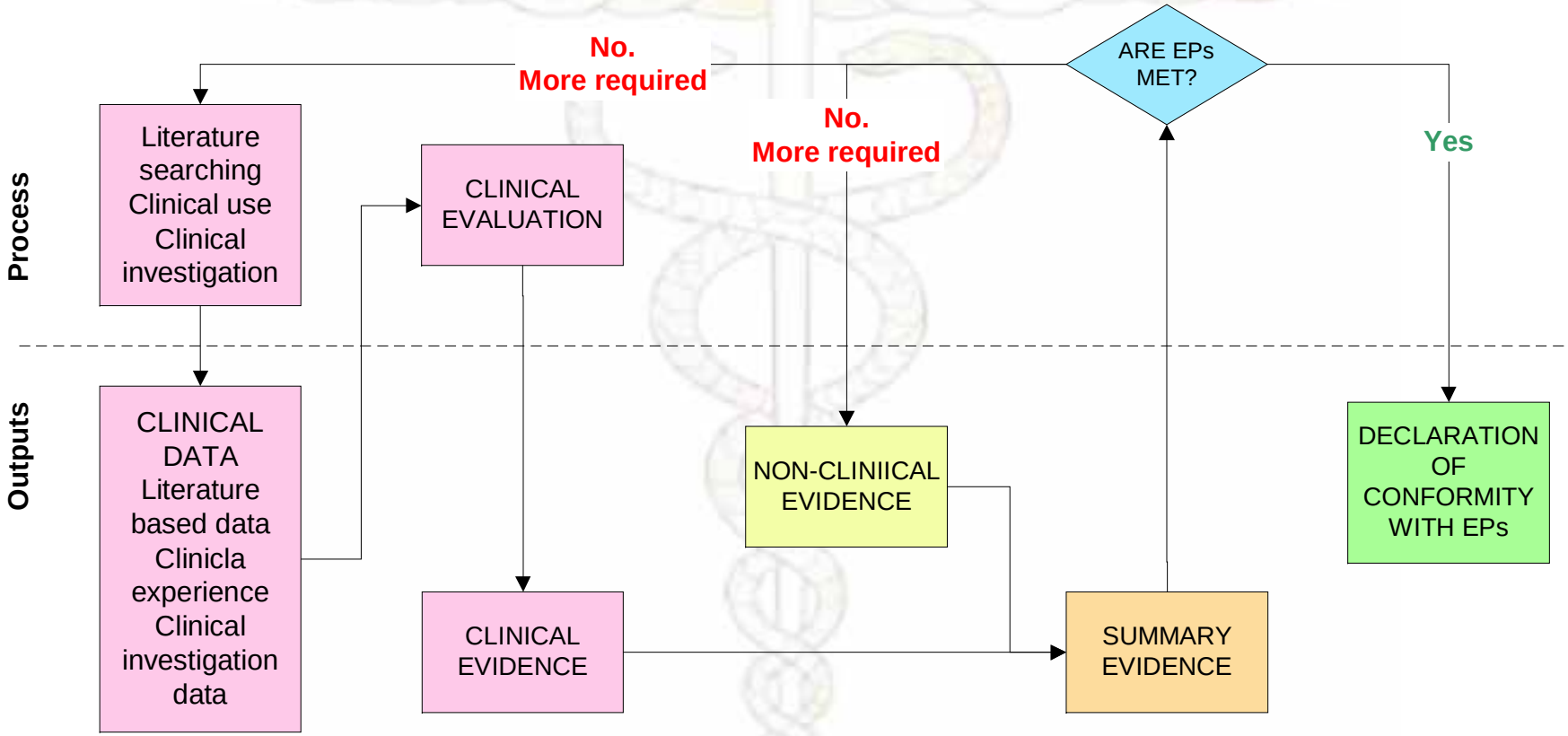


FIGURE 1: SOURCE AND APPLICATIC

SG5 SG5/N1R1

- Concept model



SG5 SG5/N1R1

- Key Definitions and Concepts
  - Clinical investigation
  - Clinical data
  - Clinical evaluation
  - Clinical evidence
- Consolidation of terminology from standards and other GHTF guidance documents

SG5 SG5/N1R1

- Key Definitions and Concepts
  - Clinical investigation
    - Any systematic investigation or study in or on one or more human subjects, undertaken to verify the safety and/or performance of a device.
  - Clinical data
    - Safety and/or performance data that is generated from the clinical use of a device.

SG5 SG5/N1R1

- Key Definitions and Concepts
  - Clinical evaluation
    - Assessment and analysis of clinical data to determine whether the relevant Essential Principles for safety and performance have been satisfied.
  - Clinical evidence
    - Clinical evidence is a report documenting the nature of the clinical data and its evaluation which together with non-clinical evidence and risk management is used to demonstrate compliance with Essential Principles.

SG5 SG5/N2R0

- Evaluation of Clinical Data
  - The primary purpose of this document is to provide guidance on the evaluation of clinical data
    - Clinical Experience
    - Literature
    - Clinical investigation
  - Driven by the intended use / claimed benefits of the device

SG5 overall objectives

Stimulating regulatory convergence in the area of clinical evaluation with the following potential benefits:

- More efficient, predictable and timely access to medical technology by patients and society worldwide
- Better understanding of medical device safety and performance by all stakeholders
- More efficient use of resources of the clinical community, regulators, and industry
- Increased transparency and confidence in GHTF global regulatory model