Global Harmonization Task Force Study Group 5

Greg LeBlanc
Vice Chair, GHTF SG5

November 2009

COOK® MEDICAL

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

Current Status

- So far, we have produced:
  - Two “final” documents:
    - *Clinical Evidence – Key Definitions and Concepts* (GHTF SG5/N1:2007)
    - *Clinical Evaluation (GHTF SG5/N2:2007)*
  - Two “proposed” documents
    - *Clinical Investigation- GHTF SG5/N3 (at finalisation stage, est. release Q1 2010)*
    - *Post-market Clinical Follow-up SG5/N4 (public comment period closed, est. release:Q1 2010)*
  - Memorandum of Understanding with ISO TC 194 (responsible for ISO 14155) – close liaison necessary to avoid overlap

Current Status

- Work In Progress:
  - Clinical Evaluation for IVDs (with SG1)
  - Adverse Event Reporting in Clinical Investigations (with SG2)

SG5 – N1 – Definitions and Concepts Document

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

SG5 – N2 – Clinical Evaluations Document

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
  - Relevant Clinical Information Includes:
    - Scientific Literature
    - Clinical Experience
      - e.g. market experience, adverse event reports
    - Clinical Investigations

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

Clinical Evaluation Guidance – Appendices

- Include:
  - Suggested Literature Search Report format
  - Possible methodology for literature screening
  - Sample criteria for data appraisal
  - A sample method of appraisal
  - Suggested Clinical Evaluation Report format

SG5 – N3 – Clinical Investigations Document

Clinical Investigations Document

- Provides guidance on use of Clinical Investigations as a tool for gathering Clinical Data not available through other means
- Provides general direction on standards for conducting study, basic principles of study design, etc.

Clinical Investigations Document & ISO 14155

- SG5 N3 provides preliminary stage guidance on determining the need for an investigation and general considerations
- ISO 14155 provides details of the technical aspects of conducting an investigation
  - While there are points of intersection (e.g. early sections of ISO 14155 Clause 4), the two documents do not generally overlap

Clinical Investigations Document

- Introduction and Scope Statements
  - Points to ISO 14155 as standard for the conduct of a Clinical Investigation and the contents of a Clinical Investigation Plan
  - Indicates that guidance was drafted primarily with use in pre-market applications in mind, but that some concepts will be broadly applicable to post-market clinical follow-up studies as well

Clinical Investigations Document

- Other sections address issues such as:
  - When do you undertake one?
  - What is the role of Risk Analysis?
  - What are basic Design Principles?
  - What are basic Principles of Study Conduct?
  - What is the role of the Study Report?
  - What are some basic Ethical Considerations?

SG5 – N4 – Post-Market Clinical Follow-Up Document

PMCF Document

- Public review period recently closed and comments are to be incorporated
- A brief overview:

PMCF Document

- Topics addressed include:
  - When is a PMCF indicated?
  - What are the basic elements of a PMCF Study?
  - How is the information obtained used?

Impact Summary for SG5 Documents

Impact of SG5 Documents

- N1 document provides a set of definitions that can be universally applied to the discussion of clinical evidence
  - Consistent terminology for everyone involved

Impact of SG5 Documents

- N2 document provides guidance surrounding the concept of clinical evaluation
  - What information should be satisfactory to support a device's presence in the marketplace
  - Outlines the elements to include in the process & what does and does not constitute clinical data

Impact of SG5 Documents

- N2 document provides guidance surrounding the concept of clinical evaluation
  - How the clinical evaluation report forms part of the clinical evidence
  - If the document is followed, it is felt that the format and content of the resultant report should be considered acceptable by reviewers

Impact of SG5 Documents

- N3 document provides guidance surrounding the design and conduct of clinical investigations
  - When a study is required/justified
  - Appropriate design and conduct
  - How the results are integrated into clinical evaluation process

Impact of SG5 Documents

- N4 document provides guidance surrounding the design and conduct of post-market clinical follow-up studies
  - When a study is required/justified
  - Appropriate design and conduct
  - How the results are integrated into the benefit/risk analysis

Going Forward…

Ongoing Work of SG5

- Adapt Clinical Evaluation document to address IVDs
  - What does “Clinical Evaluation” really mean for IVDs?
  - Being undertaken with co-operation of IVD Subgroup of SG1
- Address lack of harmonization in Adverse Event Reporting within Clinical Investigations
  - In co-operation with SG2

Going Forward

- Continued liaison with ISO TC 194 to examine areas of common interest
- Assess whether there other new topics should be addressed or go into “maintenance mode”

THANKS!

Contact Info:

Greg LeBlanc
Cook (Canada) Inc.
greg.leblanc@cookmedical.com
+1 (905) 640 7110