SG2(PD)/N87R7

PROPOSED DOCUMENT

Global Harmonization Task Force

Title: Medical Devices: Post Market Surveillance: **An XML Schema for the electronic transfer of adverse event data between manufacturers, authorised representatives and National Competent Authorities (Based on GHTF SG2 N32v5.2)**

Authoring Group: Study Group 2

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Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

Introduction

Important safety information concerning medical devices needs to be communicated by the fastest, most efficient means. The basic information necessary for medical device related adverse event reporting has already been agreed between international regulators and manufacturers representative organisations represented within GHTF Study Group 2 and issued as a final document GHTF SG2 N32R5.2. Manufacturer representatives and National Competent Authorities recognise that a harmonized electronic transfer of adverse event datasets from manufacturers systems to relevant National Competent Authorities can offer significant efficiency gains and help improve response times for all concerned parties. It is expected that electronic reporting will become the method of choice in the future. GHTF has therefore developed this guidance document to encourage harmonized global development of electronic medical device adverse event reporting, based on GHTF SG2 N32R5.2

This document presents an XML schema that has been developed using GHTF SG2 N32R5.2. It should allow manufacturers or their authorized representatives and Competent Authorities to gain experience in the use of the XML schema.

GHTF recommends that those NCAS considering introducing electronic adverse event reporting facilities for manufacturers should develop systems that use N87, rather than a completely different data structure. However, it is very likely that national competent authorities will have to accept reports in other formats (paper form, Word file, email, etc) for some time into the future.

1. Scope

This guidance provides details of an electronic format for manufacturers and Competent Authorities to use when exchanging adverse incident data electronically. The guidance comprises:

- A rationale for a customised XML schema for manufacturer reporting based on GHTF SG2 N32R5.2 (this document).
- A spreadsheet giving the field names used in GHTF SG2 N32R5.2 and the field names and workflow embedded within the XML schema (<N87R7 spreadsheet for XML schema based on N32v5.2 v2.xls>)
- An XML schema for manufacturer reporting based on GHTF SG2 N32R5.2. This consists of five separate electronic files (<n87-initial.xsd; n87-followup.xsd; n87-initialfinal.xsd; n87-final.xsd; n87-trend.xsd>) representing the portion of the schema relevant to initial, follow-up, final, combined initial and final, and trend adverse event reports

The seven electronic documents together comprise the GHTF SG2 (PD) N87R7 guidance document bundle.

Guidance on what and when to report to Competent Authorities is contained GHTF SG2 (PD) N54R6.

Note: At the time of publication of this document, GHTF SG2 N54R6 was considered to be a "Proposed Document" and therefore not final GHTF guidance. However, GHTF SG2 N54R6 is an amalgamation of final SG2 guidance documents and is available for download from the GHTF website. It is expected that by the time this document is final that GHTF SG2 N54 will also be final.

2. References

GHTF SG2 N32 R5.2 Medical Device Postmarket Vigilance and Surveillance: Universal Data Set for Manufacturer Adverse Event Reports, December 2003

GHTF SG2 (PD) N54R6 Medical Device Postmarket Vigilance and Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices (Final document being developed in SG2)

3. Definitions

XML

E**x**tensible **M**arkup **L**anguage (XML): A condensed form of Standard Generalized Markup Language (SGML) that enables developers to create customized tags that offer flexibility in organizing and presenting information. XML enables data to be organized and exchanged in ways that were previously impossible or very difficult. By using customised XML schemas, specific pieces of business data can be identified and extracted from ordinary business documents.

4. Use of the medical device adverse event reporting XML schema

This XML schema has been developed to facilitate a harmonised method for exchanging electronically an adverse event dataset based upon N32R5.2

National Competent Authorities and manufacturers are encouraged to use this internationally agreed XML schema for exchanging adverse event data.

The XML schema allows adverse event data to be completed in English and/or, where necessary, in the language required by the relevant National Competent Authorities.

5. Spreadsheet showing field names and workflow of XML schema

The spreadsheet included GHTF SG2 (PD) N87R7 guidance document bundle, <N87R7 spreadsheet for XML schema based on N32v5.2 v2.xls> shows:

- how the fields listed in GHTF SG2 N32R5.2 map into the XML schema presented in <n87-initial.xsd; n87-followup.xsd; n87-initialfinal.xsd; n87-final.xsd; n87-trend.xsd> (also included in the guidance document bundle)
- the field name changes that have been introduced into the XML schema field annotations to clarify field content descriptions
- where relevant, details of the picklist elements that will be available for each field
- the workflow built into the XML schema that determines what data field content conditions are required for initial, follow-up, final and trend reports.

6. Medical device adverse event reporting XML schema

The XML schema for adverse event reporting is provided in <n87-initial.xsd; n87-followup.xsd; n87-initialfinal.xsd; n87-final.xsd; n87-trend.xsd> which is included in the GHTF SG2 (PD) N87R7 guidance document bundle.