

October 18, 2004
**workshop
agenda**

1. Introduction

2. Background

- What is the problem?
- What is the FDA requesting? Why?

3. Typical digital ECG process in compliance with FDA guidance

- What is a digital ECG?
- Collect/Manage/Annotate digital ECGs
- Submit digital ECGs to agency for review

4. HL7 and V3 Information Modeling

- What is HL7?
- What is V3?
- HL7 information models

5. HL7's aECG Information Model

6. Implementation Topics

- Waveforms
- Annotations

7. What to submit to the FDA

8. Summary and Wrap-up

9. Interactive Q&A Session

Implementing the
**HL7XML Annotated ECG
Waveform Standard**

Overview

As of January 20th, 2004 the Annotated ECG (aECG) XML Waveform Standard was finalized and formally adopted by the Health Level 7 (HL7) standards organization. HL7's adoption of the a ECG XML Waveform Standard was the culmination of an effort initiated in November of 2001 by the US Food and Drug Administration (FDA) to enable submission of digital aECGs to establish the cardiac safety of new drugs. The final aECG Waveform Standard was authored through an ad hoc group consisting of representatives from sponsor organizations, ECG core laboratories, academic institutions and medical device companies.

With the standard finalized, sponsors and ECG core laboratories are moving quickly forward to implement compliant solutions. As expected, through these implementation activities, several questions regarding the proper utilization of the aECG Waveform Standard have surfaced including:

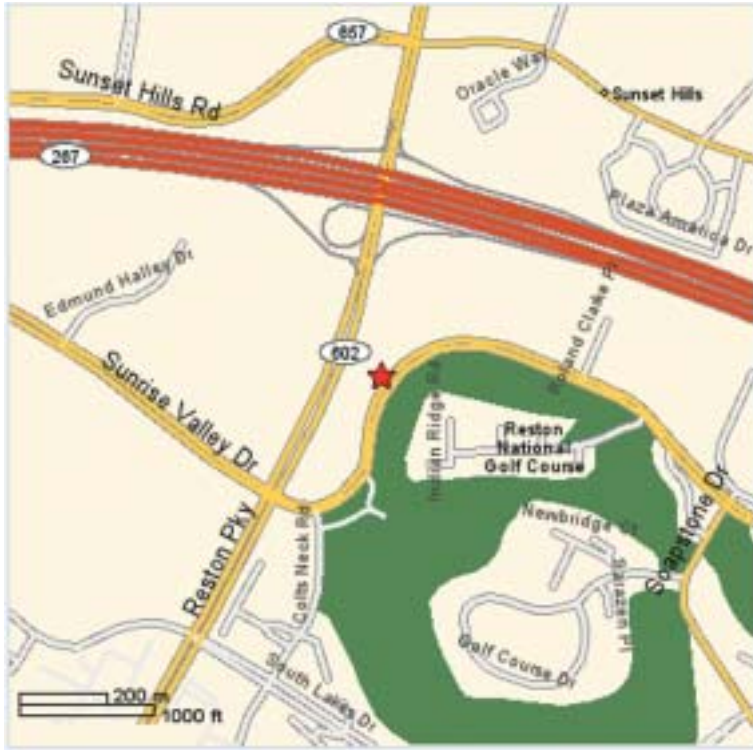
- What needs to be included in the annotated ECG XML files?
- What file structure needs to be used for individual aECGs?
- What duration requirements are there for the aECGs?
- What vocabulary can be used for the annotations?
- How to ensure proper adherence to the standard?

In order to provide answers to such implementation questions and other related issues, AMPS, LLC and Mortara Instrument, Inc. are organizing a workshop designed for representatives from sponsor organizations and ECG core laboratories who are responsible for compliance with the new aECG XML standard.

This one day workshop will feature presentations from two primary authors of the aECG XML standard, Fabio Badilini of AMPS and Barry Brown of Mortara Instrument. Included in the workshop materials will be a thorough implementation guide for the aECG XML standard. Attendance will be strictly limited to encourage open exchange and discussion between presenters and participants.



XMLFDA Seminar Venue



The hotel is located near exit 12 (Reston parkway) of the Dulles Airport access road/267 toll road.

Sheraton Reston Hotel
 11810 Sunrise Valley Drive
 Reston, Virginia 20191

We have reserved a limited number of rooms at a special rate for workshop attendees. The deadline for room reservations is September 17.

Participants will need to book their rooms directly to the Hotel by calling
 Room reservation: **1-800-325-3535**

Callers need to identify him/herself as participant to the AMPS-Mortara XMLFDA Seminar.

Rooms will be released by 9/17/2004 12am if not booked by then.

The **Workshop Registration** Fee is \$2200. Registration Forms received by September 1, 2004 will receive a special discounted rate of \$1800.

The Implementation Guide can be purchased separately for \$350. Attendees will receive an Implementation Guide with Registration.

To Register for the Conference:

Fax this page to: 414.354.4760
 Attn: Wendy Wagner

or Call: 414.354.1600
 Ask for Wendy Wagner



PLEASE COMPLETE THE FOLLOWING INFORMATION:

Last Name _____ First Name _____ Middle Initial _____
 Degrees _____ Dr. Mr. Ms.
 Job Title _____
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 (Please write your address in the format required for delivery to your country.)

Email _____

• Telephone Number _____ • Fax Number _____
 • (A Telephone and Fax Number are required for faxed confirmation).

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Name on Card _____