INTRODUCTION

Since 1996, worldwide regulatory authorities have been providing guidance on cardiac safety as assessed by the standard 12-lead electrocardiogram (ECG), with the European Union’s Committee for Proprietary Medicinal Products (CPMP) document (“Points to Consider”) for the evaluation of the potential for QT prolongation with noncardiovascular medicinal products in both preclinical and clinical studies. The initiative gained momentum with Health Canada’s March 2001 draft guidance document entitled “Assessment of the QT Prolongation Potential of Non-Antiarrhythmic Drugs,” and continued to evolve with the November 2002 joint FDA-Health Canada concept paper entitled, “The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs” (see http://www.fda.gov/cder/guidance/index.htm for details). Since 2002, an accelerating focus on cardiac safety in new drug development has been observed throughout the international clinical research industry. Throughout 2003 and 2004, cardiac safety guidance advanced from discussions held as part of the International Conference on Harmonization process, with strong input from research industry and regulatory authorities in Europe and Japan.

A key practical implication of this global ECG regulatory interest has been the evolution of the “digital ECG in clinical research initiative.” This has manifested as a move from a predominantly paper-based process of collecting ECGs in clinical trials to an environment characterized by the digital collection, interpretation, management, and reporting of cardiac safety data.
distribution of ECG safety data. The digital ECG evolution has brought a unique set of challenges and opportunities. There is increased reliance on clinical trial sites to effectively operate specially programmed digital ECG equipment. These new site activities include the electronic capture of demographic data that enable proper identification of a discrete ECG transaction at the trial, site, patient, visit, and time point levels. When conducted with appropriate planning, comprehensive support, and attentive execution, a clinical trial using digital ECGs delivers superior levels of accuracy and efficiency about cardiac safety to the clinical research process.

Digital ECGs enable enhanced collaboration and communication between all participants in the clinical trial process. These constituencies include researchers and staff, sponsor personnel, safety monitoring boards, and associated parties such as development partners, thought leaders, and even regulators. Electronic reporting and distribution of cardiac safety data creates an information platform that can be supplemented by related data (such as enrollment metrics), distance learning curricula to support site personnel engaged in cardiac safety data collection activities, and a variety of communications capabilities. These may include frequently asked questions (FAQ) databases, moderated discussion groups, and other trial specific documents and resources. Overall, these information assets can be deployed as a critical component in an e-clinical strategy. Such "digital communities" can even form the nexus from clinical research to clinical care, as the network of researchers expands to include the larger population of physicians and caregivers.

To be useful, digital communities need to deliver information that is scientifically valuable through an approach that is both technically feasible and compliant with applicable regulations. The following presents eResearchTechnology’s (eRT) (Philadelphia, PA) Digital ECG Community as a case study outlining deployment of a collaborative web-based resource that leverages the information and communications opportunities presented by the digital ECG age. eRT is a leading provider of technology and services that facilitate the collection, analysis, and distribution of cardiac safety and clinical data. The company has been making the Digital ECG Community available for several years to sponsors that have contracted with eRT to provide ECG core laboratory services.

**DIGITAL ELECTROCARDIOGRAM COMMUNITY**

The Digital ECG Community is an Internet-based web portal that provides ready access to key study metrics related to cardiac safety. The Digital ECG Community allows participants in the clinical trial to follow the progress and conduct of a study based on frequently updated data. Some of the many features this hosted service offers are secured, user profile-based access to the following:

- Analyses and comprehensive reports supporting proactive decision-making based on ECG findings and other key study metrics and visit tracking reports, across the protocol by patient and site.
- The ability to organize and publish a variety of study-related information such as newsletters, industry resources, study documentation sets, discussion groups, and FAQ databases.
- A range of valuable tools and resources to support all dimensions of clinical research, including eRT’s eHealth Education web-based training (WBT) and distance learning