



Health Insights & Outlooks

A bi-weekly newsletter

Welcome to the June 2, 2006 issue of Health Industry Insights' newsletter, Health Insights & Outlooks. We publish every two weeks, examining recent events and offering opinions on key trends in the healthcare and life science industries. Please feel free to forward this newsletter to colleagues or others who might find it relevant.

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It's Hurricane Season. How Prepared is the Health Industry?

By Lynne Dunbrack

June 1 marks the official start of the 2006 Hurricane Season. The National Oceanic and Atmospheric Administration (NOAA) predicts that there is an 80% chance of an above normal hurricane season with 13 to 16 named storms, 8 to 10 hurricanes, and 4 to 6 major hurricanes. In the wake of last year's Hurricane Katrina (and Rita and Wilma), millions of paper records were destroyed or inaccessible after the hurricanes. Disaster preparedness check lists found on the Web sites of various federal, state and local agencies, as well as private sector organizations, recommend that people store their medical records, along with other important documents, in a waterproof container or watertight plastic bag. What can the health industry do to prepare for the hurricane season?

HIPAA security regulations mandate that healthcare organizations have a disaster recovery plan in place that includes policies for backup and retrieval of data. EMRs that are adequately backed up (i.e., off-site, disaster resistant storage of data files) are one solution. Payer-based health records are another solution for providing patient clinical care summaries to providers who have not implemented EMRs. Before Hurricane Rita struck the Texas coast last year, MEDecision created patient care summaries for 830,000 BCBS of Texas members. Health plans tend to have more rigorous business continuity processes than most providers, especially physician practices. According to the Chief Operating Officer of Availity, a joint partnership between Blue Cross Blue Shield of Florida and Humana, the Availity Gateway was accessible throughout the 2005 Hurricane season. Availity is currently piloting its PBHR at 30 physician practices and an emergency department. Personal health records maintained by consumers may be the line of last defense if the PHR was pre-populated with data from providers or even claims history from payers. Some PHRs allow consumers to download their records to CDs or thumb drives for off-line back-up and portability.

Hurricanes and other natural disasters such as tornadoes and wildfires, as well as man-made disasters, underscore the need for electronic health records.

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Recognizing the Value of Drugs Despite Safety Issues

By Alan S. Louie, Ph.D.

The highly visible ongoing court proceedings with Merck and Vioxx stand in sharp contrast to the recent regulatory approval of one of the most infamous drugs of all time. Although not initially approved for use in the United States, thalidomide was widely available in the 1950's and 1960's in Europe as a sleep aid and to counteract morning sickness in pregnant women. Initial reporting of problems surfaced beginning in 1961 and it was soon discovered that severe, life threatening human birth defects were produced by the use of the drug in pregnant women. This safety issue exists to the present day.

Despite its potential safety concerns, Celgene's recent approval of Thalomid as a treatment option for newly diagnosed cases of multiple myeloma provides a valuable weapon in the fight





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against this form of cancer. The drug has also demonstrated effective treatment of leprosy and appears promising in supporting treatment of AIDS. Other than potential subterfuge in hiding potential adverse effects of Vioxx, the presence of safety issues is a common concern with most drugs. In many cases, people are living with uncontained disease progression, chronic pain, or disease complications yielding exceeding poor quality of life. Drugs with potential safety issues, including thalidomide, Vioxx, Tysabri, and even aspirin, continue to have a therapeutic role in providing treatment options. Active recognition of a drug's limitations (including so called "black box" labeling), combined with active monitoring for potential drug adverse events, can often enable near term access to proven efficacious drugs with known problems. Over the longer term, the ability to understand how drugs work and diagnostic tests to differentiate drug responders from non-responders and effectively exclude patients with potential adverse events will become reality. Drugs will rarely, if ever, be completely free of side effects for some fraction of the general population. Researchers involved finding new therapeutic solutions recognize this limitation and are working towards better solutions, which are likely to include preferred or excluded groups as drug action within the body becomes better understood at the mechanistic level.

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RFID Discovers ROI at - 90F

By Eric Newmark

The Paoli Calmettes Institute's Cell Therapy Facility and Tumor Cell Bank (one of Europe's largest cancer research facilities) is piloting RFID to enhance security and chain-of-custody tracking around its biospecimens. The institute, which holds over 170,000 biospecimens in total and banks 1300 new samples each month, has historically used a mix of handwritten labels and printed labels on its tubes and bags. The pilot's objective (using HF tags from Tagsys) is to reduce process time and manual errors by automating the preparation of biospecimen samples for cryopreservation. Most samples are stored at very low temperatures (-90F) in liquid nitrogen, which makes tracking efforts difficult since tags become unreadable in that state. Samples must be taken out of the liquid nitrogen for a few seconds to rise in temperature before their information once again becomes readable. The institute hopes to have all new incoming and outgoing samples tagged by the end of 2006.

The pilot has proven that reading and writing to tags exposed to these temperature conditions does in fact work, but more importantly, the savings and efficiency gains expected from the initiative are substantial. Hand writing labels takes 2-3 minutes per label (40-50 samples at a time), and each sample with a printed label needs to be manually removed to hand read its bar code. Further, handwriting often becomes illegible after being stored in liquid nitrogen, printed labels can smudge, and samples can simply get misplaced. Christian Chabonnon, MD, Ph.D., the director of the facility said "things like this happen all the time", and estimates 5%-10% of samples are lost due to problems like this. The tags in use cost between \$1-\$2 each, but Christian says "its not very much money when you consider the price of the process and the samples. Its been estimated that a biology core sample of human origin with all biology and medical annotation may be worth \$3K - \$5K, so paying a couple dollars for a tag is not really an issue to us." Based on the numbers provided, eliminating just the 5% of samples lost could save the facility between \$2.3M - \$3.9M annually on new samples at a total tag cost of less than \$32K.

RFID is quickly becoming the track and trace technology of choice for biospecimen management initiatives around the globe. Certain limitations surrounding real time inventory tracking do exist within a cryopreservation setting (since tags are stored at unreadable temperatures), but in most storage environments RFID is quickly proving to be a scalable low cost solution to inefficient manual processes.





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RHIO Evolution Drives Data Integration

By Marc Holland

Vendors often schedule new product launch announcements for major conferences, and TEPR 2006 was no exception. InterSystems announced the launch of Ensemble HIE, which extends its integration platform with six software services that will enable Regional Health Information Organizations (RHIOs) and other Health Information Exchanges (HIEs) to build and manage the connectivity they need to identify patients, exchange clinical data, manage patient consent, translate disparate lexicons, and provide secure access.

By now, many RHIOs have now evolved beyond their initial start-up, organizational stage, and are beginning to formulate their technical architecture and seek products that can satisfy their design requirements. Even many of those IDNs who have remained on the sidelines while others have joined RHIOs still have a need to integrate functionally similar, but technically disparate, legacy applications from their own component organizations. HII recently profiled the efforts at Mount Sinai Medical Center, which is using high-density Smart Cards as at least an interim solution to overcome the incompatibilities between EMR and other clinical systems at their nine owned and affiliated hospitals.

In a sense, there are many parallels between the integration issues RHIOs are facing and those hospitals faced 15-20 years ago when they sought to integrate their patient management and multiple departmental clinical applications. These requirements spawned a whole new market for integration platforms that became known as HL7 Interface Engines, such as SeeBeyond's e-Gate, Quovadx's Cloverleaf, and those from Siemens, Eclipsys and others. With the significant growth it has seen in its Cache installed base, which underlies many of the leading clinical systems in use by the VA and private sector hospitals and other care provider organizations, InterSystems just might be in the right place, at the right time, with Ensemble.

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Clinical Trial Management Systems Show Solid Growth

By Chris Connor

As opportunities to bring blockbuster drugs to market diminish, and pressures mount on product pricing and regulatory compliance, life science companies are desperately seeking ways to decrease the cost of development by increasing overall efficiency. Life science companies conducting clinical trials have responded to these challenges by increasing their operational focus and sharpening their study planning and execution skills. And for better or worse, CTMS (clinical trial management system) vendors stand in the critical path.

- The CTMS market is expected to increase at a 14.6% compound annual growth rate (CAGR) from 2006 to 2010
- Through 2008, CTMS adoption will continue to be dominated by project-driven selection processes.
- The success of CTMS will pressure vendors to expand the functional role of CTMS to encompass every phase of the eClinical value chain, including source data capture and management, protocol design, advanced analytics, performance management, and eClinical systems automation.
- Life science companies will continue to recognize the diminishing returns of developing their own bespoke applications to manage clinical trials. Expect to see an ever-increasing number of companies turn to commercial off-the-shelf (COTS) and technology subscription services to minimize budget and regulatory exposure.





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- As regulatory compliance pressure continues to mount, the increasing cost of continuous system validation threatens the ability to innovate. Look for life science companies to increase budget dollars available for innovation by first investing in systems that improve regulatory and compliance processes, such as CTMS.

Health Industry Insights has determined that over the next four years, CTMS will have the greatest potential impact on the functional areas of clinical operations, data management, and finance. These issues are further examined in a recently published report titled "U.S. Clinical Trial Management Systems 2006-2010 Forecast and Analysis (Apr 2006 - Doc # HI201214.) This report examines the commercial, vendor-developed, and packaged CTMS market with a focus on the U.S. market and market forces.

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Health Industry Insights Latest Research

<http://www.healthindustry-insights.com/HII/research/index.jsp>

Scott Lundstrom, Vice President of Research

2Q06 Leading Indicators in Life Science IT Spending Survey

Jun 2006 - Doc # HI201796 Survey

Worldwide Healthcare IT Spending Guide, 2004-2009

Apr 2006 - Doc # HI10030 Pivot Table

Dr. Alan S. Louie, Research Director

Better Views into Drugs and Disease: Insights from the Biomarker World Congress 2006

Jun 2006 - Doc # HI201889 News Flash

Delivering Value in Systems Biology - Genstruct Across the Spectrum

Apr 2006 - Doc # HI201075 Perspective

Lynne A. Dunbrack, Program Director – Health Payer Research

TEPR: Still Moving Towards the Electronic Patient Record

Jun 2006 - Doc # HI201880 News Flash

Care Management: How Health Plans Are Successfully Controlling Rising Medical Costs

May 2006 - Doc # HI201647 Survey

Christopher Connor, Senior Research Analyst

Will the Burden of Sarbanes-Oxley Crush Clinical Development?

May 2006 - Doc # HI201578 Perspective

U.S. Clinical Trial Management Systems 2006-2010 Forecast and Analysis

Apr 2006 - Doc # HI201214 Marketplace

Eric Newmark, Senior Research Analyst

2Q06 Leading Indicators in Life Science IT Spending Survey

Jun 2006 - Doc # HI201796 Survey

Data Integration: Pharma's #1 IT Priority

May 2006 - Doc # HI201883 Perspective



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Marc Holland, Program Director – Health Provider Research

TEPR: Still Moving Towards the Electronic Patient Record

Jun 2006 - Doc # HI201880 News Flash

Electronic Personal Health Records: A Survey of Consumer Attitudes and Usage

May 2006 - Doc # HI201461 Survey

In the News

- ◆ [Consumers Reveal Personal Health Records \(PHRs\) Are Barely on Their Radar](#); *Health Industry Insights' Report Finds Consumers Seek Control Over Medical Info*
- ◆ [Michael Brown Joins Health Industry Insights as Consulting Director](#)

Analyst Appearances

- Scott Lundstrom is speaking at the Oracle Healthcare User Group (HIUG) Conference 2006
June 4 – 7, 2006 in Orlando, FL
- Lynne Dunbrack is attending the [American Health Insurance Plans \(AHIP\) Conference](#) at the San Diego Convention Center
June 7-9, 2006 in San Diego, CA
- Scott Lundstrom, Lynne Dunbrack, Marc Holland, and Alan Louie are presenting at the [IDC IT Forum & Expo](#) at the Sheraton Boston Hotel; Chris Connor and Eric Newmark attending
June 14 – 16, 2006 in Boston, MA
- Alan Louie is presenting (entitled *Systems Biology: The Realization of Intelligent Drug Development*) at the [Drug Information Association \(DIA\) 42nd Annual Conference](#) at the Pennsylvania Convention Center
June 18 – 22, 2006 in Philadelphia, PA
- Lynne Dunbrack and Marc Holland are attending the [Health Information Technology Symposium](#) at the Massachusetts Institute of Technology
July 17 - 20, 2006 in Cambridge, MA
- **Join Scott Lundstrom for an IDC Telebriefing entitled *Electronic Health Records Fuel IT Investments in Healthcare*. Register [here](#) for the July 6, 2006 presentation.**

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