Over 230 participants attended more than 25 educational sessions to learn how industry pioneers are advancing clinical care and enhancing their financial strength by incorporating the latest molecular imaging techniques in tandem with emerging molecular diagnostics.

The first international Molecular Summit, 'Integration of Imaging and Diagnostics,' organized by Siemens and *The Dark Report*, took place in Philadelphia in February 2008, and was devoted to molecular imaging, molecular diagnostics, and advanced informatics. The goal of this meeting was to gather the finest minds in molecular medicine to share their experiences, visions, and predictions about the path toward individualized medicine.

Opening New Doors

According to Robert L. Michel, the Molecular Summit Founder and Host, "It's a historic time in diagnostics. Genetic knowledge is opening new doors, giving diagnostic medicine previously unimagined tools to diagnose disease earlier and with more precision."

This abundance of information, however, also has to be organized, stored, linked to increasingly detailed test results from medical imaging, and together they need to be made accessible for diagnostic and treatment decisions. Thus, the need for informatics is expanding rapidly. At the Summit, Bruce Friedman, MD, an active emeritus professor of pathology from the University of Michigan Medical School, Ann Arbor, MI, USA, expressed his surprise in the growth of molecular diagnostics and informatics. Friedman says he has not seen the field move forward so rapidly in his 40 years of experience in pathology.

The amount and speed of that growth as it relates to molecular diagnostics has put a strain on information systems' ability to effectively communicate test results for single patients. For his part, Michel stresses the importance of effective data management for patient care, noting, "Without informatics, the physician will be poorly served."

The development in oncology is a prime example of the need for information technology in medicine. According to Michael J. Becich, MD, PhD, Chairman of the Department of Biomedical Informatics at the University of Pittsburgh School of Medicine, PA, USA, "Seventy percent of clinical data are pathology related in oncology, and the wealth of information available for integration into the digital medical record exceeds the abilities of the current information technology systems." Furthermore, he notes that "The available tools are presently inadequate to provide information to other pathologists" and there is a great demand for seamless and automatic data "handoffs" among

"The one-size-fits-all therapy ignores the incredible genetic diversity of humans."

King Li, Chair of Radiology,
The Methodist Hospital, Houston, TX, USA, Weill Cornell Medical College,

all involved in patient care. According to panelists at the summit, seamless hand-offs include information technology that has the ability to easily retrieve information in a report format on the basis of a patient's diagnosis.

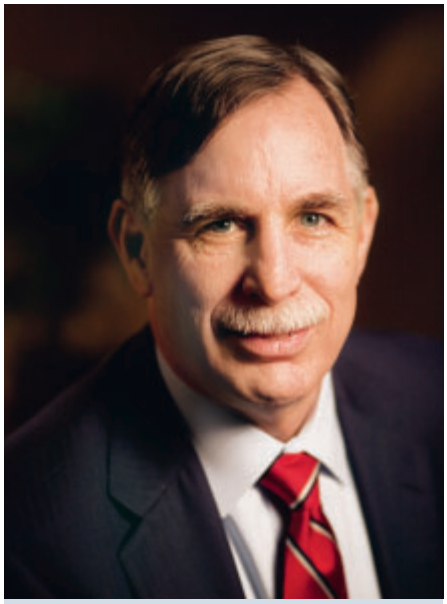
Technology and IT solutions are the promised enablers of the 21st century according to Jared Schwartz, MD, PhD, Director of Pathology and Laboratory Medicine at Presbyterian Healthcare of Charlotte, NC, USA, and President of the College of American Pathologists. In addition to extensions of existing techniques, such as immunoassays, he also expects further expansion into new arenas such as genomics, proteomics, multivariate index arrays, and biomarker panels, as well as innovations in data mining and data aggregation to access this additional information.

The integration of diagnostic test results into a sophisticated information technology system is vital to the movement toward individualized medicine and improved patient care. Siemens has long been a leader in medical imaging and more recently started a trend in the integration of imaging with diagnostics and informatics.

Beginning in 2000, Siemens invested in healthcare information technology and has since gained interests in molecular imaging and laboratory diagnostics. Thomas Miller, Chief Executive Officer of the Workflow and Solutions Division at Siemens Healthcare, a keynote speaker at the summit, believes that this integration will revolutionize healthcare and enable the advent of truly individualized medicine. "Most modern medical problems require a personalized approach," he says, "and individualized medicine will involve a tremendous amount of data corresponding to one's genetic makeup, personal history, lifestyle, and environmental influences."

Pathology: Catching Up

Today, there is less of a difference between pathologists and radiologists than in the past. Richard C. Friedberg, MD, PhD, Department of Pathology Chairman at Baystate Health in Springfield, MA, USA, and Professor of Medicine at Boston's Tufts University Medical School believes that radiologists and pathologists work in a parallel manner, providing "a junction between science and medicine." One glaring difference between pathologists and radiologists is that pathologists need to catch up in their use of information systems. Both Friedman and Becich believe that the integration between radiology and pathology data will be greatly improved with the ability to provide pathology data in a digital format that is more consistent with the information already provided by radiology.



"It's a historic time in diagnostics."

Robert L. Michel,
Molecular Summit Founder and Host,
Philadelphia, PA, USA

As with any transition, there will be barriers, along with many unknown factors, that may slow the integration of radiology and pathology. Initially, the integration will not make money because of the time and effort required for setup and the new hardware and software demands. In many institutions, there are likely to be political differences between the two departments – or even selfish agendas that can severely hinder integration. There can also be innocent personal barriers such as lack of familiarity or of experience with computer programs.

At the Summit, Michel presented an interesting and entertaining observation regarding the use of information technology based on age. Paraphrasing his anecdote, one can tell the age of various physicians based on their use of paper. First, there are Baby-Boomer physicians who were introduced to computers much later in life and like to use paper; they prefer to hold the data or images in their hands and to make comments directly with a pen. This generation uses films, files papers, and writes orders. Second, there are Generation-X physicians who were introduced to computers earlier in life and use information technology to

their benefit. This generation obtains research articles, test results, and other patient information via the computer, but they prefer to print them out to review them. Third, there are Generation-Y physicians who have always known computers, and they never use paper. Although these generational differences can be significant barriers, the presenters at the summit agreed that the differences are fading fast, especially as medicine continues to change and leadership is handed to the next generation.

The Future of Medicine

The future of medicine is headed toward an "early health model" which, according to Friedman, "Siemens is intimately interested in" because of the company's investments in molecular medicine. The early health model involves identifying preclinical and presymptomatic disease and making an early diagnosis based on molecular medicine. Currently, the healthcare system is designed to treat disease, and a very small percentage of its effort is targeted at preventing disease. Says King Li, MD, Chair of Radiology at The Methodist Hospital, Houston, TX, USA, Weill Cornell Medical College, "The one-size-fits-all therapy ignores the incredible genetic diversity of humans."

Individualized medicine is expected to be broadly used in healthy individuals to forecast disease and in patients to assess and treat disease. Li anticipates that molecular medicine will be used initially and that diagnosis and prognosis will be dependent upon individual biomarker data. Next, the information will be used to customize therapeutics based on the patient's genetics. In such a scenario, important molecules and pathways will be considered in diagnosis and treatment, and pharmacogenomics will optimize drug therapy to ensure maximum efficacy with minimal adverse effects. Molecular tracers will light up and identify diseased areas of the body, and specific areas will be targeted for intervention. Once identified, the drug dose and drug effect can also be monitored with molecular tracers.

Li also believes that pharmacogenomics can play a role in proper pharmacologic use, pointing out that underdosing, overdosing, and missed dosing cost the United States healthcare system more than one hundred billion dollars each year.

Currently, the areas of breast cancer, hematology, and cardiac transplantation are using genetics to individualize treatment options. We have known since the 1960s that there are prognostic differences in patients with different types of breast cancer, and now oncotyping is used to determine the need for chemotherapy. In fact, the CYP450 chip has been approved by the Food and Drug Administration. It contains DNA fragments, or probes, to determine a patient's genetic profile, which is then used to guide treatment. Chemotherapy is known to be effective in reducing the risk of distant metastases, but not all patients require chemotherapy. The CYP450 chip can genetically identify the 70 to 80 percent of patients with breast cancer who will not benefit from chemotherapy. Genetic information is being used in other areas of medicine to identify patients who will benefit from certain medications or interventions. Specifically, an individual patient's genetic profile is considered when using warfarin, a popular anticoagulant, and when determining the risk of rejection in cardiac transplantation.

The Role of Genetic Medicine in Industry

There are many opportunities for the application of molecular medicine within the pharmaceutical industry. Li says that

Summary

Challenge:
- Handling the information overload associated with the future of medicine
- Implementing information systems for all areas of medicine

Solution:
- Developing information technology that links both molecular imaging and laboratory diagnostics
- Linking different hospital departments and administrative units into one information system
- Educating faculty and staff about the benefits of informatics

Result:
- IT databases that hold medical information which can be retrieved in a fast, safe, user-friendly manner
- Faculty support for informatics
- Organized, efficient use of clinicians' time
- Improved patient care
- Advancements toward personalized medicine

> "Most modern medical problems require personalized management, and individualized medicine will involve a tremendous amount of data."
>
> Thomas Miller, CEO,
> Workflow and Solutions Division, Siemens Healthcare, Erlangen, Germany

Healthy Communication

MedCentral Health System, one of the largest medical providers in central Ohio, USA, recently implemented Project Expert Care: a system-wide integration of healthcare information technology, including Soarian®, a hospital information system, and NOVIUS Lab, both designed by Siemens Healthcare. *Medical Solutions* spoke with clinical chemist Eugenio H. Zabaleta, PhD.

How are improvements in workflow – enabled by automated equipment and information technology (IT) connectivity – creating a new role for the laboratory in patient care in nonacademic hospitals?
ZABALETA: Laboratory and/or imaging studies influence most of the clinical decisions made by a physician. In my laboratory, we constantly ask ourselves, "How can we help the clinician convert laboratory data into meaningful clinical information?" The laboratory result can be just a number, but that number means something when analyzed within the patient's clinical picture. This is how the clinical laboratory will become integral to the healthcare continuum – with a renewed focus on how, when, and where our results are utilized.

What have been the benefits of integrating laboratory diagnostic technology and IT in Project Expert Care?
ZABALETA: To deliver accurate laboratory test results to clinicians in a timely manner, it's imperative to have effective and efficient integration between information systems and laboratory diagnostic technology. It doesn't matter if we produce the best result possible if that result doesn't reach the physician in time to save the patient's life. How do we best communicate the information produced by the diagnostic services? There is only one answer: by having IT that can deliver it efficiently. In order to be effective and efficient, the key word for the healthcare industry should be communication, communication, communication. Did I say communication?

Are there operational changes that need to happen in order for the laboratory to become integral to the clinical decision-making process?
ZABALETA: To expand our role in the clinical process, we first have to deliver laboratory data swiftly and reliably. Automation is essential to do this. MedCentral implemented the Siemens ADVIA WorkCell® Automation Solution and the ADVIA CentraLink® Networking Solution to automate and integrate clinical chemistry, immunoassay, and specimen processing in 2003. Before the implementation, we had many variations in turnaround time in the emergency department [ED]. The turnaround time for cardiac markers, for instance, was not consistent from patient to patient. Since we implemented WorkCell, we standardized the turnaround time on the ED for cardiac markers.

We now meet the turnaround standard for cardiac marker set by the National Academy of Clinical Biochemistry. One of the benchmarks of the guideline is a turnaround time for Troponin within 60 minutes. According to an article published in April 2007 in the AACC's [American Association for Clinical Chemistry] *Clinical Laboratory News*, our lab is in the top 25 percent of labs in the nation for Troponin turnaround. This kind of operational performance is really mandatory for laboratories well integrated into clinical decision-making.
And once the test is complete, the NOVIUS® Lab system allows for auto-release of the results, increasing the efficiency of the process. How can we expect our clinicians to accept below-standard turnaround times when the clock is ticking so loudly for patients in the ED?

Synchronized workflow has allowed for connectivity among many clinical departments, not just the laboratory. Can you quantify an economic value as a result of MedCentral's new IT infrastructure?
ZABALETA: Laboratory procedures at MedCentral jumped from 9,975 per full-time equivalent [FTE] in 2004 to 10,971 in 2006. Beyond the laboratory, many other measures have also improved, such as length-of-stay, from an average of 5.4 days in 2003 to an average of 4.87 days in 2006. The hospital expects to save six million US dollars a year with the new effort. And that's a conservative estimate. We wouldn't be surprised if the savings prove to be even greater than that.

If you had to pick one feature of the Siemens IT Solution that your physicians like best, what would it be?
ZABALETA: The longitudinal record seems to be one of the favorites. *MF*

Nonstop knowledge sharing: Even the breaks at the Molecular Summit were filled with profitable discussions.

pharmaceutical companies could save a tremendous amount of money by using molecular tracers to identify drugs that are unlikely to produce specific results in vivo. In this scenario, drug development would be halted at a much earlier stage if the drug were determined to have no effect on its target, rather than performing costly studies that produce negative results. The pharmaceutical industry is also a leader in informatics and in the development of laboratory information systems because of the requirements associated with managing large, complex research data from clinical studies. Hospitals and the healthcare industry are following the pharmaceutical industry's lead, but considerable advancement is required to handle all of the clinical information and its subsequent scheduling and billing concerns in order for successful integration to occur.
The landscape of medicine is likely to change with the development of individualized medicine. Leaders in molecular medicine anticipate more information being available to clinicians in a less invasive manner. For example, there is the potential for blood draws to replace imaging and invasive tests such as biopsies. However, with the rapid advancement of molecular medicine, ethical considerations must also be established and resolved. There is a lot of excitement and optimism surrounding the move toward more individualized medicine, and leaders at the summit unanimously agreed that this is just the beginning of what promises to change the way healthcare is delivered.

Robert L. Bard *is a certified freelance medical writer and clinical researcher at the University of Michigan's Division of Cardiovascular Medicine, Ann Arbor, MI, USA.*

Further Information

www.siemens.com/diagnostics