Put it On the Board, 5/13

Omnyx digital pathology OK'd for routine use in Canada, Europe

The Omnyx integrated digital pathology (IDP) system, developed in a GE Healthcare–University of Pittsburgh Medical Center joint venture, has obtained a Health Canada class II medical device license and the CE Mark in the European Union.

These designations make it possible for pathologists to use the IDP system to create, manage, store, annotate, measure, and view digital whole slide images for routine pathology use. The license and the CE Mark permit the use of whole slide images from specific third-party scanners.

The University Hospitals Coventry and Warwickshire (UHCW) NHS Trust, UK, a teaching trust that serves more than 1 million people, took part last year in a three-month beta test of the Omnyx IDP system. David Snead, MBBS, consultant pathologist and clinical director of cellular pathology at UHCW, said in a statement that "through a well-thought-out system architecture and workflow program, Omnyx could feasibly link a number of pathology departments to work as one large team. This would help pathologists achieve great time efficiency. With efficiency, cost saving should soon follow."

Toronto's University Health Network Laboratory Medicine Program was a beta and clinical test site. Andrew Evans, MD, PhD, UHN's director of telepathology, said in a release that Health Canada's approval "helps to reassure pathologists that this technology can be used safely and effectively for routine diagnostic work."

PCR platform, kit cleared for H7N9

Life Technologies' Applied Biosystems 7500 Fast Dx Real-Time PCR instrument has been cleared for use under the CDC protocol created for emergency screenings of patients suspected of harboring the avian influenza (H7N9) virus.

Cleared under the FDA's emergency use authorization, the 7500 Fast Dx Real-Time PCR instrument, in addition to Life's SuperScript III One-Step qRT-PCR reagent kit, is intended to be used with the CDC's human influenza virus assay. Life Tech is increasing production of its reagents and shipping them to labs around the world.

CollabRx forms Pan Cancer molecular oncology editorial board

CollabRx has formed a Pan Cancer (biomarker-focused) molecular oncology editorial board to be led by Razelle Kurzrock, MD, who will serve as chief editor.

The Pan Cancer editorial board will apply a broad molecular oncology perspective in identifying biomarkers that are clinically actionable in any cancer type. The board will focus initially on the development of a Web-based application that will associate specific biomarkers with expert-vetted and clinically relevant information on drugs and clinical trials. Functionality will be extended in stages; at launch, the application will address sequencing-based biomarkers such as gene mutations, insertions/deletions, fusions, and other aberrations. CollabRx will make a version of this application free online for physicians and researchers. Subsequently, pathologists and oncologists will be able to use the application at the point of care to annotate their own data generated on any next-generation sequencing platform or sequencing-based test results obtained from any laboratory.

Dr. Kurzrock is director of the Center for Personalized Therapy at UC San Diego Moores Cancer Center, vice chief of the Hematology-Oncology Division in the UC San Diego School of Medicine, and senior deputy center director of clinical science at the Moores Cancer Center.

CollabRx uses IT to aggregate and contextualize knowledge on genomics-based medicine with insights from cancer

experts.

‘Time for omic ancillary systems’

Commercial electronic health records may eventually evolve to handle omic data efficiently, but until then dedicated omic ancillary systems will be essential, write the authors of a March 27 *JAMA* viewpoint, “Crossing the omic chasm—a time for omic ancillary systems” (309[12]:1237–1238).

A recent Institute of Medicine report said the current document-centric approach to genomic, proteomic, and other omic data won’t scale, making storage of raw omic data in current-generation EHRs infeasible, write Justin Starren, MD, PhD, Division of Health and Biomedical Informatics, Northwestern University Feinberg School of Medicine; Marc Williams, MD, Genomic Medicine Institute, Geisinger Health System; and Erwin Bottinger, MD, Charles Bronfman Institute for Personalized Medicine, Mount Sinai School of Medicine, New York, NY.

“An individual’s germline genetic sequence changes little over a lifetime,” they write, “but understanding of that sequence is changing rapidly…. This necessitates systems that dynamically reanalyze and reinterpret stored static genomic results in the context of evolving knowledge.”

Increasingly, next-gen sequencing and other such testing will become routine, “creating large, complex data sets and setting the stage for ‘omic’ ancillary systems,” they say, calling them “one way to bridge the omic chasm without waiting for an entirely new generation of EHRs to emerge.”

Thermo Fisher to acquire Life Tech

Thermo Fisher Scientific and Life Technologies have signed a definitive agreement under which Thermo Fisher will acquire Life Tech for about $13.6 billion plus the assumption of net debt at close ($2.2 billion as of year end 2012). The transaction is expected to close early next year.

Approved by both companies’ boards of directors, the transaction is expected to create an industry leader to serve research, specialty diagnostics, and applied markets; strengthen technology and innovation through complementary offerings; and provide attractive financial returns to shareholders.

First next-generation sequencing assay for GE Healthcare

GE Healthcare on April 8 announced that Clarient Diagnostic Services, a GE Healthcare company, will offer a next-generation sequencing assay that will target the 26 most common oncogenes and tumor suppressor genes, selected for their implication in solid tumor indications such as lung, breast, and colon cancers and melanoma. The assay, which is for use in clinical trials, will be performed at Clarient.

The test is the first next-gen sequencing assay GE Healthcare launched since it acquired Seq-Wright, a research lab offering nucleic acid sequencing and other genomic services. The acquisition provided a platform for Clarient to expand its clinical diagnostic offerings to include next-gen sequencing.

FDA clears BD Diagnostics’ *C. diff* assay

BD Diagnostics on April 8 received FDA clearance to market in the United States its BD Max Cdiff assay. Performed on the BD Max system, the test is designed to detect the toxin B gene (*tcdB*).

“The BD Max Cdiff assay is a simple, easy-to-use, fully automated method for detection of these dangerous bacteria,” Tom Polen, president, BD Diagnostics-Diagnostic Systems, said in a statement.

The assay acquired the CE Mark in March 2012 and has demonstrated excellent performance in Europe, BD Diagnostics said in a release.

Foundation Medicine, Sloan-Kettering to co-develop test for hematologic cancers

Foundation Medicine and Memorial Sloan-Kettering Cancer Center will co-develop a new Foundation Medicine molecular diagnostic product designed to match patients who have hematologic cancers with the most rational targeted therapies or clinical trials for their cancer. Leaders in hematology from Memorial Sloan-Kettering will provide clinical and genomic expertise.

The new test is expected to be available commercially by the end of this year.