

Put It on the Board, 10/13

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LifeTech names TriCore an NGS Center of Excellence

TriCore Reference Laboratories and Life Technologies have signed an agreement to establish TriCore as a regional Next-Generation Sequencing Center of Excellence. The partnership is part of Life's initiative to establish a global alliance composed of centers capable of running the most advanced NGS-based oncology panels for clinical research.

TriCore has entered the agreement in collaboration with the Department of Pathology of the University of New Mexico Health Sciences Center, with which it already shares several initiatives.

Life Tech's panels are designed to identify genetic mutations in research samples that can serve as potential drug targets suitable for further studies. Life expects to spur a collaborative effort among the members of its alliance to advance screening methods for clinical research samples.

In Ontario, success and satisfaction with synoptic reports

Nine years after Cancer Care Ontario, the provincial government agency responsible for the provision of quality cancer services, began working to improve cancer pathology reporting in the province's hospitals by standardizing the content, format, and transmission of reports to the Ontario Cancer Registry, 97 percent of those hospitals have implemented synoptic pathology reporting, with a 94 percent completeness rate against the CAP cancer protocol standard.

In addition, "Standardized synoptic cancer pathology reports: So what and who cares?," a study that will be published next month in Archives of Pathology & Laboratory Medicine, found that physician satisfaction with synoptic cancer pathology reporting as a clinical decision support tool is strong.

The Ontario project consisted of three phases that involved a partnership between Cancer Care Ontario and the Ontario Association of Pathologists, Ontario Cancer Registry, Canadian Partnership Against Cancer, and the province's 116 hospitals.

The foundational phase of the project focused on "engagement of the pathology community and other groups, like vendors," says John Srigley, MD, coauthor of the Archives study and former head of Cancer Care Ontario's Pathology and Laboratory Medicine Program. "The other major piece was manual chart auditing and feedback. We had coders at the Ontario Cancer Registry identify the data we were looking for. This audit and feedback piece was important because it showed pathologists who were still doing narrative reports that they were less complete than synoptic-like reports." Dr. Srigley is also chief and medical director of the Program of Laboratory Medicine and Genetics at Trillium Health Partners, Mississauga, Ontario, and a professor in the Department of Pathology and Molecular Medicine at McMaster University.

In the first phase of the project, the CCO and the Canadian Partnership Against Cancer provided funding to hospitals so they could implement electronic reporting systems. "We limited it to five checklists [lung, colorectal, prostate, endometrium, and breast], and we did it one hospital at a time," Dr. Srigley says. "We were able to get a very high compliance with true synoptic reporting for those five major cancer sites, and that led us to the final phase, where we implemented it in the rest of the hospitals [in the province]—including ones that were slow to engage because they had LISs that weren't very responsive—and expanded it to 63 checklists."

That second and final phase of the project included a series of national (not just provincial) educational forums, in which pathologists discussed how to use a particular CAP cancer protocol. "We've now had over 25 of those

sessions in the last four years.” Equally key was the monthly series of hospital conference calls “where we had a lead pathologist and a lead informatics person for all the cancer-reporting hospitals in the province. That central support was so important,” says Dr. Srigley, who is a liaison to the CAP Cancer Committee from CCO and the Canadian Association of Pathologists.

To determine how satisfied Ontario’s pathologists, surgeons, and oncologists were with synoptic reporting, Dr. Srigley and several of his colleagues conducted the survey, once the first phase of the project had been completed, that formed the basis for the Archives study. In all, 498 surveys were completed, with respondents rating their satisfaction with synoptic reports on a five-point scale. A score of five indicated that the respondent considered synoptic reports “significantly better” than narrative reports. As the study’s authors write: “. . . the vast majority of physicians who responded reported that the standardized synoptic pathology reports were significantly better than narrative reports for all items, with mean scores ranging from 3.84 to 4.77.”

Pathologists who responded to the survey indicated that synoptic reports took them more time to produce than narrative reports, largely because of technological issues. So why did they report greater satisfaction with the synoptic reports?

Perhaps because, as Dr. Srigley says, they realized that synoptic reporting would allow them to better monitor clinical performance and quality. “They understood from an early stage of the project that pathology reports contain performance indicators,” he says. “Pathologists, like any other physicians, respond to data. For example, the retrieval of lymph nodes in colorectal cancer is a clinical performance indicator. To have this stuff be clinically relevant and used for quality improvement—that’s really the ultimate thing.”

Medtronic seeks code for MiniMed 530G

With its unveiling of the first FDA-approved system that includes the name “artificial pancreas,” Medtronic Diabetes has applied to the Centers for Medicare and Medicaid Services for a new reimbursement code.

Medtronic announced approval last month of the MiniMed 530G with Enlite, approved under a new FDA category called “OZO: Artificial Pancreas Device System, Threshold Suspend.” The system combines an insulin pump with a continuous glucose monitor that automatically suspends insulin for up to two hours when sensor glucose values reach a preset level—and the patient doesn’t respond to an alarm.

Medtronic Diabetes spokeswoman Amanda Sheldon said insurance coverage for the new system will be based now on existing reimbursement codes for insulin pumps and continuous glucose monitors. But that could change, Sheldon said in a statement early this month. “We have applied for a new code with CMS for sensor-augmented pumps. We will evaluate additional reimbursement codes based on this new category of devices,” she said.

Ventana ALK IHC assay approved for Xalkori in China

Ventana Medical Systems has the approval of the Chinese Food and Drug Administration (CFDA) for the Ventana ALK immunohistochemistry assay as a companion diagnostic to aid in identifying patients for Pfizer’s CFDA-approved oncology product Xalkori (crizotinib).

The Ventana ALK (D5F3) rabbit monoclonal primary antibody assay is designed to identify the ALK-positive patients among non-small cell lung cancer patients. The approval is based on a retrospective study that included 1,100 Chinese subjects across three national hospitals in which the Ventana assay demonstrated 99.23 percent concordance with Abbott’s Vysis ALK Break Apart FISH Probe Kit.

Life Tech releases EZQC Online

Life Technologies has launched its EZQC Online, a Web-based tool for quality control management in molecular diagnostic labs. EZQC Online contains three modules: a guidance tool for initial validation and verification of

molecular tests, a tool to help labs meet CLIA standards for calibration verification, and a tool for ongoing QC monitoring that provides an opportunity for peer-to-peer comparisons.

The Validations/Verifications module includes a comprehensive database of guidelines and templates that can be used to design validation protocols and analytical reports. The tool's QC Monitoring module allows labs to monitor test performance, alerting personnel to data drift and to potential failures before they occur. In addition to tracking internal lab testing quality, the online tool offers a feature through which labs can gauge the performance of their assays against that of other laboratories. The data are anonymized, and each user sets the levels of data sharing to ensure confidentiality of results.

Beckman's AccuTnl+3 cleared for use on UniCel Dxl series

The Food and Drug Administration has cleared Beckman Coulter's Access AccuTnl+3 troponin I assay for use on the UniCel Dxl series of immunoassay systems.

The Access AccuTnl+3 troponin I assay was cleared in June for use on Beckman's Access 2 immunoassay analyzer. The new troponin assay is now cleared for use on all of the company's immunoassay systems, as well as the UniCel DxC integrated chemistry and immunoassay series.

Dako, Omnyx launch digital solution

Dako and Omnyx LLC, a joint venture of GE Healthcare and the University of Pittsburgh Medical Center, are launching clinical image analysis for digital pathology in Europe.

As part of the collaboration which began in 2010, Dako has used its expertise in staining and image analysis to develop algorithms that are incorporated into the Omnyx digital pathology platform as part of Omnyx's overall strategy of providing pathologists with a comprehensive digital workflow. The HercepTest image analysis tool is now accessible in the Omnyx system and has been customized for Dako's breast cancer prognostic markers.