Put It on the Board, 6/17

CMS grants Qualified Clinical Data Registry status to Pathologists Quality Registry

The Centers for Medicare and Medicaid Services has approved the CAP's Pathologists Quality Registry as a Qualified Clinical Data Registry, or QCDR. This makes it a reporting option for pathologists in fulfilling reporting requirements under Medicare's Quality Payment Program.

As a CMS-approved QCDR, the Pathologists Quality Registry will collect medical quality data from a pathologist or pathology group practice for physician quality reporting under the Quality Payment Program, or QPP. The registry will send data directly to the CMS to track quality and foster improvement in patient care. This will also ease the reporting burden for pathologists and improve opportunities to increase Medicare reimbursements through the Medicare QPP. Getting QCDR status from the CMS is a strong indicator that the Pathologists Quality Registry will continue to meet QPP reporting requirements in the future.

The Pathologists Quality Registry is set to launch at the CAP17 annual meeting in October so CAP members can begin submitting 2018 data on Jan. 1, 2018.

The registry also provides access to quarterly benchmarking reports that enable practices to improve care provided to patients. The registry will include 16 measures, eight of which are the current Physician Quality Reporting System (PQRS) measures developed by the CAP.

The CAP is working with FIGmd, the leading provider of clinical data registries to specialty societies, in developing the Pathologists Quality Registry.
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FDA okays assay to identify ALK+ NSCLC patients

Roche announced FDA approval of the Ventana ALK (D5F3) CDx Assay as a companion diagnostic to identify ALK-positive non-small cell lung cancer patients eligible for treatment with the Novartis drug Zykadia (ceritinib). The Ventana ALK (D5F3) assay is the only immunohistochemistry test approved by the FDA as a companion diagnostic for Zykadia.

The assay is intended for the qualitative detection of the anaplastic lymphoma kinase protein in formalin-fixed, paraffin-embedded NSCLC tissue stained with a BenchMark XT or BenchMark Ultra automated staining instrument. It is indicated as an aid in identifying patients eligible for treatment with Xalkori (crizotinib) or Zykadia.
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Sciex first with FDA-cleared vitamin D assay for mass spec

Sciex Diagnostics announced the first FDA-cleared (via the de novo pathway) LC-MS-based vitamin D assay kit, the Vitamin D 200M Assay, exclusively for the Sciex Topaz System. The Topaz is a fully integrated LC-MS platform driven by ClearCore MD software designed for use in clinical laboratories.

The CDC has established a Vitamin D Standardization-Certification Program and the Sciex Topaz Vitamin D 200M Assay kit has met the performance criteria, Sciex said. While individually quantitating D2 and D3 isomers, the Topaz System running the Vitamin D 200M Assay kit also automatically differentiates between D3 epimers, providing the specificity needed for accurate diagnostic results in a single analysis.

The Vitamin D 200M Assay for the Topaz is intended for in vitro diagnostic use in the quantitative determination of total 25-hydroxyvitamin D (25-OH-D) through the measurement of 25-hydroxyvitamin D3 (25-OH-D3) and 25-hydroxyvitamin D2 (25-OH-D2) in human serum using LC-MS/MS technology.
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OGT pushes forward hybridization-based targeted sequencing

Oxford Gene Technology has made several advances in hybridization-based target enrichment protocols that enable researchers to prepare samples for sequencing in one day. Researchers can access the high-quality results of hybridization-based targeted sequencing with a speed comparable to that of amplicon-based approaches, according to the company.

Oxford Gene's hybridization-based targeted sequencing delivers coverage uniformity that makes it possible for researchers to detect low frequency variants consistently down to one percent variant allele frequency at a read depth of >1,000×. The company's latest protocol developments enable even more researchers to quickly and precisely focus in on regions relevant to their research.

Oxford Gene's hybridization assay enhancements improve speed and enable lower input levels of DNA to be used. The company has optimized its enzymes and buffers to allow pooling of library preparation steps, enabling users to complete the enrichment protocol in less time. This includes a short enzymatic fragmentation step, combined end-repair and adaptor ligation steps, and an optimized hybridization of 30 minutes for good quality DNA samples. In addition, the company's NGS panel optimization yields good data with as little as 10 ng of starting material, according to OGT.
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Sysmex to acquire OGT

Oxford Gene Technology announced it has signed an agreement to be acquired by Sysmex. Sysmex will acquire all of OGT's shares, gaining access to OGT's genetic analysis technologies and expertise in the cytogenetics domain. OGT will become a wholly owned subsidiary of Sysmex.

With the acquisition of OGT, Sysmex will enter the cytogenetics market with fluorescence in situ hybridization and array comparative genomic hybridization products.

Product development synergies have been identified that combine OGT's expertise in genetic assays for hematology, solid cancer, and rare disease with Sysmex's expertise in instrument development and in vitro diagnostics to expand offerings in genomic medicine. OGT says R&D teams from OGT and Sysmex will collaborate, for example, to develop an automated system for FISH testing by combining Sysmex's automation technology with OGT's FISH reagent development expertise.[hr]