EMAs and the EMA: New Developments in Clinical Data Access

By Jorge Gallego

The European Medicines Agency (EMA) has released a policy that will enable researchers to access clinical trial data, opening up new possibilities for medical research. The policy, which was approved in June, will allow researchers to download clinical trial reports on specific approved drugs, providing a wealth of information that can be used to improve the development of new drugs and treatments.

The EMA policy has provoked debate, with some critics arguing that it will expose sensitive information and harm patients. However, the policy is designed to balance the need for transparency with the protection of patient privacy. The EMA will consider exceptions to the policy on a case-by-case basis, and will work with researchers to ensure that data is used ethically.

Researchers have already begun to take advantage of the new policy. For example, scientists at the Massachusetts General Hospital (MGH) have been able to use the policy to access data from clinical trials of a drug called erlotinib, which is used to treat lung cancer. This data has allowed them to develop new treatments for the disease.

The EMA policy is a significant step forward in the area of clinical data access, and it is likely to have a major impact on the future of medical research. As more researchers gain access to this data, we can expect to see new breakthroughs in the fight against cancer and other diseases.
French Collaboration to Advance Data Analysis

Genetic analysis offers unprece-dented power to diagnose tumors and target therapies, but it also brings the challenge of managing many gigabytes of data. Now, a French collaboration has formed to develop advanced scientific software that will help make sense of all this information.

The Interpretation of Clinical Exome, or ICE, project includes French cancer center Gustave Roussy; the French National Health and Medical Research Institute, known as Inserm, which is providing nearly $3 million; and two companies: the genomics services firm IntegraGen and an engineering and technology consulting firm, Sogeti High Tech. The four collaborators bring expertise in genomic sequencing, data management, software development, and clinical practice.

Bernard Courtieu, chairman and CEO of IntegraGen, says sequencing a single patient takes 20 gigabytes of data, and matching that with the dozens of targeted drugs expected to be approved in the next few years will be a major choke point in care. The main goal, he says, will be to match the patient’s genomic profile with available drugs, something that will soon be too complex for doctors to do on their own.

The ICE Program also intends to provide what a U.S. oncologist describes as “genomic profiling for dummies,” so that doctors who have a limited amount of time to spend with a patient will be able to derive and share meaningful information about that person’s profile.

The collaborators expect to complete an early version of the software in 2016, at which point the market will be 1 to 2 years before the device is sold. IntegraGen, which is providing nearly $3 million; and two companies: the genomics services firm IntegraGen and an engineering and technology consulting firm, Sogeti High Tech. The four collaborators bring expertise in genomic sequencing, data management, software development, and clinical practice.

Jeffrey Smerage, MD, PhD, who conducts research on CTCs at the University of Michigan Comprehensive Cancer Center in Ann Arbor, agrees the technology is not ready for routine clinical use.

Smerage, who was not involved in the study, says researchers must still determine how methods used to grow CTCs influence their gene expression and whether CTCs and metastatic tumors are biologically the same. Even so, the findings make Smerage “very optimistic” about the possibility of using CTCs to guide therapy.

For more news on cancer research, visit Cancer Discovery online at http://CDnews.aacrjournals.org.

NOTED

- The FDA granted traditional approval to idealisib (Zydelig; Gilead) for use with rituximab (Rituxan; Genentech) for the treatment of relapsed chronic lymphocytic leukemia. The agency also granted accelerated approval to the drug for the treatment of relapsed follicular B-cell non-Hodgkin lymphoma and relapsed small lymphocytic lymphoma.

- Roche announced that a phase III study of the MEK inhibitor trametinib (Mekinist) in combination with its BRAF inhibitor dabrafenib (Tafinlar) based on an interim analysis showing an overall survival benefit. The trial was comparing the combination to vemurafenib in patients with BRAF V600 mutation-positive advanced melanoma.

- GlaxoSmithKline halted a phase III trial of its MEK inhibitor trametinib (Mekinist) in combination with its BRAF inhibitor dabrafenib (Tafinlar) based on an interim analysis showing an overall survival benefit. The trial was comparing the combination to vemurafenib in patients with BRAF V600E or V600K mutation-positive advanced melanoma.

- New York’s Cold Spring Harbor Laboratory received a $50 million gift from the Jim and Marilyn Simons Foundation to establish a center focused on using quantitative biology to interpret genomic research data from a variety of diseases.

- Los Angeles, CA-based Puma Biotech- nology announced that women with early-stage HER2-positive breast cancer who took neratinib (PB272) for adjuvant treatment of their disease as part of a phase III clinical trial experienced 33% improvement in disease-free survival compared with those who took a placebo. Based on the study’s findings, Puma plans to file for FDA approval of neratinib in 2015.

- The American Thoracic Society, American College of Chest Physicians, and other organizations in the Forum of International Respiratory Societies issued a position statement taking a dim view of electronic cigarettes. “As a precaution,” the statement reads, “electronic nicotine-delivery devices should be restricted or banned until more information about their safety is available. If they are allowed, they should be closely regulated as medicines or tobacco products.”