By Carrie Printz

NCATS Advisory Council Recommends Strategies to Strengthen CTSA Program

Following a June 2013 Institute of Medicine (IOM) report on ways to strengthen the National Institutes of Health's Clinical and Translational Science Awards (CTSA) program, a group for the National Center for Advancing Translational Science (NCATS) has developed a set of strategic goals to improve the program.

The group, composed of representatives with extensive expertise in key subject areas addressed in the IOM report, zeroed in on specific recommendations from IOM, then created strategic goals and measurable objectives to achieve them, says working group co-chair Mary L. (Nora) Disis, MD, of the University of Washington School of Medicine in Seattle.

The major goals revolve around developing workforce, fostering collaboration, and improving methods and processes. Highlights of the goals include:

- Building an environment that supports and values translational science as "the place to go" for those who want to pursue high-impact careers in health sciences;
- Engaging stakeholder communities so they contribute meaningfully across the translational science spectrum;

National Center for Advancing Translational Science

Dr. Petra Kaufmann, NCATS director of clinical innovation, is eager to put strategic goals into action to strengthen the Clinical and Translational Science Awards program.

- Integrating translational science across the entire lifespan to attain health improvements for all; and
- Enabling CTSA programs to function individually and together as a research engine transforming the way translational science is conducted across the nation.

"We will know when collaborations have improved when we see that there are collaborations between NCATS and external partners like the FDA and industry partners and that the same kinds of collaborations are occurring at all 62 CTSA sites," says working group co-chair Ron Bartek, president of Friedreich's Ataxia Research Alliance, a nonprofit organization based in Downington, Pennsylvania, dedicated to curing Friedreich's ataxia through research.

"We are carefully considering this working group report as we develop next steps for this crucial program," says Petra Kaufmann, MD, NCATS director of clinical innovation. "The 4 strategic goals outlined in the report are of particular significance in our efforts to move forward as quickly as possible with implementation strategies."

U.S. FDA in Line with Japan, Europe for New Drug Approvals

The U.S. Food and Drug Administration (FDA) is keeping pace with its regulatory counterparts in Japan and Europe, according to a recent study by the Centre for Innovation in Regulatory Science (CIRS) in London.

The study reports little difference between the FDA's record for number of drugs approved compared with similar agencies in other countries.

In 2013, the FDA approved 29 drugs, while Japan and Europe approved 28 and 30, respectively. In particular, Europe had a significant increase in approvals last year compared with 2012 because it was "catching up" on compounds that had already been approved by the FDA, wrote FDA commissioner Margaret Hamburg, MD, in an online article for the FDA Voice earlier this year.

In terms of length of time to drug approval, the FDA outpaced its Japanese and European counterparts. The study reports the FDA's median approval time for new drugs in 2013 was 304 days compared with 342 days in Japan and 478 days in Europe. At the same time, of the 21 new drugs approved by all 3 agencies from 2009 to 2013, 76% were first approved by the FDA.

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The U.S. FDA approved 29 new drugs in 2013, a number on par with drug approvals in Japan and Europe last year.

John Jenkins, MD, director of the Office of New Drugs at the FDA's Center for Drug Evaluation and Research, puts the report into context: "We don't consider ourselves to be in a race with other countries' regulatory authorities, but we are proud that our system is working very efficiently to the benefit of patients in the U.S.," he says.

"We have to take caution in recognizing that new drug applications aren't submitted to all countries at the same time," Dr. Jenkins adds. "The U.S. is often the first country where companies will seek approval."

That wasn't always the case. In the 1980s and early 1990s, the U.S. was rarely first to approve new drugs; however, over the past 2 decades, the FDA has been committed to changing that "drug lag" scenario, says Dr. Jenkins.

The agency's accelerated breakthrough therapy designation—established in July 2012—is the most recent program to quickly bring promising drugs to market. At press time, the FDA had granted 44 such designations and approved 6 of these drugs.

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University of Texas Biobank Launches Automated Tool to Enhance Research

A new software tool may help scientists more efficiently search for clinical data and human samples in a biobank maintained by the University of Texas (UT) Health Sciences Center at Houston.

Dubbed the Sample Location and Enhancement Distribution (SLED) application, the automated system provides sample request management and allows investigators to easily search UT's Center for Clinical and Translational Science (CCTS) Biobank.

The biobank consists of more than 200,000 human samples—including plasma, serum, DNA, buffy coat, and red blood cells—and related clinical data from contributing investigators. The biobank staff is working to obtain tissue samples as well.

"In the past, we always used a very manual process," says CCTS Biobank program manager Jennifer Sanner, PhD, noting that the previous system required multiple documents to be sent by email and many databases to be queried in order to find samples. SLED centralizes the process into a single automated system, enabling researchers to make queries directly at one online location and eliminating the need for multiple emails and databases.

Although SLED currently is only active for UT institutions, it can be implemented at any medical research center and is available to all members of the Clinical and Translational Science Awards (CTSA) consortium, says CCTS Biobank coordinator Krystle Nomie, PhD. Dr. Nomie and her colleagues can provide consultation on how to build a SLED-type program, she says, and are considering enabling researchers from CTSAs nationwide to access SLED. For more information about SLED, contact Dr. Nomie at Krystle.J.Nomie@uth.tmc.edu.

Michigan State University Latest CTSA to Join ResearchMatch

The Clinical and Translational Sciences Institute (CTSI) at Michigan State University (MSU) is the latest affiliate of the Clinical and Translational Science Awards (CTSA) consortium to join ResearchMatch, an online system that links volunteers for medical research studies with researchers.

Currently, 55 of the 62 CTSAs across the country are using ResearchMatch. MSU researchers have used the online resource to recruit patients for studies involving exercise motivation and obesity as well as health-related smartphone applications.

"It's been met with a lot of excitement from researchers," says Andrea Amalfitano, DO, PhD, director of the MSU CTSI. "We actually need to bring more researchers into the fold because there are plenty of people interested in participating."

Dr. Amalfitano describes ResearchMatch as being similar to a dating site in that it provides a "match" for volunteers and researchers. Interested volunteers fill out a short online questionnaire about themselves and their health background, then wait to be contacted by a researcher. Volunteers can narrow or widen their search criteria for different types of studies, and the program preserves their anonymity until they decide to participate in a study.

For more information on ResearchMatch, see https://www.researchmatch.org/?rm=CTS.

ResearchMatch, an online resource for medical research study participants and investigators, has attracted more than 60,000 volunteers since its launch in 2009.

Older Diabetes Patients with Depression Have Higher Risk of Death

Researchers at the University of California, Los Angeles (UCLA) have found that depressed patients age 65 and older with diabetes had a 78% greater risk of early death compared with their counterparts who were not depressed.

By comparison, mortality risk was 49% higher in general for diabetics with depression compared with those without depression. For diabetics younger than 65, the effect of depression on mortality was not statistically significant. The researchers' findings were reported in a study published in the May 2014 issue of the *Journal of the American Geriatrics Society*.

Previous studies have shown that the risk of premature death is nearly double for people with diabetes versus those without diabetes and that diabetics are about twice as likely to develop depression, notes lead author Lindsay Kimbro, project director in the division of general internal medicine and health services research at the David Geffen School of Medicine at UCLA.

Seniors with diabetes and depression are at a higher risk of premature death.

Kimbro and colleagues analyzed data from 3,341 people with diabetes who participated in the Wave 2 survey of the Translating Research into Action for Diabetes study. They reviewed information from 1,402 patients age 65 and older and 1,939 participants age 18 to 64 and measured mortality risk as the number of days until death since the time of the interview.

The study suggests that early diagnosis of depression in older diabetes patients should be a priority, Kimbro says. "Screening for depression is a very effective use of resources," she adds.