**What's New** NEW HEALTHCARE-RELATED PRODUCTS, SERVICES, AND COMPANIES

# inVentiv Health Expands Global REGULATORY AND COMPLIANCE SERVICES

*Trending Now: Essential compliance services provide regulatory teams with expert consulting as the European Union begins to implement the first major change in clinical trial regulation in 15 years.*

**INVENTIV HEALTH,** a global provider of clinical development and comprehensive commercialization services, has expanded its compliance products and services to assist biopharmaceutical companies conducting non-interventional studies (NIS) in any of 52 countries around the world. Clients of the new services will have access to an NIS Regulatory Intelligence Database.


Lynn Okamoto

The announcement comes one year before the European Union (EU) implements the first major change in clinical trial regulation in 15 years. The new regulation, EU CTR 536/2014, was adopted last year and is scheduled to take effect in May 2016. It repeals a previous EU Directive governing clinical trials. The new regulation is expected to spark considerable confusion around the conducting of non-interventional trials (also known as observational studies). The confusion is likely to arise over the many questions remaining around vague regulatory language, as well as the need for every EU country to review and alter existing national regulations to assure alignment with EU regulation. The new regulation also creates an entirely new category of trial with its own compliance requirements.

"The impending regulatory change is happening at the very moment when real-world data from non-interventional studies has never been more important," says Lynn Okamoto, executive VP of late stage, inVentiv Health Clinical Division. "Data obtained from patients in real-life conditions are now essential for building the evidence required by payers for payment and reimbursement decisions."

Ms. Okamoto says inVentiv Health's new compliance offering will be of use to pharmaceutical company executives working in regulatory affairs, medical affairs, QA auditing, project management, pharmacovigilance or anyone involved in the design or conduct of non-interventional studies (NIS) who require detailed, country-level information to assure compliance and reduce business risks.

## Around the Globe

**Quintiles** has opened its greater China regional headquarters in Shanghai, further expanding its ability to help Chinese companies expand globally and multinational companies succeed in the world's second-largest biopharmaceutical market. Quintiles' 4,000-square-meter (43,000 square feet) headquarters in Shanghai's Feng Lin Science Park now has almost 300 employees and is designed to host 450. Quintiles Greater China has employees in almost 30 cities and offices in Beijing, Shanghai, Dalian, Hong Kong, and Taipei, allowing it to serve all major population centers and study sites.

## Lilly Reveals Plan for Innovation Center in Cambridge, Mass.


Dr. John Lechleiter

Eli Lilly and Company has announced plans to establish a new drug delivery and device innovation center in Cambridge, Mass., a strategic location that will help attract top scientists and bioengineers, as well as enhance Lilly's local business development presence.

The Lilly Cambridge Innovation Center, a makerspace located in Kendall Square, will allow leading life-science experts and organizations to explore how emerging technologies and connectivity can advance drug delivery and device innovation to improve patient health.

Lilly Chairman, President, and CEO John Lechleiter, Ph.D., says the company is locating a portion of its delivery and device organization in Cambridge, one of the nation's leading regions for research and development of medical delivery technologies, to take advantage of the area's rich engineering talent base and life sciences ecosystem.

## Critical Path Institute Launches New Neonatal Consortium

The Critical Path Institute (C-Path) has formed its ninth consortium: The International Neonatal Consortium. The new consortium concentrates on conditions commonly observed in neonatal intensive care units (NICUs).

Therapeutic areas include neonatal brain, lung, and gastrointestinal injury; neonatal sepsis; retinopathy of prematurity; and neonatal abstinence syndrome.

This consortium is the latest in a series of successful developments for C-Path, including celebration of its 10th anniversary and the opening of a new office in London.

The C-Path-appointed executive director of the new consortium is Dr. Alan Bedrick, who continues to serve as chief of neonatology and developmental biology at the University of Arizona College of Medicine – Tucson.

"Only by marshalling forces of the global neonatal community can we address the urgent needs for the care and treatment of neonates," Dr. Bedrick says. PV