

FOR IMMEDIATE RELEASE:

New Executive Committee Named to Clinical Trials Transformation Initiative

Durham, North Carolina - September 5, 2012 - The Clinical Trials Transformation Initiative (CTTI) has named a 14-member Executive Committee, resetting CTTI's strategic direction, and ensuring that the organization informs and facilitates meaningful improvements to clinical trial design and conduct.

"Clinical trials are a critical component of how we develop medical evidence, and they are not meeting the societal need for answers about which strategies and therapies are most effective," said Robert Califf, M.D., co-chair of the CTTI Executive Committee, vice chancellor for clinical and translational research at Duke University Medical Center, and director of the Duke Translational Medicine Institute. "We believe we can improve the system in a major way through focused effort of the entire clinical research community, including patients themselves. The CTTI Executive Committee understands the need to transform clinical trials, as well as how to do so in ways that align the mutual interests of patients, investigators, and companies that develop medical products. Under this new leadership, CTTI will be able to make substantial improvements to the conduct of clinical trials."

Established by the Food and Drug Administration (FDA) and Duke University as a public-private partnership in 2007, CTTI comprises 60 member organizations working to identify practices that will improve the quality and efficiency of clinical trials. FDA and European regulators have cited this work in their efforts to modernize clinical trials.

The CTTI [Executive Committee](#) includes distinguished U.S. and international thought leaders in government, academia, industry, and patient advocacy who are experienced at envisioning and facilitating improvements in health care and medical research systems. Added Pamela Tenaerts, M.D., CTTI's Executive Director, "The founding Executive Committee played a critical role in establishing and setting the direction of CTTI during its formative years. We are now ready to expand the scope of our projects and focus more on transformational efforts."

"Because of the broad array of engaged stakeholders, CTTI is in a unique position to drive major changes in the clinical trial system in the midst of massive global reforms," said Rachel Sherman, M.D., director for the Office of Medical Policy at the FDA's Center for Drug Evaluation and Research and co-chair of the CTTI Executive Committee. Dr. Sherman also added, "There are a number of other initiatives focused on improving the clinical trials enterprise and our Executive Committee will enable us to better integrate and align these collective efforts."

In addition to Califf and Sherman, the new CTTI Executive Board members are:

Hans-Georg Eichler, MD, MSc
Senior Medical Officer
European Medicines Agency (EMA)

Michael Lauer, MD
Director, Division of Cardiovascular Sciences
National Heart, Lung, and Blood Institute (NHLBI)
National Institutes of Health

Elliott Levy, MD
Senior Vice President, Global Pharmacovigilance and Epidemiology
Bristol-Myers Squibb Co.

Freda Lewis-Hall, MD, DFAPA
Executive Vice President, Chief Medical Officer
Pfizer, Inc.

Briggs Morrison, MD
Executive Vice President, Global Medicines Development
AstraZeneca Pharmaceuticals LP

Garry Neil, MD
Partner and Head of R&D
Apple Tree Partners

Richard Platt, MD, MSc
Professor and Chair, Department of Population Medicine, Harvard
Pilgrim Health Care Institute and Harvard Medical School

Nancy Roach (Patient Advocate)
Colorectal Cancer Coalition

Jean Rouleau, MD, FRCPC, FACC
Scientific Director
Institute of Circulatory and Respiratory Health of the Canadian Institutes of Health and Research

Robert Temple, MD
Deputy Center Director for Clinical Science
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Professor Tom Walley, CBE, MD, FRCP
Director NIHR Evaluations Trials and Studies
National Institute for Health Research

Bram Zuckerman, MD
Director, Division of Cardiovascular Devices
Center for Devices and Radiological Health
U.S. Food and Drug Administration

More information about the Executive Committee members and information about CTTI and its projects are available on the CTTI website at www.ctti-clinicaltrials.org.

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