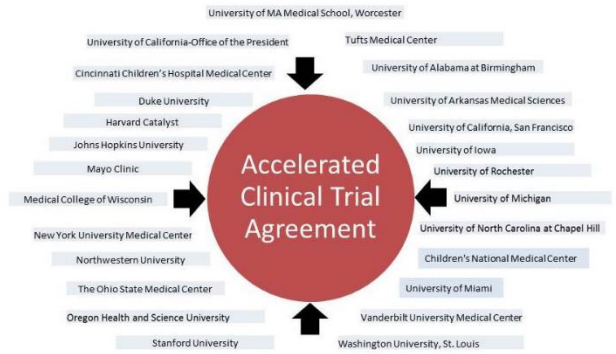
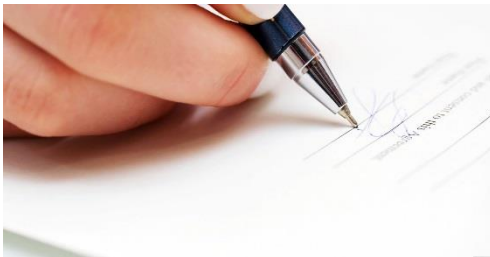


Many organizations face challenges in finalizing clinical trial agreements. Data from a 2010 Clinical and Translational Science Awards (CTSA) Contracts Processing Study¹ showed that an average contract negotiation of contract terms (exclusive of budget and IRB approval) of 55 days could be reduced to 22 days if a “master agreement” was used. This information prompted CTSA awardees to develop efficient contracts that, if adopted, could help further reduce delays in trial start-up.

With support from the National Institutes of Health’s National Center for Advancing Translational Sciences, grant #5U54TR000123, the [Accelerated Clinical Trial Agreement \(ACTA\)](#) was developed by 25 leading academic institutions and medical centers engaged in clinical research and translational science in collaboration with the University Industry Demonstration Partnership (UIDP) and with input from several pharmaceutical companies. The ACTA is a single agreement to be used, voluntarily, by each participating institution and sponsor, to reduce contract negotiations for industry sponsored multi-site studies. Adoption and use of the ACTA will expedite the contract negotiation process and reduce the time it takes to start up industry-sponsored, multi-center clinical trials.



To date, approximately 113 organizations representing more than ~275 research sites, including: academic medical centers, universities, hospitals and physician practices, have agreed to the terms of the ACTA and accept the ACTA without revision. Those interested in using the ACTA, or additional accelerated agreements can learn more at www.ara4us.org.



The initial ACTA was drafted and finalized by participating CTSA institutions and shared with external reviewers — AAHRPP, Shire, Pfizer and Epizyme — for their input. The UIDP joined this initiative in March 2014.

Use of the ACTA is voluntary; accepting the terms does not in any way mandate its use by any party.

Next Steps include:

- Broad awareness for viability with Industry and other Institutions
- Continues development of an electronic “store front” to house the ACTA and register participants
- Develop and Disseminate additional contracting agreements:
 - ACDA (Accelerated Confidential Disclosure Agreement), CRO-ACTA (Clinical Research Organization- ACTA, federal subcontract, MTAShare (Material Transfer Agreement), and many others resources.



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(1) * *Observational study of contracts processing at 29 CTSA sites.* [Clin Transl Sci.](#) 2013 Aug;6(4):279-85. [Kiriakis J](#), [Gaich N](#), [Johnston SC](#), [Kitterman D](#), [Rosenblum D](#), [Salberg L](#), [Rifkind A](#).

Examples of Institutions/Organizations that have accepted the ACTA

- Advanced Neurosciences Institute
- Aarhus University
- Accriva Diagnostics
- Apellis Pharmaceuticals Inc
- Aurora Denver Cardiology Associates
- Austin Heart PLLC
- AZCERT
- Baylor College of Medicine
- Beamer Medical Center /Urgent Care/ Medical Clinic
- Biogenini
- Brookview Hills Research Associates, LLC
- Case Western Reserve University School of Medicine
- Children's Hospital Colorado
- Chiltern International
- Cincinnati Children's Hospital Medical Center
- Clinical Physiology Associates
- Dartmouth College
- Director, Research Regulatory Affairs
- Duke University- School of Medicine
- Emory University
- Expedite Research, LLC
- Florida Health Center, Research Dept.
- Future Care Solution, LLC
- Georgetown University
- Georgia Regents University
- Good Samaritan Hospital San Jose
- Gordon Sussman Clinical Research Inc.
- Gradalis Inc
- Grunberger Diabetes Institute
- Harold and Muriel Block Institute for Clinical and Translational Research at Einstein and Montefiore
- HCA Affiliated Hospitals and Physician Practices (More than 165 institutions)
- Icahn School of Medicine at Mount Sinai
- ICON
- Indiana University
- Johns Hopkins School of Medicine
- KoNECT
- Kypha, Inc.
- Los Robles Hospital
- Mayo Clinic
- Medical University of South Carolina
- Medpace, Inc.
- MedStar Health Research Institute
- Mercy Hospital/HCAhealthcare Mercy Research
- Michigan State University
- NeuroTexas Institute
- New York University School of Medicine
- Northwestern University
- Oregon Health
- Pennsylvania State University
- Pharma Research International, Inc
- Pharmtrace Klinische Entwicklung GmbH
- Pinnacle Research Group, LLC
- PPD
- Presbyterian/St. Luke's Medical Center
- QUEST Research Institute
- Rheumatology Associates, P.A.
- Richmond Family Practice
- Rush University Medical Center
- Sancilio
- Scripps Translational Science Institute
- St. David's North Austin Medical Center
- Stanford University
- Sucampo Pharmaceuticals, Inc.
- Tapimmune, Inc
- Terumo Cardiovascular Systems
- The Medical College of Wisconsin, Inc
- The Ohio State University
- The Regents of the University of Michigan
- The Research Foundation for SUNY/Stony Brook University
- The Research Foundation for the State University of New York, University at Buffalo
- The Rockefeller University
- The University of Texas Health Science Center at Houston
- The University of Texas Southwestern Medical Center
- The Woman's Hospital of Texas
- Trials and Training Consult
- Tufts Medical Center, Inc
- UC Health
- UCSF
- University at Buffalo, SUNY
- University Hospitals Case Medical Center
- University of Alabama at Birmingham
- University of Arkansas for Medical Sciences
- University of California Davis
- University of California, Irvine
- University of California, Los Angeles
- University of California, Riverside
- University of California, San Diego
- University of California, San Francisco
- University of Cincinnati
- University of Colorado Denver | Anschutz Medical Campus
- University of Florida
- University of Iowa
- University of Kentucky
- University of Louisville
- University of Massachusetts Worcester
- University of Miami
- University of Missouri, Columbia
- University of North Carolina at Chapel Hill
- University of Pennsylvania
- University of Rochester
- University of Southern California
- University of Texas Health Science Center at San Antonio
- University of Texas Medical Branch at Galveston
- University of Wisconsin - Madison
- UNM Health Sciences Center
- UPMC
- Vanderbilt University Medical Center
- Verrill Dana LLP
- Visterra, Inc.
- Wake Forest University Health Sciences
- Washington University
- WCG
- Wisconsin Center for Advanced Research