

Standard Terms of Agreement for Research Trial (START) Clauses



NEGOTIATION OF AGREEMENTS IS A KEY BARRIER TO TIMELY INITIATION OF CANCER CLINICAL TRIALS

Clinical Trial Agreements typically involve a trial sponsor (a pharmaceutical, biotech, or medical device company), a research institution and a principal investigator. Separate agreements are negotiated in their entirety for each clinical trial.

Due to the lengthy, complex negotiation process, it can take as many as 300 days to negotiate an agreement, which can delay the start of a trial and delay availability of new cancer treatments to patients in need.

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Access to standardized legal language for key elements of clinical trial agreements can increase the efficiency of contract negotiations, resulting in reduced costs and accelerating the entry of new therapies into clinical trials.

Representatives from the *Life Sciences Consortium of the CEO Roundtable on Cancer*, a non-profit organization composed of corporate executives from major American companies representing diverse industries, and several NCI-designated Cancer Centers have developed a set of standardized clauses for use in clinical trial agreements.



The START clauses represent a toolkit that provides standardized legal language for key agreement elements common to most clinical trial agreements. By starting the negotiation process with commonly agreed upon language, the START clauses can simplify and accelerate the contracting process. Although developed with cancer clinical trials in mind, the START clauses are applicable to all types of clinical research.



“Our research demonstrates that the length of time required to open a trial has a dramatic negative impact on eventual accrual to the study, so these templates will not only affect the ability to launch trials, but also their eventual success.”

*Dr. David Dilts, Co-Director
Center for Management Research in
Healthcare, Vanderbilt University*

The START clauses focus on two types of agreements:

- Company-sponsored clinical trial agreements
- Investigator-initiated clinical trial agreements

The START clauses contain model language in six key areas:

- Intellectual property
- Study data
- Indemnification
- Subject injury
- Confidentiality
- Publication rights

The START clauses were developed following review of nearly 80 redacted copies of final negotiated clinical trial agreements from participating organizations, including company-sponsored and investigator-initiated trials.

For more information, and to download the START clauses toolkit, please visit the NCI's Coordinating Center for Clinical Trials web site at <http://ccct.cancer.gov>.

“Anything that can codify potential contract language and speed the negotiations is of significant value... There are always going to be specifics from trial to trial that differ, but if we can start with these generic endpoints, hopefully we can save a lot of time.”

*Dr. Shelley Earp, Director
Lineberger Comprehensive Cancer Center
University of North Carolina*

Participants in Development of START Clauses

CEO Roundtable on Cancer Life Sciences Consortium

AstraZeneca
Eli Lilly & Company
GlaxoSmithKline
Johnson & Johnson
Novartis
OSI Pharmaceuticals
Pfizer, Inc.
Quintiles Transnational
Sanofi-Aventis
Schering-Plough
Wyeth Pharmaceuticals

NCI-Designated Cancer Centers

City of Hope
Dana-Farber/Harvard
Fox Chase
Johns Hopkins
Mayo Clinic
MD Anderson
Moffitt
Roswell Park
UNC Lineberger
University of Arizona
University of California,
San Francisco
University of Chicago
University of Colorado
University of Pittsburgh



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