

Cooperative Group Trials An Industry Perspective

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On behalf of the *Life Sciences Consortium* of the



Why Industry Likes Working with Cooperative Groups

- Access to large numbers of patients
- Speed of accrual
 - Variable in recent years
- Ability to work with world class institutions and physicians
- Ability to bring innovative medicines to patients sooner

Issues Industry Has In Working With Cooperative Groups

- Length of time to initiate and open trials
- Variability of data format
- Quality of data, submission readiness
- Contracting issues
 - Multiple institutions
 - Disparate Contracting Language
- Potential IP issues

Possible Solutions

- START Clauses of *Life Sciences Consortium*
- Consolidation of Cooperative Groups (per IOM report of 2010)
 - Increased Efficiency
- Standardized reporting methods and processes
 - Unified quality of data

The CEO Roundtable on Cancer

- **Founded in 2001** at request of *President George H.W. Bush*, the 41st President of the United States
- **Comprised of CEOs** from major American companies, representing diverse industries and institutions
- **Non-profit organization** - 501(c)(3)



The Life Sciences Consortium

A CEO Roundtable on Cancer Task Force
representing a model collaborative of companies
working together to get innovative, improved,
cancer therapies to patients faster.



Standard Terms of Agreement for Research Trials (START) Clauses

Created in partnership with:

- *CEO Roundtable on Cancer's* Life Sciences Consortium
- National Cancer Institute
- Academic cancer centers
- Hogan Lovells



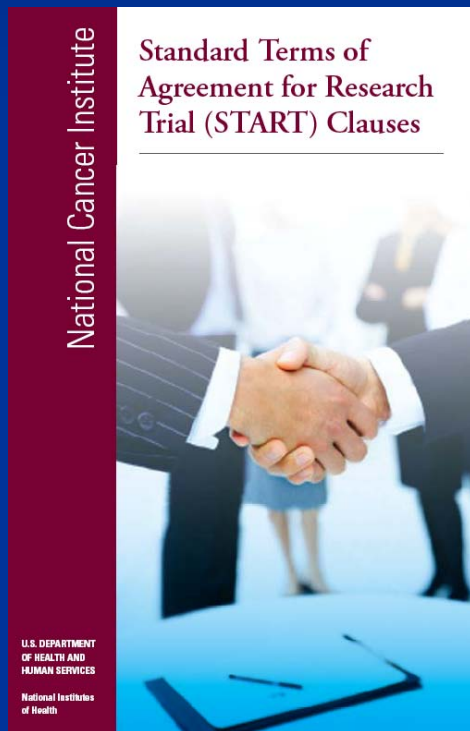
START

(Standard Terms of Agreement for Research Trial)

Clauses

- A series of standardized clauses or language designed to simplify and streamline the contracting process for clinical research
- Applies to company sponsored trials as well as Investigator Initiated trials
- Developed by the *Life Sciences Consortium* in conjunction with NCI and Hogan Lovells

START Clauses



Freely available for download:

Life Sciences Consortium: <http://ceo-lsc.org>

The National Cancer Institute:
<http://restructuringtrials.cancer.gov/initiatives/standardization/highlights/start/faqs>

Elements of the Clauses – 6 Key Areas

- Intellectual Property
- Study Data
- Indemnification
- Subject Injury
- Confidentiality
- Publication Rights

Conclusion

- Collaboration between industry and Cooperative groups makes sense on a number of levels
- Issues can be addressed by standardization of processes and contracting language
- Collaboration may bring innovative health solutions to patients sooner
- Collaboration is in the best interests of scientific progress