



Council of Academic Hospitals of Ontario

Clinical Studies Agreement Initiative

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Negotiation timelines have become a serious
barrier to conduct of research

A Principled Approach

Principled Approach

- A common approach
- Focus on the substantive issues
- Language will follow
- Balance resolution of issues with number of contracts to be negotiated
- An approach that will stand the test of time?

The CenterWatch Monthly

January 2004

A Thomson CenterWatch Publication

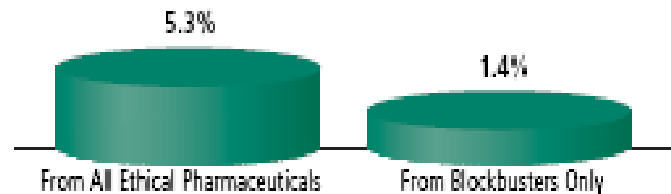
Volume 11, Issue 1

2003 in Review Shifts in the Foundation of Drug Development

► CenterWatch editorial looks back on a year filled with signs of fundamental shifts and changes in the clinical research enterprise. Service providers that are able to survive these fundamental shifts stand to benefit greatly in the long term.

Pharmaceutical Market Losing Steam

Projected annual sales growth 2000–2005



Source: IBM Business Consulting Group

Can Standardization Help the Contract Quagmire?

► Investigative sites are increasingly finding contract negotiations to be one of the largest causes of study conduct delays. Reasons cited include lack of standard terminology and ordering of contract sections, and mutually acknowledged areas of disagreement.

Standard Contract Language?

- Initial question raised in OICR initiative
 - UK & Australia did it!
 - Are we 'fighting' over language?
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- Context: company-initiated clinical trials

Ontario-wide Collaborative Approach

- Clinical Study Agreement Working Group
- University of Toronto
- OICR
- CAHO

Phases One - Five

- **Phase One:** Document Development
- **Phase Two:** Implementation by academic hospitals of Ontario
 - E.g. Policy document to be published on CAHO website & hospitals to hyperlink to official version
- **Phase Three:** Encourage use as negotiation tool by non-academic sites
- **Phase Four:** Encourage use by companies as template development & negotiation tool
- **Phase Five:** Negotiate across Canada to develop a Canada-wide standard

Statement of Principles to be Considered When Negotiating a Clinical Studies Agreement

- Public statement of expectations
- Meant to limit the number of issues to negotiate
- Policy statement?
- Adopted by academic hospitals in Ontario
- What does it mean to endorse these principles?

Overview of Best Practices

- “Clinical Trial Agreement Best Practices for Agreements with Private Industry Sponsors”
 - Complementary to Principles
 - Living document
 - Internal document
 - Guidance document only
 - Not intended as legal advice

This slide is based on slides developed by Laurel Evans for CAURA in May 2007

Living Documents & Future Improvements

- Mechanism for feedback on the documents
- Frequency of revised versions
- Impact on adoption of documents vs. endorsement of documents

Future Improvements & Living Documents

- Broadening the scope of applicability
 - Community hospitals
 - Researchers
- Side documents
 - Tackle other related agreements (CDAs)
 - Description of relevant legal issues
- Training/certification of negotiators
- Dynamics of working with industry

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Panel Discussion & Overview

- Can the documents be adopted with minimal changes to reflect each province's laws?
- Are legal requirements the only variation across the country?
- What mechanism is needed for sites to adopt the documents in each province?
 - Provincial mechanism?
 - Country-wide mechanism?

Panel Discussion & Overview

- How will we broaden the scope of applicability of the documents & develop a country-wide mechanism of adoption at the same time?
- Are the documents too Ontario focused?
- Is the Quebec approach a good model for all provinces?
- What mechanism is needed for future improvements that will apply across the country?