

MAGI NEWS

"All the News that's Contractually Permitted to Print per Sections 5.3 and 14.2"

Highlights:

- **Call for Speakers**
- **MAGI Membership**

First Issue of MAGI News in the Journal

MAGI News is now a feature of the Journal of Clinical Research Best Practices.

CTA Trivia Question

Timonics Biotech is running out of time to find a key opinion leader for its pivotal trial for Punctuate, a potential breakthrough in the treatment of punctuality disorders. Dr. Justin Thyme is interested, but wants to discuss the study with his colleagues at Circe University prior to their attendance at the annual meeting of the Association of Time Perception, the first meeting of the Association in over seven years. As Chairman of the Circe Psychiatry Department, Dr. Thyme signs the confidentiality agreement on behalf of the University, so he can share information about the study with his colleagues. (Normally, he would sign just for himself.) Timonics Biotech sends him the protocol and investigator's brochure to read on the plane. As a legal clerk at Timonics Biotech is filing the confidentiality agreement, she wonders if Dr. Thyme actually has signatory authority for Circe University. If not, Dr. Thyme's colleagues will be legally free to discuss the study at the meeting with attendees from competitors of Timonics Biotech. At this point, it is impractical for Timonics Biotech to obtain separate confidentiality agreements from all of Dr. Thyme's colleagues.

Call for Speakers

In 2006, we will hold "Negotiating Clinical Trial Agreements & Budgets" conferences in Boston (May 21-24) and San Francisco (September 24-27). Mark your calendar and your travel budget! Let me know ASAP if you would like to be a speaker. The last conference earned our best ratings yet: "Excellent" from 48% of attendees. We are adding a second track; more, longer sessions for our diverse audience; and more workshops and networking events. A draft agenda is at <http://www.srinstitute.com/CS367>.

MAGI Membership

MAGI now has members from over 500 organizations in the clinical research industry, including most of the leading ones.

Notable Changes in Version 1.05 FYR

There were several changes, but none of much consequence. A redlined copy of v1.05 is available to MAGI members.

Regional Laws, Regulations & Customs

Our database of state and international CTA requirements is growing. Please contribute! The database is at <http://www.firstclinical.com/magi/documents>.

CTA Trivia Answer

Even though Dr. Thyme said he could sign the confidentiality agreement on behalf of Circe University, Timonics Biotech's rights under the confidentiality agreement are subject to a court's determination of whether, after reasonable diligence, it had reasonable cause to take his word for it. In this case, Timonics Biotech made no attempts to verify his authority, for example by calling someone in the Circe University Clinical Trials Office. Based on previous experience, it should have known that few universities give signatory power to department chairs in such matters. Further, if Timonics Biotech had visited the Circe University Clinical Trials Office webpage, it may have noticed that Dr. Thyme's name was not on a list of people authorized to sign contracts on the University's behalf.

Fortunately for Timonics Biotech, by the time Dr. Thyme arrived at the meeting, the punctuality branch of the association had already finished their business and departed, while the procrastination branch had not yet arrived. Timonics Biotech was thus able to fax Dr. Thyme a binding confidentiality agreement signed by the Circe University Director of Clinical Research before any harm was done.

Join MAGI Today

MAGI's flexible model clinical trial agreement streamlines the process of negotiating clinical trial agreements, thereby taking months out of the drug development timeline and speeding medical products to market. It also reduces study start-up costs and aggravation for sponsors, investigators and CROs. We believe that our inclusive membership and flexible model agreement will lead to broad use in the industry.

Our 500+ current members are from all parts of the industry:

- 8 of the 10 largest pharmaceutical companies
- The 7 largest U.S. CROs
- Over 2/3 of the U.S. News & World Report's Top-20 hospitals in all 17 therapeutic areas

Membership is free. Members agree to read our model CTA and suggest improvements. By participating, you are not obligating your organization to use the model agreement. Everything is done by email and telephone. Learn more about joining MAGI or sign up today at <http://www.firstclinical.com/magi/>.

"We can agree to save lives!"