PhRMA Adopts CLINICAL-TRIAL PRINCIPLES

Voluntary principles describe the relationship of PhRMA companies with others involved in clinical research and establish the rules to protect the safety of research participants.

The Pharmaceutical Research and Manufacturers of America (PhRMA) executive committee has unanimously adopted principles for the conduct of clinical trials and the communication of clinical-trial results.

In the principles, PhRMA companies commit to the timely communication of all meaningful results of clinical trials, whether those results are positive or negative. Furthermore, the results always are to be communicated in an objective, accurate, balanced, and complete manner.

"PhRMA members always have been committed, and remain committed, to sponsoring clinical research that fully complies with all legal and regulatory requirements," says Alan F. Holmer, president of PhRMA.

These clinical-trial principles reaffirm our members' strong commitment to the safety of research participants and to ensure the integrity of research and the timely communication of research results, says Alan F. Holmer, President of PhRMA.

The principles, many of which reflect existing practices by the industry, become effective for trials begun after Oct. 1,2002.

Among other provisions, the PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results provide for the following:

• Clinical trials conducted in accordance with all applicable laws and regulations, as well as recognized principles of good clinical practice (GCP), wherever in the world trials are conducted.

• The independence of clinical investigators and others involved in clinical research is respected so they can exercise their own decision-making authority to protect research participants. Compensation to clinical investigators will be reasonable and based on their work. Compensation will not be paid in the stock of the sponsor.

• Before trials begin, they are reviewed by institutional review boards (IRBs) or ethics committees (ECs) that have the right to disapprove, require changes, or approve the study. All participation in a clinical trial is based on informed consent, freely given without coercion.

• There will be timely communication of meaningful study results, regardless of the outcome of the study. The results must be reported in an objective, accurate, balanced, and complete manner, with a discussion of the limitations of the study. Study sponsors will not suppress or veto publications.

• Any investigator who participated in the conduct of a multisite clinical trial will be able to review relevant statistical tables, figures, and reports for the entire study at the sponsor's facilities or another mutually agreeable location.

• Consistent with the International Committee of Medical Journal Editors and major journal guidelines for authorship, the principles clarify that only those who make substantial contributions to a publication should receive acknowledgement as an author of or contributor to the publication.

PRA International Launches PEDIATRIC CLINICAL DEVELOPMENT AND RESEARCH CENTER

PRA International has launched a Pediatric Clinical Development and Research Center in Lenexa, Kan.

The center is under the direction of pediatric expert, Dr. Martin Behm,director of pediatric clinical pharmacology. PRA now is poised to offer pediatric clinical-trial services to its clients.

"PRA is proud to have the ability and expertise to contribute to the success of pediatric clinical trials," says Bucky Walsh, senior VP of business services at PRA International. "We want to help our clients comply with the legislation that mandates that all new medications marketed for pediatric indications undergo sufficient studies."

PRA's Pediatric Clinical Development and Research Center offers support for all aspects of pediatric clinical trials, including program consulting, study design, protocol writing, and pediatric-oriented infrastructure.

Additionally, the center has a staff with clinical experience and specialized knowledge in the field of pediatrics.

LabConnect Completes INREACH ACQUISITION

LabConnect has completed its acquisition of the intellectual property and technology assets of inREACH Corp., a provider of laboratory software solutions. LabConnect is using inREACH's lab and technology expertise to enhance its laboratory data reporting capabilities and other clinical-trial-related applications.

"Customers and investigator sites tell us the importance of being able to quickly access reliable, user-friendly lab reports," says Sergey Boytsov, director of clinical trial information services at LabConnect. "inREACH's suite of applications provides the best fit that we have identified for the central lab market today."

inREACH's 10 years of software development experience for laboratory information management systems enables LabConnect to improve upon its current reporting capabilities for the benefit of sponsors and investigators. For example, LabConnect's Web-based reporting technology provides secure access to trended study participant lab results in real-time for sponsors and investigators — the only central lab providing such a product today. The acquisition also includes inREACH's participant recruitment data mining application.

inREACH CEO, Eugene Baillie, M.D., a pathologist and past president of the American Society for Clinical Pathology, joins LabConnect as its medical director.

"As a pathologist, I can relate to how physicians want to have their lab data reported," Dr. Baillie says. "We developed our applications with the user and security in mind, and I'm delighted with its application in clinical trials."

Life Science Insights Offers INTELLIGENCE SERVICE

Life Science Insights is very excited about the launch of our new service targeting the venture-capital community, says Dr. Irena Melnikova, Senior Research Analyst, Life Science Insights.

Life Science Insights (LSI), a subsidiary of IDC, has announced a new service designed for venture capitalists managing their investment dollars. The Venture Capital/Private Equity Advisory Service offers clients access to comprehensive research on emerging products and market trends, as well as competitive analysis and profiles of life-sciences companies. For additional commentary and strategic advice, clients also have direct access to LSI's team of experts.

Clients are provided with end-user profiles and insight on global opportunities that may exist to meet end-user business challenges. Through one-on-one discussions, analysts can identify market risks, gauge barriers to entry, and validate deal opportunities for clients. Other offerings include portfolio consulting and custom consulting to examine potential exit strategies or possible channel alternatives.

GSP Consulting Partners With BIOENTERPRISE

As part of a strategic relationship, GSP Consulting Corp. is providing consulting services to BioEnterprise Corp.

The federal government represents a significant source of funding for bioscience commercialization activities. GSP Consulting has demonstrated an impressive track record of securing these funds, says Baiju Shah, President of BioEnterprise.

"We initially considered more than a dozen cities across the country for our next expansion," says John Dick, one of GSP's two founding partners, who will be leading the firm's expansion efforts in the region. "Northeast Ohio has exciting new technologies, a leading-edge research community, and innovative organizations such as BioEnterprise growing new companies. Still, the region has historically underperformed in attracting public dollars for technology projects. GSP can bring great value to local industry."

WHAT'S NEW ON THE SHELVES

CLINICAL ENGINEERING HANDBOOK — a book by clinical engineer, Joseph Dyro, supports and advances patient care by applying engineering and managerial skills to healthcare technology.

As the biomedical engineering field expands throughout the world, clinical engineers play an evermore important role as the translator between the worlds of the medical, engineering, and business professionals. They influence procedure and policy at research facilities, universities, and private and government agencies, including the Food and Drug Administration and the World Health Organization.

Published in July 2004 by **Elsevier**, the Clinical Engineering Handbook provides readers with prospects for the future of clinical engineering, as well as guidelines and standards. From telemedicine and IT issues to sanitation and disaster planning, this book brings together the important aspects of clinical engineering.

For more information, visit books.elsevier.com.

CLINICAL TRIALS: ENSURING PATIENT SAFETY AND DATA INTEGRITY — The FDA has stepped up its enforcement of clinical trials by increasing bioresearch monitoring and inspections and by conducting more reviews of trial sites and institutional review boards (IRBs). In addition to the increased attention from the FDA, the pharmaceutical industry also is facing scrutiny from other federal agencies, including the National Institutes of Health, the Department of Justice, and HHS' Office of the Inspector General, all of which have sharpened their focus on clinical-trial operations.

The book, published by **FDANews,** outlines steps to: determine how and when to use a DMC; recruit appropriate and qualified members; structure an all-inclusive DMC report; apply statistical principles to help minimize bias and maximize precision; submit information for serious or life-threatening diseases to a clinical-trials data bank; formulate data safety monitoring plans for all phases of clinical trials; manage data safety monitoring and IRBs for multicenter clinical trials; and facilitate acceptance of clinical-data using international standards.

Also included are dozens of sample meeting agendas, data reports, and the full text of official guidelines. There's an exclusive section written by Janet Wittes, Ph.D., an international authority on the design and analysis of clinical studies. She uses a memorable approach to illustrate how to run a DMC, making the process easy to understand and apply to clinical-trials data.

For more information, visit fdanews.com/wbi/bookstore.

GETTING YOUR DRUG APPROVED: FDA'S OWN GUIDELINES, VOLUMES I AND II — A step-by-step guide, published by **FDANews**, to getting drugs approved. Organized in an easy-to-use format, this two-volume set includes the latest guidelines on the forms, regulations, and procedures that the FDA will use to determine whether a proposed new drug will make it to market, including guidelines for understanding the Part 11 final guidance, preparing NDAs, managing records, organizing clinical-trial results, and more. The fully expanded Volume I — originally published in 2000 and updated in 2003 — provides valuable guidelines for: drug master files; 21 CFR Part 11 electronic submissions of ANDAs and NDAs; preparation of investigational new drug products (human and animal); organization and content of the clinical section of an application; formatting, assembling, and submitting new drug and antibiotic applications; format and content of the chemistry, manufacturing, and controls section of an application; and more.

Volume II covers: electronic submissions of INDs; combination products and intercenter review; fast-track drug-development programs; PDUFA; safety data; labeling; advisory committees; and more.

For more information, visit fdanews.com/wbi/bookstore.

International Team Develops MULTILINGUAL RECORD SYSTEM

According to Securamed Founders Peter Panas (left) and Kintan Brahmbhatt, launching the service commercially to a broad range of users posed two main challenges: data entry and data authenticity. Securamed overcame these challenges with a "no-typing-necessary" interface.

An interdisciplinary research team, comprised of medical professionals, computer scientists, and linguists from nine countries, has collaborated to design Securamed, a multilingual portable medical record system.

After a series of successful pilot implementations in the United States, Canada, the United Kingdom, Switzerland, France, Germany, Singapore, India, and China, the team has launched Securamed to remove the linguistic barriers of health communications.

"Because confidentiality is one of the paramount issues facing the e-healthcare industry, Securamed's infrastructure is designed to protect individual privacy and confidentiality through compliance with the Health Insurance Portability and Accountability Act (HIPAA), U.S. Safe Harbor regulations, and European Union medical information privacy standards," says Peter Panas, Securamed's president. "The Securamed system uses the strictest standards of 256-bit data encryption and does not collect or track any identifying information, thus making the user anonymous."

According to Securamed's chief architect, Dr. Navin Barot, the quality of care patients receive depends on the quality of information their physicians have access to. In an emergency, access to crucial medical information can be the primary factor in saving a person's life.

"During international travel, Securamed enables foreign physicians to access a person's medical information in their native language," he says. "Initially funded through grants and private angel investments, Securamed is working with leading employers and health plans to incorporate its services as employee benefits."

PUBLIC RELATIONS AGENCY Launched

R.J. Sincovich Communications Inc., which specializes in all facets of marketing communications, has been launched by Robert J. Sincovich, owner and president. The agency's personnel have decades of experience in print, broadcast, and Web-based communications for numerous Fortune 500 companies.

"There are any number of opportunities for companies large and small to benefit from the speed and flexibility afforded through a personalized approach to public-relations support," Mr. Sincovich says. "Our present clients have seen this work for them, and it is the mission of the new firm to leverage these skills to help grow our clients' businesses."

"Above all, the objective of R.J. Sincovich Communications is to take on responsibilities for clients where well-defined benefits can be attained," says Robert J. Sincovich, Owner and President. "When mutual growth can be achieved, then the ideal client-agency relationship has been established."

Client experience has involved numerous leading pharmaceutical, medical-device, and diagnostics companies, in addition to chemical, industrial, and consumer product manufacturers. Initiatives have involved government organizations and personnel, professional associations, consumer and patient advocacy groups, medical professionals, and industry opinion leaders across many business categories. Audience outreach has included medical professionals, business-to-business interests, and direct-to-consumer awareness efforts.

FDA Adopts NEW STANDARD FOR SUBMITTING CLINICAL-TRIAL DATA

The Food and Drug Administration (FDA) has developed a standard format for sponsors of human drug clinical trials to submit data to the agency.

The Study Data Tabulation Model (SDTM), which was developed by the Clinical Data Interchange Standards Consortium (CDISC), is expected to accelerate the FDA's review of clinical-trial data and new drug applications and provide a consistent framework for government, academia, and industry to enhance data integration opportunities.

This initiative reflects the importance of data standards in healthcare and the commitment of the FDA to support this activity. Because the data are organized in a standardized way, it is easier for people to use the data even if they did not generate it, says Randy Levin, M.D., Acting Associate Director for Medical Informatics, FDA.

"The consistent framework allows us to build software that can be reused across different studies, and it also allows reviewers to use training and experience with the data organization across the studies," says Randy Levin, M.D., acting associate director for medical informatics at the FDA.

The adoption of the SDTM is consistent with the FDA's Critical Path Initiative, which was launched in March to develop solutions to the task of ensuring that breakthrough medicines are safe and effective. The SDTM helps automate the largely paper-based clinical-trials research process and foster easier communication and collaboration among clinical researchers. By providing a consistent framework and format for clinical-trial information, this standard enhances data integration opportunities and helps reduce data-management barriers for sharing the latest clinical-trial data.

"The importance of a standard for the exchange of clinical-trial data cannot be overstated," says Dr. Lester M. Crawford, acting FDA Commissioner. "FDA reviewers spend far too much valuable time simply reorganizing large amounts of data submitted in varying formats. Having the data presented in a standard structure improves FDA's ability to evaluate the data and helps speed new discoveries to the public."

The FDA is currently exploring approaches to require the use of the SDTM standard for regulatory submissions.

Grey Healthcare Group Buys HURD STUDIOS

It's very rewarding to educate healthcare providers by translating complex physiologic processes into clear, concise visualizations that elucidate the unique benefits of new drug therapies, says Jane Hurd, Founder and President of Hurd Studios.

Grey Healthcare Group (GHG) has acquired New York-based Hurd Studios, which enables GHG to offer clients highly proprietary creative and medical-education programs.

"The visualization of science is more critical than ever with the unprecedented pace at which science is unraveling the inner workings of cells and molecules," says Jane Hurd, founder and president of Hurd Studios. "As novel therapeutic molecules are discovered, it has become increasingly necessary for the medical community to understand their structure and mechanism of action."

Ms. Hurd, as well as Stephen Biale, CEO, both continue in their positions.

"We're delighted to have Hurd join our network," says Lynn O'Connor Vos, CEO and president of GHG Inc.

"All our divisions are eager to work with Hurd to offer our clients powerful and compelling communication," she says.

SFBC International Acquires TAYLOR TECHNOLOGY

SFBC International Inc. has increased its bioanalytical-service capabilities through the acquisition of Taylor Technology Inc. (TTI).

TTI offers quantitative bioanalytical mass spectrometry services primarily in Phase I through Phase IV of drug development and has experience in developing, validating, and performing methods for the quantitative analysis of drugs and/or metabolites in biological fluids. TTI specializes in supporting developmental new drug programs for pharmaceutical companies.

SFBC is jointly marketing TTI and SFBC's wholly owned subsidiary SFBC Analytical Inc., which operates a bioanalytical laboratory in Philadelphia, as SFBC Analytical.

SFBC entered into long-term employment agreements with senior management, including Dr. Paul Taylor, president and founder of TTI. Dr. Taylor reports directly to Dr. Marc LeBel, president and CEO of SFBC Anapharm.

"In addition to having a highly complementary client base, the acquisition of TTI enables us to provide an additional technology platform for new and existing clients for bioanalytical services and enhances our extensive expertise in the market," Dr. LeBel says.

Additionally, SFBC Anapharm, a wholly owned subsidiary of SFBC International, has opened a bioanalytical laboratory at the company's facility in Toronto. The new 10,000 square-foot laboratory will be devoted to the company's technology: high-pressure liquid chromatography-tandem mass spectrometry. The lab is expected to open in January 2005. SFBC intends to invest about $4.0 million in capital expenditures, comprised of equipment, software, and build out for the new bioanalytical laboratory in Toronto.

"The combination of TTI and the expansion in Toronto enable us to significantly strengthen our position within the industry and provide us with additional revenue opportunities within a broader base of branded and generic pharmaceutical companies," says Dr. Lisa Krinsky, chairman and president of SFBC International. "The increased capabilities and capacity gained through these two initiatives enable us to more effectively meet the increasing demand for our services."

Dr. Gregory Holmes, executive VP of SFBC International, says the company continues to experience significant demand for its bioanalytical services throughout North America and Europe and is pleased that it has been able to achieve two key milestones to further enhance and expand its core capabilities and capacity.

Follow up

BIOENTERPRISE CORP., Cleveland, is a business formation, recruitment, and acceleration company that supports the growth of emerging medical device, biopharmaceutical, and healthcare services companies. For more information, visit bioenterprise.com.

FOOD AND DRUG ADMINISTRATION, Rockville, Md., is responsible for protecting the public health by assuring the safety, efficacy, and security of drugs, biologics, medical devices, and cosmetics. For more information, visit fda.gov.

GREY HEALTHCARE GROUP, New York, comprised of 10 companies with 42 offices in 16 countries, provides an extensive array of integrated services in support of brand acceleration and sales. For more information, visit ghgroup.com.

GSP CONSULTING, Pittsburgh, provides assistance to companies and organizations seeking new funding, government sales, and research partnerships in the biosciences and technology industries. For more information, visit gspconsulting.com.

HURD STUDIOS, New York, is a scientific multimedia firm with animation, video production, and marketing capabilities. For more information, visit hurdstudios.com.

LABCONNECT LLC, Columbia, Md., is a privately held organization that provides central laboratory services for the clinical-trials industry. For more information, visit labconnectllc.com.

LIFE SCIENCE INSIGHTS, Framingham, Mass., a subsidiary of IDC, provides market research, analysis, and consulting services to decision makers in the life-sciences markets. For more information, visit life-science-insights.com.

THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA), Washington, D.C., represents research-based pharmaceutical and biotechnology companies. For more information, visit phrma.org.

PRA INTERNATIONAL, McClean, Va., is a contract research organization with more than 2,500 employees. For more information, visit praintl.com.

R.J.SINCOVICH COMMUNICATIONS INC., Doylestown, Pa., is a full-service public-relations agency. For more information, e-mail sinkwork@msn.com.

SECURAMED, Munster, Ind., provides health communication services to employers, membership groups, and individuals. For more information, visit securamed.com.

SFBC INTERNATIONAL INC., Miami, is a contract research organization specializing in the areas of Phase I and Phase II clinical trials and bioanalytical laboratory services. For more information, visit sfbci.com.

TAYLOR TECHNOLOGY INC., Princeton, N.J., is a contract bioanalytical laboratory focused on quantitative bioanalytical mass spectrometry services for the pharmaceutical industry. For more information, visit taytech.com.