

# Integrated Drug Development News

Spring 2007

## Cato Research Launches Argus Safety™ Web—Cost Effective, Friendly, Web-Based Interface for Safety Reporting

By David Montgomery, PMP (Cato Research, Durham)

Cato Research (CATO), in partnership with Relsys International, Inc. ([www.relsys.net](http://www.relsys.net)), launched a hosted version of Argus Safety™ Web in the first quarter of 2007. Argus Safety Web supports drug safety business processes from within an easy to understand graphical interface. Drug safety leaders from around the world contributed to the design of Argus Safety, delivering on its primary objective to create an advanced product that excels at meeting the requirements of a global drug safety enterprise.

As the industry-leading safety system, Argus offers a number of advantages, including global regulatory reporting with a fully E2B compliant reporting service, comprehensive data collection of adverse event information, integrated data safety analysis using multi-dimensional analysis tools from Business Objects™ and Cognos™, and a flexible drug safety workflow system allowing effective utilization of resources.

The potential benefits of Argus Safety Web are significant, especially for small and mid-size pharmaceutical and biotechnology companies. Implementation costs are minimal—there is no need to invest in hardware or software, no servers or security infrastructure at the client site are necessary. Also, ongoing administrative costs are less—maintaining a validated environment and administering the system are the responsibility of CATO. CATO also serves as your help desk and is available to answer application and Pharmacovigilance system-related questions with Relsys support available if needed. Finally, the cost of upgrades is included in your contract so that your system will stay current and up-to-date with the latest updates from Relsys.

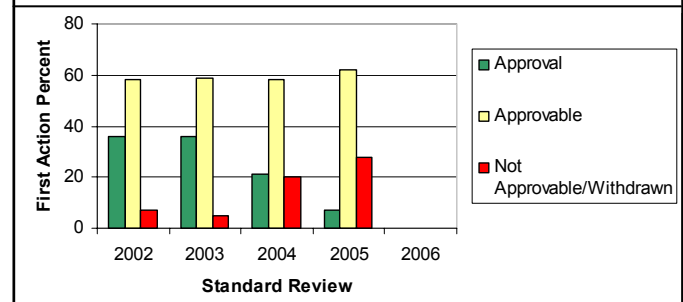
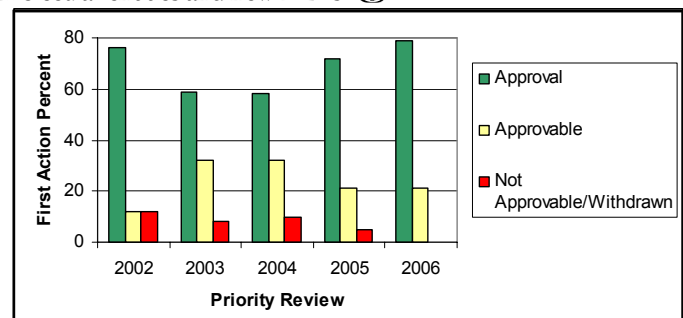
This service extends beyond what a typical managed hosting provider can offer. In addition to the industry-leading Pharmacovigilance solution and a secure, state of the art infrastructure, clients will also have access to CATO's extensive

*See Web-Based Safety System, Page 2*

## Priority Review Improves the Approval Rate for New Molecular Entities and New BLAs

By Cathy Anderson, Ph.D., R.A.C. (Cato Research, Durham)

Your regulatory strategy is key to timely approval. Data recently reported by CDER (summarized below) shows that priority review more than doubles the likelihood of immediate approval for new molecular entities and new BLAs. 🌱



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## FDA News: Recently Released Draft and Final Guidances

By Sara Arrantinis, Ph.D., R.A.C. (Cato Research, San Diego)

FDA released a number of new draft and final guidances in the first quarter of 2007. Following is a list of selected new guidances most likely to be of interest, along with their release dates:

- ICH Draft Guidance: E15 Terminology in Pharmacogenomics - 08 January 2007
- Draft Guidance for Industry: Minimally Manipulated, Unrelated, Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution in Patients with Hematological Malignancies - 16 January 2007
- Guidance for Industry: Certain Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Recovered From Donors Who Were Tested For Communicable Diseases Using Pooled Specimens or Diagnostic Tests - 23 January 2007
- Guidance for Industry: Class II Special Controls Guidance Document: Cord Blood Processing System and Storage Container - 31 January 2007
- Guidance for Industry: User Fee Waivers for Fixed Dose Combination and Co-Packaged HIV Drugs for the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief - 08 February 2007
- Combination and Co-Packaged HIV Drugs for the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief - 08 February 2007
- Draft Guidance for Industry: Developing Products for Weight Management - 15 February 2007
- Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products - 27 February 2007
- Draft Guidance for Industry: Complementary and Alternative Medicine Products and Their Regulation by the FDA - 27 February 2007
- Draft Guidance for Industry: Advisory Committee Meetings - Preparation and Public Availability of Information Given to Advisory Committee Members - 27 February 2007
- Guidance for Industry: Orally Inhaled and Intranasal Corticosteroids: Evaluation of the Effects on Growth in Children - 06 March 2007
- Guidance: Drug Safety Information – FDA's Communication to the Public - 07 March 2007
- Draft Guidance for Industry: Indexing Structured Product Labeling - 19 March 2007
- Draft Guidance for Industry and FDA Staff: Modifications to Devices Subject to Premarket Approval - The PMA Supplement Decision-Making Process - 26 March 2007
- Draft Guidance for Industry and Review Staff: Target Product Profile - A Strategic Development Process Tool - 30 March 2007

HTML and .pdf versions of these, and all FDA Guidances, are available at [www.fda.gov](http://www.fda.gov).

Answer to Count The Triangles on page 4: 44

## Online Registry Targets U.S. and Canadian Investigators—Speeds Clinical Site Recruitment

By Maya Bablou, Sandy Dormeus, and Mabel Ruscitti (Cato Research, Canada)

### Are you looking for experienced investigators to conduct your clinical trials?

Cato Research is dedicated to finding qualified and experienced investigators and clinical sites to participate in our clinical trials. To that end, CATO implemented an online [Investigator Registry](#), compiling information from investigators experienced in all trial phases and therapeutic areas. This registry targets a large pool of investigators throughout the U.S. and Canada, and allows CATO to respond quickly to our sponsors' ongoing and future clinical trials needs.

Investigators access the Investigator Registry through the Cato Research web site ([www.cato.com](http://www.cato.com)). They register online and provide CATO with their contact information, site information, and clinical experience. This information is stored in a database that allows searches based on specific parameters such as geographical region, previous trial experience, clinical specialty, and therapeutic area. CATO can rapidly identify the most suitable sites and investigators for a sponsor's study to ensure timely trial initiation and overall trial success.

CATO is dedicated to continuously providing our sponsors with innovative tools, such as the Investigator Registry, to meet their clinical trial needs. Please contact us ([InvData@cato.com](mailto:InvData@cato.com)) if you are currently in search of qualified investigators for your clinical trial, or have any questions about the Investigator Registry. 🌱

*Web-Based Safety System, continued from page 1*

expertise in drug safety, global regulatory reporting and strategy, non-clinical and clinical development, CMC management, and regulatory consulting.

Though a hosted web application service may not be the best fit for all companies, if you have limited capital resources, have safety systems based in Access or Excel, or you have a smaller safety staff, this solution may be perfect your needs. Please contact David Montgomery or Laurie Girard today for more information about Argus Safety Web (Cato Research Durham: 919-361-2286). 🌱

### SOLUTION TO THE WINTER 2007 PUZZLE OF THE QUARTER—SUDOKU

4	8	1	2	5	7	9	3	6
6	2	5	9	3	4	7	8	1
3	7	9	1	8	6	2	4	5
1	4	2	6	9	8	5	7	3
8	5	3	4	7	1	6	2	9
9	6	7	3	2	5	8	1	4
2	9	8	5	4	3	1	6	7
7	1	4	8	6	9	3	5	2
5	3	6	7	1	2	4	9	8


## Comprehensive Library Services—Now Available from Cato

**Research** *By Cindy Williams MLS, AHIP (Cato Research, Durham)*

The CATO research library has long been a valuable source of research and information within CATO. Now, in response to numerous requests from our sponsors, CATO is making this comprehensive resource available to other companies on a contract or fee-for-service basis.

CATO's Library Services:


1. Reference services
2. Mediated literature and database searches
3. Certified translation services
4. Evaluation of existing book and journal collections
5. Document delivery and interlibrary loans (with full compliance in either paper or electronic format)
6. Training on cost-free internet resources, instruction on searching PubMed and NCBI databases, instruction on searching fee-for-service and proprietary databases
7. Consulting services to support the establishment of new library collections or the expansion of existing collections.

CATO's librarians, Cindy Williams (MLS, AHIP) and Meg Gabehart (MSLS) have 28 years' experience in corporate, academic, hospital, government, and business libraries. They excel in information management and organizational skills and are experts in information access and distribution procedures. For more information about CATO's Library Services, please contact Cindy Williams, Senior Librarian at 919-361-2286 or [cwilliam@cato.com](mailto:cwilliam@cato.com). 

## GS Review™ Software Ensures Accurate eCTD Submissions

*By Shannon Strom, Ph.D., R.A.C. (Cato Research, Durham)*

The electronic submission viewing software Global Submit Review™ (GS Review) is used exclusively by the Food and Drug Administration (FDA) to review submissions in electronic Common Technical Document (eCTD) format.

Cato Research is pleased to announce the implementation of GS Review and its integration into CATO's standard review process for electronic submissions. The software has several advantages such as advanced dossier lifecycle management, on-line reviewing capabilities, and easier navigation of the submission compared to paper format. Using GS Review, CATO can ensure that all electronic submissions created by CATO will load, review, and validate correctly into the FDA's electronic reviewing system. Implementation of this software as standard business practice offers a single technical solution for the lifecycle management of regulatory submissions, and it represents a significant cost-savings over time for most sponsors. For more information on CATO's regulatory capabilities and the GS Review software, please contact Mike Cato (Facilitator of Regulatory Operations) by email at [mcato@cato.com](mailto:mcato@cato.com) or by phone at (919)361-2286. 

## CALENDAR OF UPCOMING REGIONAL AND NATIONAL EVENTS

### MAY 2007

- **15-16 MAY—GLOBAL R&D CONGRESS: STRATEGIC PLANNING FOR DISCOVER, DEVELOPMENT, AND CLINICAL OPERATIONS IN CHINA, INDIA, AND OTHER EMERGING REGIONS**, PARK HYATT HOTEL, PHILADELPHIA, PA
- **17-18 MAY—INDEXING STRUCTURED PRODUCT LABELING: CLINICAL AND PRACTICAL APPROACHES USING DATA ELEMENTS IN SPL**, GRAND HYATT WASHINGTON AT WASHINGTON CENTER, WASHINGTON, DC
- **22-23 MAY—SMARTSTART/UNYTECH VENTURE FORUM**, ALBANY MARRIOTT, ALBANY, NY
- **23-24 MAY—VACCINE DEVELOPMENT SUMMIT: PROPELLING INDUSTRY THROUGH COLLABORATION AND SCIENTIFIC MINDSHARE**, HILTON PHILADELPHIA CITY AVENUE, PHILADELPHIA, PA

### JUNE 2007

- **4-6 JUNE—5TH BIODEFENSE VACCINE AND THERAPEUTICS CONFERENCE**, ALMAS TEMPLE CLUB, WASHINGTON, DC
- **6-8 JUNE—STRUCTURE-BASED DESIGN: SOPHISTICATED APPROACHES TO DRUG DISCOVERY**, WORLD TRADE CENTER, BOSTON, MA
- **17-21 JUNE—43RD ANNUAL DIA MEETING**, GEORGIA WORLD CONGRESS CENTER, ATLANTA, GA
- **18-20 JUNE—BIO VENTURE FORUM EAST**, MARRIOTT CHATEAU CHAMPLAIN, MONTRÉAL, QUÉBEC CANADA
- **21-22 JUNE—REGULATIONS AND GUIDELINES FOR DEVICE CLINICAL RESEARCH - SOCRA**, SHERATON BALTIMORE CITY CENTER HOTEL, BALTIMORE, MD
- **24-27 JUNE—2007 AMERICAN ASSOCIATION OF PHARMACEUTICAL SCIENTISTS NATIONAL BIOTECHNOLOGY CONFERENCE (CO-SPONSORED BY FDA)**, SAN DIEGO CONVENTION CENTER, SAN DIEGO, CA

### LATER 2007

- **06—09 AUGUST, 12TH ANNUAL WORLD CONGRESS DRUG DISCOVERY & DEVELOPMENT OF INNOVATIVE THERAPEUTICS**, WORLD TRADE CENTER, SEAPORT HOTEL, BOSTON, MA
- **27-30 SEPTEMBER—2007 SOCRA CONFERENCE**, ADAMS MARK DENVER HOTEL, DENVER CO
- **8-9 OCTOBER—7TH ANNUAL BIOTECH 2007**, LOEWS PHILADELPHIA HOTEL, PHILADELPHIA, PA

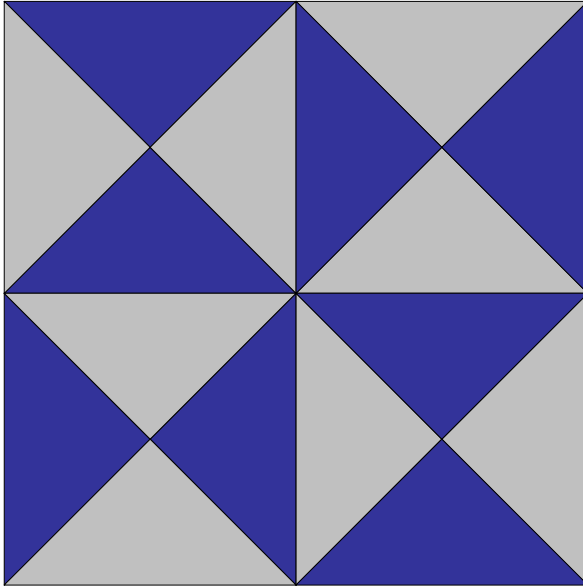
**\*\*\*SPECIAL EVENT\*\*\*** UPCOMING CATO RESEARCH WASHINGTON OPEN HOUSE WINE TASTING AND RECEPTION, MORE INFORMATION TO BE ANNOUNCED AT [WWW.CATO.COM](http://WWW.CATO.COM)

FOR A COMPREHENSIVE LISTING OF DRUG DEVELOPMENT AND BIOTECHNOLOGY EVENTS WORLDWIDE, PLEASE VISIT THE CATO BIOTECHNOLOGY CALENDAR: [HTTP://WWW.CATO.COM/FYI/](http://WWW.CATO.COM/FYI/)

## Puzzle of the Quarter

### Count the Triangles

How many triangles (of all sizes) can you find in this illustration? (Answer at the bottom of page 2)



#### ABOUT CATO RESEARCH

Founded in 1988 and headquartered near Research Triangle Park, NC, Cato Research is a full-service contract research organization providing strategic and tactical support for clients in the pharmaceutical and biotechnology industries. Services range from design and management of preclinical and clinical studies to submission of the regulatory documents required for marketing approval. Located in the United States, Canada, Europe, Israel, and South Africa, Cato Research consistently demonstrates an unsurpassed level of responsiveness, flexibility, attention to detail, and passion in bringing a sponsors' products to market rapidly and cost effectively. For more information, visit the Cato Research web site at [www.cato.com](http://www.cato.com), email us at [newsletter.cato.com](mailto:newsletter.cato.com), or call Cato Research at 919-361-2286 and speak directly to one of our drug development experts.



#### ABOUT CATO BIOVENTURES

Cato BioVentures is the venture capital affiliate of Cato Research Ltd. helping both entrepreneurs and established management teams build successful life science companies. Cato BioVentures offers promising life science companies immediate access to a broad range of essential CRO services on a noncash basis. Access to these time-critical CRO services enables management to achieve key value-added development and regulatory milestones with less reliance on other sources of capital. For more information, visit the Cato BioVentures web site at [www.catobioventures.com](http://www.catobioventures.com).



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