Phase Forward Expands CLINICAL-TRIALS SIGNAL DETECTION SYSTEM

Phase Forward has unveiled a new version (2.0) of its clinical trials signal detection system — CTSD. The CTSD system enables clinical safety and medical monitoring staff to: analyze clinical data for the purpose of detecting, evaluating, and tracking potential safety signals; screen clinical data for safety issues, including the detection of clinical syndromes; develop safety profiles for new compounds as early as Phase II clinical trials; and make informed decisions earlier in the development process, creating opportunities for reducing development costs and potential acceleration of a drug's

"By enabling our customers to flag potential risks earlier in the clinical-trial phase - long before widespread patient exposure to a drug the product supports improved drug safety and helps manage development costs, says **Bob Weiler, President** and CEO of Phase Forward.



time-to-market. CTSD 2.0 offers functionality for detecting clinical syndromes with a newly developed issue cluster mining technique, enhanced statistical tools such as multivariate Bayesian logistic regression, and expanded signal tracking and data visualization options.

The system also is integrated with the company's WebSDM (Web Submission Data Manager) platform to offer seamless support for the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) data standard. The CDISC standard is used to support the CTSD product's advanced data mining functions.

Skila Launches **PERFORMANCE MANAGEMENT SOLUTION**

Skila has released iperformance, its next-generation solution for performance management. Because executive managers at pharmaceutical and biotechnology companies are under pressure to enhance performance visibility, allocate resources more efficiently, and quickly respond to rapidly changing market conditions, simply monitoring performance is not enough.

iperformance has been designed to enable managers to use predictive information to optimize results and alert managers to trends that affect their business objectives. Skila's iperformance solution allows managers to drill down into specific issues, understand root causes, and make decisions based on data that are connected to corporate objectives and have strategic context.

inVentiv Releases **SECOND EDITION OF PROPRIETARY SELLING SKILLS PROGRAM**

inVentiv Health Inc.'s Professional Development Group has released the second edition of its flagship selling skills program, The RxAdvantage.

The core of The RxAdvantage program explores the attitudes, emotions, and behaviors of highly successful sales professionals in addition to a traditional pharmaceutical sales model. The program includes a well-designed follow-up process focused on the application of the skills at the customer level.

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Bryan Horveath, VP and managing director of the Ventiv Professional Development Group (VPDG), says the company's selling skills program is designed to provide the foundation for today's healthcare sales professionals to create meaningful dialogues with their valued customers.

The RxAdvantage tool spans all levels of the sales cycle, and it includes a comprehensive sales management coaching process as an added benefit.

TrialStat Unveils CLINICAL ANALYTICS 4.0

TrialStat Corp. has released Clinical Analytics (CA) 4.0, the latest version of its on-demand EDC platform, which provides a suite of new features that further enhance the quality, accuracy, and security of customers' clinical-trial data, while automating its analysis and management. Using CA 4.0, users can access, through the Web or a handheld device, an affordable and robust on-demand EDC platform that scales with the specific needs of their research, regardless of the therapeutic area or clinical phase.

CA 4.0 offers a suite of clinical data management and enhanced security features. These new features include:

- Clinical Intell (CI): CI provides advanced, user-configurable reporting across base and aggregated data sets.
- Enhanced Double Data Entry: This dedicated DDE module improves support for studies that still use paper to capture all or some of their data by providing streamlined data entry and conflict detection interfaces.

CA 4.0 offers a suite of clinical data management and enhanced security features.

- Integrated Post Data Entry Validation and DCF Generation: While CA 4.0 already delivers comprehensive data validation at the point of capture, this enhancement permits the design and use of complex validation rules that can be run against a full data set any time. The system also allows DCFs/queries to be automatically created based on a predefined rule set.
- Standard and Custom Data Dictionary Automation (DDA): The DDA module allows study managers to upload and use any standard dictionary, such as MedDRA and WHOART, in their pro-

jects. Form fields designated as coded feature a guick look-up interface to allow coding personnel to easily select dictionary terms rather than hand enter them. Customers can also migrate their custom dictionaries to CA 4.0.

On Demand Encryption: This sophisticated module obscures highly sensitive data elements, such as health-card numbers, so that only users that created them and their colleagues at different research sites can view their details.

Liquent InSight Publisher 3.5 Accelerates

REGULATORY PUBLISHING

InSight Publisher 3.5
helps streamline the
entire regulatory
submission process,
enhancing efficiency
and helping to bring
new drugs to
market faster.

Thomson Scientific, part of The Thomson Corp., has released InSight Publisher 3.5, which is designed to accelerate the publishing process for drug submissions to the world's regulatory authorities. By enabling life-sciences companies to create all of the components of both electronic and paper submissions from a single

assembly structure, In Sight Publisher 3.5 helps streamline the entire regulatory submission process.

In Sight Publisher 3.5 also provides other new features to accelerate drug applications, including:

- Step-by-step wizards for eCTDs and study reports that help streamline the creation of submissions and reports that comply with ICH, Japanese, Canadian, U.S., and other regional specifications;
- eCTD Conformity Checking that automatically performs 50 eCTD validation checks, including 32 ICH compliance requirements;
- Templating capabilities that let companies predefine the structure of their content and the placement of paper publishing elements, such as tabs, slip sheets, and cover pages;
- An eCTD import wizard that helps organizations to continue their life-cycle management of previously completed eCTD submissions.

Thought Leadership in 30 — **NEW PODCAST SERIES**

Be Seen. Be Heard. Inc. has announced the availability of a Podcast series and companion moderated blog, called Thought Leadership in 30.

Doris Gilman, president of Be Seen. Be Heard, acts as executive producer and host. She interviews guest thought leaders on business topics that impact the life-sciences industry. Topics include marketing, health economics, patient and consumer issues, professional communications, regulation, policy, government, public health, clinical trials, and industry news. Each Podcast episode is 30 minutes,

Doris Gilman, President of Be Seen. Be Heard. Inc., is executive producer and host of Thought Leadership in 30.

syndicated through iTunes, and listed on several online Podcast directories.

These person-to-person communications allow executives to demonstrate their thought leadership through the power of voice and the written word, delivered through e-mail and the Web.



Follow up

BE SEEN. BE HEARD. INC., New York, helps healthcare businesses generate greater visibility for their expertise by establishing common ground and meaningful exchange. For more information, visit seen-heard.com.

INVENTIV HEALTH INC., Somerset, N.J., provides commercialization and complementary services to the global pharmaceutical, life-sciences, and biotechnology industries. For more information, visit inventivhealth.com.

PHASE FORWARD, Waltham, Mass., provides integrated data management solutions for clinical trials and drug safety. For more information, visit phaseforward.com.

SKILA, Morris Plains, N.J., is a customer-driven company and a developer of best-in-class knowledge-driven management solutions for the pharmaceutical industry. For more information, visit skila.com.

THOMSON SCIENTIFIC, part of The Thomson Corp., Philadelphia, provides information solutions to the worldwide research and business communities. For more information, visit thomson.com.

TRIALSTAT CORP., Ottawa, Ontario, delivers clinical data management on demand by combining its full suite of data management services with the company's software. For more information, visit trialstat.com.

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