What's New

NEW HEALTHCARE-RELATED PRODUCTS, SERVICES, AND COMPANIES

Cooney/Waters and Russo Partners Launch

New Agency

TRENDING NOW: Integrated communications service provides healthcare companies with support throughout their business and product lifecycles.

Cooney/Waters and **Russo Partners** has launched **CLEARPATH HEALTH COMMUNICATIONS**, an integrated service that provides healthcare companies with seamless communications support throughout the lifecycles of businesses and products — from early development to commercialization.


Tony Russo

Clearpath pairs the corporate and financial communications expertise of Russo Partners with the strategic marketing capabilities of Cooney/Waters to help small- to mid-sized companies reach and influence their target audiences as they move through each lifecycle stage. Clearpath's counselors are scientists, physicians, marketers, and former journalists who have expertise in the translation of complex science and medical issues into understandable, compelling stories with effective campaigns that are focused and scalable based on the client's need.

"As we work with our clients to help them navigate today's complex environment and resource constraints, they have increasingly told us they need one highly knowledgeable and skilled communications partner to guide them through the entire process," says Tony Russo, CEO and founder of Russo Partners. "Clearpath enables us to add value through a holistic approach as our clients move from early-stage development through commercialization of their products and services."

Tim Bird, president and chief operating officer of Cooney/Waters, adds that both Russo Partners and Cooney/Waters are passionate about scientific innovation, breakthrough medicines, and technologies.

"Clearpath allows us to work with clients as one integrated team powered by decades of healthcare investor relations, public relations, and marketing experience," he says.

Clearpath offers corporate communications, investor relations, strategic marketing and communications solutions, advocacy relations, and issue-oriented communications to healthcare companies. Clients of Clearpath collaborators include pharmaceutical, biopharma, medtech, diagnostics, healthcare IT, and healthcare services companies.

For more information, visit clearpathhealthcommunications.com.

Initiative Launched to Identify Drugs for Repurposing

The IP & Science business of Thomson Reuters, a provider of intelligent information, has entered into a strategic initiative with NuMedii, a biotech company dedicated to revolutionizing drug discovery.

The partnership, which pairs NuMedii's technology with hand-curated drug and disease information and systems biology expertise of Thomson Reuters, creates a repository of content and methodologies to systematically identify new applications for existing drug compounds.

The companies are leveraging a comprehensive collection of data, knowledge, and predictive technologies to identify therapeutic candidates with the greatest probability for clinical success, in turn fulfilling NuMedii's mission to discover and de-risk drugs that target new pathologies.

"NuMedii is blending various innovative technologies and life-science data to create a next-generation drug discovery and development engine," says Gini Deshpande, Ph.D., founder and CEO of NuMedii. "This unique partnership allows NuMedii access to an unparalleled source of knowledge from Thomson Reuters, enabling us to turbocharge our search and discovery of new applications for existing therapies."

NuMedii's big data technology uses machine learning, pattern matching, and network biology algorithms to find new indications for existing drugs. Three publications by researchers at Stanford University have already shown the promise of NuMedii's approach. In each case, researchers demonstrated novel activity for existing drugs in preclinical experiments as predicted by NuMedii's technology. Most recently, researchers showed that certain antidepressants identified with NuMedii's technology have activity in experimental models of small cell lung cancer.

After a novel treatment is identified and validated in appropriate preclinical models, NuMedii will optimize the formulation and administration of the drug for the new use and advance the program to early clinical development. In most cases, NuMedii expects to leverage the expedited 505(b)(2) regulatory pathway for drugs previously approved by the FDA. NuMedii ultimately looks to license the drug to specialty pharma companies, as it has done with Aptalis Pharma. In its work with Thomson Reuters, NuMedii will own and be responsible for any resulting drug development programs.

"Our collaboration with NuMedii is an opportunity to combine the information sources available with novel analytics, data integration, and biomedical expertise in a way that has not been done before outside of a lab," says Joe Donahue, senior VP, Thomson Reuters Life Sciences. "We are excited to be working with NuMedii to use this approach to speed the discovery of new drug candidates."

For more information, visit numedii.com. PV

WHAT'S NEW ON THE SHELVES

The American Association of Pharmaceutical Scientists (AAPS) has announced four titles in the popular AAPS Advances in the Pharmaceutical Sciences book series. The new publications are available through international science publisher Springer.

The AAPS Advances in the Pharmaceutical Sciences series, published in partnership with Springer, is designed to deliver well-written volumes authored by scientific leaders and authorities from around the globe, addressing innovations in drug research and development and best practice for scientists and industry professionals in the pharmaceutical and biotechnology industries. The four new titles are as follows: **MELT EXTRUSION: MATERIALS, TECHNOLOGY AND DRUG PRODUCT DESIGN**, edited by Michael A. Repka, Ph.D., Nigel Langley, Ph.D., and James DiNunzi, Ph.D.; **PHARMACO-IMAGING IN DRUG AND BIOLOGICS DEVELOPMENT: FUNDAMENTALS AND APPLICATIONS** edited by Brian R. Moyer, M.S., Narayan P.S. Cheruvu, Ph.D., and Tom C.-C. Hu; **STERILE PRODUCT DEVELOPMENT: FORMULATION, PROCESS, QUALITY AND REGULATORY CONSIDERATIONS** edited by Parag Kolhe, Ph.D., Mrinal Shah, Ph.D., and Nitin Rathore; **TRANSPORTERS IN DRUG DEVELOPMENT: DISCOVERY, OPTIMIZATION, CLINICAL STUDY AND REGULATION** Edited by Yuichi Sugiyama, Ph.D. and Bente Steffansen, Ph.D.

Learn more about each new volume by visiting aaps.org/books.

Lippincott Williams & Wilkins (LWW), part of Wolters Kluwer Health, has introduced a completely revamped, interactive edition of **DESIGNING CLINICAL RESEARCH**, a leading manual for clinical researchers for the past 25 years. Every chapter has been updated to cover recent advances in the field, and the new fourth edition is the first to offer four-color graphics and a fully interactive digital experience that gives readers a practical and user-friendly approach to designing a clinical study.

Viewable through a browser or as a download to a tablet or smartphone, the digital package includes the complete text with customized navigation and a rapid, index-based search capability. In addition, new features that distill key information and enhance understanding have been added, including the text's first four-color graphics, as well as new figures and tables. Updated chapters cover recent advances and new developments in the field, such as non-inferiority trials for comparative effectiveness research, incidence-density case-control studies, confounding and effect modification, ethical aspects of whole genome sequencing, automated data management approaches and new NIH grant-writing requirements.

Included in the manual are exercises for planning a study and new cases to illustrate the resolution of ethical dilemmas in clinical research. A purchase includes access to a dedicated Designing Clinical Research website with teaching materials and interactive sample-size calculators.

Designed for physicians, nurses, pharmacists, and health scientists in training, Designing Clinical Research, is available now for $82.79. For more information or to purchase, visit lww.com/hulley.

The Regulatory Affairs Professionals Society (RAPS) has published the updated, second edition of its regulatory reference book, **FUNDAMENTALS OF INTERNATIONAL REGULATORY AFFAIRS**. This edition has been significantly expanded to cover additional topics with global implications. The book is a trusted reference for healthcare product regulatory professionals involved in multinational product development and marketing.

Since the first edition of Fundamentals of International Regulatory Affairs was published in 2010, the global regulatory environment has changed markedly. The new edition reflects significant developments in the harmonization of requirements and regulations by international bodies such as the International Conference on Harmonization (ICH), the World Health Organization (WHO), and the relatively new International Medical Device Regulators Forum (IMDRF), which supplanted the Global Harmonization Task Force (GHTF) last year.

Fundamentals of International Regulatory Affairs, second edition, is available in print and as an e-book for $249.95 with free shipping for RAPS members or $309.95, plus shipping, for non-members.

For more information, visit raps.org.

Theorem Clinical Research has released **SMART THINKING**, a book that brings together theories and insight into the future of the industry, online as a free download on Theorem's website.

Smart Thinking was created by Theorem during the 2013 Drug Information Association (DIA) Annual Meeting, a conference for professionals involved in the discovery, development and lifecycle management of pharmaceuticals, biotechnology, medical devices, and related healthcare products.

Throughout the event, attendees were invited to share their theories on a range of industry topics, including: electronic medical records, global regulations, the Sunshine Act, the acceleration of personal technology, and more. A caricature artist was available to sketch participants. These theories and associated caricatures are used throughout the book and provide information on each topic.

For more information, visit theoremclinical.com/smartthinking.