

Pooled ECG Data Could Enhance Cardiac Research

BY JEFF EVANS
Senior Writer

The Food and Drug Administration has begun a new initiative aimed at improving the ability to identify and predict cardiac side effects of drugs and devices under development.

In partnership with the Duke Clinical Research Institute (DCRI), Durham, N.C., the FDA first will use an electronic database of 200,000-300,000 digital electrocardiogram recordings to understand the effects that some drugs and devices may have on heart function. The recordings have been submitted from about 30 clinical trials that were con-

ducted as a part of new drug applications during the last 2 years, Dr. Norman Stockbridge, director of the division of cardiovascular and renal products at the Center for Drug Evaluation and Research, said in a teleconference.

The database standardizes recordings that have been pooled from different ECG waveforms into a single, digitized format for analysis.

For decades "we've received generally low-quality copies of ECGs on paper," said Dr. Janet Woodcock, deputy commissioner for operations at the FDA. "We've been really limited in our ability to use this information to understand why some treatments affected a patient's heart or even to

be able to predict whether treatment would affect someone's heart."

The FDA and DCRI are developing a consortium to leverage the resources and expertise of members from academia, industry, patient advocacy groups, other government agencies, and nonprofit organizations to discover where ECG data can fill gaps where new cardiac biomarkers are needed and to prioritize research projects based on the findings.

One immediate application of the ECG database will be to review gender differences in the effects of drugs on ECG recordings, since it is not known if differences in drug responses drive the higher risk of drug-induced arrhythmias in

women, compared with men, Dr. Woodcock said.

The electronic ECG database will help to identify new ways of detecting problems such as QT interval prolongation with greater precision and at earlier stages, said Dr. Robert Califf, director of DCRI.

"QT interval prolongation has been the downfall of many drugs, but also it is a side effect of many useful drugs, including all of the atypical antipsychotics," Dr. Califf pointed out.

Other early work with the ECG database is involved in describing placebo groups in studies and differences in the parameters of the QT interval in men, women, and people of different body sizes

CLASSIFIEDS

Also Available at www.familypracticenews.com

PROFESSIONAL OPPORTUNITIES



Where Profession and Lifestyle come together!

We're growing. Grow with us.

BE/BC Family Practice Opportunities

Kadlec is nestled near the banks of the Columbia River, in southeastern Washington, where you'll enjoy over 300 days of sunshine in the heart of Washington wine country.

Join Our Strong Team of Physicians!

- Multi-specialty Clinic Employment Model
- Integrated Delivery System
- Hospitalist Program
- State-of-Art Facility

Live in a Vibrant Community!

- Academically Recognized Schools
- Economically Thriving Community
- Low Crime Rate
- Abundance of Outdoor Activities

All Our Best!

KADLEC
Medical Center

E-mail your CV to:

physician-recruitment@kadlecmed.org
For information, please call: 509-942-2115
EOE

timing

a question of

The right EM practice, at the right time, with the right people

CORSICANA, TX, Just South of Dallas – Newly partnering with Navarro Regional Hospital, The Schumacher Group is committed to providing a positive place for you to practice good medicine. This facility offers a 12 bed ED and cares for 22,000 patients annually. Double physician coverage. Call Mary at 800.893.9698 x 4192

PARAGOULD, AR, ED Staff Physicians needed – Serve in one of the most progressive, vibrant hospital communities in Northeast Arkansas. This hospital offers a 13-bed ED and cares for 19K patients annually. This new ER offers you a state-of-the-art facility to practice in. Superb medical staff backup and double coverage during peak times. Ask about our sign on bonus. Call Shelia at 800.893.9698 x 1120

The time is right to come join us in making a difference in emergency medicine.

The Schumacher Group®

For additional opportunities, view our website: www.tsGED.com

New York City

Dreaming of an exciting practice opportunity and the lifestyle this international city has to offer? This could be the time to make those dreams come true. A leading physician group seeks a quality BE/BC family practitioner. The position offers a salary guarantee and comprehensive benefit package. Work 4-1/2 days per week, 1:4 "at home" call, refer to hospitalist program. Contact Michelle "Mickey" Conner at 866-464-3428 or mconner@hortonsmithassociates.com

Moving?

Look to Classified Notices for practices available in your area.

CONTINUING EDUCATION

St Louis Area

Traditional Family Practice without Obstetrics in family oriented community 45 minutes to St. Louis associated with brand new 46 bed hospital affiliated with large St. Louis Health System. 1-5 call. \$140-14

5k salary, bonus and benefits. Donohue and Associates 800-831-5475 Fax: 314-984-8246 E/m: donohueandassoc@aol.com

Learn Spider Vein Treatment "Cosmetic Sclerotherapy Made Simple" Training Manual & DVD

Other Unique Practice Support Products for Vein & Aesthetic Practices

www.paconcepts.com

904-699-6297

Disclaimer

FAMILY PRACTICE NEWS assumes the statements made in classified advertisements are accurate, but cannot investigate the statements and assumes no responsibility or liability concerning their content. The Publisher reserves the right to decline, withdraw, or edit advertisements. Every effort will be made to avoid mistakes, but responsibility cannot be accepted for clerical or printer errors.

FOR INFORMATION ON CLASSIFIEDS:

Contact: Robin Cryan, 360 Park Avenue, New York, NY 10010. (800) 379-8785, (212) 633-3160. FAX: (212) 633-3820. Email ad to: r.cryan@elsevier.com

INDEX OF ADVERTISERS

and other clinical features, he added.

“For studies that help us refine how we measure ECGs, we can use that to improve the standards” for measuring drug safety, Dr. Woodcock said. “For example, we still don’t know the meaning of some of the degrees of QT prolongation.”

“FDA might change its guidance [to pharmaceutical companies] based on information we get from this, and this might even change how drugs are developed,” she said.

Many other biomarkers outside of ECG data will be considered under the FDA-DCRI partnership, which is a part of the FDA’s Critical Path Initiative to modernize the drug development process.

“All of industry that’s interested in cardiac biomarkers will be participating in this to the extent that they wish,” Dr. Califf said. ■

American Express		Eli Lilly and Company		Pfizer Inc.	
Corporate	63	Byetta	30a-30b	Lyrica	3
Astellas Pharma US, Inc.		Cymbalta	51-52	Caduet	34-37
Adenoscan	53-54	Merck & Co., Inc.		Chantix	41-44
Boiron		ProQuad	12a-12f	Roche Laboratories Inc.	
Oscillococcinum	39	Januvia	24a-24b	Corporate	15
Duramed Pharmaceuticals, Inc. (a subsidiary of Barr Pharmaceuticals)		Gardasil	56a-56d	Tamiflu	48a-48b
Seasonique	27-30	Novartis Pharmaceuticals Corporation		Sanofi Aventis U.S. LLC	
Endo Pharmaceuticals		Galvus	46a-46b	Corporate	32-33
Opana	17-19	Diovan HCT	67-68	Sanofi Pasteur Inc.	
Florida Department of Health		Novo Nordisk Inc.		Fluzone	22a-22b
Florida SHOTS	16	NovoLog Mix 70/30	11-12	ADACEL	60a-60b
Forest Laboratories, Inc.		Levemir	55-56	Sepracor Inc.	
Namenda	8a-8b	Nutramax Laboratories, Inc.		Lunesta	20a-20b
Lexapro	44a-44b	CosaminDS	10	Takeda Pharmaceuticals North America, Inc.	
Genzyme Diagnostics		Ortho-McNeil Neurologics, Inc.		Rozerem	6-8
OSOM Tests	66	Topamax	58-60	Wyeth Pharmaceuticals Inc.	
				Effexor XR	4a-4d, 64a-64d

CLASSIFIEDS

Also Available at www.familypracticenews.com

CONTINUING EDUCATION

CONSIDERING THE ADDITION OF COSMETIC SERVICES? ATTEND THE SEMINAR THAT STARTED IT ALL.

Of course you have questions! This is new and exciting territory. As the nation’s longest running educational seminar in aesthetic medicine, MedCOSMETIC® can provide the answers you’re looking for. We are the leading resource for information and training to help transform your medical practice.



Our day-long seminar features lectures by physicians in your field who will show you the science and deliver proven marketing techniques and business solutions to enable your success.



Experience Live Case Demonstrations

Injectables and fillers:

- Botox® Cosmetic
- Restylane®

Laser and light-based procedures:

- Hair Removal
- Vein Treatment
- Enhanced Skin Rejuvenation
- Full Body Rejuvenation™

Invest in Your Future — Build Practice Profits Fast.

Registration fee for up to 6 CME credits is \$195 (\$95 for non-physicians accompanied by a registered physician). Fee includes: All Lectures, Course Syllabus, Certificate, continental breakfast, lunch and refreshment breaks.

Seminar Schedule

- Chicago, Illinois
Oct. 21, 2006
- Arlington, Virginia
Oct. 28, 2006
- Miami, Florida
Nov. 4, 2006
- Nashville, Tennessee
Nov. 11, 2006

APPROVED FOR UP TO 6 CATEGORY I CREDITS

Enjoy exhibitor discounts on products and services.



BOTOX Cosmetic is a registered trademark of Allergan, Inc. Restylane is a registered trademark of HA North American Sales AB. Full Body Rejuvenation is a trademark of Laserscope. MedCOSMETIC is a registered trademark of MedCOSMETIC.

For more information or to register, call Linda Lerner at 913.345.9300, ext. 18, email llerner@medcosmetic.com or log on to www.medcosmetic.com

Project HOPE Improving Health Through Education

Give to **PROJECT HOPE** Dept. A, Washington, D.C. 20007

Family Practice News
Classified listings can now
also be seen at:

www.elsevierhealthcareers.com



Put your money
where your heart is.

**American
Heart
Association**

WE'RE FIGHTING FOR YOUR LIFE