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**36th ACCP Annual Meeting
September 9-11, 2007**

The Palace Hotel, San Francisco, CA

American College of Clinical Pharmacology

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New Hartford, New York 13413
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MLWQTC507



**American College
of Clinical Pharmacology**

Symposium:

**INDUSTRY AND REGULATORY
EXPERIENCE WITH
THOROUGH ECG TRIALS (TQT):
TWO YEARS AFTER ICH E14**

Co-Chairs:

Joel Morganroth, M.D., FCP
eResearch Technology, Inc.
Philadelphia, PA

Nenad Sarapa, M.D.
Daiichi Sankyo Pharma Development
Edison, NJ



Wednesday, May 2, 2007

**Baltimore Marriott® Waterfront Hotel
Baltimore, Maryland**

Industry and Regulatory Experience with Thorough ECG Trials (TQT): Two Years after ICH E14

Wednesday, May 2, 2007 • Baltimore Marriott® Waterfront Hotel • Baltimore, MD

Need: After the ICH E14 guidance was finalized (Ref. ICH E14 below), the Thorough QT Trial (TQT) has become required in development of new drug candidates and available agents that are brought back for new indications. The TQT design and its data analysis is still incompletely defined by the FDA and understood by pharmaceutical sponsors, creating a need for learning opportunities for pharmaceutical industry physicians and scientists. The Symposium will create the opportunity for pharmaceutical statisticians to learn about the current and novel approaches to statistical analysis of ECG data, which has been described as challenging by the PhRMA Statistical Expert Team. The FDA has recently established a QTc Interdisciplinary Review Team which performs centralized review of all TQTs and QTc-related data from sponsors. Pharmaceutical sponsors are not familiar with the structure and function of the FDA QTc Interdisciplinary Review Team and the principles of their regulatory decision-making, which creates another learning opportunity for the ACCP Symposium. Lastly, QTc prolongation is considered a suboptimal biomarker of pro-arrhythmic risk and scientists in academia are developing new approaches for risk assessment in clinical trials, which they intend to propose for regulatory decision-making. Academicians will be interested in attending the Symposium to learn about the current principles advocated by the regulatory authorities.

Ref. International; Conference on Harmonization. E14 Guidance: The Clinical Evaluation of QT Interval Prolongation and Proarrhythmic Potential for Non-antiarrhythmic Drugs. 2005 Available from: <http://www.emea.eu.int/pdfs/human/ich/000204en.pdf>

Target Audience: Physicians, pharmacists and scientists from pharmaceutical or biotech companies with responsibilities in the area of clinical research and development of novel drug candidates in all therapeutic classes, clinical drug safety, risk management and pharmacovigilance, regulatory affairs, preclinical pharmacology and toxicology. Physicians and pharmacists employed by Contract Research Organizations dealing with cardiac safety and those employed by ECG service providers (central ECG laboratories, data management companies, ECG equipment manufacturers and software technology companies), consultants, and those in academia.

Background Requirements of Prospective Participants: Familiarity with the principles of ICH E14 guidance on the clinical assessment of QTc prolongation and pro-arrhythmic risk for non-cardiac compounds. Familiarity with general clinical and regulatory principles of clinical trials in the development of novel drug candidates.

Goals:

1. To describe the regulatory review of pro-arrhythmic risk with novel drugs in the US and Europe under the auspices of the ICH E14 guidance.
2. To compare the current principles of the statistical analysis and interpretation of TQT results versus the potential advantages of the modeling of exposure-response relationship.
3. To explain the potential added values from concentration-QTc effect modeling of the clinical trials data from the sponsor's and the FDA's perspectives.

Objectives: At the conclusion of the ACCP QTc Symposium, participants will be able to:

1. Define the global overview of the current approaches to the assessment of pro-arrhythmic risk-benefit ratio for novel drugs under development.
2. Describe the first in-depth public presentation of the US FDA QTc Interdisciplinary Review Team (including the description of its structure, operational function and the clinical lesson learned from reviewing pharmaceutical sponsors' submissions).
3. Define the update to the regulatory experience with the implementation of ICH E14 guidance in Europe and the issues identified during the process.
4. Explain the activities of the ICH E14 Working Group since the adoption of the final E14 guidance in 2005.
5. Explain the implications of thorough QT studies for the late stage drug development.
6. Describe the differences between the current central tendency-based statistical analysis and the exposure-response modeling of QTc and plasma concentration data.

CONTINUING EDUCATION CREDIT

Certificates of CME credit and statements of ACPE credit will be issued within six weeks to participants who complete and return the appropriate application, pre- and post-test answer sheets, and evaluation forms to the registration desk or to the ACCP Executive Office on or before May 25, 2007. Attendees should claim only those hours of credit that they actually spent in the activity. No partial CME or CPE credit will be issued.

The American College of Clinical Pharmacology is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The American College of Clinical Pharmacology designates this educational activity for a maximum of 7.0 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.



The American College of Clinical Pharmacology is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. ACPE universal program #238-000-07-003-L01. Contact hours: 7.0 (0.70 CEU).

Notice to pharmacists licensed in Florida: ACCP is not registered with a CE Broker.

Schedule:

I—Denotes panelist for Panel Discussion I
II—Denotes panelist for Panel Discussion II

8:30 - 8:35 AM

Welcome and Introduction

Lawrence J. Lesko, Ph.D., FCP - *FDA, Silver Spring, MD*

8:35 - 8:50 AM

State of the Art Lecture

Douglas C. Throckmorton, M.D., Ph.D. - *FDA, Silver Spring, MD*^{I/II}

8:50 - 9:20 AM

FDA QTc Interdisciplinary Review Team:

Why it was formed and how it works

Leslie A. Kenna, Ph.D. - *FDA, Silver Spring, MD*^I

9:20 - 9:50 AM

FDA QTc Interdisciplinary Review Team:

Clinical lessons learned about TQT studies

Norman L. Stockbridge, M.D., Ph.D. - *FDA, Silver Spring, MD*^{I/II}

9:50 - 10:20 AM

European Regulatory Experience with TQT Studies:

General issues for the industry & regulators with E14

Rashmi Shah, MBBS, M.D. - *Consultant, Bucks, UK*^I

10:20 - 10:30 AM

Update on the ICH E14 Implementation Group Process

Philip T. Sager, M.D. - *AstraZeneca, Wilmington, DE*^I

10:30 - 10:50 AM

Break

10:50 - 11:50 AM

Panel Discussion^I - Moderator: Philip T. Sager, M.D.

John E. Koerner, Ph.D. - *FDA, Silver Spring, MD*

Pierre A. Wicker, M.D. - *Pfizer, New London, CT*

11:50 - 1:00 PM

Lunch

1:00 - 1:30 PM

Current E14-derived Approach to Design and Statistical Analysis of TQT Studies

Joanne Zhang, Ph.D. - *FDA, Silver Spring, MD*^{I/II}

"Conventional" (time point/central tendency-based) approach; design considerations (reduction of variability); sample size determination; statistical tests for negative TQT (what if just one time point shows positive outcome?); criteria for sensitivity validation; potential value from the intersection union test

Application of Concentration-QTc Modeling (exposure response relationship) to Support Regulatory and Drug Development Decisions

How to better explain the TQT outcome defined by E14 endpoints? How to reduce false positives? How would the regulators define the negative PK/PD relationship? Use of pooled phase 1 data to predict TQT outcome.

1:30 - 2:00 PM

FDA Perspective

Christine E. Garnett, Ph.D. - *FDA, Silver Spring, MD*^{II}

2:00 - 2:30 PM

Sponsor's Perspective

Richard L. Lalonde, Pharm D., FCP - *Pfizer, Inc., Ann Arbor, MI*^{II}

2:30 - 3:00 PM

Statistical Analysis of ECG Data –

Commentary on the current approaches and future directions

Brian Smith - *Amgen, Thousand Oaks, CA*

3:00 - 3:20 PM

Break

3:20 - 4:20 PM

Panel Discussion^{II} - Moderator: Joel Morganroth, M.D., FCP

Jogarao Gobburu, Ph.D. - *FDA, Silver Spring, MD*

4:20 - 4:50 PM

Logistics of QTc Assessment in Clinical Trials

Joel Morganroth, M.D., FCP - *eResearch Technology, Inc., Philadelphia, PA*^{I/II}

Nenad Sarapa, M.D. - *Daiichi Sankyo Pharma Development, Edison, NJ*^{II}

4:50 - 5:00 PM

Summary and Conclusions

Nenad Sarapa, M.D. - *Daiichi Sankyo Pharma Development, Edison, NJ*^{II}

ACCOMMODATIONS & TRAVEL INFORMATION

A block of rooms has been reserved at the **Baltimore Marriott® Waterfront Hotel • 700 Aliceanna Street • Baltimore, Maryland 21202**

*******DO NOT CALL THE HOTEL!*******

To reserve your room at the room block rate of \$229 for single/double, you must call or register online with our housing bureau, GTA Meeting Services, by the **reservation deadline of April 6, 2007**. All room rates are exclusive of applicable and local taxes which are currently 12.5%.

GTA MEETING SERVICES

Toll Free within the U.S.: 800-456-3585

Outside the U.S.: 302-658-3585

Fax: 302-658-0613

Online Reservations: <http://gtams.com/>

We strongly encourage you to stay at the Baltimore Marriott® Waterfront Hotel while attending this symposium. Sleeping rooms drive meeting space. In order for the College's programs to continue to grow, ACCP is obligated to contract a considerable block of sleeping rooms. If ACCP does not fill this block, it will incur a considerable financial penalty, which can have serious implications for future programming.

TRAVEL GTA Meeting Services will be pleased to assist you in obtaining the lowest fare to attend the meeting. To assure the availability of the lowest fare, your reservations should be made as far in advance as possible. Your e-tickets and documentation will be emailed or faxed to you at least 10 days prior to the meeting.

LOCAL TRAVEL The Baltimore Marriott® Waterfront Hotel is 12 miles from the Baltimore-Washington International (BWI) Airport. Estimated taxi fare from the airport is \$23 dollars one way. The Baltimore Metro Subway and Penn Train Station are approximately one mile away.

TEMPERATURE & COMFORT Since people are comfortable at a variety of different temperatures, for your continued comfort, it is always advisable to bring a sweater or a lightweight jacket to all meeting room functions. The outside average temperatures for early May in Baltimore are approximate lows of 53°F and highs of 73°F.

NOT A MEMBER OF ACCP? Save \$150!

**Apply for ACCP Membership before April 20, 2007
and register at the ACCP member rate for this symposium.**

Step 1. Complete the symposium registration form below, including payment information at the ACCP member rate.

Step 2. Print and complete both pages of the ACCP Membership Application, located at www.ACCP1.org, under "Membership Information". Attach your Curriculum Vita (C.V.) and other accompanying documents as required for various categories of membership. Please do **NOT** send dues with the application for membership.

Step 3. Mail or fax all documents with your registration form to:

ACCP

3 Ellinwood Court

New Hartford, NY 13413-1105

Fax: 315-768-6119

Missed the deadline?

Register on-site at the ACCP membership rate by bringing all the required documentation with you to the symposium and submitting at the Registration Desk.

HOTEL RESERVATION REQUEST FORM

**Fax (302-658-0613) to GTA Meeting Services <OR>
reserve online at <http://www.gtams.com/> by April 6th**

Name _____

Address _____

Address _____

Address _____

City _____ State _____

Zip _____ Country _____

Email Address _____

Phone _____

Fax _____

Check In Date: _____ Check Out Date: _____

Number of People Staying in the Room: _____

Room Preference (*circle one*): Smoking Non Smoking

Bedding Preference (*circle one*): King Two Doubles

Other requests: _____

Credit card type (*check one*):

VISA MASTERCARD DISCOVER AMERICAN EXPRESS DINERS CLUB

Credit card number: _____ Exp. _____

Name on Credit Card: _____

**Normal Check in is 5/1/07 and check out is 5/2/07.
The room rate is \$229.00 per night
plus 12.5% state tax.**

NOTE: All requests concerning smoking/non smoking, bedding type and other requests, while usually accommodated by the hotel, are not guaranteed. Other requests such as more than 2 people in a room or requests for a crib may incur an additional charge.

Your credit card will **not** be charged until:

1. You check in at the hotel <OR>
2. You fail to check in at the hotel and have not cancelled your reservation.

**You must cancel your hotel reservation at least 3 days
in advance to avoid a charge to your credit card.
Call 800-456-3585 (outside the U.S. 302-658-3585)
to cancel or change a reservation.**

QTc Symposium Registration Form

Mail or fax (315-768-6119) to ACCP <OR> register online at www.ACCP1.org by April 26, 2007

Name _____

Affiliation _____

Address _____

Address _____

City _____ State _____ Country _____ Zip _____

Email Address _____

Phone _____ Fax _____

Will you require continuing medical or pharmacy education credit? (*please check which apply*) Yes, CME Yes, CPE No

Do you require any special services in accordance with the Americans with Disabilities Act? (*please specify*) _____

Do you have any special dietary needs? (*please specify*) _____

Check all that apply:

Early Bird Rate



	Before 3/30	On-site After 3/30	Subtotal
<input type="checkbox"/> Members*	\$350	\$500	_____
<input type="checkbox"/> Non-Members	\$500	\$650	_____
<input type="checkbox"/> Student Members	\$160	\$200	_____
<input type="checkbox"/> Student Non-Members**	\$200	\$240	_____
<input type="checkbox"/> Guest*** <i>Print Name Below</i>	\$135	\$135	_____
Total:			_____

**EARLY BIRD REGISTRATION FEES MUST BE
RECEIVED ON OR BEFORE MARCH 30, 2007.
On-site registration fees will apply after March 30.**

ALL INCLUSIVE RATES! *Registration fees include admission to the symposium, electronic syllabus, continuing education fees, continental breakfast, lunch and breaks.*

- * Member rates are extended to Members of ACCPharmacology, ASCPT, AAPS and any international Clinical Pharmacology Society
- ** Student non-member registrations must be accompanied by a letter verifying student status from medical school, hospital or program director.
- *** All guests must be registered. Guests of registered participants are not entitled to receive the electronic syllabus or CE credit.

Method of Payment (*Check one*)

- Check in U.S. Dollars on a U.S. Bank made payable to ACCP
- Visa Mastercard American Express

Cardholder Name (*print*) _____

Credit Card Number _____ Expiration Date _____

Authorized Signature _____

Amount in U.S. dollars authorized to charge \$ _____
for QTc Symposium

CANCELLATION/REFUND/SUBSTITUTION POLICY

Registration cancellations in writing will be accepted until **4 PM Eastern Time on March 30, 2007**. An **administrative charge of \$100** will be deducted from all refunds. For those registrants unable to attend, substitutes may be sent.

Hotel & travel cancellations should be handled through **GTA Meeting Services (in the U.S. 800-456-3585; outside the U.S. Phone: 302-658-3585 or Fax: 302-658-0613)**. Ticket refunds and changes will be governed by the rules of the carrier providing the service.

The College Tax ID Number is 22-1950891.