

CORRONA News

Winter 2011

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Up Front

*Joel Kremer, MD, President and
Chief Executive Officer*

The summer of 2011 saw the launch of CORRONA's Treat to Target (T2T) trial. Working from the EULAR position paper published this year (Smolen et al, *Annals Rh Dis* 2010;69: 631-7), we have designed what we believe is a rational and exciting trial. Yes, we want to see the implications of T2T in the US, as this kind of trial in this country has not yet been reported. But a co-primary endpoint of T2T has to be feasibility. That is, will patients (and docs) accept a mandatory acceleration of treatment if a particular metric (we're using a CDAI) has not been met? The answer is, we don't really know yet.

To be sure, one of the key components of mandatory acceleration is communication with patients (de Wit et al, *Treating rheumatoid arthritis to target: the patient version of the international recommendations* *Annals Rh Dis* 2011;70:891-5). Patients are unlikely to 'get it' if we simply tell them that we have to add or change a drug if they are feeling okay at the time of this communication. After all, if not for the indoctrination we have all received in our training (of the negative implications of poorly controlled hypertension), would we really bother to insist on an adjustment of antihypertensive medications for a consistent diastolic BP of 90? The patient is usually feeling just fine at this time, but they do accept a change in their

medication as both the doc and the patient want to avoid a stroke or MI.

Many docs believe that they are already doing T2T now. We are however defining T2T as a mandatory acceleration of treatment (think diastolic BP) if the CDAI is not in the low disease activity range (<10). You are a good rheumatologist and you are likely treating RA aggressively, but our bet is that you probably don't mandate acceleration if your patient hasn't met a specific disease metric. If we are wrong, we apologize in advance. If we are right, please consider joining us in the T2T trial. You would have a 50% chance of being randomized to "Usual Care", whatever that is for you. We believe that the remuneration offered by CORRONA is attractive.

Isn't it time that we defined the differences in outcomes (think MI and stroke) in a US population of RA patients which is treated with a tight T2T philosophy? If you are interested in learning more about the CORRONA T2T trial, please contact our project manager, Christine Barr (Cbarr@corrora.org).

On an entirely different note, CORRONA will be expanding to include both gout and ankylosing spondylitis registries! Stay tuned for further details.

The Nuts and Bolts of CORRONA

James Cavan, MS, Chief Operating Officer

As we look forward to 2012, CORRONA wants to thank all of our participating clinical sites, investigators, related professionals and participants for their support over the last year. 2011 was a time of significant growth for us with the launch of our T2T study, the establishment of CORRONA International and CORRONA Clinical Trials and many new faces (see below). Our primary mission continues to be quality research data and our database has never been stronger. CORRONA CORE (RA) registry now contains 36,354 patients, and 220,433 visits. This represents a remarkable 85,925 patient years of data.

2012 will likewise be another year of growth and change. CORRONA International will add new countries and expand the data elements collected abroad. New highly focused registries will be launched to gather data on gout, SpA (The traditional 5 subsets of spondyloarthritis) and potentially lupus. Additionally, CORRONA Clinical Trials continues to gain acceptance among industry and the clinical trial community. Please let me know if you have interest in participation in these evolving programs.

I'm proud to introduce our new staff:

Kerry Welch, Project Manager: Gout and PQRS

Kerry graduated from UMass Boston with a degree in Biology. During her 14 year career she has held positions in data management and proposal development, gaining exposure in a variety of therapeutic areas. She joined the pharmaceutical industry and held project management positions at Pfizer, Antigenics and Novelos Pharmaceuticals, focusing mainly on oncology. Most recently she was with PHT, a noted patient record outcomes company. As part of her various clinical project manager responsibilities, she has managed CRO, drug shipment, medical imaging, EDC and IVRS components.

*Judith Scott, RN, MPH., Project Manager:
CERTAIN sub-study*

Judith began her career in clinical research in 1992, as a Clinical Research Associate for Pfizer in the department of anti-infectives in Groton, CT. Her many years as an RN in an acute care setting, and her interest in the

changes in clinical care left her well positioned to begin her career as a Clinical Research Associate. Over the past few years, she has worked as a contract CRA. This enabled her to expand her skills and become more versatile with regard to all aspects of trial design, conduct and completion.

Matthew Perkins, Senior Developer

Matthew is the Senior Developer for CORRONA's software systems. He brings nearly two decades of development and QA experience to the task of crafting and enhancing a software environment that complements CORRONA's far reaching vision. Matthew has held certifications such as Microsoft's MSD, taught database and software development, and run his own consulting company working with both individuals and businesses. Matthew has experience in nearly every facet of the development lifecycle, from tech support to CTO.

For the full bios of Kerry, Judith, Matt and all of the CORRONA team, please go to www.corrona.org.

As always please let me know if you have any suggestions or need help with anything related to CORRONA.

CORRONA Expanded Its Borders

Patty Grier, Managing Director, International Operations

Dimitrios Pappas MD, Scientific Director, International Registry

In September, CORRONA International, LLC, a wholly owned subsidiary of CORRONA, Inc., launched an International RA Registry in three regions outside the United States. The international registry is a prospective, multi-center, longitudinal, observational registry, which plans to recruit 5790 RA patients.

Patients will be recruited from Asia, Eastern/Central Europe, and Latin America. Initially 145 sites in Argentina, Brazil, Czech Republic, Hungary, India, Mexico, Poland, Romania, Russia, and the Ukraine will participate. CORRONA International, LLC is working with a global CRO to assist with the conduct of the registry in each of these countries.



The very first patient in the registry was enrolled in Poland on September 6, 2011 by Professor Leszek Szczepański. We are excited to be working and collaborating with an exceptional group of investigators from around the globe. The following investigators were the first to enroll patients in their respective countries:

Poland – Professor Leszek Szczepański

India – Dr. Smruti Ramteke

Mexico – Dr. Hilario Ávila Armengol

Czech Republic - Dr. Roman Záhora

Hungary - Dr. Edit Tóth

To date over 800 patients have been enrolled into the registry across the initial 5 countries; the remaining 5 countries are expected to begin their enrollment before the end of 2011. Under the leadership of Drs. Dan Furst and Allan Gibofsky, a cadre of renowned key opinion leaders in every country has been assembled.

The primary objectives of the registry are to systematically collect and analyze longitudinal outcomes for RA patients, compare regional differences in comorbidities and adverse events, with a focus on cardiovascular outcomes, and to regionally compare DMARD and biologic utilization, effectiveness and safety. Obtaining data on background rates of serious adverse events in these regions will be beneficial in contextualizing SAE rates in RA global clinical trials.

Clinical data will be collected following the established national CORRONA registry model. Patient and physician questionnaires will be completed at a baseline registry visit and again at follow-up visits occurring every 6 months. Detailed information on disease activity, patient functionality, comorbidities, biologic and non-biologic DMARD treatment and adverse events will be captured. Questionnaires to obtain granular data about targeted adverse events (cardiovascular, peripheral vascular, infectious and malignancy events) have been prepared. Supporting source documents for adverse event verification and adjudication will be collected.

The CORRONA team is very excited about our expansion and believes this will be a worthwhile project, advancing our understanding of how Rheumatoid Arthritis and its treatment and complications differ in various regions of the world.

Ringling in the New Changes

Kimberly Gottfried, Director of Site Operations

CORRONA has recently submitted V.10 of the CORRONA & CERTAIN protocol and questionnaires to the NEIRB for review and approval. Effective early January 2012, all sites with NEIRB approval will commence use of the V.10 protocol and V.10.0 questionnaires. We urge all academic sites requiring local IRB approval, please submit the V.10.0 protocol and questionnaires as soon as possible. For academic sites, please continue to use V.9.1 questionnaires until you receive approval to use V.10.0.

The significant V.10 changes:

- 1) The Pharmacogenetics study has been closed. You will no longer receive the consent for this sub-study.
- 2) Inclusion of quantiferon (QFT) testing results in the PPD section of Section M on the physician review questionnaires. The next version of the questionnaires will contain a separate section to capture QFT results.
- 3) Increase the enrollment upper limit to 150 patients for sites participating in the CERTAIN sub-study.

Effective as of last January 1, 2011, NEIRB will no longer include the study expiration date on the consent form. Consent forms will continue to include the date of approval and (if applicable) the version number in the footer of the document. Example: Approved by NEIRB on 1/01/11 Version 1.0

Once all studies have this new process in place, the consent form will only be re-issued when there is a change to the content of the document.

This change will decrease the volume of correspondence between NEIRB and investigative sites, and it will create a more efficient process for tracking the currently approved consent form.

NOTE: Patients previously enrolled in the CORRONA Main Protocol or CORRONA CERTAIN Sub-study do not need to re-sign newly issued consents.

Last month, patient overdue lists were sent to your site for review and reconciliation. While we encourage you to either contact these patients for a follow-up visit or exit these patients after 15 months of inactivity, no formal response back to CORRONA is required. We anticipate providing these reports to your office every 3-6 months to help facilitate a follow-up workflow for your staff and patients.

In the event a patient is exited from the CORRONA Main Protocol registry, a final exit form should be completed. If the patient subsequently wishes to re-join CORRONA, the patient should continue with regular follow-up visits, retaining the originally assigned patient ID number, as if they never exited the program. We do NOT wish to ‘re-enroll’ these patients. If you have re-enrolled such patients in the past, please contact CORRONA to discuss remedial action.

Orencia SQ debuted in late September 2011. In order to capture this change in formulation in Section I of the Physician Review Questionnaires, please choose “other” in the biologic section and free text “Orencia SQ”. For CERTAIN patients who have taken Orencia IV anytime in the past and now are being considered for Orencia SQ, the patient will NOT be eligible for enrollment into the CERTAIN sub-study.

However, if the patient has been enrolled into the CERTAIN Sub-study on Orencia IV, and “without interruption” begins Orencia SQ, they can continue in the CERTAIN Sub-study without having to be re-enrolled. These study parameters also apply to Actemra when switching from IV to SQ.

New Section I drug use documentation requirements went in to effect in late October 2011. New drug starts, both biologics and non-biologics, reported for the first time no longer require dose and frequency information in Section I. For all new drug starts, select ONLY the drug being started and the radio button indicating you are starting the drug today or since last visit. The dose and frequency will be captured at the next CORRONA visit. Previously, CORRONAbase may have requested this information in error, but these errors can now be cleared by selecting the “Show Errors” button and the red required field edit checks will no longer appear.

Wishing you all the warmth and happiness of the holiday season, and the very best in the New Year!

TAE Talk

Jan Henderson, Director of Adverse Event Reporting

As we quickly approach the end of another year, we are actively contacting each site to submit any and all outstanding queries and requests for TAEs that have never been entered in CORRONAbase. Many of you have by now received pre-populated questionnaires that were related to events which were reported in the Physician Follow-Up Questionnaire but had not yet completed the appropriate TAE.

Very shortly, we will begin collecting all data on the new V.10.0 questionnaires. Since we will be closing the opportunity for you to enter outstanding V.9.1 events, we ask that you get these entered as soon as possible. If you cannot get them entered prior to the launch of V.10.0, we request that you fax them to us directly for collection and data entry.

Differences in V.9.1 and V.10.0:

You will experience very few differences in our updated questionnaires. A common new data capture is in the header of each of the Target Adverse Events. We ask you to complete the actual date of when you are completing the questionnaire.

This helps us place events which may occur between follow-up visits but never get reported in the next follow-up visit. It also helps us define any duplicate reporting of events.

Found on the Participant Exit Questionnaire are four new cardiovascular options to further define the cause of death.

We are confident you will find few changes that capture data beyond what you have experienced in the current version.

FAQs:

Q: “This patient had an infection of ----. Do I need to complete a TAE?”

A: Two things will qualify an infection for a completed questionnaire.

- o Was the patient hospitalized?
- o Did the patient receive IV antibiotics?
- o If the answer is “Yes” to either of these questions, you will need to complete the Infection Adverse Event questionnaire!

Q: “The patient had a heart attack which happened between CORRONA follow-up visits. The biologic they were on was discontinued in this last visit because we thought the event may be related to the drug. I have checked discontinued in the Targeted Adverse Event questionnaire and entered the date but it will not accept the visit date since it is after the event.”

A: Since the drug was discontinued after the date of the event, you would need to check “current” as the patient was still on the drug at that time.

Q: “The source documents we received indicate the patient had more than one cardiovascular event on the date it was reported. How do I capture all of these on one questionnaire?”

A: With all of the Targeted Adverse Events, if the patient has had more than one event during that reported time, please complete a questionnaire for each of the events.

As a reminder, always refer to the bottom of each Targeted Adverse Event Questionnaire when in doubt if you

are using the correct event. Each indicates the event(s) for which we require a TAE to be completed when reported in a follow-up visit or an event reported during a non-CORRONA encounter.

Please be reminded that any required fields which are left blank will prevent the TAE form from being signed. Your site will not receive credit for unsigned forms. Some of you already know that we actively keep in touch with you to collect outstanding required data and source documents!

Your questions are always welcomed and they always help us improve the way we address issues in how we train our sites and update our questionnaires. Never hesitate to contact us with your comments or questions!

We thank you for your continued help and support and extend our wishes for Happy Holidays and New Year.

Gout is Coming!!

Kerry Welch, Project Manager, Gout

We are very excited to announce the upcoming launch of a Gout Registry! In late November, CORRONA received funding for a new Gout Registry. This is the first new rheumatologic disease which CORRONA has added since our inception.

We are targeting a second quarter 2012 launch, and have already begun work on our questionnaires. The registry will be lead by Leslie Harrold MD, MPH with support from Dr. Allan Gibofsky, MD, JD and Vice President of Corrona and from several noted gout experts.

Dr. Harrold is an Associate Professor of Medicine at the University of Massachusetts Medical School, and a Senior Research Associate at the Meyers Primary Care Institute (a joint endeavor of the University of Massachusetts Medical School, the Fallon Foundation and Fallon Community Health Plan).



She is a board-certified rheumatologist and health services researcher with extensive experience using administrative data to identify patients with rheumatic conditions and assess their medication usage and health care utilization. Her research has focused on patients' ability to manage their own condition, particularly in the area of gout. She currently holds a career development award (K23AR053856) from the National Institute of Arthritis and Musculoskeletal and Skin Diseases entitled "Assessing and Improving Arthritis Medication Adherence: Gout as a Model." Through this grant Dr. Harrold has explored barriers to, and facilitators of optimal gout care.

Please watch for updates regarding the Gout Registry in the near future. Of course, CORRONA will be paying health care providers for completion of the registry questionnaires. If you would like to hear more information, please contact gout@corronea.org. We hope you will join our new endeavor!!

The Treat to Target Trial is Ramping Up!

Christine Barr, BSN, MPH, Project Manager, Treat to Target

CORRONA is delighted to announce the launch of the Treat to Target (T2) trial in July 2011. Enrollment activities are underway at nearly a dozen US Rheumatology sites as of December 1. Our strong team of early investigators has kicked off enrollment activities and helped to pilot and refine the data collection forms for this important trial. Kudos to the Investigators and Coordinators that are spear-heading this effort. This quarters high enrollers are:

**Site 15: Allergy, Asthma & Arthritis Associates
Dover, NJ**

**Principal Investigator: Steven Golombek, MD
Study Coordinator: N/A**

**Site 6: Rheumatology Consultants
Knoxville, TN**

**Principal Investigator: J. Frederick Wolfe, MD
Study Coordinator: Doris West**

**Site 65: Danbury Orthopedics
Danbury, CT**

**Principal Investigator: Michael Spiegel, MD
Study Coordinator: Shannon Rajotte**

What is the T2T Trial?

This 12 month study will examine outcomes and feasibility of implementing a Treat to Target approach to the management of active Rheumatoid Arthritis. As such, the study was designed to collect information on barriers to more aggressive RA management, in addition to medication changes and standard disease activity measures. There is much to be learned, and we are thrilled with the level of support, interest and enthusiasm for the project among U.S. Rheumatologists. We plan to enroll a total of 888 subjects (444 per treatment arm) by July 2013.

How Does it Work?

Following selection and IRB approval, entire sites are randomly assigned to one of two possible arms. Both arms will enroll medically appropriate subjects with active RA defined as a CDAI >10, for the purposes of this protocol.

- Sites randomized to the Treat to Target arm will complete assessment visits as frequently as monthly and be prompted by the protocol to accelerate therapy (using a flexible menu of options) in medically appropriate subjects with sustained levels of moderate to severe disease activity.
- Sites randomized to the "Usual Care" control arm will complete study visits every 3 months. Treating Rheumatologists at these sites will continue usual disease management practices.

A series of brief trial-specific questionnaires will be collected in addition to CORRONA Patient and Physician forms, and an ESR drawn at each visit.

Next Steps for Interested Sites

If your site is interested in being considered for the T2T trial, please contact us to request additional information. We hope to have recruited and activated all participating sites by early 2012.



Table 1

Update for Active Sites: Protocol Amendment One
Active sites should all have recently received updated Central IRB approval documents and the revised informed consent forms, which should be used for new subjects going forward. The T2T protocol was recently amended in an effort to streamline enrollment procedures and allow for direct enrollment of subjects not already participating in CORRONA.

Hardcopy updates to the protocol and supporting documents were distributed to active sites in late December, and should be added to the study Manual of Procedures binder upon receipt. The Protocol Signature Page should be signed and returned to Aimee Whitworth or Christine Barr.

Please contact Christine Barr at cbarr@corrora.org with any questions about the T2T protocol, or to learn more about participating as a site.

Refresher on the CERTAIN Project

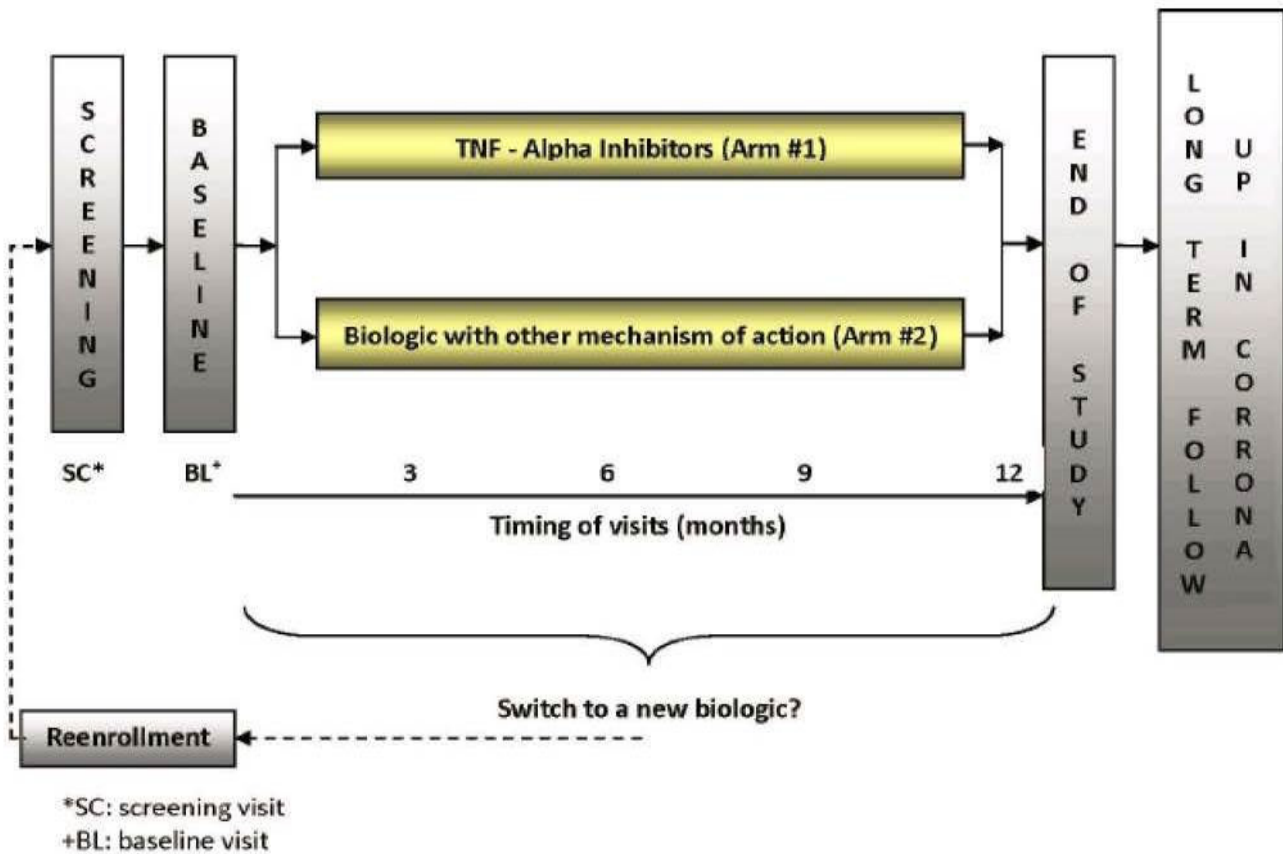
Judith Scott, RN, MPH, Project Manager, CERTAIN
Dimitrios Pappas, MD, Scientific Director, CERTAIN

The Comparative Effectiveness Registry to study Therapies for Arthritis and Inflammatory Conditions (CERTAIN) is a prospective cohort study of adult patients with Rheumatoid Arthritis (RA). The CORRONA CERTAIN Sub-study has been designed to systematically compare the effectiveness, and safety of biologic medications (e.g., anti-TNF therapy, abatacept, rituximab, tocilizumab) and investigate biomarkers of response to biologics. RA patients treated with a biologic agent are eligible to participate. After screening, a baseline visit takes place at the time of initiation of treatment and then every 3 months for 1 year. The design of the study is depicted in figure 1 and the schedule of the evaluations in table 1.

	Baseline	Followup Visits
	0 Month	3,6,9,12 Months
Clinical Assessments		
Medication exposures (including biologics) and compliance	x	x
Tender & Swollen Joint Count (0 - 28)	x	x
Physician Global Disease Activity (100mm VAS)	x	x
Patient Global Disease Activity (100mm VAS)	x	x
Patient Pain (100 mm VAS)	x	x
Patient Fatigue (100 mm VAS)	x	x
EuroQol 5D	x	x
HAQ DI	x	x
Laboratory Assessments		
Complete blood count (with automated differential)	x	x
Rheumatoid factor and iso-types	x	
Anti- cyclic citrullinated peptide antibody	x	
High-sensitivity C-reactive protein (hsCRP)	x	x
Immunoglobulin panel (IgM, IgG, IgA)	x	x
Traditional non fasting lipoprotein analyses (HDL, Total cholesterol, Triglycerides)	x	x
Direct quantitative LDL (fasting specimens not required)	x	x
Serum, plasma, whole blood (RNA)	x	x*
AST ALT, Albumin, Total and direct Bilirubin, BUN, Creatinine, Glucose, Calcium, Serum uric acid, CK, LDH	x	x
DNA (optional component).	x	x

*collected at 3 and 6 month follow-up visits

Figure 1



Results for clinic tests (serology CBC, CMP, CRP, lipid profile etc) are provided to the investigators.

The CORRONA CERTAIN Sub-study was launched in late November 2010 and approximately 700 patients have been enrolled to date. Currently 28 CORRONA sites and 87 investigators are participating. We would like to thank all participating investigators, coordinators and other site personnel for their efforts.

Sites prescribing at least one biologic per week are welcome to join the CORRONA CERTAIN sub-study. Please contact Kim Gottfried at KGottfried@corrona.org to express your interest in participating.

Reminder: Patients must be adults with RA who start a biologic and have moderate disease activity as defined by CDAI greater than 10.

Biologic naïve and experienced patients switching to a new biologic are eligible as long as they don't start a biologic with which they have previously been treated.

Please remember that the baseline visit blood samples must be obtained prior to the first dose of the selected biologic.

In order to ensure prompt compensation to the patients and accurate payments to the site, we request the data be entered into CORRONAbase by the end of the week when the visit occurred.

We would like to thank all of our CORRONA-CERTAIN sub-study sites for their continuing participation and enrollment.



The following sites, in no particular order, have achieved the highest enrollment thus far.

Altoona Ctr for Clinical Research, Duncansville, PA
Principal Investigator : Alan Kivitz, MD
Research Coordinator: Kim Zebroski

St Paul Rheumatology, Eagan, MN
Principal Investigator : David Ridley, MD
Research Coordinator: Sandie Campbell

Seattle Rheumatology Associates, Seattle, WA
Principal Investigator: Philip Mease
Research Coordinator: Cathy Loeffler

Columbus Arthritis Center, Columbus, OH
Principal Investigator : Kevin Schlessel MD
Research Coordinator: Ameer Holland

Center for Rheumatology, Albany, NY
Principal Investigator : Joel Kremer MD
Research Coordinator: Teresa Michaels

CERTAIN Sub-Study

Judith Scott RN, MPH, Project Manager, CERTAIN

Although I am still fairly new to CORRONA, I am very pleased to have been able to meet so many of you, at least over the phone. If I haven't connected with you yet, I am hoping to do so very soon. However, no need to wait. If you have some time, or a question, please feel free to contact me. My email is jscott@corrora.org, my phone is 508-330-0606.

For those of you who don't know me yet, I will be managing the CERTAIN Sub-study. I started with CORRONA in October of this year. My background, after many years as an RN in acute care settings, is primarily clinical research, both Pharmaceuticals and Medical Devices. As a CRA, I have been lucky enough to travel to different countries and meet amazing people who share similar interests both professionally and personally.

As a project manager, I have also been fortunate enough to work on interesting and meaningful projects. For the past three years or so, I have been working as a contract employee for several smaller companies. These environments provided me an opportunity for new perspective on the very early stages of product development, especially with regard to devices and predictive assays. Being with CORRONA will afford me a chance to work within a virtual company, while learning the tenets of a registry, as well as the Sub-studies; especially CERTAIN.

Continued on page 11

CORRONA Employees and Consultants

Joel Kremer, MD, President and Chief Executive Officer
Allan Gibofsky, MD, JD, Vice President
Jeff Greenberg, MD, MPH, Chief Scientific Officer
James Cavan, MS, Chief Operating Officer
Tim Harrington, MD, Chief Site Quality Officer
Dimitrios Pappas, MD, Scientific Director CERTAIN sub-study, Scientific Director International Registry
George Reed, PhD, Scientific Director, Biostatistics
Leslie Harrold, MD, MPH, Scientific Director, Epidemiology
Dan Furst, MD, Head of Publications
Kim Gottfried, MS, RN, CCRA, Director of Site Operations
John Block, Director of Informatics
Jan Henderson, MS, Director, Adverse Event Reporting
Lisa Lemire, MBA, Director of Regulatory Compliance and Accounting
Christine Barr, BSN, MPH, Project Manager, Treat to Target
Katherine Saunders, MS, Senior Analytic Coordinator
Patty Grier, Managing Director, international operations
Judith Scott, RN, MPH, Project Manager, CERTAIN
Kerry Welch, Project Manager, Gout
Julie Lapham Hunt, Executive Assistant
Aimee Whitworth, Assoc. Project Manager, International and Treat to Target
Matthew Perkins, Senior Developer

Dispatches from ACR 2011 (Chicago, IL)

Kate Saunders, MS, Senior Analytic Coordinator

As the CORRONA registry continues to mature and gain statistical power, we are fortunate to be able to share meaningful findings with the Rheumatology community by publishing and presenting at international and national meetings. This year, thirteen CORRONA abstracts were presented at the recent ACR 2011 meeting in Chicago, IL.

We thank you, your staff, and your patients for continuing to provide robust data that provides the foundation for our work!

Posters Presented at ACR 2011

Factors Associated with Work Status and Missed Work Days in Patients with Rheumatoid Arthritis.

Lead Author: Leslie Harrold, MD, MPH

Risk for Herpes Zoster in Patients with Rheumatoid and Psoriatic Arthritis. Lead Author: Dimitrios Pappas, MD

Factors Associated with Relapse of Remission in Rheumatoid Arthritis. Lead Author: Leslie Harrold, MD, MPH

Effect of Weight, Body Mass Index and Weight-Based Dosing on Persistency of Anti-TNFs in Psoriatic Arthritis. Lead Author: Jeffrey Greenberg, MD, MPH

A profile of RA patients treated with Tocilizumab in a US registry population. Lead Author: Dimitrios Pappas, MD

Is there a relationship between TNF- α inhibitors or Disease Activity on the Lipid Profile of Psoriatic Arthritis patients? Lead Author: Asena Bahce-Altuntas, MD

Trend of Tumor Necrosis Factor Inhibitors Use Among Patients with Rheumatoid Arthritis: Analysis from the Consortium of Rheumatology Researchers of North America Registry. Lead Author: Pim Jetanalin, MD

Application of the New American College of Rheumatology/European League Against Rheumatism Rheumatoid Arthritis Remission Criteria in a United States Cohort. Lead Author: Iris Navarro-Millan, MD

Oral Presentations at ACR 2011

Comparative Effectiveness of Abatacept Versus Subsequent Anti-TNF Agents Among Rheumatoid Arthritis Patients with Previous Anti-TNF Exposure.

Lead Author: Leslie Harrold, MD MPH

Higher frequency of metabolic syndrome in psoriatic arthritis compared with rheumatoid arthritis may be explained by high triglycerides and increased rates of obesity and diabetes.

Lead Author: Asena Bahce-Altuntas, MD

Successful Tapering of Glucocorticoids (GC) in Rheumatoid Arthritis Patients-Results From the Consortium of Rheumatology Researchers of North America Registry.

Lead Author: Thasia Woodworth, MD

Clinical Disease Activity and Acute Phase Reactant (APR) Levels Are Discordant Among Patients with Active Rheumatoid Arthritis (RA) and Contribute Separately To Predicting Outcome at 1 Year.

Lead Author: Jonathan Kay, MD



CERTAIN Sub Study Continued from page 9....

As we move into the second year of active enrollment for the CERTAIN sub-study, I'd like to thank you for your continued attention to this very important study. This is the first time different treatments will analyzed for safety and efficacy against one another. Each subject enrolled in this study is critical to the success of the CERTAIN Sub-study.

We had our first, monthly, site staff conference call on Nov 15th 2011. We will be scheduling these site staff conference calls for different times each month. The goal is to provide a forum for site staff to communicate, not just with us, but with one another. It is a great opportunity to bring up questions, ideas, suggestions, problems, etc. If you have encountered a situation when enrolling the subjects or while entering data, or any other scenario, it is a highly likely that someone else has struggled or solved the same issue. Please bring it up and share your thoughts, ideas and solutions.

For those of you who were unable to join the November conference call, I sent around a summary of the discussion topics. If you have a specific item to be discussed, please let me know and I will add it to the agenda, or you can bring it up during the discussion session near the end of the call.

The next task at hand is to assist the statisticians as they are preparing the next quarterly report. As they review the data, they will be reporting to us with regard to any questions, or discrepancies they may find. In return, Beatrice Gonzalez, the CERTAIN Senior Data Manager, and I will be sending queries to you to clarify, or correct as needed. If you have any questions, or would like some assistance in completing the queries, please don't hesitate to contact either one of us.

Thank you for your continuing efforts and participation in the CERTAIN Sub-study.

CORRONA is proud to announce that Dr. Harrington, Chief Site Quality Officer, has published a book in November, *Great Health Care - Making It Happen*. Congratulations Dr. Harrington on a job very well done!



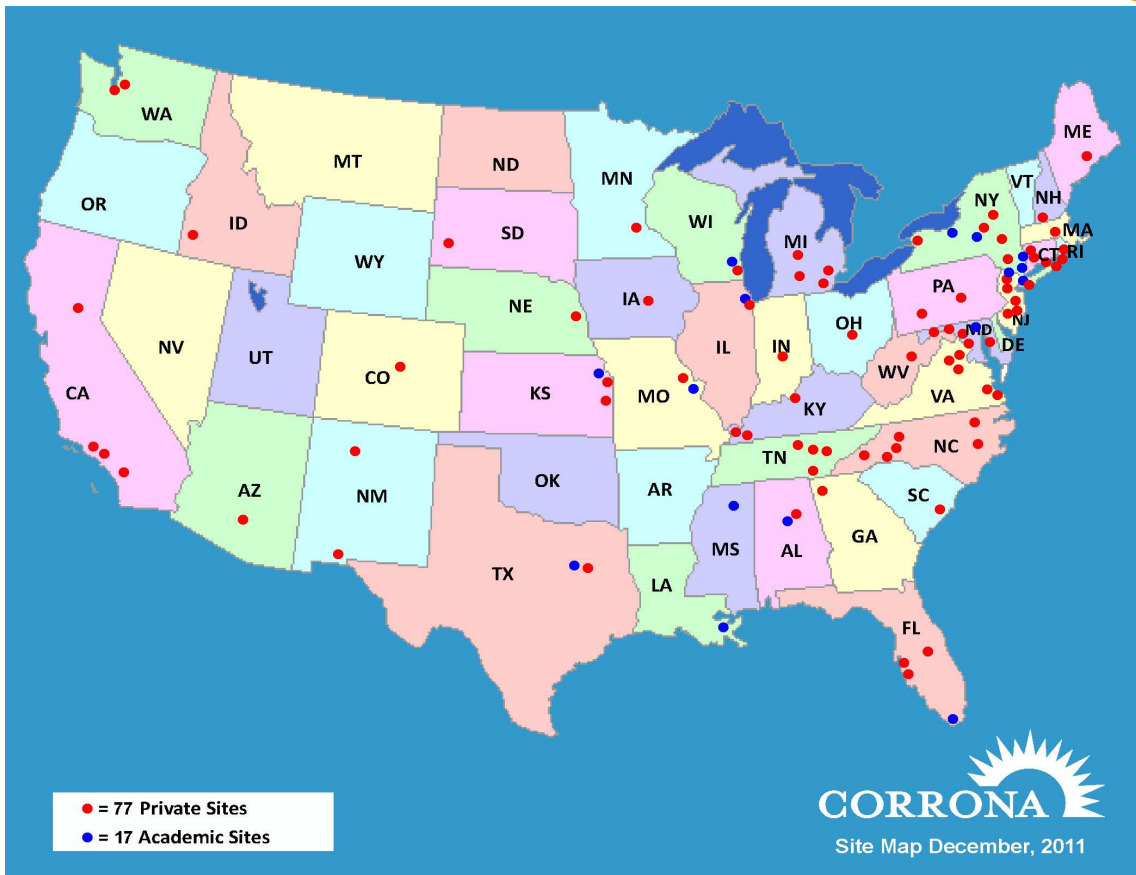
Great Health Care *Making It Happen*
Harrington, J. Timothy; Newman, Eric D. (Eds.)
2012, 2012, XVI, 272 p. 53 illus., 40 in color.
Softcover, ISBN 978-1-4614-1197-0 \$39.95

Available November 2011

- Essential reading for all physicians and health systems managers
- Provides prescriptive advice on how health care can be delivered dependably and at the lowest possible cost
- Provides models from health care systems which have successfully implemented these positive changes
- Illustrates efficient practice strategies for the treatment of resource draining chronic diseases such as diabetes, rheumatoid arthritis, obesity, and congestive heart failure
- A call to arms that will transform how health care is delivered

Contact to order: Julie.handel@springer.com
(Special pricing for bulk orders available)
<http://www.springer.com/medicine/book/978-1-4614-1197-0>

CORRONA ACROSS AMERICA



More than 540 participating physicians
More than 34,000 participating patients

Upcoming Events in 2012

Please visit us at

EULAR Berlin, Germany June 6-9	ACR* Washington, DC November 9-14
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* Exhibiting

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