CORRONA News

Fall 2013

In This Issue:

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Joel's Corner

Joel Kremer, MD, President and Chief Executive Officer

One of the many virtues of a large registry is that it is possible to 'nest' other studies at the sites of the physicians who are participating. A little background might help on the differences between data collection in a registry and a nested trial within a registry.

Registries are designed to be observational. That is, they collect data on actual events in the course of usual patient care. As such, they are not contrived to show an outcome, but should simply represent the typical clinical activity of physicians and patients in the geographic area of its origin.

Because of established relationships with physicians and site personnel and our established research infrastructure it should be easier to conduct a non-observational trial at registry sites. The CORRONA Treat to Target (T2T) trial is a very good example of a nested trial conducted at registry sites. (The CERTAIN Comparative Effectiveness trial is another example of a nested trial and we will review CERTAIN in future issues of the newsletter.)

The T2T trial is a prospective parallel trial which is comparing a T2T arm with Usual Care (UC). Subjects in the T2T arm have a mandated acceleration of treatment if their CDAI score is >10! (You will recall that the CDAI is a simple total of tender and swollen joints, and a physician and patient global VAS score. So a patient with 4 T and 4 S joints with a VAS score [10 cm line] of 3 and 5 has a total CDAI score of 16.) In addition, subjects with a CDAI score of >10 (definition of moderate disease is score of 10 to 22) were mandated to see their rheumatologist monthly until the score settled in to the mild disease activity (CDAI<10) range.

The "target" of a T2T has to be a metric which is acceptable. If we can't measure progress, then we have nothing. We chose the CDAI as the results are immediately available to the physician and it does involve a hands on examination of joints as recommended in the consensus publication by Smolen et al. (Ann Rheum Dis 2010;69:631-7).

We are happy to say that we achieved our enrollment targets in the precise time interval projected when the study was planned. New patient enrollment was completed and closed this past July. As subjects are followed for a year, the study will not end until July of 2014.

Leslie Harrold, MD, MPH at University of Massachusetts Medical School will also be studying the circumstances which may be associated with adherence to the T2T guidelines.

This kind of hard look at behaviors and attitudes associated with newly learned clinical pathways should provide some additional insights and lead to a better understanding of the possible impediments to actually managing a patient to achieve a low disease activity metric. Our T2T Project Manager, Christine Barr, RN, BS, MPH has lead this effort and has done an outstanding job in managing this trial. The sites know and love Chris!

We also want to thank our 31 sites within the CORRONA network for their diligence and outstanding efforts in helping the team to achieve our enrollment goals in a timely manner!

As is always the case, we couldn't do it without you and we are enormously grateful!

Update on the Gout Registry

Jennifer O'Connor - Director of Project Management

CORRONA is proud to announce the Gout registry, launched in late 2012, now has 33 active sites. From these active sites, almost 1,000 patients were enrolled as of September.

CORRONA cannot thank the participating sites enough for all the hard work that they have put into having this registry. We especially appreciate your diligence of faxing the enrollment forms every week. This has greatly strengthened our ability to report current enrollment numbers to interested parties.

Please keep up the strong enrollment but as we get ready for the second year of the registry, please focus on getting the follow-up forms collected. We recognize that Gout patients' follow-up can be tricky but would appreciate the effort you can put in. It is important to note that follow-up visits receive $100 per patient per follow-up and the enrollment receives $200 per patient per enrollment.

It is important to remember, the Gout registry is a longitudinal observational registry. CORRONA would like to follow the patient throughout their care with you as their physician.

CORRONA's Gout team is continuing to try to improve and streamline the process. Most of you have probably noticed by now that we are sending out monthly query reports to each site so we can have plenty of time to address issues prior to the close of the quarter.

I am always available at JOconnor@corrona.org with any questions about the Gout registry.

CORRONA is not currently accepting new sites for the Gout Registry. Our success that has been mentioned before has been accounted to 33 wonderful sites. Thank you again for all your hard work. Let's make year two of this registry as successful as year one!

SpA Registry is Really Taking Off

Jennifer O'Connor - Director of Project Management

Since its launch in March 2013, CORRONA's Spondyloarthritis/psoriatic arthritis registry has taken off like a rocket! With over 600 patients enrolled as of August, it is projected to meet our goal of 1000 patients by the end of the year!

The success is largely due to the 22 sites we currently have enrolling patients. We continue to add sites to this registry each week. The SpA/PsA registry is a lucrative registry for sites to participate in as enrollments are $250 and each follow up is $100. If your site would be interested in participating in this registry, please e-mail me at JOConnor@corrona.org. We are always looking for additional sites to add to this registry.

The SpA team is working diligently with our IT group as well as TrialMaster to create an electronic data capture (EDC) to allow you to enter data from the forms at your site. It is expected for this to be available to the sites by quarter two 2014. In the meantime, we would appreciate you faxing in the enrollment forms each week. This helps us gauge how you, the sites, are doing with enrollment and we can report these numbers to interested parties.

The SpA team will continue to send out monthly query reports to each site. This will allow plenty of time to address any issues there might be about enrollment forms by the end of the quarter for payment.

I am always available at JOconnor@corrona.org with any questions about the SpA/PsA registry.

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Treat to Target RA Trial (T2T): Enrollment Now Complete!

Christine Barr, BSN, MPH, Senior Project Manager
Kevin Soe, Project Manager

About the Treat to Target Trial:

Launched in summer 2011, the Treat to Target trial is the first of its kind in the U.S. Thirty-one sites have been cluster randomized to either the Treat to Target (Intervention) Arm, or the Usual Care (Control) Arm. Participants totalling 541 with moderate to severely active Rheumatoid Arthritis (defined as CDAI score >10) have been recruited by participating US rheumatology practices. All enrolled participants are followed for 12 months.

- T2T arm sites complete study visits as frequently as monthly, and are prompted to accelerate therapy at least quarterly until low disease activity is achieved (CDAI < 10).

Treatment Acceleration is defined as any one of the following options:

- o Initiation of a traditional or biologic DMARD
- o Increase in dose or frequency of administration of a traditional or biologic DMARD
- o Change from oral to subcutaneous route of Methotrexate administration

- UC arm sites complete study visits every 3 months. Rheumatologists at these sites otherwise continue their usual approaches to RA management.

Status Update:

We could not be more pleased to report that the recruitment period for the T2T trial has come to a close. 541 total participants were enrolled. Our enrollment goal of 530 participants was reached on July 29, 2013—exactly 2 years from the date the 1st participant was enrolled. To say that this team of sites is incredible would be a massive understatement. The dedication, hard work, enthusiasm and consistent contributions by the investigators and staff at our participating sites have kept us going and impressed us most profoundly. You are truly amazing.

We have now entered the last 12 months of follow-up and we still need your help! Your careful tracking of enrolled participants and timely and complete data submissions continue to be critical to the success of this ground breaking study. It is important for us to follow as many participants through completion of 12 month visits as possible. Please continue to reach out with questions that may arise as you follow your enrolled participants. Please contact Kevin Soe at ksoe@corrona.org if you have questions regarding the T2T trial.

CERTAIN Fall News

Tanya Sommer, MS ANP-BC, Project Manager

The CERTAIN team is pleased to be approaching our goal of enrolling 2733 subjects. Currently we have screened/enrolled ~2450 subjects and ~2300 have completed Baseline visits. With over 40 actively participating sites, the CERTAIN study is pushing forward making terrific strides. We are still hoping that we can meet our enrollment goals by the end of December 2013 and we are really relying on your help in order to accomplish this goal.

<u>What's New?</u>

EDC PLATFORM NEWS: Our New EDC platform is almost completely functional. We finished the last round of user appointed testing in September. This platform offers a variety of user friendly tools to assist your site with everything needed to reliably and efficiently capture and record data.

The following Internet Explorer settings should be implemented to all computers running Internet Explorer 10 in order for both the Trial Master Application and browser to work fluently together.

A. Make sure the IE menu bar is exposed (File- Edit- View - Favorites – Tool - Help). If the menu bar is not visible, the user will need to make it available by right clicking on an open gray area on the browser and select "Menu Bar".

B. Once the menu bar is visible, click on Tools from the menu bar make sure the POP Up blocker is disabled, then go back to Tools and select the Compatibility view settings option and add the Trial Master website.

C. In order to downgrade from IE10 to IE8, press the F12 key. This will open the Developer Tool option. Then, select the IE8 browser version option.

Should you have any problems please contact: OmniComm Customer Care
Toll Free North America: 1 866.996.6332 - Option 1
CustomerCare@omnicomm.com

SUCCESFUL PILOTING OF THE FIRST CERTAIN ONLINE SURVEY:

CERTAIN has expanded its data collection abilities to a new level by surveying the CERTAIN enrolled patients via the internet. The first CERTAIN internet survey was sent to the patients in August 2013. The survey was programmed in the Qualtrics survey engine and sent to 854 patients by e-mail. The patients were informed about the survey over 3 months by a letter sent to them alongside the gift cards for their participation. There is no cost of participation for the patients and after responding to the survey, they choose to receive either a $25 value Visa gift card by e-mail or a $25 amazon.com e-gift certificate as a token of appreciation for their participation. We encourage the sites to add e-mail addresses of the new patients as e-mail is the method of administration for this INTERNET survey and upcoming ones in the future.

You may also encourage patients who have not provided an e-mail address to do so if they are interested in participating in future surveys. Patients may directly contact Aseem Bharat from the University of Alabama directly 205 975 1758(tel.) 205 975 6859(fax) or abharat@uab.edu. A big thank you to all of our sites for making this survey a success!

CERTAIN Information Used for ACR Presentations!

CERTAIN is well represented at the ACR with a design poster, a multitude of poster presentations focusing on the cardiovascular aspects of RA and an oral presentation comparing the effect of biologic agents on lipids and cardiovascular risks presented by Dr. Dimitrios Pappas.

The posters and oral presentation will be presented at the following times:

Effect Of Tocilizumab On Treatment Patterns, Effectiveness and Safety With Laboratory Values For Patients With Rheumatoid Arthritis: Analyses From The CORRONA-Certain Study
Authors: DA Pappas, A John, JM Kremer, C Karki, T Sommers, GW Reed, JR Curtis, A Shewade, JD Greenberg
Poster Presentation # 2344 on Tuesday, October 29, 2013, 8:30 AM - 4:00 PM in Exhibit Hall B2-C-D

Shift in Cardiovascular Risk and Lipid Levels in Rheumatoid Arthritis Patients Using ATP-3 Guidelines: CORRONA CERTAIN Study
Authors: DA Pappas, A John, JR Curtis, GW Reed, T Sommers, JD Greenberg, A Shewade, JM Kremer
Poster Presentation # 370 on Sunday, October 27, 2013, 8:30 AM - 4:00 PM in Exhibit Hall B2-C-D

Management of Hyperlipidemia in Patients with Rheumatoid Arthritis: Results from the CORRONA CERTAIN Study
Authors: DA Pappas, A John, JM Kremer, GW Reed, T Sommers, JD Greenberg, A Shewade, J Curtis
Poster presentation # 362 on Sunday, October 27, 2013, 8:30 AM - 4:00 PM in Exhibit Hall B2-C-D

Effect of Biologic Agents on Lipids and Cardiovascular Risk in Rheumatoid Arthritis Patients
Authors: DA Pappas, A John, JR Curtis, GW Reed, T Sommers, JD Greenberg, A Shewade, DH Solomon, JM Kremer
Oral Presentation # 2827 on Wednesday, October 30, 2013, 9:00 AM - 10:30 AM in San Diego Convention Center: 6 D

SIMPONI ARIA AND CERTAIN:

CERTAIN welcomes your subjects starting SIMPONI ARIA (golimumab)! If you are considering enrolling a subject who will be starting Simponi Aria please consider the following prior to Screening. As you know the visits for infusion for Simponi Aria would be: Baseline, 1 month, 3 months, 5 months, 7 months, 9 months, 11 months. As you see in Baseline, 3 months and 9 months would be on track with the CERTAIN schedule. The patient will have to come in additionally for the 6 month visit and for the 12 month visit just for CERTAIN. If the patient is willing to accept the protocol defined visit schedule then YES, we would be happy to enroll them.

Helpful Tips from Tanya

1. Subject CERTAIN visits and enrollment:
Please remember while a patient is enrolled and followed in CERTAIN the data is entered into ONLY the Trial Master CORRONA_CERTAIN database. Once they have completed CERTAIN (or exited before completion of the 12 month visit) they should return to the CORRONA RA Registry for long term follow up. These patients can continue long term follow up with the same

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patient ID number and data should be entered into the Trial Master CORRONA_RA registry platform.

2. Off-site or remote monitoring:
We at CERTAIN will begin to perform site or remote site monitoring of many of our sites who have been monitored once or twice over the past two years. These sites will be notified directly to fax several CERTAIN participant forms via a secure fax machine to the monitoring team from the University of Alabama. We will then complete a series of off-site source data verification and queries will be directed to you directly though Trial Master. For sites that are new, or never have been monitored in the past on site monitoring will continue to be scheduled.

3. Memos to File:
These can now be completed in the TrialMaster system! This is an easy way to document incidents, problems or other issues that arise while they are still fresh in your mind. They capture circumstances as fully as possible. These should be completed for missed visits. Missed visits completed out of window, trouble with blood draws, etc.

TAE Talk

Jan Henderson, Director Adverse Event Reporting & Carlene Carlson, Project Assistant

Since our last newsletter we have gone through several learning stages with the collection of our Targeted Adverse Events! Fortunately, you have taught us nearly as many things about the new system as we have taught you! With the implementation of Trial Master, it became vitally important to accurately report events on the Provider Follow-up Questionnaire. How you report the adverse events on the follow-up determines the specific Targeted Adverse Event generated by the system.

Do not report any events in Question 15 which are already listed in Questions 6 and 7 of the physician follow-up questionnaire. Events reported in Question 15 will generate a Generic TAE and may not be the correct questionnaire for the event being reported or may also generate a duplicate.

Infections should be reported only if the patient was hospitalized and/or received intravenous antibiotics. Remember to scroll over to the right side of the Follow-up questionnaire to check the box (es) for these criteria when reporting such an event. When these data have been missed, we do not know if this is a qualifying event or not.

Your accurate report is the only validation of the event and accurate accounting for payment.

When you submit a TAE that is being reported in a Follow-Up visit, we encourage you to enter the visit prior to the TAE. The TAE is then auto-generated by the reported event in the Follow-Up and much easier to be completed. If the TAE is entered prior to the visit, either the visit or the stand-alone TAE must be created. When the visit is created later, you are asked to complete the reported event again. You then must indicate that the event has been previously reported. You are saving time and eliminating confusion by entering the visit first.

On the TAEs, we continue to see dates of first/last doses of listed medications left blank. If the patient was taking the drug at the time of the event, the "current" box must be checked. In all cases the radio button at the end of the line must be checked either "yes" or "no" to indicate whether or not the drug was discontinued due to the event being reported. All of this information must be completed before the form can be signed.

Please review all questions on the TAEs to make sure they are answered. When a TAE is missing any information, it cannot be signed and your site will not receive credit for submitting it.

As always, we thank you for your continued submissions of events and the supporting documentation. Your partnership in this effort is part of the reason research continues to open new doors for treatment and hope.

RA Registry News - A Leaf of a Different Color - *Kimberly Gottfried, MS, RN, CCRA, Director of Site Operations*

CORRONA wishes to extend a heartfelt thank you to providers, support staff and most of all patients at each of our registry sites. As mentioned in this newsletter and elsewhere, CORRONA has 24 abstracts and oral presentations at the American College of Rheumatology Annual Scientific Meeting in San Diego this year. If your fall travel plans include attendance at the ACR meeting, please be sure to stop by the CORRONA booth (Booth #1639) and say hello to myself and some of our distinguished CORRONA colleagues. We are there to assist with any questions about your current participation and share with you some exciting news about upcoming new registry options!

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The EDC system of choice for the RA Registry, Trial Master, will soon debut some new changes at your next login session. Some of these changes include:

- Ability to enter lab values using a single result date
- Enter lab value results that occur after the actual visit date
- Change to radio buttons instead of drop down boxes for QOL questions and subject medical history

It is important to note that in order for your visit to be eligible for reimbursement that all pages must be signed, including the Initial Signature Page. In addition, the check box must be checked on the Initial Signature Page in order for the visits to be recognized as complete. The simplest process to sign all pages is to select the patient ID, and then the "Sign All" link. Another handy tool in Trial Master, which allows you to systematically look at incomplete visit pages, is the Tasks Tab and the links Incomplete iCRFs and iCRFs to Sign.

We have received many compliments on the Trial Master EDC system, and are always interested in hearing about your data entry experiences and your opinion on improving overall system performance.

As you know, all incomplete data entered into the former CORRONAbase and any data captured on version 11 of the provider and subject questionnaires and not previously entered in CORRONAbase have been requested to be sent to CORRONA. These data will be entered into a separate database (see CORRONA e-mail communciation dated 22-March-2013) in order to facilitate and ensure accurate mapping of data fields across past and present versions. This data entry effort is ongoing and we anticipate all data entry, query resolutions, and reconciliations to be completed by December 31, 2013. If you have not already forwarded your eligible V11 questionnaires to CORRONA for inclusion in this distinct and separate V11 database, please do so at your earliest convenience. PLEASE remember to redact any and all personal health information (PHI) from your records prior to submission. CORRONA is not to see or receive any PHI from your office at any time or for any reason!

CORRONA International: Continuing Follow-Up

Aimée Whitworth, Project Manager
Dimitrios Pappas, MD, MPH, Scientific Director

CORRONA International is continuing to follow up the approximately 6000 enrolled patients across three geographic regions (Eastern Europe, Latin America, and Asia) and 10 participating countries.

Data regarding disease activity, functionality, prevalent and incident comorbidities and adverse events as well as detailed medication usage are recorded from physicians and patients during regular clinical encounters. These happen approximately every six months after the enrollment visit.

Continuous contact with our local Key Opinion Leaders, region specific CROs, and our outstanding international investigators contributed to the success of the registry in terms of consistent follow-up of enrolled patients. Follow-up time continues to build rapidly for the enrolled patients. In addition, due to meticulous work from our sites we have completed the second round of adverse event data collection and adjudication.

While we are currently following already enrolled patients we are planning the opening of phase II of the registry. Phase II will allow enrollment of additional patients in the existing sites but also in additional sites, countries and regions.

Our investigators' work on accurate data collection allows a better insight in the natural history of RA for patients from different geographic origins and is highlighting regional variations in disease activity and therapeutic approaches. The first analyses of the collected data led to submission and acceptance of abstracts in the national meeting of American College of Rheumatology in San Diego.

The titles and authors of the accepted abstracts are listed below:

The CORRONA International Registry-
Authors: DA Pappas, K Lampl , JM Kremer, SC Radominski, J Gal, F Nyberg, A Malaviya, A Whitworth, O Rillo, A Gibofsky, T Popkova, M Ho, I Laurindo, G Reed, E Kerzberg, L Horne, R Zahora, K Saunders, B Pons-Estel, AU Onofrei, JD Greenberg
Poster Presentation: Resgistry Poster Number 4
Sunday, October 27 – Tuesday, October 27, Salis Pavillian

Variations in Disease Activity and Therapeutic Management of Rheumatoid Arthritis in Different International Regions: A Comparison of Data from the CORRONA International and CORRONA US Registries
Authors: DA Pappas, K Lampl , JM Kremer, SC Radominski, J Gal , F Nyberg , A Malaviya, A Whitworth, O Rillo, A Gibofsky, T Popkova, M Ho, I Laurindo, G Reed, E Kerzberg, L Horne, R Zahora, K Saunders8, B Pons-Estel, AU Onofrei, JD Greenberg
Poster Presentation: Poster Number 1303
Monday, October 28, 2013, 8:30 AM - 4:00 PM
Exhibit Hall B2-C-D

Prevalence of Cardiovascular Risk Factors and Cardiovascular Disease in Rheumatoid Arthritis Patients Across International Regions: A Comparison of CORRONA International and CORRONA US Registries
Authors: DA Pappas, K Lampl , JM Kremer, SC Radominski, J Gal , F Nyberg, A Malaviya, A Whitworth, O Rillo, A Gibofsky, T Popkova, M Ho, I Laurindo, G Reed, E Kerzberg, L Horne, R Zahora, K Saunders , B Pons-Estel, AU Onofrei , JD Greenberg
Poster Presentation: Poster Number 392
Sunday, October 27, 2013, 8:30 AM - 4:00 PM
San Diego Convention Center-Exhibit Hall B2-C-D

We would be very excited to meet our CORRONA International investigators who will be attending the ACR meeting in San Diego. CORRONA International investigators are welcome to contact Aimée at awhitworth@corrona.org to schedule a meeting with the CORRONA International team.

TIPS for investigators and research coordinators

Follow up visits:
- All patients should have a follow up registry visit every 6 months (+/- 3 months window) after the enrollment visit. This will substantially add to the robustness of our registry and our ability to answer our research questions. Please make every possible effort to not forget to submit data to the registry for patients who appear in your clinic for a regular follow up visit that happens to occur within the allowed follow up window.

- An occasional missed follow up visit may be allowed for extenuating circumstances. However, patients who miss 2 consecutive follow up registry visits may be subjected to permanent exit from CORRONA International. In addition, sites with more than 10% of such patients may be permanently removed from the registry.

Targeted adverse events:
- Incident cardiovascular events, malignancies and serious infections are of particular interest for our registry and our research. Some of these events are termed Targeted Adverse Events (TAE) and are indicated as such in the physician follow up questionnaire. Please remember to query your patients for any such events that may have happened in between registry visits. It is also important that the corresponding dedicated to the event TAE form should be completed on time and all the appropriate source documents are collected and submitted de-identified to CORRONA international. Completion of TAE forms and collection of the appropriate source documents may be a time consuming process and for this reason additional reimbursement is provided.

- As a reminder, section 10 of the protocol lists all source documents that are required for every TAE. Notes by the rheumatologist are not acceptable unless the rheumatologist was the treating physician for the specific event. If source documents are unattainable, then please complete the TAE within Trial Master System and indicate that source documents will not be collected.

For questions or interest in the study, please contact the Project Manager, Aimée Whitworth at awhitworth@corrona.org.

Dispatches from the CORRONA Biostatistics and Epidemiology Group

Kate Saunders, MS, Director of Epidemiology and Outcomes Research

As the CORRONA team gets ready to head out to ACR in San Diego, we wanted to fill you in on the publications from the last few months.

Our investigators have published four articles so far this year (see listing below). Also, CORRONA has been well-represented over the summer at National and International meetings including EULAR 2013 in June, DIA 2013 in June and The International Society for Pharmacoepidemiology (ISPE) 2013 in August. In all, CORRONA had five podium presentations and 12 posters accepted for these three scientific meetings! We will continue to update you on our publication activities. Thank you for your continued collaboration with CORRONA.

Manuscripts

Curtis JR, Shan Y, Harrold L, et al. Patient perspectives on achieving T2T goals: A critical examination of patient reported outcomes. Arthritis care & research 2013 doi: 10.1002/acr.22048. Published Online First: 5 June 2013

Dewitt, EM, Li Y, Curtis JR, Glick HA, Greenberg JD, Anstrom KJ, Kremer JM, Reed G, Schulman KA, Reed SD. Comparative Effectiveness of Nonbiologic versus Biologic Disease Modifying Antirheumatic Drugs for Rheumatoid Arthritis. J Rheumatol. 2013 Jan 15. [Epub ahead of print]

Diogo D, Kurreeman F, Stahl EA, Liao KP, Gupta N, Greenberg JD, Rivas MA, Hickey B, Flannick J, Thomson B, Guiducci C, Ripke S, Adzhubev I, Barton A, Kremer JM, Aldfredsson L; Consortium of Rheumatology Researchers of North America; Rheumatoid Arthritis Consortium International, Sunyaev S, Martin J, Zhernakova A, Bowes J, Eyre S, Siminovitch KA, Gregersen PK, Worthington J, Klareskog L, Padyukov L, Raychaudhuri S, Plenge RM. Rare, Low-Frequency, and Common Varients in the Protein-Coding Sequence of Biological Candidate Genes from GWASs Contribute to Risk of Rheumatoid Arthritis. Am J Hum Genet. 2013 Jan 10;92(1):15-27. doi: 10.1016/j.ajhg.2012.11.012. Epub 2012 Dec 20.

Sarsour K, Greenberg JD, Johnston JA, Nelson DR, O'Brien LA, Oddoux C, Ostrer H, Pearlman A, Reed G. The Role of the FcGRIIIa Polymorphism in Modifying the Association Between Treatment and Outcome in Patients with Rheumatoid Arthritis Treated with Rituximab Versus TNF-α antagonist therapies. Clin Exp Rheumatol. 2013 Mar- Apr 3; 31(2): 189-94. Epub 2013 Jan 9.

EULAR 2013

Mease P, Collier D, Saunders KC, Grant S, Bitman B, Chaudhari M, Greenberg J. Biologic Therapy, Time to Low Disease Activity, and Effect of Mono Vs. Background Oral DMARD Therapy Among Psoratic Arthritis Patients in a US Registry. Ann Rheum Dis 2013;72(Suppl3):671. Poster

Harrold L, Greenberg J, Saunders K, Karki C, Kifayeh N, Kremer J. Characteristics of Gout Patients Cared For By Rheumatologists – Results From The CORRONA Gout Registry Site Survey. Ann Rheum Dis 2013;72(Suppl3):561. Poster

Pappas DA, Lampl K, Kremer JM, Nyberg F, Gibofsky A, Ho M, Horne L, Saunders K, Onofrei AU, Greenberg JD. The CORRONA International Rheumatoid Arthritis Registry: Variations in Disease Avtivity and Management Across Participating Regions. Ann Rheum Dis 2013;72(Suppl3):209. Poster

Verstappen S, Askling J, Yamanaka H, Greenberg JD, Ho M, Michaud K, Symmons D, Nyberg F. Methodological Challenges When Comparing Demographic and Clinical Characteristics of International Observational Studies. Ann Rheum Dis 2013;72(Suppl3):552. Poster

Strand V, Williams S, Miller PSJ, Saunders K, Grant S, Kremer JM. Discontinuation of Biologic Therapy in Rheumatoid Arthritis (RA): Analysis From the Consortium of Rheumatology Researchers of North America (CORRONA) Database. Ann Rheum Dis 2013;72(Suppl3):71. Podium

Pappas DA, John A, Curtis JR, Kremer J, Reiss W, Shewade A, Silverman GJ, Greenberg JD. Prevalence of Low Immunoglobulin Levels And Associations With Rheumatoid Arthritis Factors. Ann Rheum Dis 2013; Ann Rheum Dis 2013;72(Suppl3):448. Poster
Pappas DA, John A, Kremer J, Reed G, Greenberg JD, Shewade A, Solomon DH, Curtis JR. Effect of Biologic Agents On Lipids And Cardiovascular Risk In Rheumatoid Arthritis Patients. Ann Rheum Dis 2013;72(Suppl3):49. Podium

Harrold L, Reed G, Magner R, Shewade A, John A, Reiss W, Greenberg J, Kremer J. Comparative Effectiveness of Rituximab Versus Anit-Tumor Necrosis Factor Switching For Rheumatoid Arthritis Patients. Ann Rheum Dis 2013;72(Suppl3):460 Poster

Huynh D, Etzel C, Cox V, Kremer J, Greenberg J, Kavanaugh A. Anti Citrullinated Peptide Antibody (ACPA in Patients With Psoriatic Arthritis (PSA): Clinical Relevance. Ann Rheum Dis 2013; Ann Rheum Dis 2013;72(Suppl3):673 Poster

Labitigan M, Shrestha A, Jordan N, Reed G, Magner R, Bahce-Altuntas A, Broder A. Moderate to High Disease Activity In Psoriatic Arthritis Is Associated With Elevated Total Cholesterol and Triglycerides. Ann Rheum Dis 2013;72(Suppl3):15 Podium

Lillegraven S, Greenberg JD, Reed GW, Saunders K, Curtis JR, Harrold L, Hochberg M, Pappas D, Kremer JM, Solomon DH. Use of TNF Inhibitors Is Associated With A Reduced Risk Of Diabetes In RA Patients. Ann Rheum Dis 2013;72(Suppl3):106 Podium

Nyberg, F, Askling J, Greenberg JD, Michaud K, Yamanaka H, Symmons D, Ho M. Using Epidemiological Registry Data To Provide Background Rate Context For Adverse Events In A Rheumatoid Arthritis Drug Development Program – A Coordinated Approach. Ann Rheum Dis 2013;72(Suppl3):413 Poster

Finckh A, Scherer A, Kremer JM, Greenberg JD, Lubbeke A, Schwarz H, Rathbun A, Gabay C, Reed GW. Obese Patients With Rheumatoid Arthritis Have Reduced Response Rates To Biologic Anit-Rheumatic Agents. Ann Rheum Dis 2013;72(Suppl3):403 Poster

DIA 2013

Saunders K, Barr C. Characteristics of a US Rheumatoid Arthritis Cohort: Baseline Data from the CORRONA RA Registry. Drug Information Association. 23-27 June 2013. Boston, MA. Poster

ICPE 2013

Nyberg F, Askling J, Greenberg JD, Michaud K, Yamanaka H, Symmons D, Ho M. Using Epidemiological Registry Data to Provide Background Rate Context for Adverse Events in a Rheumatoid Arthritis (RA) Drug Development Program - A Coordinated Approach. International Conference on Pharmacoepidemiology and Therapeutic Risk Management 25-28 August 2013. Montreal, Canada. Poster

Pappas DA, Kremer J, Greenberg J, Shewade A., Solomon D, Curtis JR. Dyslipidemia, Inflammation and Cardiovascular Risk in Patients with Rheumatoid Arthritis. International Conference on Pharmacoepidemiology and Therapeutic Risk Management 25-28 August 2013. Montreal, Canada. Podium Presentation.

Geier J, Saunders KC, Reed G. Contextualization of Safety Endpoints in a Rheumatoid Arthritis (RA) Development Program: Collaboration with the Consortium of Rheumatology of North American Registry (CORRONA). International Conference on Pharmacoepidemiology and Therapeutic Risk Management 25-28 August 2013. Montreal, Canada. Poster

Upcoming Events

Please visit us at

American College of Rheumatology (ACR)
October 27-29, 2013
San Diego Convention Center
San Diego, California
Booth: 1639

European League Against Rheumatism (EULAR)
June 11-14, 2014
Le Palais des Congrès de Paris
Paris, France

DIA
June 15-19, 2014
San Diego Convention Center
San Diego, California

Please visit our website, www.corrona.org, for an updated list of events CORRONA will be attending.

CORRONA Employees are now International
Julie Lapham Hunt, Operations Coordiantor

It has been established in previous newsletter articles that CORRONA is a different kind of organization. CORRONA is 100% decentralized. This means we all work from our homes in various areas of the country and now the world. Being decentralized allows us to find the cream of the crop for employees rather than having to focus on one area of the country.

Until recently, our employees have all been in the United States. In August, Dr. Dimitrios Pappas moved back to Greece to be closer to his family. With our decentralized model, there have been few problems with Dr. Pappas' move. The main problem has been trying not to schedule teleconference when it is 3 am in Greece.

We hope as CORRONA continues to grow so does the number of states and countries where our employees are located.

Here is a breakdown of the number of CORRONA employees per state:

New York: 8
Massachusetts: 10
Minnesota: 2
Texas: 4
Maine: 1
Utah: 1
Washington: 3
Virginia: 2
New Hampshire: 2

The moral of the story:
you never know where someone you are writing to or speaking with could be in the world!

The CORRONA Team

The Executives
Joel Kremer, MD, President and Chief Executive Officer
James Cavan, MS, Executive Vice President and Chief Operating Officer
Allan Gibofsky, MD, JD, Vice President
Jeff Greenberg, MD, MPH, Chief Scientific Officer
George Reed, PhD, Cheif Statistical Officer

Board of Directors
Joel Kremer, MD – Chairman of the Board
Stanley Cohen, MD
John J. Cush, MD
Robert Lento
Arthur Kavanaugh, MD
Philip Mease, MD
William Palmer, MD
David Printy

Medical Directors
Dimitrios Pappas, MD, Scientific Director, CERTAIN and International
Leslie Harrold, MD, MPH, Scientific Director, Gout
Philip Mease, MD, Scientific Director, SpA

Biostaticians
Ying Shan, MD, MPH, Senior Biostatistician
Carol Etzel, PhD, Lead Biostatistician
Mei Liu, PhD, Senior Biostatistician
Katherine Sanders, MS, Director of Epidemiology and Outcomes
Vanessa Cox, MS, Programmer
Chitra Karki, MPH, Analytic Coordinator
Sabrina Devarkis, MPH, Analytic Coordinator *

Project Managers
Kim Gottfried, MS, RN, CCRA, Director of Site Operations
Jennifer O'Connor, Director of Project Management and Project Manager, SpA and Gout
Tanya Sommers, MS ANP-BC, Project Manager, CERTAIN
Aimee Whitworth, Project Manager, CORRONA International
Kevin Soe, Project Manager, Treat to Target
Elinita Rosseto, Project Manager, PQRS*

Pharmacovigelance
Christine Barr, BSN, MPH, Director of Pharmacovigenlance
Jan Henderson, MS, Director, Adverse Event Reporting
Carlene Carlson, Adverse Event Reporting Assistant

Operations
Lisa, Lemire, MBA, Controller
Julie Lapham Hunt, Operations Coordinator
Michelle Whittemore, Bookkeeper
Jodi Lane, Scientific Administrative Assistant

Information Technologies
Matthew Perkins, Director of Information Technologies
Bob Hall, Senior Database Administrator
Roger Mann, Quality Assurance and Release Manager*
Michael Loessberg, Senior Developer/Analyst*

Registry Support Staff
Carol Miller
Haley Garrett
Season Swartz
Tammy Carey
Rene White*
Darcie Arensmeyer*

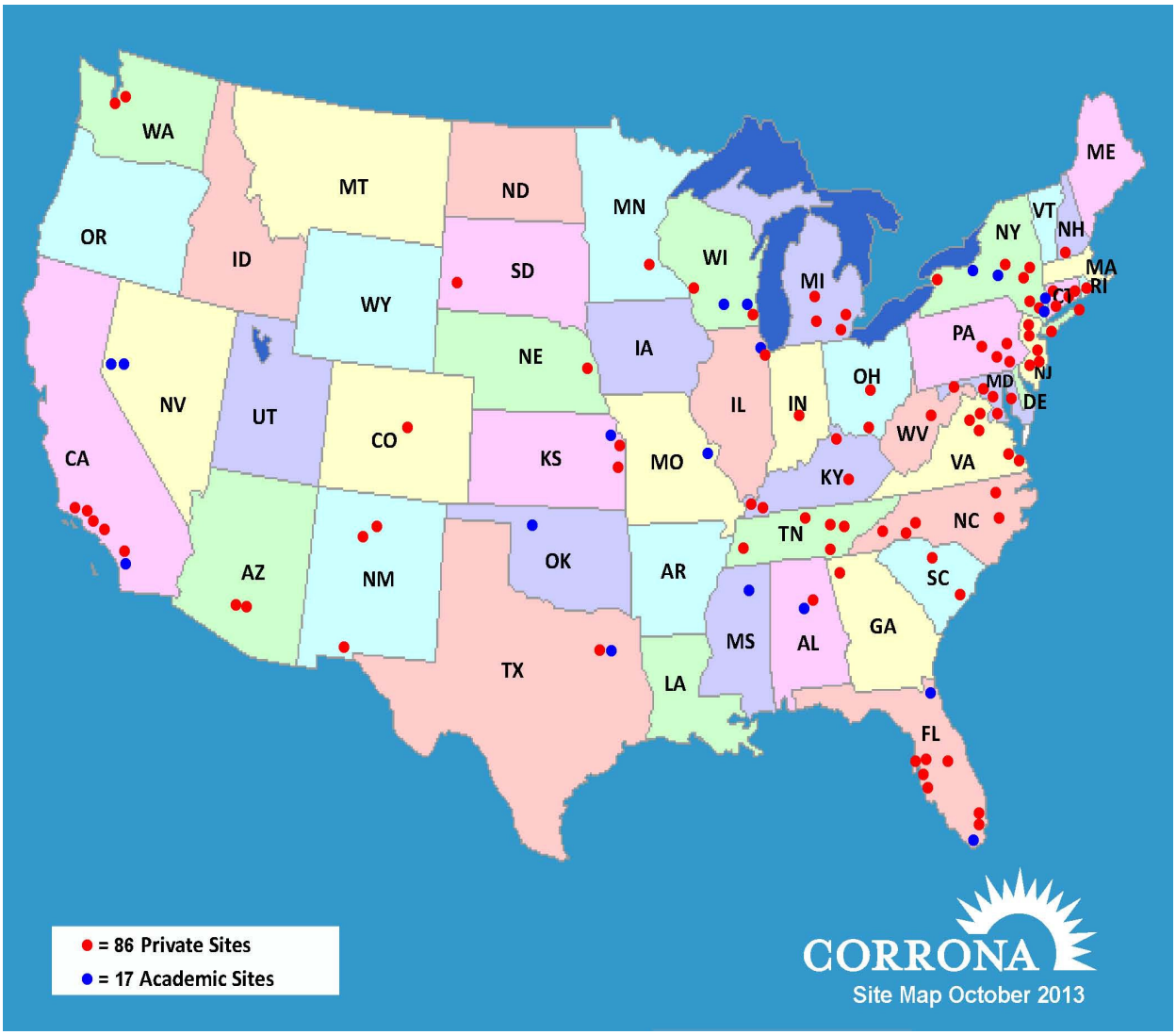
Scientific Advisors

Claire Bombardier, MD	Jeff Curtis, MD, MPH
Carol Etzel, PhD	Daniel Furst, MD
Mark Genovese, MD	Jeff Greenberg, MD, MPH
Leslie Harrold, MD, MPH	Marc Hochberg, MD, MPH
Kathryn Hobbs, MD	Joel Kremer, MD
Philip Mease, MD	Dimitrios Pappas, MD, MPH
Robert Plenge, MD, PhD	George Reed, PhD
Christopher Ritchlin, MD, MPH	
Eric Ruderman, MD	Ken Saag, MD
Naomi Schlesinger, MD	Lee Simon, MD
Dan Solomon, MD, MPH	Vibeke Strand, MD
George Tsokos, MD	Desiree van der Heijde, MD

* New since last newsletter

CORRONA
data to empower

CORRONA ACROSS THE UNITED STATES



More than 570 participating physicians
More than 44,660 participating patients

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CORRONA
data to empower™