You may have noticed from our communications that CORRONA is expanding beyond RA and Psoriatic Arthritis (PsA). Our Gout registry was initiated last quarter of 2012 and is really off to a good start.

We will be initiating our Spondyloarthritis (SpA) registry under the direction of Philip Mease, MD, who many of you may know. He has developed the SpA questionnaires in collaboration with a group of renowned SpA investigators. We recognize that not all rheumatologists consider themselves as SpA experts, although we all treat this disease.

Of interest, is that we are moving PsA to the SpA registry (out of the CORRONA CORE registry which will now include only RA). The good news is that grouping both SpA and PsA together is conceptually sound and we can perform measures which are more targeted and academically appropriate for these diseases. The (other) good news is that the SpA registry pays handsomely at $250 for a baseline form and $100 for a follow-up. Once you become familiar with the questionnaires, it is anticipated that they will be fairly easily integrated into your working day. If you are just starting the process, it is always ideal if an office worker could preview your schedule to identify a patient who you might want to enroll in the registry. Kim Gottfried can walk your coordinator through the process if you are not already doing it.

We have dedicated a lot of time and effort into getting the SpA process right. As with all new measures, it is still possible that we have overlooked something. We very much welcome your constructive input. Kim Gottfried (kgottfried@corrona.org) and Jennifer O’Connor (joconnor@corrona.org) are happy to receive your comments. You know Kim as she handles all site related issues and Jennifer is the specific Project Manager for the SpA registry.

As with RA and Gout, the CORRONA questionnaires work best if they become the centerpiece of your interaction with the patient. Try doing the form first! You will see that you have gathered virtually all of the data you need for a complete visit with excellent billing documentation! We recommend scanning the CORRONA document into the EMR for easy access and documentation that you have performed these measures and collected the data in the event of an audit.

If you do the forms first, you will have leftover time to do your EMR entry or just catch up on the personal side with your patient. Remember, the questionnaires are designed to be the centerpiece of your encounter. We think you’ll be happy that you have adopted this process, now for RA, Gout and Spondyloarthropathies.
I hope that all of you see the faint glimmer of spring on the horizon. We continue to appreciate all of our participating sites ongoing support of CORRONA. Our various registries have started the process of cutting over to TrialMaster by OmniComm. This transition will allow us to be more flexible in our data collection efforts and ultimately allow sites options for how to submit data.

In this newsletter I am very pleased to announce the transition of several long time CORRONA affiliates to employees of the company.

George Reed, PhD has long been the statistical leader of CORRONA during his tenure as faculty at UMass. We are pleased to announce that George has joined CORRONA in a full time role on the Executive team as our Chief Statistical Officer. Dr. Reed has had a critical role in every CORRONA query, poster, abstract or manuscript for years. We are looking forward to his continued scientific vision, guidance and leadership.

Dimitrios Pappas, MD, MPH is a familiar name to many involved in the CORRONA CERTAIN sub-study or CORRONA International. He has held academic postings at Johns Hopkins and Columbia University. Dimitrios will continue with his oversight of the above programs, as well as continue with the development of new subscribers and new registry programs.

Ying Shan, MD has joined George Reed from UMass as a Senior Statistician. Ying has been involved with CORRONA data and processing queries for many years and maintains a deep understanding of our data.

Mei Leu, PhD. Adding to our Texas footprint, Mei has joined us as a Senior Statistician. She was last conducting research at MD Anderson and has an interest in pharmacoeconomics. We look forward to her contribution to CORRONA’s growing biostats team.

Season Swartz has joined CORRONA to support the CERTAIN project. She has quickly become a valued utility player across several projects in the company. Season has a background in various business and project management support situations.
CERTAIN is pushing forward decisively and successfully! 1800 Patients have currently been enrolled by 45 participating sites. The enrollment goal of 2750 is anticipated to be achieved within an additional year.

We would like to take this opportunity to update you regarding some new developments in CERTAIN.

Since November 1st we increased the CERTAIN payment as follows: $675.00 for the set of screening/baseline visit(s) and $300 for each of the 4 follow up visits. For every patient completing the study through month 12 the total payment is $1875.00.

We are updating our electronic data collection (EDC) system to a more user friendly platform. You have probably been asked to complete a short training in order to be able to access this new system. The update in our EDC has already begun. We will keep you updated via email announcement to make sure you are accessing and entering you data in the new system.

If you are a CERTAIN investigator or research coordinator feel free to join our twice a month round table discussions via teleconference! We use this forum to discuss everything related to CERTAIN: from recruitment and retention strategies, to changes being implemented, timelines, and tips for quality data collection. We frequently have guest speakers from billing, information technology and the science team who have joined these calls and are more than happy to answer your questions. But most importantly during these calls we seek directions and feedback from YOU, our most valuable players.

The CERTAIN Team has expanded! Please welcome Season Swartz CERTAIN Project Assistant whose responsibilities includes data entry assistance and information distribution.

Below we are providing a reminder of CERTAIN’s design

CERTAIN is a comparative effectiveness and safety study for biologic agents used for the therapy of RA. CERTAIN is nested within the CORRONA RA registry.

Every patient with RA starting a new biologic for the (first time ever) with at least moderate disease activity (CDAI>10) is eligible to participate after their physicians decision to start a TNF antagonist or a biologic of alternative action. CERTAIN does not mandate initiation of specific agents – the choice of the biologic to be started is entirely at the discretion of the treating physician. However, the ratio of enrollments in the two study's arms (TNF antagonists vs biologics of alternative action) will be monitored and if it exceeds 3:2 in either direction sites may be notified to hold enrollments in one of the study’s arms.

A baseline visit follows a short screening evaluation. Then patients are seen every 3 months (+/- 2 weeks) for a year. Blood sample collection is mandatory at baseline and every follow up visit. Results for a complete blood count with differential, comprehensive metabolic profile, high sensitivity CRP, CCP antibodies, rheumatoid factor, lipid levels (with direct LDL) and immunoglobulin levels will be provided to the site to avoid duplicate blood draws necessary for clinical care. At baseline, blood for DNA is collected, and in the first three visits RNA, serum and plasma is stored for future research. Patients upon completion of the study are followed long term within the CORRONA registry.

Gout Registry is Up and Running!
Nijad Kifayeh, Project Manager, Gout

With the arrival of 2013 we are excited to report that the CORRONA Gout Registry is officially up and running!

The registry saw its first subject enrollment on November 6, 2012. Thanks to the hard work and diligence of our participating sites, an additional 288 subjects have been enrolled as of Feb. 6, 2013.

We would like to take this opportunity to thank all of our participating providers and their staff for their tremendous efforts in identifying potential registry subjects, and the meticulousness shown in completing the questionnaires. We are energetically continuing to enroll the sites that have expressed interest in participating and you will be hearing from me soon.
Quality control checks (queries) are currently being conducted on all data received and audit reports have begun to circulate back to our sites. If you receive an audit findings report, we ask that you please ensure that these findings are addressed appropriately in a reasonable amount of time. Please contact me with any questions about these queries or audit findings.

Based on site feedback and the minimal findings in the latest QC measures, we are happy to report that the Gout Registry has been positively received by both providers and patients. Your input is extremely important to us. Please continue to share your comments and/or concerns which may help us streamline and strengthen our data collection initiative.

The door remains open to any sites interested in participating. Please keep an eye out for Gout Registry communications and please do not hesitate to reach out to me at nkifayeh@corrona.org for more information.

CORRONA Clinical Trails Opportunity  
**Sara Kremer, Managing Director**

In January we informed our sites about a landmark clinical trial designed to address the question of whether reducing inflammation in patients will reduce rates of heart attack, stroke and cardiovascular disease. The study is called the Cardiovascular Inflammation Reduction Trial (CIRT) and is funded by the National Heart, Lung and Blood Institute (NHLBI). Dr. Paul Rikder at Brigham and Women’s Hospital is the principal investigator. His seminal work, over more than a decade, has established the relationship between inflammation and cardiovascular disease. Drs. Michael Weinblatt, Dan Solomon and Joel Kremer are collaborating and giving advice about Methotrexate utilization.

Clinical practices who can enroll at least 20 patients are encouraged to participate. Eligible patients will have a history of osteoarthritis, myocardial infarction within the past 5 years, and a diagnosis of Type 2 diabetes and/or metabolic syndrome.

If you missed our initial communication and would like to receive additional information about this study please contact me at skremer@corrona.org.

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**Getting Ready for PQRS 2013**  
*Aimee Whitworth, Project Manager, PQRS*

I would like to give a big THANK YOU to the sites, providers and coordinators who have participated in the 2012 PQRS year. It has been great to work with and your efforts are greatly appreciated by CORRONA. Fifty providers showed interest in the program and twenty-nine providers successfully submitted patients into CORRONA PQRS.

By submitting data earlier this year, we avoided the last minute rush. This allowed more providers to participate successfully. CORRONA is in the final stages of closing out this PQRS reporting year.

For 2013, the rules for PQRS have been changed by CMS. Providers who successfully participate will receive a 0.5% bonus of their total 2013 Part B allowed charges to be paid in 2014. This will avoid a 1.5% deduction in overall Part B Medicare payments in 2015 for not participating in 2013.

It is to your benefit to participate in CORRONA’s PQRS program in 2013 or participate through another alternative. Our program is simple because it is based on the data submitted on visit questionnaires rather than requiring chart review. If you’re a participating physician in CORRONA and completing the questionnaires you have already completed half of the work!

Each provider will be required to report only 20 patients rather than the 30 that were previously required. Out of those 20, only 11 will need to be Medicare FFS insured, while the remaining nine patients may have any type of insurance coverage.

For those interested in PQRS 2013, a start-up package will be sent to CORRONA sites within the next few weeks.

If you have further questions please contact me, Aimee Whitworth, at AWhitworth@corrona.org.
TAE Talk
Jan Henderson, Director of Adverse Event Reporting

As most already know, we have been asking for completed TAE questionnaires on past cardiovascular events. You will be seeing similar requests for cancer and infection events very soon. Your quick return with these requests is greatly appreciated.

We do ask that you do not change the event that has been entered for you. The event is what you have entered in the physician follow-up visit and we are asking you to tell us if that event can be confirmed or not. If you cannot confirm that specific event, please tell us the event did not happen and why. If a different event occurred, please complete a second TAE for that specific event and submit to us with source documents. You will be reimbursed for both!

Some of you are not completing the TAE and we are spending a lot of time requesting the missing information. The most common and frequent omissions are:

- What is the Event!
- Is the patient enrolled in CERTAIN
- When source documents have been reviewed, please remember to fax those to us as well.
- Most will answer the outcome/status of the event but but neglect to answer the information if it is an ongoing event or full recovery.
- Prior history of the event.
- Drug names may be entered but dose, frequency, etc. are left blank.

Please remember, many of these fields are required data and the TAE cannot be completed for reimbursement. If you are not doing your own data entry, you should review each question to make sure it has been completely answered prior to faxing to us.

As always, we want to express our appreciation to everyone who has been so responsive to our queries, requests, and your independent submission of events.

The American Board of Internal Medicine (ABIM) approves CORRONA’s Quality Improvement Pathway for 2013-2014
Timothy Harrington, MD
Aimee Whitworth, Project Manager, PQRS

CORRONA’s “PQRS Rheumatoid Arthritis Measures Bundle” reporting has received a two year initial approval for 2013 and 2014 from the ABIM to be part of its Approved Quality Improvement (AQI) Pathway program for Maintenance of Certification. Rheumatologists who are engaged in quality improvement through CORRONA’s AQI Pathway can now earn Maintenance of Certification (MOC) practice performance credit. This activity is eligible for 20 points towards the Self-Evaluation of Practice Performance requirement of Maintenance of Certification (MOC). You may use this link for a complete list of approved AQI Pathway options: www.abim.org/moc/aqip.aspx

The assumption central to this CORRONA QI program is that standardized clinical data collection and reports will lead to more reliable care than variable traditional processes. The specific aims are to increase the use of the CORRONA data for quality improvement and RA disease management, and to monitor the impacts on measures compliance and disease outcomes by participating physicians.

The CORRONA AQI Pathway provides another benefit for investigators by leveraging the data already collected for CORRONA research. The use of the PQRS measures for this program will also facilitate MOC candidates’ Medicare PQRS reporting for 2013 and 2014.

For more information about the CORRONA AQI Pathway, please contact Aimee Whitworth at AWhitworth@corrona.org.

Program Description

This is a Quality Improvement Plan-Do-Study-Act project performed by the rheumatologist and their practice team with support from CORRONA’s AQI Project Team to improve performance on a quarterly report of the
If physicians are already engaged in rigorous quality improvement activities through their hospital or another organization we want them to receive Maintenance of Certification credit for that activity,” said Elizabeth Blaylock, Vice President of PIM Development of the American Board of Internal Medicine. “CORRONA has built a program that supports physicians in their efforts to measure and improve patient care.”

CORRONA International Update

Henry Calderon, Project Manager, International Registry
Aimee Whitworth, Assoc. Project Manager, International Registry
Dimitrios Pappas MD, MPH, Scientific Director, International Registry

CORRONA International has enrolled over 6,000 patients with Rheumatoid Arthritis in the first 16 months since inception. Patients have been enrolled across India, Czech Republic, Russia, Romania Ukraine, Poland, Hungary, Brazil, Mexico, and Argentina.

We have been watching our registry mature in a rapid and robust fashion as enrolled patients are returning for follow up visits. Patient and physician derived data will soon be available for analysis and generation of new knowledge.

We would like to take the opportunity to acknowledge the contribution of participating investigators across the globe. Such a rapid accumulation of quality data would not have been accomplished without their efforts. We would also like to emphasize the crucial role of our key opinion leaders and local CROs whose dedication was instrumental in the creation of what we consider state of the art observational registry.

An intense quality control mechanism is in place to ensure that collected data from enrollment and follow up visits undergo the necessary scrutiny to ensure accuracy, reliability, and validity of the research we are conducting. CORRONA International’s newly assembled data quality control team is conducting queries on already collected data. As a result, participating sites are currently receiving queries regarding the occasional missing or erroneous data.

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We have recently upgraded to an electronic data capture (EDC) system. It is a more user friendly environment for data capture, fully functional, and provides more capabilities for study monitoring. Participating investigators and research coordinators are currently completing the short training to continue uninterrupted data entry.

Nominees are being gathered for the CORRONA International Scientific Review Committee (CI-SRC) who will guide the development of a publication and scientific plan for the registry. Nominations will be reviewed by the CORRONA science leadership team. Please contact Dr. Dimitrios Pappas, Scientific Director at DPappas@corrona.org with any questions, late nominations, or self-nominations for membership to CI-SRC.

If any international colleagues would like more information about this registry please visit the CORRONA International website, www.corronainternational.com or contact Project Manager, Henry Calderon at HCalderon@corrona.org.

Treat to Target RA Trial: Study Updates
Christine Barr, BSN, MPH Senior Project Manager

Background:
Launched in summer 2011, the Treat to Target trial is the first of its kind in the U.S. Entire sites are cluster randomized to either the Treat to Target (Intervention) Arm, or the Usual Care (Control) Arm. Patients with moderate to severely active Rheumatoid Arthritis (defined as CDAI score >10) are being recruited by participating US rheumatology practices. All enrolled subjects are followed for 12 months.

- T2T arm sites see their subjects for study visits as frequently as monthly, and are prompted to accelerate therapy at least quarterly until low disease activity is achieved.

Treatment Acceleration is being defined as any one of the following options:
- Initiation of a new traditional or biologic DMARD
- Increase in dose or frequency of administration of a traditional or biologic
- Change 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:
It has been a productive quarter for the T2T Investigators and Project Team. 7 additional sites joined the team, for a total of 26 activated sites. Our final group of sites have been selected and are in the start-up process. A total of 30+ sites will ultimately be contributing data to this landmark trial. A total of 365 subjects have been enrolled, as of February 2013. We continue to make excellent progress toward our overall goal of 560+ total enrollments. We’ve entered our final 6 months of the planned recruitment period! We hope to complete enrollment in July.

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Each site has been working hard to achieve their individual goals of 16 total subject enrollments. Many thanks to all participating sites. Your shared commitment to this project is a constant source of inspiration. It is amazing to see how much is being accomplished by this extraordinary team.

Ten sites have already achieved their enrollment targets! Congratulations to this talented group of investigators and the research teams at these sites.

Please keep up the good work and, as always, keep the questions and feedback coming.

Please contact Christine Barr at cbarr@corrona.org with any questions about the T2T protocol, or to learn more about participating as a site. Please Note: Given aggressive project timelines, only highly motivated investigators and sites are currently being prioritized for rapid start-up.

RA Registry News (formerly known as Coordinator's Corner)

Kimberly Gottfried, MS, RN, CCRA, Director of Site Operations

On February 26, 2013 CORRONA’s former CORE Registry, collecting data on RA and PsA patients; officially became the RA Registry. PsA (psoriatic) patients formerly enrolled in CORE will be automatically exited and sites will be invited to participate in the NEW! SpA/PsA Registry. The SpA/PsA Registry is a separate registry which will require a new IRB approval and separate data collection protocol. The SpA/PsA Registry is the third CORRONA based registry, joining both the Gout and RA registries already in place. For information on participating in the SpA/PsA registry, contact Jennifer O’Connor, the SpA/PsA Project Manager, at joconnor@corrona.org.

In addition to our new registry name, CORRONA also introduced a new EDC (electronic data capture) system, TrialMaster; and a new version of the RA data collection questionnaires (V12). The new look and feel of both the new EDC system and questionnaires will take some getting used to, but we are confident you will come to love the simplicity and new features of both.

Your access to TrialMaster requires training on the new system via a set of training modules entitled eLearning.
Only those individuals who wish to access the TrialMaster system are required to complete the training. If you have not received a username and password to do so, please contact Kimberly Gottfried at kgottfried@corrona.org.

The V12 questionnaires are a streamlined version of V11, with mostly a rearrangement, some eliminations and a few additions to the information already gathered on the V11 physician and patient questionnaires. There is no formal training needed for the V12 questionnaires; however V12 specific reference manuals and a brief power point presentation highlighting the most significant differences between V11 and V12 will be available to you shortly. Longer range plans include the development and launch of reporting tools that are user accessible directly through the TrialMaster system.

Please, as always, remember that CORRONA values your ongoing support and is available to field your questions, hear your concerns and assist with any technical or operational issues. For TrialMaster specific questions, we are pleased to announce, that the technical support team at Omnicomm is available at 1.866.996.6332 Monday through Friday 2:00 am EST to 8:00 pm EST (7:00 am GMT to 1:00 am GMT). Outside normal hours, please leave a voice mail and a call will be returned to you within 30 minutes. Email support is available Monday through Friday from 2:00 am EST – 8:00 pm EST (7:00 am GMT to 1:00 am GMT). E-mails will be responded to within 30 minutes. After hour e-mails will be responded to the next business day.

Thank you everyone for your support and patience through these transitions!

Upcoming Events

Please visit us at

California Rheumatology Alliance 9th Annual Medical and Scientific Meeting**
May 18-19, 2013
Loews Santa Monica Beach Hotel
Santa Monica, California

European League Against Rheumatism (EULAR)
June 12 - 15, 2013
Feria de Madrid
Madrid, Spain

National Organization of Rheumatology Managers (NORM)**
September 13 - 14, 2013
Hyatt Regency Long Beach
Long Beach, California

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

** Exhibiting
CORRONA Featured in The Rheumatologist!

The December 2012 issue of *The Rheumatologist* featured an article about CORRONA by Gretchen Henkel. The article began with the history of why Dr. Joel Kremer starting the company in 2000, a time of great importance for physicians and patients to have information on treatments for RA based on safety, effectiveness and cost. Dr. Kremer approached pharmaceutical companies to propose his team would build a patient registry that would collect data on patient data at every visit in return for a subscription to the data basebiostatistical data.

Ms. Henkel speaks with many of the CORRONA executives and key advisors and points to why they became involved with CORRONA and feel CORRONA is important to provide quality data. These credits went to Dr. Joel Kremer (Founder, Chief Executive Officer and President) but also Dr. Jeffrey Greenberg (Chief Scientific Officer), Dr. Tim Harrington (Chief Quality Officer), Dr. Philip Mease (Scientific Director - SpA), Dr. Jeffrey Curtis (Scientific Advisor - CERTAIN), and Dr. Dimitrios Pappas (Scientific Director - CORRONA International and CERTAIN).

Dr. Kremer has mentioned, numerous times in the CORRONA newsletter, how CORRONA employees have caught the “CORRONA Virus” and how it affects the work they do. He has defined this virus as the “uncontrollable desire” to do good things and working well with other collaborators in the CORRONA environment. The consequence is – nobody seems to work a 40-hour week.

Many of the registries that CORRONA has rolled out to the sites were highlighted in the article, including the nuances of the CERTAIN sub-study, partially developed by Dr. Curtis and now overseen by Dr. Pappas, the rolling out of CORRONA International into areas of the world where there is very little data about Rheumatoid Arthritis, and the launch of the SpondyloArthritis registry.

Ms. Henkel finished the article by Dr. Kremer stating that CORRONA has done great work but there is a great amount of hard is yet to be done.

To read this article go to www.the-rheumatologist.org, Issue Archive, December 2012.

www.corrona.org

Recent Publications

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 Biological Disease Modifying Antirheumatic Drugs for Rheumatoid Arthritis.** *J Rheumatol.* 2013 Jan 15. [Epub ahead of print]


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.* 2012 Dec 13. [Epub ahead of print]


The CORRONA Team

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Allan Gibofsky, MD, JD, Vice President
Jeff Greenberg, MD, MPH, Chief Scientific Officer
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Philip Mease, MD, Scientific Director, SpA

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CORRONA ACROSS THE UNITED STATES

More than 629 participating physicians
More than 41,597 participating patients

Company Policy: CORRONA, Inc. respects all academic institution affiliations. CORRONA pays a maximum overhead of 25%
CORRONA does not pay overhead for participation as an affiliate site in the various data collection programs.

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