

CORRONA News

Fall 2012

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Joel's Corner

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

CORRONA Nested Trials

Most of you are probably aware that CORRONA is conducting two very different nested trials at sites within the CORRONA network. CORRONA is also receiving requests from our pharmaceutical partners to identify patients for their clinical trials within the US. We call this latter activity CORRONA Clinical Trials (CCT). We can offer our sites an array of new trial opportunities, some sponsored from within CORRONA itself, and some from pharma companies who wish to identify appropriate candidates within our network of digital data.

The trials sponsored from within CORRONA include the CERTAIN and Treat to Target (T2T) trials.

- CERTAIN is our Comparative Effectiveness trial of all of the TNF antagonists vs. the three biologics with an alternative mechanism of action in a ratio of 3:2. All routine labs along with hsCRP and lipids (with measured LDL, so that the patient does not have to fast) are performed centrally and results go back to the site. Aliquots of serum and plasma for later biomarker analysis on all starts are obtained at baseline, 3 and 6 months.

CERTAIN is still enrolling and we are looking for a few good sites. It pays well. If you have a friend or colleague who is interested in putting their research staff to better use, please forward their names to us and we will do the rest.

- The T2T trial will be the first to actually test the hypothesis that using a

standard metric and accelerating treatment to achieve that metric is doable in the U.S. T2T has a unique design of mandated acceleration in the T2T arm if a CDAI score remains in the moderate disease or high disease activity range (10-22 and >22 respectively).

Sites randomized to the T2T arm must accelerate if a patient's CDAI is >10 and if there is no contraindication to acceleration. These results will be compared with a Usual Care (UC) arm in which patients are simply followed in the manner in which the rheumatologist typically manages them.

We are using what is called a block randomization schema in which a site does either T2T or UC, but not both because of the potential for contamination of treatment philosophies if physicians within the same site were to do both arms of the trial.

T2T is also enrolling and also pays well. Again, if you are an interested CORRONA site, or know of any sites who might be interested in this trial, please let us know. You can simply email me at jkremer@corrora.org.

Using a registry to perform nested studies is a relatively novel idea. We will actually be included in the 3rd version of the AHRQ publication update on Registries.

AHRQ has chosen CORRONA's experience with both CERTAIN and T2T to be included in their case studies of real-world examples of how registries can facilitate nested trials.

Dimitrios Pappas participated in the AHRQ meeting which was responsible for putting together this latest version of their guidebook on registries. This AHRQ publication has become the bible for U.S. efforts at observational data capture. So thank you Dimitrios, and thank you to our investigators at our sites in 42 states! We couldn't do it without you!

The Nuts and Bolts

James Cavan, Chief Operating Officer

I'm always the last one to finish my submission for the CORRONA newsletter. Julie has become skilled at reminding me, with increasing sternness, of my tardy status. With so many active programs and projects to attend to and in planning, I hope I am always the last one.

We once again find ourselves in a transition of our IT solution. This is partly as a result of our dramatic growth and research expansion and partly to address the long heard concerns and comments from our sites. Across the fall and early winter we will be migrating to the TrialMaster product by OmniComm. This product is used globally and has been used in over 3,000 clinical trials.

We are making plans for a release of V.12 questionnaires. These will be simplified and streamlined questionnaires that reflect the changes in the market and feedback from sites and subscribers.

New registry programs have started development with their respective Project Managers and scientific teams. You will hear more about the gout and SpA registries soon.

This newsletter highlights the exciting growth in our Biostatistical and Epidemiological resources. Please see the summaries of our 3 new Biostats/Epi team members and new SpA registry Project Manger.

Carol Etzel, PhD. – Lead Biostatistician

Carol J. Etzel, Ph.D. is a native Texan, who was born and raised in the Houston area and currently resides in Houston. She received her Ph.D. in Statistical Science from Southern Methodist University in 1999. For the past 13 years, she has conducted research at the University of Texas M.D. Anderson Cancer Center, first as a

post-doctoral fellow and after several promotions, Tenured Associate Professor in Epidemiology. Although her primary area of research has focused on epidemiologic and genetic risk assessment models for incident cancer, she has also worked with oncologists in identifying clinical and genetic factors related to cancer progression, recurrence and risk of second malignancies. She also completed research in identifying genetic risks for RA when she was first at M.D. Anderson. Although she loves a good traditional statistical method, she has a keen interest in data mining and recursive partitioning techniques. She has been the Principal Investigator on several NIH/NCI grants.

Jennifer O'Connor, MPH – Project Manager, SpA Registry

Ms. O'Connor leads the CORRONA SpA registry and manages our questionnaire development process. She has worked for several years in clinical research in the realms of cardiac surgery, emergency medicine and now rheumatology. During that time she had the opportunity to work with several projects and help establish an emerging electronic data capture platform.

Jennifer earned her Master's in Public Health – Global Health from Tufts Medical School. With this degree she was able to pursue her number one passion of travel, taking several trips to Africa and Latin America with a focus on research and public health.

Chitra Karki, MPH, Analytical Coordinator

Chitra received a master's degree in public health from University of Wisconsin-Madison with an emphasis in epidemiology.

She had previously worked with Wisconsin Division of Public Health in infectious disease epidemiology where she performed statistical analyses and gained experience in quality control and data management. She has also worked with large longitudinal cohort studies like Women's Health Initiative (WHI) and Atherosclerosis Risk in Communities (ARIC) at UW-Madison performing nutrition/genetic association studies and coordinating projects across multiple sites within United States.

Chitra has presented in many national meetings and co-authored several reports, papers and posters on infectious disease epidemiology at state level and nutritional and genetic epidemiology in large longitudinal cohorts.



She will be supporting the Biostatistics and Epidemiology group and will assist with subscribers and investigator queries and analysis plans. She will also work with investigators on scientific presentations and manuscripts.

Vanessa Cox, MS, Research Statistical Analyst

Vanessa holds a Bachelor's degree in Mathematics and Master's degree in Statistics from Texas A&M University and recently began a Ph.D. in Epidemiology at UT School of Public Health. She has worked as a Statistician at MD Anderson for 6 years. Previously, Vanessa worked for a contract research organization, Synergos, and at the Houston Center for Quality of Control and Research Studies. Vanessa's current research includes barriers and access to medical care.

Data Now and Data Future

Matthew Perkins, Acting Director of Informatics

At CORRONA, data is what we do. All of us work in one aspect or another of collecting, protecting, transforming and analyzing data. And not just any data - our proprietary data. Data that CORRONA has built up over a ten plus year period to become the largest rheumatoid arthritis patient database in the world. From that view, it becomes easy to see why it is a necessity that we protect and control the lifeblood of the company, our patient and physician information.

Learning this over time at CORRONA, one of the first things I proposed when taking on the position of Acting Director of Informatics was to move our data internally to take control of it. I suggested a data warehouse to be able to manage and secure it. What does a data warehouse really mean though? A data warehouse is defined as a database used for reporting and analysis, but at CORRONA it will be that and more. Our data warehouse will:

- Hold all records from all databases previous and future.
- Enable both standard reporting and reimbursement reporting.
- Provide a direct ETL (Extract Transform Load) process to our Biostat team.
- Be secured and protected to above industry standards, with extra attention given to the access of our PHI information.

In short, the coming data warehouse will provide CORRONA control over its data and how it is used both inside and outside the organization, including www.corrona.org

being able to generate data queries ourselves, the ability to write and update our own reporting, full control over who can access the records and when, and much better data access across all teams.

For the Biostat team it will mean, simply, and incredibly, that the ETL errors will **not** only be acknowledged, but cleaned and removed as we move forward. It will mean less work required for the statisticians on the science side cleaning and organizing. Overall, it will mean when there is a problem with our data, or in the way in which we access our data, we will be able to fix it.

The data warehouse process has already started as many of you know. We are going to be hosted at NaviSite, one of the top rated managed hosting companies in the world. Once our data is accessible from our current external vendor, we will begin analyzing and designing the master schema and access layer at the new hosting site. Over the coming months, we will create and update the reporting to run from our internal data. During that process the Informatics and Biostat teams will be creating a new ETL layer to combine data from all incoming systems into a Stata (portmanteau of the words statistics and data, references general purpose statistical software created by StataCorp.) data for export back to the Biostat team. That includes combining data from CORRONABase V.11, V.12, and the new standalone CERTAIN database coming at OmniComm. And that's all just in the next few months.

The vision for the future, for the way forward from the features and qualities listed above, is grand and wide open. Since we control our data, we can be agile and responsive to the market. We can grow as much or as little as needed. We will most likely take our EDC (Electronic Data Collection) servers in house. We may support tablets or OCR (Optical Character Recognition) data gathering or something else altogether. What we won't do is let another company tell us what we can and can't do with our data from this point forward. Our data is now becoming ours and when this process is finished, no one but CORRONA will control our data ever again.

Now and in the future, that will enable CORRONA be whatever it needs to be. That is my goal in all of this. To let the data drive the needs of the hardware, hosting and resources.



Whenever I find myself asking what is best for CORRONA here (as I often do), I often back up and ask, what is best for CORRONA's data here? That is the key now and in the future. As long as we are asking ourselves not only what is best for CORRONA, but what is best for our unique, proprietary and important patient and physician information, the direction forward will remain clear.

Coordinator Corner – Late Summer 2012

Kimberly Gottfried, Director of Site Operations and CORE Registry Project Manager

End of Garden Harvest Tips:

Lately, we have received many questions regarding the retention and storage of CORRONA paperwork. While registries, including the CORRONA Data Collection Program, in general are not subject to FDA or OHRP regulations (per the NEIRB - August 2012), the NEIRB recommendation is that CORRONA set the policy for record retention and destruction. To that end we offer the following guidelines for record storage:

For all paper documents associated with the CORRONA Data Collection Program:

- We will allow sites to electronically store such documents (including patient informed consents) providing all documents are readily available in the event of a monitoring visit and/or regulatory agency audit.
- There must be a secondary electronic back-up; i.e. external media, server or electronic management service in place in the event of a failed primary electronic source of study related documents.
- In all instances, records are required to be maintained and stored for a period of two years after the study has been closed by CORRONA.

Site Staff Updates -- Please note: in the event of staff changes, and especially coordinator changes, it is the responsibility of the site to notify both CORRONA and your local IRB of record whenever such changes occur. CORRONA expects notification to occur within one week's time of such changes in order to facilitate website access, training requirements, good clinical practice (GCP) process and timely fulfillment of regulatory filing requirements. All changes should be reported initially to Kimberly Gottfried, and subsequently to the specific project manager for any secondary studies your site might be involved in.

NEIRB -- The NEIRB annual study renewal reports are due. The current version of the protocol (Version 11.0, dated April 23, 2012) is due to expire on September 21, 2012. It is important to submit your CORRONA Data Collection Program (Protocol 02-021) Renewal Report ASAP in order to continue CORRONA study activities with either the CORE or CERTAIN protocols. Failure to submit a timely renewal will place your site in suspension status and all study related activities will be put on hold until corrective action paperwork has been filed with the NEIRB. If you require year end enrollment totals or other assistance with your renewal report, please contact Kimberly Gottfried at (518) 727-9997 or kgottfried@corronda.org.

Overdue Visit Lists -- Nearly all sites have received their overdue visit lists and site performance stat reports by now. We want to thank everyone who has started to address these lists and begun to schedule overdue appointments and exit patients to improve your overall "active" stats.

Did you know that you can now access similar reports on demand directly through CORRONAbase? In general, the timely scheduling of follow-up visits allows you to more closely monitor the effectiveness of new drug starts with documented follow-up visits in a 4-8 month window post new drug initiations, and more accurately recall significant medical events and changes in drug regimens.

Orencia -- As more patients begin to use the subcutaneous formulation of Orencia, we note that the current version (V11.0) of the patient questionnaires does not provide an option for capturing injectable Orencia (Orencia SQ). Please have your study subjects leave this section blank, and do not record as Orencia IV.

This information should however be captured on the physician questionnaire in Section I using the "Other" option in the biologic section. Any injection reactions reported by the patient can be captured in Section F of the physician questionnaire under "Injection Reaction", using the appropriate drug code from the list provided in Section F. The next version of the questionnaires (V12), due out in early 2013, will accommodate this drug option.

Best wishes for a bountiful autumn season!



Quality Matters

Timothy Harrington, MD, Chief Quality Officer

Many of our investigators face the need each 10 years to maintain their specialty certifications in Internal Medicine and Rheumatology through the American Board of Internal Medicine's Maintenance of Certification (MOC) program.

One of the requirements is to perform a practice quality improvement (QI) project. This usually involves reviewing patients' medical records to document some aspects of their care, and monitoring this performance over time. ABIM allows individual physicians to create their own program, but also certifies MOC programs including the ACR's that physicians may use to satisfy this requirement. Most physicians elect the latter path.

Several of our investigators have recently asked if their CORRONA participation might satisfy their MOC QI requirement. After looking into this, we are applying to ABIM for certification, and should hear about the results of the application process by January 1, 2013. We have no reason to believe this won't be successful and are informing you in case you are up for MOC in 2013.

Briefly, CORRONA's ABIM MOC QI will be based on the same 6 RA performance measures used for PQRS reporting. All of the data to satisfy these measures is collected during each established RA patient encounter reported to CORRONA. The physician does not have to do any of the typical chart review work. This is similar to the PQRS program. We will also involve the measures of RA disease activity, which are calculated in our recently deployed Site Report. More details will follow on how this will work as a QI project.

Stay tuned for the results of our application. If you have any questions, feel free to contact Aimee Whitworth (awhitworth@corrona.org), Kim Gottfried (kgottfried@corrona.org), or me (tharrington@corrona.org).

Gout Registry is at our doorstep!!

Nijad Kifayah, Project Manager, Gout

We are excited to announce our national Gout Registry is fast approaching with a targeted launch date in September 2012.

Our goal for the Gout Registry is to create a national cohort of gout patients cared for by rheumatologists; to better understand the natural history of gout, comorbidities, current treatment practices, response to therapy and safety issues related to medication therapy. Subjects to be recruited for this registry will be male or female who are at least 21 years of age and diagnosed by their rheumatologist as having gout.

Subjects will be assessed by their rheumatologist at six-month intervals during routine clinical encounters. Data relating to gout disease activity/severity, functional status, comorbidities, medication use, adverse events and the results of diagnostic tests will be collected.

With your help, we look forward to advancing rheumatology research and improving the quality of rheumatology patient care.

The door is open to any site interested in participating. Please reach out to me at nkifayah@corrona.org for more information.

Treat to Target Study (11-216) Updates

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

Status Update: 205 Total Enrollments reported through Aug. 30th 2012. Target Last Patient Enrollment: July 2013.

The T2T Study was launched 1 year ago by a small number of dedicated U.S. Rheumatologists. The tenacity of our active sites has been nothing short of inspiring as we have worked to launch the study. This important study will provide insights not only into outcomes associated with implementation of a T2T treatment strategy in subjects with active RA, but also the real-world feasibility challenges involved with such an approach in U.S. patient populations.

Recruitment:

It has been a very busy summer thanks to the consistent efforts of our strong team of participating sites! We have some new-to-CORRONA sites now on board and doing a fantastic job with their early recruitment efforts.

We were so pleased with our strong summer numbers and looking forward to keeping the momentum going through the fall months. Four new sites are expected to have IRB approval before the end of September. It is an exciting time as we enter our final year of recruitment activities!

What is Usual Care?

Well... you tell us! Usual Care (UC) sites, your subjects are needed! It is critical to maintain recruitment balance between randomization arms to ensure adequate powering and ability to make comparisons between the groups. Our UC sites are incredibly important to the success of this project. You are helping to define standard practices in U.S. Rheumatology practices. This is an important contribution to your specialty and a great way to generate additional revenue, with data collection activities every 3 months for 1 year.

T2T Repowered

The CORRONA Team is delighted to be further expanding our T2T team of investigators! In the interest of setting manageable site recruitment goals and ensuring optimal powering of the trial for the future analytics, a total of 30+ sites will be needed with each site enrolling a minimum of 16 total subjects over the course of their participation. We will be working with individual sites to customize recruitment plans for the next year.

Five sites have already met their 16 patient minimums - Congratulations to sites 15, 38, 65, 131, and 163! At the time of this print, there are several more on the cusp! We could not be more proud of our initial group of committed sites! Congratulations to those of you with anniversaries approaching this quarter. (Sites 1, 5, 6, 13, 15, 38, 65, 83, 131, 150.) We could not possibly pull this off without your amazing, ongoing support and early partnerships on this important research study.

Thank you for your interest and support. If you have questions or would like information about joining our team of T2T Study Investigators, please contact us: Christine Barr, cbarr@corrona.org or (518) 605-3444.

CORRONA CERTAIN Sub-study

*Tanya Sommers MS ANP-BC, Project Manager,
CERTAIN*

The CORRONA CERTAIN Sub-study wishes to say “Thank you” to all of the CERTAIN participants and sites as we approach 1400 enrolled patients!

CORRONA's CERTAIN sub-study offers a unique opportunity for the practitioner and patient to contribute to comparative effectiveness and safety research of biologic therapies for Rheumatoid Arthritis.

Robust data are being collected using CORRONA questionnaires across the United States and a rich database is gradually being formed. Biologic samples, including serum plasma RNA and DNA, are stored for research on biomarkers and pharmacogenetics. During the months of June and July the CERTAIN team Stopped, Looked and Listened. We would like to personally thank each PI, SUB-I and Coordinator for giving up time during your valuable evenings to participate in the CERTAIN mid-study webinar. Your enthusiastic participation, great ideas, constructive suggestions and intelligent feedback is a testimony to your dedication to the CORRONA CERTAIN Sub-study.

The webinar helped to identify KEY ELEMENTS for successful patient recruitment and follow-up. Major suggestions to overcome enrollment and other challenges included:

Incorporating a team approach for pre-screening patients. Sites that have introduced a communication system between the biologic preauthorization personnel and the CERTAIN research coordinator were able to identify every patient eligible for enrollment. At these sites, once a biologic agent is approved by the insurance, the research coordinator is notified and can approach the patient to return for a screening and baseline CERTAIN visit.

Involving joint assessors, nurse practitioners, rheumatology fellows to perform a CERTAIN visit. Remember... the physician does not need to be present during a CERTAIN visit.

If a trained joined assessor trusted by the physician is present the CERTAIN visit can be completed in the absence of a rheumatologist. Of course the rheumatologist will have to sign the physician questionnaires and take the ultimate responsibility for the accuracy of the data collected and submitted.

In addition to the above suggestions from the sites, we proceeded to an **INCREASE IN SITE COMPENSATION**. We couldn't be more excited to increase site compensation. On July 1st, 2012, site remunerations for Baseline visit increased from \$350.00 to \$525.00 for each enrolled CERTAIN Subject. Sites may continue to complete Screening and Baseline visits together, when appropriate, for a complete compensation of \$650.00 for the combined visits!

\$125 Site Remuneration - Screening/Enrollment Visit (2 page CERTAIN form)

\$525 Site Remuneration - Enrollment Visit (month 0) (effective July 1, 2012)

\$250 Site Remuneration - Follow-up visit (months 3, 6, 9, 12)

Finally, we are delighted to launch the CERTAIN Research coordinator **CHAMPION Program**. We have recruited a TEAM of experienced CERTAIN coordinators who will be available twice a month for round table discussions to assist and guide new site coordinators. Welcome **Irina Castillo** from Zephyrhills, FL and **Amanda Hutchins** from Lansing, MI.

We have made many changes this spring and summer in an effort to save time for you and your staff. Your enthusiastic response and participation in our webinars is greatly appreciated. In our opinion, this reflects the great appetite for quality research. We again thank you for your time and effort to make CERTAIN a success!



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Fall into PQRS 2012

Aimee Whitworth, Associate Project Manager PQRS

With fall quickly approaching we are nearing the end of another PQRS year. We have provided participating sites with a list of potential PQRS patients in the spring and will do so again in late October.

Please remember: each physician will need at least 30 Medicare Fee for Service patents entered into the CORRONA PQRS sub-registry in order to qualify for the 2012 CMS incentive. As we have learned, it is better to start identifying these patients early rather than to wait until the end of the year and realize they were in need of a visit in 2012.

To make it easier for coordinators and physicians this year, we will be providing you a potential patient list to help identify patients and have kept the 2011 patient data in the PQRS CORRONAbase system. If the patient has a qualifying visit in 2012, you will be able to select the appropriate visit from a drop down menu and select the RA measures button. This feature has kept the patient PHI information intact to help prevent transcription errors.

We hope this will help save time and make the entire PQRS process easier. If you have any questions or concerns, please feel free to contact me, Aimee Whitworth, at awhitworth@corronea.org.

Cheers to the last big push for PQRS 2012!

TAE TALK

Jan Henderson, Director Adverse Event Reporting

As summer nears the end, we can all reflect back to the heat and humidity - Mother Nature has certainly tested us this year. The first sign of leaves turning to their autumn colors is upon the upper mid-west with high hopes for a long fall and cooler temperatures! I hope you have all had the opportunity to enjoy some of the summer days and found some rest and relaxation.

Since the last newsletter, we have carefully reviewed many aspects of the TAEs you have submitted to CORRONA. Below are several points we would like for you to review to help better understand the needs and expectations of the TAEs being reported.



INFECTIONS: We have encountered many events which do not need to be reported as serious. For infections, there are two major considerations:

- Was the patient hospitalized or diagnosed in the hospital?
- Did the patient receive IV antibiotics to treat the infection?

If one or both of the questions above can be answered with a “Yes”, then you are required to complete the Infection TAE. If neither can be answered with yes, you should not complete the TAE. As we move forward with our review of infections submitted which do not show us a “Yes” answer for at least one of the questions, please know that these will not be payable. We ask that you submit only serious infections and seek the source documents.

MULTIPLE EVENTS: It is not uncommon to review the source documents and discover more than one event has been diagnosed. The patient may have been treated for pneumonia and also diagnosed with a UTI or a stroke may have revealed other cardio events.

- Please complete the appropriate TAE for each of the events that have been diagnosed.
- Source documents will be applicable for each of the reported events.

SOURCE DOCUMENTS: A large number of events have been submitted without source documents and indicating the patient would not give their consent.

- Please refer to the Authorization and Informed Consent each patient has completed and signed at the time of their enrollment in the CORRONA Data Collection Program.
- On page 3, included with Confidentiality and Privacy, you will find the patient has agreed to make their “entire medical record” available for use in connection with the CORRONA Data Collection Program.
- We do acknowledge that some situations may require further consent from the patient when requesting records from other providers or hospitals. However, we find these situations to be few. Submitting the signed consent when requesting documents should be sufficient.

NEUROLOGIC, CARDIO, OR INFECTION: Some of you have received requests to complete a different TAE from which you have submitted. Most common is the Neurologic TAE being submitted for an event which should be documented under Cardiovascular.

- You will find definitions on the last page of each of these three TAEs which will assist you in selecting the appropriate questionnaire.

- If you still have questions, please do not hesitate to call or send an e-mail prior to completing the wrong TAE. We are always here to assist you and save you time!

REPORTING EVENTS IN THE NEXT FOLLOW-UP VISIT:

We know how easy it is to forget to document an event which occurred since the last follow-up visit. We have discovered some of these being reported in other follow-up visits, not the “next” visit and often times not being reported at all.

- Do you pre-populate a follow-up questionnaire for the next patient visit and include it in their chart?
- Do you have a system in place which will remind you to include that event in the next visit? If so, would you care to share this with everyone?

UNSIGNED AND INCOMPLETE TAES: Have you recently reviewed the number of incomplete or unsigned events at your site? You may find several that can now be completed and signed when they were due to a bug in the system. This has been de-bugged and signing them will now qualify for payment!

- Select “All Physicians” for the Physician ID.
- Select any of the TAEs in the dropdown box for “Form Type”.
- Uncheck “Signed” and check “Unsigned” after “Form Status”.
- Search.
- When the cursor hovers over the date of an event, review only those which do not indicate BULK LOAD!

PARTICIPANT EXIT: Please continue to fax exit questionnaires to us at (877)364-7052!

- Be sure to indicate the study from which the patient is exiting.
- If you know the patient has not been seen because they are in remission, please do not check “Lost to Follow-up” but check “Other” and complete the free text information.
- If death is indicated, please make an attempt to provide the date of death.

THE “REPORTS” TAB: We have had several requests for the number of events you have reported at your site. Please take advantage of the “Reports” tab at the top of your search page.

- You may generate your own reports for the “Big 3” TAEs by clicking on the reconciliation for Cancer, Cardio, and Infection. Select the options for the parameters and hit “Apply” to generate your report.
- At the top of the electronic report, clicking on the word “Actions”, you may export your report in various formats and save on your computer or in your files.
- Returning to your main search page, you may select the remaining TAEs by name following “Form Type” and it will display the number of events you have reported at the bottom of the page.

THE BIG THREE TAEs: Thanks to all of your hard work and continued efforts to report the CORRONA targeted adverse events, we are happy to report some of the results of your submissions! Other articles in this newsletter will reveal to you the number of abstracts, posters, and publications made possible through the CORRONA data collection process. Since first starting to collect the adverse events, we have growing numbers for you on the “Big Three” which have been submitted!

- Cancer/Malignancy – over 1400 events.
- Cardiovascular – over 760 events.
- Infection – over 2500 events.

SOURCE DOCUMENTS: Again, because of your work, we have 80% of events reported which have been submitted with source documents. We would love to raise that percentage but can only do that with your help. Please make every effort you can to help raise that number, even when you document “patient reported”. We do feel there is documentation somewhere for every serious event.

Great successes are achieved through team work. Thank you for being such strong players and helping us reach these high levels. Please do not hesitate to contact me (jhenderson@corronda.org) at any time with your questions or concerns!

Good news from CORRONA Clinical Trials!

Sara Kremer, Managing Director, CORRONA Clinical Trials

The concept and model upon which CCT is based continues to draw keen interest from industry sponsors of Phase II and Phase III trials. The ease with which CORRONA can identify sites with protocol eligible patients considerably shortens the trial start up time for both the trial sponsor and the site.

With one new contract in place and several pending, CORRONA sites that are doing research may expect to hear from CCT this fall. As in the past, we will contact sites to determine their interest in participating in a particular trial.

With the site’s permission, we will release contact information to the sponsor of the trial and provide the site with a list of CORRONA ID numbers for patients who meet the study criteria.

If you are interested in learning more or have any questions, please feel free to contact me at skremer@corronda.org.

ACR 2012: CORRONA Wants to See YOU There!

Julie Lapham Hunt, Operations Coordinator

With the ACR right around the corner we are very excited to see many familiar and new faces at our NEW booth. CORRONA’s booth will be bigger, better and located at **1509** on the exhibit floor of the Walter E. Washington Convention Center.

The ACR meetings are always very busy for the CORRONA staff, but we want to make an effort to make time for you. Please contact me (JLHunt@corronda.org) or Kimberly Gottfried if you would like to schedule time to meet with our staff to discuss problems, inquire about our new registries or just to scheduled time to catch up.

On Sunday, November 11 and Monday, November 12, we will be hosting cocktails and nibbles for our investigators and coordinators. [This is by invitation only.](#) Please keep an eye out for emails regarding this event from me or Kimberly Gottfried.

For ACR 2012, CORRONA is patting ourselves on the back because **18** abstracts based on the CORRONA data were accepted for either poster or podium presentation. Many of these abstracts were investigator initiated. Kudos to our investigators who will be presenting in November! Please see the chart below of the accepted abstracts. We encourage everyone to take some time to review the posters or sit and listen to the podium presentation. While you are there, just think “I contributed toward this presentation!” Leading up to the ACR, please watch our for press releases about the dates and times the posters and oral presentations will be presented.

Name of Presentation	CORRONA Author	Presentation Type
Persistency and predictors of persistency of adalimumab among rheumatoid arthritis (RA) patients in a US registry.	Allan Gibofsky, MD	Poster Presentation
Adalimumab Treatment is Associated with Decreased Concomitant Rheumatoid Arthritis Medication Use over 24 Months	Daniel Furst, MD	Poster Presentation
2002-04 vs.2007-09: Initiation of Combination, and Tapering/Discontinuation (DC) Patterns of TNFi and MTX in a US (RA) Patient Registry: Analysis with CDAI Scores	Joel Kremer, MD	Poster Presentation
Disease Activity and Treatment Strategies in a Moderat Rheumatoid Arthritis Population: Data from the Consortium of Rheumatology Researchers of North America, Inc.	George Reed, PhD	Poster Presentation
A methodology for estimating disease state transitions: repeated measures Markov models with covariate dependence.	George Reed, PhD	Oral Presentation
Transitions among disease activity states: estimates and models of covariate associations	George Reed, PhD	Poster Presentation
Rituximab for treatment of rheumatoid arthritis	Leslie Harrold, MD, MPH	Poster Presentation
Characteristics Associated with Biologic Initiation as Monotherapy Versus Combination Therapy In Patients With Rheumatoid Arthritis (RA) In A United States Registry Population	Dimitrios Pappas, MD, MPH	Poster Presentation
Predictors of Initiating Biologic Monotherapy in Biologic Naïve Patients With Rheumatoid Arthritis in a United States Registry Population	Dimitrios Pappas, MD, MPH	Poster Presentation
Patient and Provider Factors Associated with Compliance with Rheumatoid Arthritis Treatment	Leslie Harrold, MD, MPD	Oral Presentation
Subcutaneous Nodules Are Significantly Associated with Cardiovascular Events in Patients with Rheumatoid Arthritis: Results from a Very Large US Registry.	Prashant Kaushik, MD	Oral Presentation
DMARD and Biologic Use during Pregnancy in Rheumatoid and Psoriatic Arthritis Patients in the CORRONA registry	Jack Cush, MD/ Artie Kavanaugh, MD	Poster Presentation
DMARD Use Among Elderly With Rheumatoid Arthritis	Rebecca Manno, MD	Oral Presentation
Use and Long Term Use of Complementary and Alternative Medicine in Rheumatoid Arthritis Patients.	Peri Pepmueller, MD	Poster Presentation
Major Adverse Cardiovascular Events are more common in Rheumatoid Arthritis than in Psoriatic Arthritis and are Associated with Different Risk Factors	Christopher Richlin, MD	Poster Presentation
Standardized Data Collection Supports High Performance in Reporting Rheumatoid Arthritis (RA) Measures to the Medicare Physicians' Quality Reporting System (PQRS).	Timothy Harrington, MD	Poster Presentation
How Much Can Patient Reported Outcomes Improve among Rheumatoid Arthritis Patients Who Have a Clinical Response to Biologic Therapy but Have Not Attained Low Disease Activity?	Jeffrey Curtis, MD	Poster Presentation
African Americans and Hispanics and Disease Severity	Jeffrey Greenberg, MD, MPH	Poster Presentation

We look forward to seeing you at ACR! Don't be a stranger, stop in to booth **1509** and say HELLO!

CORRONA INTERNATIONAL UPDATE

Henry Calderon, Project Manager, Int'l Registry

Dimitrios Pappas MD MPH, Scientific Director, Int'l Registry

CORRONA International continues to rapidly enroll Rheumatoid Arthritis patients in countries outside the United States.

CORRONA International is delighted to continue to interact with talented investigators across the globe and obtain their feedback and insight. We are grateful for the enthusiasm participating investigators have demonstrated and their commitment to quality research. CORRONA International would like to take this opportunity to wholeheartedly thank them for their contributions.

The CORRONA International team is observing the maturation of our registry that includes rich and robust data. Patients are returning for their follow up visits and our project management team is monitoring completion of follow-up visits as accumulation of regular longitudinal data. This is an important milestone as this data is of crucial importance for the registry. In moving forward, CORRONA International's newly assembled data quality control team is conducting queries on already collected data. As a result, participating sites have started to receive queries regarding the occasional missing or erroneous data and each site has responded promptly and with detail.

While enrollment in the international registry increases, CORRONA is working hard on developing publications and a scientific plan for this unique dataset. In the fall of 2013, CORRONA will circulate a request for proposals (RFP) to participating investigators. This RFP will be open exclusively to rheumatologists who have either contributed patient data to the CORRONA International registry or have been involved in the registry design and study launch.

CORRONA is extending the deadline for nominations for participation to CORRONA International Scientific Review Committee (CI-SRC) until September 30th 2012. This committee's primary responsibility would be to review, score and prioritize research proposals submitted by participating investigators in CORRONA international.

CORRONA International investigators and key opinion leaders are eligible to be nominated by others or self-nominated.

Nominations will be reviewed by the CORRONA leadership team. Final selections will be based on research interests and publication record/scholarship of nominated persons. Geographic representation across the three regions participating in the registry will be an additional criterion for selection of CI-SRC members.

Requests and/or nominations for participation on the CI-SRC should be submitted to Dimitrios Pappas, M.D., Scientific Director, at: DPappas@corrona.org

If any of your international colleagues would like more information about this registry please have them visit the CORRONA International website at:

www.corronainternational.com or contact Henry Calderon, Project Manager, at: HCalderon@corrona.org

The CORRONA Team

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 and International

George Reed, PhD, Scientific Director, Biostatistics

Carol Etzel, PhD, Lead Biostatistician

Leslie Harrold, MD, MPH, Scientific Director, Epidemiology

Dan Furst, MD, Head of Publications

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

Matthew Perkins, Acting Director of IT

Jan Henderson, MS, Director, Adverse Event Reporting

Lisa Lemire, MBA, Controller

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

Katherine Saunders, MS, Senior Analytic Coordinator

Sara Kremer, Managing Director, CORRONA Clinical Trials

Tanya Sommers, MS ANP-BC, Project Manager, CERTAIN

Nijad Kifayeh, MPH, Project Manager, Gout

Jennifer O'Connor, Project Manager, SpA

Julie Lapham Hunt, Operations Coordinator

Aimee Whitworth, Assoc. Project Manager, International;
Project Manager, PQRS

Henry Calderon, Project Manager, International

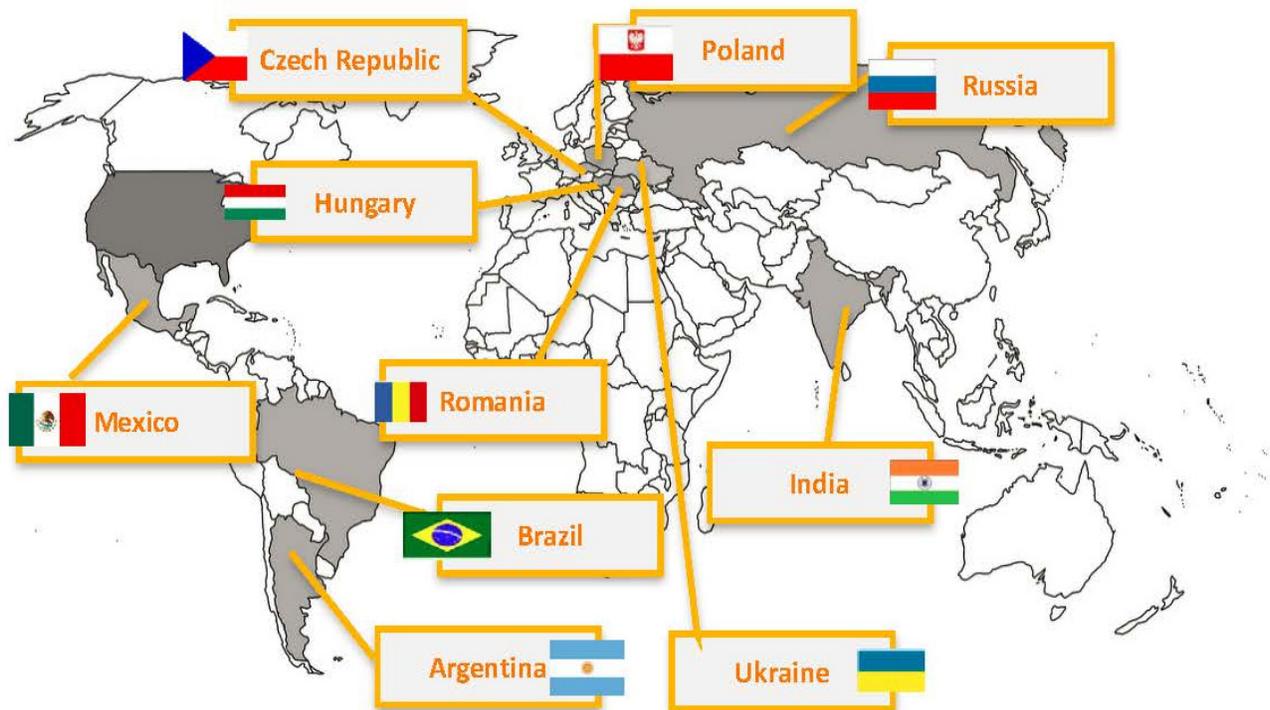
Vanessa Cox, MS, Programmer

Chitra Karki, MPH, Analytic Coordinator

Jodi Lane, Scientific Administrative Assistant



CORRONA ACROSS THE WORLD



More than 120 participating international physicians
More than 3,900 participating international patients

Upcoming Events in 2012 - 2013
Please visit us at

ACR** Washington, DC November 9-14	EULAR Madrid, Spain June 12-15
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** Exhibiting

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.