Meaningful use is on everyone’s mind these days; same with PQRS. CMS tells us that they will be paying us for these activities if we do them right. In order to “do them right” rheumatologists will have to complete the necessary fields on patients with RA. Fortunately, these fields are all found in the CORRONA RA forms! Completing 25 patients who are on Medicare in the course of your routine follow-up visits during the course of this year will qualify you for both PQRS and Meaningful Use! This is because CORRONA is an ABIM-approved registry to report these items for the appropriate credit.

If you do not presently have the 25 patients on Medicare enrolled, you can newly enroll them if they meet our enrollment criteria (either new onset RA in the last year or any patient starting a new biologic or JAK inhibitor).

So you will get the PQRS and Meaningful Use credits you need by simply doing your usual CORRONA follow-ups or enrolling the appropriate new patients.

And CORRONA will of course pay you for the new and follow-up patients while you are getting the credit you need to satisfy CMS requirements. What a deal!

Publications: CORRONA had a total of fourteen peer reviewed publications in medical journals in the year 2013. We are immensely proud of our hard-working, diligent biostat/epidemiology team. We couldn’t do it without their efforts!

And of course we couldn’t do it without you, our valued sites! Thank you!

2013 Publications:


CORRONA and the National Psoriasis Foundation Collaborate on Psoriasis Registry

*James Cavan, Chief Operating Officer*

On January 8, 2014, CORRONA and the National Psoriasis Foundation (NPF) announced a collaboration on a national psoriasis registry. This registry is the first of its kind in psoriasis.

The psoriasis registry design will mirror the previous registries CORRONA has launched since 2000, including Rheumatoid Arthritis, Gout and Spondyloarthritis. The data will be gathered through wide-ranging questionnaires completed by physician and patients at their dermatology appointments. These data will be available to interested academic institutions and pharmaceutical companies to study.
The psoriasis registry will look at treatment, safety, and effectiveness. This collaboration will hopefully identify the possible causes of the disease, examine the relationship between other health conditions and the psoriasis, and study the quality of life for Psoriasis patients.

**About the National Psoriasis Registry**

National Psoriasis Foundation (NPF) is the world’s largest nonprofit serving people with psoriasis—the most common autoimmune disease in the country, affecting up to 7.5 million Americans—and psoriatic arthritis, an inflammatory arthritis that affects up to 30 percent of people with psoriasis. The NPF’s priority is to provide the information and services people need to take control of their condition, while increasing research to find a cure. In addition to serving more than 2.1 million people annually through patient and professional health education and advocacy initiatives, NPF has funded more than $10 million in psoriatic disease research grants and fellowships. Learn more about the Psoriasis Foundation at www.psoriasis.org or call 800.723.9166.

CORRONA and the NPF expect to launch the psoriasis registry and begin enrollment to medical dermatologist in the second quarter of 2014.

Without the hard work of our current investigators making the CORRONA RA registry as robust as it is, we would have never had the opportunity to branch out into this other disease area. Thank you for all of your hard work.

2014 is going to be another busy and prosperous year for CORRONA. We are very excited about the opportunities that we have in the works and look forward to sharing when the time is right.

**CORRONA and National Psoriasis Foundation Psoriasis Registry Medical Directors**

Bruce Strober, MD - University of Connecticut
Mark Lebwohl, MD - Mount Sinai, New York
Andrew Robertson, PhD - National Psoriasis Foundation

**The List of CORRONA Publications, Presentations and Posters is More than Just a List…**

*Carol Etzel, PhD - Director of Biostatistics*

In fact, this list of CORRONA publications, presentations and posters that are at the end of most newsletters and on our website are the culmination of a vast, concerted effort to disseminate information from large patient registries involving Rheumatoid Arthritis, Psoriatic Arthritis, Spondyloarthritis and Gout. This list is just the tip of the iceberg; the final product that the public sees above the surface. However, it is under the surface where the bulk of the work takes place.

**It all starts with a question.**

A CORRONA subscriber or a CORRONA investigator asks a question. One question could be, “Are there racial disparities in disease activity” (see Greenberg et al. 2013) or “What are the characteristics of patients who switch biologics” (see Mease et al. 2013) or even “Do obese RA patients have different response to biologics than non-obese patients (see Finckh et al. 2013). Sometimes a series of related questions are asked. The question (or questions) is posed to the CORRONA Biostatistical Team (a.k.a the Biostats Team) through a standard process of submitting a CORRONA query form. Within the query form, the submitter provides information related to the intended use of the results (internal review or public domain – publication), background and purpose, specific aims (this is where the question or questions are posed), patient population and variables of interest. There is also space in the query form for the submitter to propose analyses and example tables. The Biostats Team then works with the subscriber or investigator to answer the query.
The Biostats Team is a group of Ph.D. and Masters-level Statisticians and Epidemiologists, (led by CORRONA’s Chief Statistical Officer) who have experience in the design and analysis of complex medical datasets. After the query is submitted, a member of the Biostats Team determines how the query can be answered using data from the CORRONA registry. This part of the process is called operationalizing the query. The Biostats Team member drafts a Statistical Analysis Plan (SAP) that details the design of the study to answer the query. This includes the eligible population which patients meet criteria for this query, which visits for the population will be used, what elements from the questionnaires are necessary, and what statistical analyses will be used.

The SAP also includes sample tables of results, graphs and figures. Each query needs a unique SAP, because like snowflakes, no two queries are exactly the same. The SAP is sent to the individual who submitted the query for review and, if needed, revision. After approval of the SAP, the Biostats Team member completes the analyses, writes a detailed report and then reviews the report with the original query submitter. Sometimes the initial analysis will prompt follow-up questions and additional analyses are requested, the SAP is then updated and agreed upon and a revised report with the additional analyses is created.

If the query was originally posed to submit an abstract to a professional meeting, such as the annual meeting of the American College of Rheumatologists (ACR) or the annual meeting of European League Against Rheumatism (EULAR), then the Biostats Team collaborates with the subscriber or investigator to develop an abstract for submission. Whether the abstract is accepted as an oral presentation or poster presentation, the Biostats Team continues to collaborate with the development of the presentation slides or poster layout, all the while ensuring that the results from the final report are correctly and clearly disseminated. The Biostats Team remains part of the collaborative team of investigators that works to move the results of the final report to a journal-ready manuscript.

The success of CORRONA in contributing to science in the public domain is due to the scientific rigor applied to each query but also to the rich database created over the last 12 years with contributions from the Rheumatology community.

Without the effort to gather complete, accurate data elements at patient visits these queries could not be answered and there would be no such list to brag about. This is the part of the process that you are most involved in, collecting the data: enrolling new patients, reminding current CORRONA patients to fill out their CORRONA follow-up questionnaires, ensuring that the Provider and laboratory forms are completely filled out, and then entering in all the completed forms. And by completing this data collection, you have made the list possible and helped answer important questions in the Rheumatology community.

RA Registry News.... Spring is on its way!
Kimberly Gottfried MS, RN, CCRA

According to my wall calendar anyway, spring is technically on its way.

Until it gets here however, here are a few ideas for keeping busy and keeping our CORRONA data in good order when completing the v13 CORRONA RA Registry questionnaires.

This newsletter edition will focus on proper provider questionnaire completion in the medications sections – specifically questions 9-11 on the provider enrollment questionnaire and questions 8 – 10 on the provider follow-up questionnaire. The following snippets are from questions fielded from actual sites regarding collection of data related to medication histories, current use, and change in regimens.

Provider Enrollment Questionnaires –

- Biologics, small molecule, DMARD and corticosteroid medications used in the past:
  o Dose and Frequency and stop date all should be recorded under the “Past but not Current” medication column.
  o Every medication should also have a start date.
- Biologics, small molecule, DMARD and corticosteroid medications stopped prior to today’s visit (in between CORRONA visits):
  o Should be recorded under the “Past but not Current” medication column
  o Every medication should have a start date
  o At least one reason code for stopping the medication is required

- Medications started AND stopped between CORRONA visits:
  o Should be recorded under the “Past but not Current” medication column
  o Every medication should have a start and a stop date.
  o At least one reason code for stopping the medication is required

- Medications being discontinued at today’s visit:
  o Dose and frequency should be recorded under the “current medication column”
  o The “stop drug” radio button should be selected
  o At least one reason code is required

- Medications being started at today’s visit:
  o All that is required is to select the drug being prescribed and “start drug” button
  o You do not need to record the medication under the “current” medication column
  The medication dose and frequency will be recorded in the “current” medication column at the next CORRONA visit
  o Remember to indicate in question 10 if any loading dose was used for a biologic being started today

- Medications with change in dose or/and frequency at today’s visit:
  o Record the start date, dose and frequency prior to any changes made today in the “current” medication column
  o Select the “change dose” radio button
  o Provide at least one reason code for the change in dose

Remember: in the “current” medication column we list the medications the patient is on before any changes at today’s visit. We list the medication dose and frequency before any changes are being made today. The new dose and frequency will be captured at the next follow-up visit.

Provider Follow-up Questionnaires –
NOTE: Historic medication use DOES NOT need to be re-captured from the enrollment questionnaire at every subsequent follow-up visit, UNLESS the start date was not previously provided.
Sites randomized the T2T arm were prompted to escalate therapy and complete study visits as frequently as monthly, until low disease activity (CDAI ≤10) was achieved. Sites randomized to Usual Care completed study visits every three months and continued “usual practices” for RA management. Clinical outcomes and feasibility of implementation will be compared at Month 12.

Current Status: The T2T trial has successfully transitioned into the final six months of study follow-up. It has been exciting to see so many participants completing 12 months of study follow-up, when critical comparisons between the two study groups are made. It continues to be incredibly important to include as many subjects as possible. We truly appreciate your sustained efforts to complete study assessments whenever possible. We remain very interested in having reasons reported for missed visits during the expected study follow-up period. It is important for us to understand real-world barriers encountered when following these subjects.

Data Management: In addition to remaining focused on participant retention, these final months will also be critical for getting the provided data very clean, complete, and ready for upcoming analyses. We very much appreciate your prompt responses and turn-around of any data queries sent to your site.

- We will issue DCF reports regularly through the final data lock this summer. You’ll be asked to provide updates on critical clinical information if missing at the time of the initial report.
- Visit tracking summaries are provided each query cycle showing all T2T visits that CORRONA has on file for subjects at your site. This tool is available to assist you in identification of study visits that may have been completed but have not yet been submitted to or received by CORRONA.

Remember: in the “current” medication column we list the medication dose and frequency the patient is on before any changes are being made at today’s visit.

To review once again the general rules related to:

Starting Medications: New drug prescriptions should be captured at the time the decision to start the drug is made. The only two fields required to indicate a new drug start are 1) the selection of the new drug name by checking the box in front of the drug name; and 2) selection of the “start drug” radio button. At the next follow-up visit, you will record the actual start date, dose and frequency in the current user columns.

Changing the Dose of a Medication: The dose and frequency of the medication of interest will be captured in the current user column BEFORE ANY CHANGES MADE TODAY. The radio button for “Change Dose” should also be selected. At the next follow-up visit, the new dose and/ or frequency will be captured.

In essence, we wish to capture successive data that shows a definitive stop and stop date with reason codes in a temporal fashion.

Finally, please do not forget to complete and sign all pages in TrialMaster for each and every visit, including the Initial Investigator Signature page. All unsigned visits will remain unpayable until signed.

Treat to Target Trial: Winter Updates
Kevin Soe, Project Manager

Background: The Treat to Target (T2T) trial was launched in July 2011. Enrollment was completed in 2013 with 536 adult subjects with active RA (CDAI>10) were enrolled at 31 sites. Each site was randomized to either the T2T (intervention) arm or Usual Care (control) arm.

www.corrona.org
We can’t thank you enough for your ongoing efforts to follow active participants through completion and bring your study files fully up to date. The trial is expected to complete data collection on time, with the last Month 12 visits occurring in July 2014. Our success to date has been directly tied to the dedication and hard work of our participating sites, to which the T2T team remains tremendously grateful. We appreciate your continued commitment during the final months of this important project!

Please reach out to me at ksoe@corrona.org, if there are any questions about the T2T trial.

CERTAIN Spring News
Tanya Sommers, MS ANP-BC

We would like to extend a sincere “THANK-YOU” to more than 40 sites and 110 investigators for for closing in on the recruitment objective of 2711 biologic initiations. We would also like to extend our appreciation to the research coordinators who have been instrumental in the success of this study. We are fortunate to have a network of Rheumatology professionals who have invested such a dynamic interest in the success of the CERTAIN sub-study. As we continue to follow the enrolled subjects over the next year we are “certain” that our investigators and coordinators will continue to be diligent with fulfilling all the requirements of this demanding and complex study.

Important reminders for investigators and research coordinators:

Site Reimbursement: It is important to note that in order for your site to be reimbursed for a specific visit all pages of the visit need to be completed and you MUST SIGN the last page of the questionnaires’ titled “INITIAL SIGNATURE” page. This form indicates that the information contained in the visit has been reviewed for all of the questionnaire(s) for this patient and you find the data to be complete and accurate. Without this form signed the visit will not show up as completed and payable. 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.”

Memos to file: Please complete Memo to file within the Trial Master system by clicking the “blue plus sign” by the variable you wish to notate. This is an easy way to document incidents, problems or other issues that arise while they are still fresh in your mind. The Memo to File captures circumstances as fully as possible. These should be completed for missed visits, visits out of window, trouble with blood draws, etc.

Data Clarification/Query Resolution: A simple way to find your queries is to click on the Tasks Tab and select “My Queries.” Once opened, you can click on the underlined number in the ID column to be directed to the specific open query. Scrolling to the right will give you more information related to the specific query such as who assigned it and why.

To reply and resolve: click the respond button, and be sure to save your note when you’re finished. This response will be sent to the individual who generated the query to review and close.

Exit: When your subject has exited the study because a) they have completed follow up visits through Month 12 of the trial or b) discontinued the biologic prior to month 12 (early termination) or c) lost to follow up, an exit form must be generated to capture the end to that specific enrollment time period.

Early Termination: When a subject discontinues a biologic between CERTAIN visits please make all possible attempts to schedule a CERTAIN follow-up visit as close to the discontinuation date as possible – preferably within a week. This visit should be indicated as an “Early Termination Visit”. The CERTAIN questionnaires should be completed and blood samples should be collected. Also an Exit form should be completed. As a reminder, if the decision to stop a medication is made at the time of a specific CERTAIN follow up visit this visit should also be indicated as an “Early Termination Visit”. An exit form should also be completed.

www.corrona.org
ICON Lab Kits: These do expire! Please check your lab kits expiration date prior to using them. ICON Central Laboratories has global Site Service Specialists who are familiar with your study and are available via telephone, e-mail and fax to help you. Toll Free: 1-877- 797-4422 Fax: 1-631-306-5399 or E-mail: LabSiteHelp@iconplc.com. They routinely help sites by: processing supply re-order requests;
Sending reprints of laboratory reports; calling laboratory alert values; resolving any missing/discrepant information; answering questions about specimen collection, packaging and/or shipping; responding to other laboratory-related questions/concerns. Additional information is available on their website, www.icolabs.com.

CORRONA International
Aimee Whitworth, Project Manager
Dimitrios Pappas, MD, MPH Scientific Director

Since its launch in September of 2011, the CORRONA International Rheumatoid Arthritis registry has enrolled 5696 patients across three geographic regions (Eastern Europe, Latin America and Asia) and 10 participating countries. Enrolled patients are now completing 24 months of follow-up.

The first data accumulated provided invaluable insight in RA management across different regions of the world. The data shows variations in disease activity, therapeutic approach, and prevalence of cardiovascular disease. These findings have already been presented in international meetings and were received with enthusiasm.

As follow-up time of enrolled patients accumulates, we are preparing to proceed to longitudinal analyses focusing on drug utilization, effectiveness and safety of traditional and biologic DMARDs, and how these may vary among the different populations participating in the registry. Our goal remains to generate knowledge about the disease evolution in patients with different geographic origins and treated in different health care systems. We also expect that our findings will create the context within which data from randomized clinical trials performed in non-US regions can be better evaluated.

Note to the investigators:
The CORRONA International team would like to thank our international investigators and research coordinators who continue to make this registry a success.

As always, we are interested in hearing about your study experiences as well as your opinion on improving the operational aspects of our research.

We would like to provide some reminders to our valued investigators and research coordinators:

- Please remember to enter all visit data into our electronic data capture (EDC) system within 14 days of the visit.
- In order for us to use the data for research, the information entered should be complete and signed off.
- All patients should return for a follow up registry visit every 6 months. Missed visits are allowed on occasion but consecutive missed visits will lead to the exiting the patient from the registry.
- Adverse events indicated as “targeted adverse events (TAEs)” on the CORRONA questionnaires entail completion of the corresponding TAE questionnaires and collection of all the required source documents pertinent to the event. As a reminder, section 10 of the protocol lists all source documents that are required for every TAE.

If there are any questions or concerns about the international registry please feel free to contact me at awhitworth@corrona.org.

Getting Ready for PQRS 2013 submission
Elinita Rosseto, Project Manager, ABIM/PQRS

I would like to take this opportunity to thank all the sites, providers and coordinators who are participating in the 2013 PQRS year. Your patience and tremendous efforts in identifying your PQRS patients and submitting them early is greatly appreciated! Fifty-two providers expressed interest in the program and forty-two providers have successfully submitted patients. CORRONA is now in the final stages of closing out 2013 PQRS year.

For 2014, the rules for PQRS have been changed by CMS. 2014 PQRS measures group reporting can only be done with a registry.
It would be easier if providers report 2014 PQRS within a registry instead of using claims because providers need only report 20 patients with a measures group and some measures groups have less than 9 measures (Individual 2014 PQRS measures reporting has increased to 9 measures). Providers who successfully participate will receive a 0.5% bonus of their total estimated 2014 Medicare Part B allowed charges to be paid in 2015. The penalty for 2014 for not reporting is a 2.0% deduction in overall Part B Medicare payments in 2016. It is to their benefit to participate in CORRONA’s PQRS program in 2014 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 25 patients as in 2013 PQRS. Out of those 25, only 11 will need to be Medicare FFS insured, while the remaining nine patients may have any type of insurance coverage. But we always encourage sites to submit more.

Please watch out for PQRS 2014 communications within the next few weeks. If you have further questions please contact me, Elinita Rosseto, at ERosseto@corrona.org.

Interested in Participating in ABIM through CORRONA? Here is some information!

Elinita Rosseto, Project Manager, ABIM/ PQRS

The American Board of Internal Medicine (ABIM) approves CORRONA’s Quality Improvement Pathway for 2014-2015.

Do you need to engage in a quality improvement program and earn credits for ABIMs MOC Part IV AND submit to CMS PQRS?

CORRONA is pleased to announce that we can now offer you both activities!

CORRONA’s “PQRS Rheumatoid Arthritis Measures Bundle” reporting has received a 2-year initial approval for 2014 and 2015 from the ABIM to be part of its Approved Quality Improvement (AQI) Pathway program for Maintenance of Certification (MOC). Providers who successfully participate will receive a 0.5% bonus of their total estimated 2014 Medicare Part B allowed charges to be paid in 2015. The penalty for 2014 for not reporting is a 2.0% deduction in overall Part B Medicare payments in 2016. It is to their benefit to participate in CORRONA’s PQRS program in 2014 or participate through another alternative.

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 2014 and 2015.

For more information about the CORRONA AQI Pathway, please contact Elinita Rosseto at Erosseto@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 6 RA bundle PQRS measures from baseline to the end of a 1 year project, and to develop a plan for managing active disease using the CDAI and MD Global results provided in CORRONA’s Site Report. The activity may be completed in a shorter period by using previously collected data on established CORRONA subjects. Enrollment of patients with moderate to high RA disease activity will be encouraged to facilitate documentation of improvement.

Rheumatologist investigators participating in the CORRONA ABIM MOC AQI Pathway which will collect and report a standardized data set as is already done for CORRONA research during each routine follow up visit, and at a minimum of once in a year on at least 25 AQI enrolled RA patients.
These reports by design include the six PQRS RA measures, other key clinical data, and disease activity measures.

At the conclusion of the data collection and feedback period, each participant will review their performance and prepare a brief Summary Report to submit to the CORRONA Project Committee. These Summary Reports and the candidate’s PQRS and Site Reports on their enrolled patients will serve to test whether patient care improves as a result, and will be the basis for CORRONA’s Project Team certifying the candidate’s completion of the Pathway to ABIM.

After completing the CORRONA ABIM AQI Pathway, you can then attest to your participation by submitting a report to ABIM through your Physician Homepage on www.abim.org. Simply login using your ABIM ID and password and click “Submit AQI Project Report” listed under “My Maintenance of Certification Program.” ABIM will grant MOC points after the sponsor (CORRONA) verifies your participation in the activity.

ABIM Certification

ABIM is an independent, not-for-profit organization that grants board certification—a well-accepted marker of physician quality—to internists and subspecialists. Certification is a rigorous, comprehensive program for evaluating physician knowledge, skills and attitudes to assure both patients and payers that a physician has achieved competence for practice in a given field. ABIM requires that physicians periodically recertify through the ABIM’s MOC program.

“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 at the of the American Board of Internal Medicine. “CORRONA has built a program that supports physicians in their efforts to measure and improve patient care.”

Follow CORRONA on Social Media!

Julie L. Hunt, Operations Coordinator

Want more information on CORRONA with just a few key taps of your keyboard on your computer or mobile device? Follow CORRONA on social media!

In late 2013, CORRONA joined the worlds of Twitter, Facebook and LinkedIn. On these sites, CORRONA will give news on our registries or collaborations and any important information for our subscribers and investigators.

Going to ACR or EULAR? Follow us on Facebook and Twitter to get daily notifications about the abstracts using CORRONA’s data being presented that day!

As we go further into 2014, CORRONA hopes to broaden its appearance on social media. Till then, you can find us on Facebook, LinkedIn and Twitter.

Facebook: Corrona

Twitter: @CORRONA_Data

LinkedIn: CORRONA
The CORRONA Team

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George Reed, PhD, Chief Statistical Officer

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Carlene Carlson, Adverse Event Reporting Assistant

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Roger Mann, Quality Assurance and Release Manager
Michael Loessberg, Senior Developer/Analyst

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Haley Garrett
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Tammy Carey
Rene White
Darcie Arensmeyer
Elizabeth Perkins*
Paul Kinsella*
Dung H. Le*

Scientific Advisors
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Carol Etzel, PhD              Daniel Furst, MD
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Leslie Harrold, MD, MPH       Marc Hochberg, MD, MPH
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George Tsokos, MD             Desiree van der Heijde, MD

* New since last newsletter

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Sabrina Devarkis, MPH, Analytic Coordinator

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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

* New since last newsletter
More than 590 participating physicians
More than 45,600 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.