

THE NDB Research

NEWSLETTER

News for Participants in the National Data Bank for Rheumatic Diseases

July 2012

Notes from the Director

Frederick Wolfe, MD

There is one series of questions that has been present since the beginning of the NDB – questions that deal mostly with ordinary symptoms. Ordinary symptoms are things that we all have from time to time. Such symptoms include items like headaches, abdominal pain, back pain, fatigue, and so on. The NDB includes symptoms like these as well as really less common symptoms such as “yellow skin or eyes (jaundice).” With the July 2012 questionnaire, we will have modified the questionnaire. We are including the same questions, but asking you to give us more information about the symptoms. Specifically, we want to know if you have the symptoms but were “not bothered at all” by them, or “bothered a little,” or “bothered a lot.” The only practical difference for you is to add this extra information if you have any of the listed symptoms.

Toward the end of the questionnaire you will also find a similar set of 16 questions. They will be pretty easy to answer, too. So what is all of this about symptom questions?

We have learned over the years that counting symptoms is another good way to understand how your illness affects you. It could affect you because of side effects to treatment or because your illness itself produces symptoms. Many other researchers have been gathering symptom questions. The second 16-question symptom questionnaire is becoming a standard way of asking about some symptoms. We included it so that we could standardize our symptoms questionnaire by comparing it with the way other researchers do it.

By the way, the symptom questionnaire helped us in developing the American College of Rheumatology 2010 Fibromyalgia criteria and in reporting how people feel and are concerned about drug side effects.

Speaking of fibromyalgia, the NDB has collaborated with researchers in Germany to understand how much of a problem symptoms are for ordinary people living in Germany. We applied many of our research methods to this “population-based” study. Finally, we are submitting a preliminary abstract on

the extent of work disability in people with fibromyalgia.

“We have learned over the years that counting symptoms is another good way to understand how your illness affects you.”



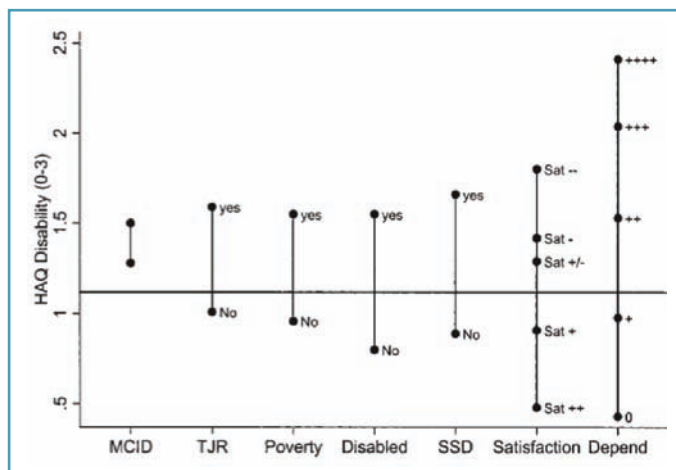
Join Us On Facebook

You can find us on Facebook as “National Data Bank for Rheumatic Diseases.” We will try to keep you up to date with any news items that occur between questionnaires. You can also connect with other participants and NDB staff who have joined our group.

Notes from the Director *Kaleb Michaud, PhD*

Every six months our questionnaire has some minor changes, some questions are removed and others are added as Dr. Wolfe discussed regarding the symptom questions. We really do try to limit the number of questions we ask and every question asked is linked to important research. I want to describe some more standardized questions we ask every time.

One of the most important aspects of having arthritis or a rheumatic disease is its impact on physical function. This includes daily activities such as standing in line, walking around the block, and opening doors. We have several questions that, when combined, create scores that tell us how much difficulty one has. For those of you who have reviewed your online patient report or some of our research papers, you may have seen something called the HAQ (Health Assessment Questionnaire). This is the most common and important measure of function or disability. Unfortunately it has over 41 questions inside it. A few years ago we developed one much shorter with 10 questions called the HAQ-II that measures the same thing as the HAQ. Both have scores from 0 to 3 in which 0 is normal/good function and 3 is unable to move. Most in the NDB have a score of around 1.1 and this changes with new treatments, flares, and other illnesses. I've included a figure from one of our papers that show the differences in HAQ scores for participants in different social and disease states.



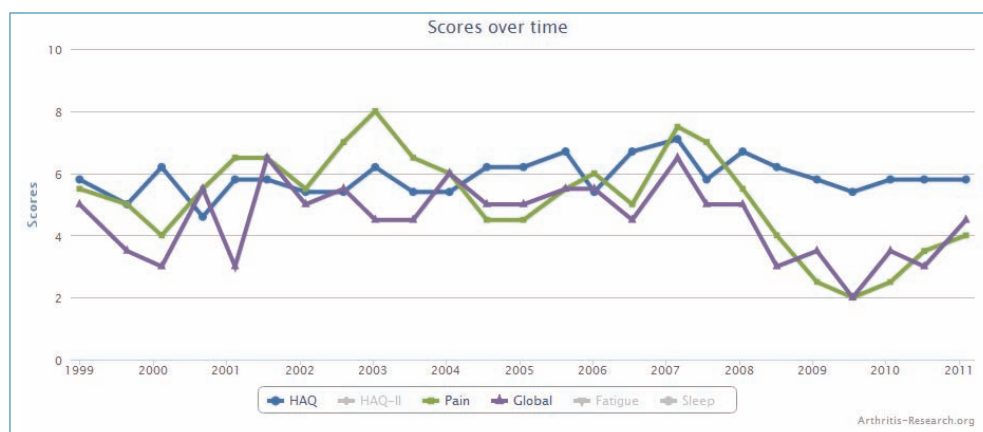
This is from Wolfe, Michaud, & Strand, *The Journal of Rheumatology* 2005; 32:4. Expanding the definition of clinical differences: from minimally clinically important differences to really important differences. Analyses in 8931 patients with rheumatoid arthritis. MCID = Minimal Clinically Importance Difference, TJR = Total Joints Replaced, SSD = Social Security Disability, Depend = total number of people dependent on for help

Almost all of the 100+ research papers that have come from the NDB use the HAQ score, so unfortunately we're unable to drop those 41 questions any time soon. Just like when we created the HAQ-II to create a shorter version, we're developing a computer-based measure of function that would get this down to only 4 or 5 questions. This would be used most often in the clinic when you visit your rheumatologist.

View your NDB results online

Many of the questions we ask every six months give researchers and doctors scores that show how you're doing. We have heard from many of you that you want to see your results. You can now get these scores any time you need them on our website. If you don't already have an account on our website, start on this page: www.arthritis-research.org/user/register. Having an account helps protect your privacy and lets you access your scores.

You will be able to see scores for every questionnaire you've ever completed for the NDB, and print them for your own information or to show to your doctor. Please email us at webquest@arthritis-research.org if you have any questions about the website or your scores.



Welcome New Participants!

Everyone who works for the NDB and all of the doctors and researchers who benefit from our research are extremely grateful for the dedication of you, the participant, to helping this project. Many of you have been with us for several years or more. But every 6 months we are also glad to see many new people join us. Here is a quick primer on the NDB for the new and a refresher for the old timers.

The NDB is a non-profit organization that performs research in rheumatoid arthritis, osteoarthritis, fibromyalgia, lupus and other rheumatic diseases. The research is designed to improve the treatment and outcomes of these conditions.

The NDB is an independent organization that conducts its own research without influence from pharmaceutical, insurance, financial or other outside interests. Our research is so well respected that we are often hired to provide independent drug safety verification to the government.

Your personal information will always remain private. We do not sell or share any identifying information about NDB participants. Before we work with researchers or collaborate with other research groups we remove any of your answers that could be used to identify you.

Nearly all of our research is available for you to read on our website. We are glad to answer your general questions about rheumatic diseases and treatments, but we are not able to give personal medical advice.

NDB research is different in an important way: Participants report on themselves; data is not collected by doctors or medical staff. With patient-reported data, researchers get a perspective that short, small clinical trials cannot provide. Our long-term study offers a much broader view of treatment and results. Clinical trials are good at identifying common side effects, but rare or subtle problems, or problems that take longer to develop, are better detected by studies like the NDB. The same is true of long-term effectiveness of a treatment.

So, welcome to the NDB, or thanks again for your continuing participation! If you ever have any questions or need help with your questionnaire, feel free to contact us.

Refer a Friend

Here's a really easy way to let a friend know about the NDB.

Just give us your friend's email address and we'll send out an email invitation to join the study. Go to <http://www.arthritis-research.org/participate/tell-friend>.



LATEST RESEARCH

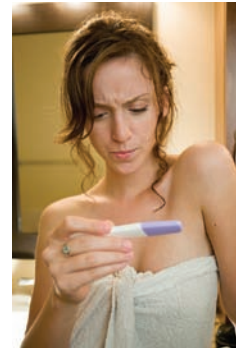
Diabetes and Association with RA Treatment

Diabetes is an important disease that has become much more common in the US. There has been little done showing any possible connection between arthritis and diabetes, though recent studies showed some RA-treatments may be associated with type 2 diabetes mellitus. We reviewed 10,853 RA patients in the NDB who did not have diabetes mellitus when they started completing our questionnaires. We found that RA patients got diabetes 20% more often than people without RA. We also found that patients that were taking hydroxychloroquine (plaquenil) had a much less chance of getting diabetes while taking prednisone was associated with an increased chance.

Pregnancy and Women with RA and Systemic Lupus Erythematosus (SLE)

Some of you women may remember completing an extra form that we mailed out in regards to women and reproduction. We thank all of you that completed the form and from that data we were able to find out the following:

- That more than one-half of women diagnosed with RA or SLE had fewer biologic children than desired
- The rate of infertility is higher in RA patients than in SLE patients-many studies have tried to find out why, but it is still unclear
- Even though infertility does not appear to be significantly increased by SLE patients, having fewer children than desired was associated with pregnancy loss
- Concerns about the well-being of a pregnancy, offspring and disability contributed to a decrease in the number of pregnancies conceived in women with RA and SLE



There is still more research to come regarding medications and reproductive health.

Pain is an Important Predictor to Patients' overall social well-being

Using the NDB data base along with the Swiss Clinical Quality Management Program for Rheumatoid Arthritis data base, data from health related quality of life questions showed that pain was the most important predictor of a patient's overall well-being. It is also a reminder to doctors to pay attention to patients' symptoms and not to forget to treat arthritis pain, as it could impact patients' well-being more than anything else.

Arthritis Internet Registry (AIR) Update

Two years ago, with the help of the Arthritis Foundation, we began to recruit patients with rheumatic diseases into the Arthritis Internet Registry (AIR). AIR is an internet-based patient registry and biospecimen collection using the combination of the patient-study infrastructure of the NDB, the nation-wide availability of Quest Diagnostics Incorporated blood collection sites and the patient outreach of the Arthritis Foundation. Participants in AIR complete the same questionnaires as the participants in the NDB, but are noted as AIR participants due to the way they enrolled into the data bank. Some AIR participants consent to donate blood samples for the biospecimen collection. After two years, we have had over 2,000 participants join and we have collected over 300 biospecimens on a variety of rheumatic diseases.

At last year's American College of Rheumatology Annual Meeting we were able to provide an overview of the data that was collected. The data from a full one year showed that participants were from all 50 US states and RA was the main diagnosis reported by 67% of the participants, 21% reported OA, and 12% were other rheumatic



diseases (eg. 4% psoriatic arthritis, 2% lupus, 2% fibromyalgia, etc.). It also showed that participants were mainly female (89%), younger (average age of 52 years old), married (66%), college educated (86%) and on average developed their condition 14 years before joining the AIR registry.

For those of you who may not know, AIR is a groundbreaking study using the power of the internet to create a community of arthritis patients for discovery research. AIR recognizes the importance of research to improve the lives of arthritis patients and the needs of patients to discuss their disease with other patients. The purpose of AIR is to bring together a community of arthritis patients to enable discovery research and social networking via the internet. AIR has been focused on enrolling patients, collecting relevant clinical data, and collecting blood biospecimens for discovery research. Such research includes understanding genetic predictors of RA risk, cardiovascular complications and response to RA therapies. As AIR grows, we will add social networking capabilities to allow arthritis patients to communicate with other arthritis patients about their disease.

Meet the AIR Researchers and Advisors

AIR is a partnership between leading academic researchers, the Arthritis Foundation and Quest Diagnostics Incorporated. The main researchers and advisors working on and supporting AIR are the following:



Robert Plenge, MD, PhD

Dr. Plenge is a clinical rheumatologist and human geneticist at Harvard Medical School. His research interest is to translate genetic discoveries to care of patients with common autoimmune diseases, such as rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE).

Dr. Plenge has contributed substantially to a thriving research group at the Broad Institute and in Boston to understand the genetic basis of immune-mediated diseases.



His future goals include understanding how newly identified gene variants change the immune system to cause disease and how these variants can be used in the rheumatology clinic to treat patients more effectively.

He is an assistant professor at Harvard Medical School in the Harvard/Partners Center for Genetics and Genomics and the Department of Medicine. He is also the director of genetics and genomics in the Division of Rheumatology, Immunology and Allergy at Brigham and Women's Hospital.

Dr. Plenge was awarded the Young Investigator Award (2008) in the Department of Medicine (Brigham and Women's Hospital), a Career Award for Medical Scientists through the Burroughs Wellcome Fund (2008), and an Excellence in Tutoring Award given by Harvard Medical School (2007 and 2008).



Kaleb Michaud, PhD

Dr. Michaud is an Assistant Professor of Medicine in the Section of Rheumatology & Immunology at the University of Nebraska Medical Center in Omaha. Since 2001 Dr. Michaud has provided statistical analysis and research project guidance to the National Data Bank for Rheumatic Diseases, the largest non-administrative, observational open-cohort study of patients with rheumatoid arthritis (RA) in the world. In addition, he is the principle investigator for the Rheumatoid Arthritis Investigators Network (RAIN) database and is a researcher with the Veterans Affairs RA (VARA) registry.

His primary interests are in the pharmacoepidemiology, burden of disease, mortality, and cost-effectiveness of treatment for people with RA. He currently receives support from an Arthritis Foundation's New Investigator Award, has been appointed an Adjunct Affiliate at Stanford University's Center for Primary Care and Outcomes Research, and has been invited to the Young Investigators Initiative Workshop Program, US Bone & Joint Decade.



Stanley J. Naides, MD
*Medical Director, Immunology R&D
Quest Diagnostics Nichols Institute
San Juan Capistrano, California*

Dr. Naides is certified by the American Board of Internal Medicine with a subspecialty certification in rheumatology. He completed fellowships in rheumatology at the University of California, San Diego and in immunology research at Harvard Medical School. Dr. Naides next joined the Medicine faculty at the University of Iowa where he studied parvovirus B19 disease and was the founding Director of the Helen C. Levitt Center for Viral Pathogenesis and Disease. Before joining Quest Diagnostics, he was a tenured professor in the departments of Medicine, Microbiology & Immunology, and Pharmacology at the Pennsylvania State University / Milton S. Hershey Medical Center where he held the Hallowell Endowed Chair, was Chief of Rheumatology, and active in graduate and medical education. He has served on national committees including the NIH Immunity and Host Defense study section and Arthritis Foundation grant review committees.



John Hardin, MD
*Arthritis Foundation Vice President
of Research*

John Hardin, MD, serves as the vice president of research for the Arthritis Foundation. In this capacity, Dr. Hardin acts as the lead scientific reviewer and spokesperson on research, medical studies and the treatment of arthritis and related diseases.

The Arthritis Foundation has played an important role in Dr. Hardin's career. In 1984, Dr. Hardin, in conjunction with his collaborators Drs. Joan Steitz and Michael Lerner, received the Arthritis Foundation's first Lee Howley Prize for outstanding research. The team's research served as a milestone in the understanding of how genetic information is translated into the proteins that make up all of the cells of the body.

Dr. Hardin's subsequent work showed that the immune system of patients with lupus responds to these Sm and U1-RNP particles as though they were foreign pathogens. This work set the stage for current work that seeks to understand why the immune system produces specific autoantibodies in the different diseases that cause arthritis. Hardin remains active in research and is currently studying how factors such as vitamin D regulate the immune system and thereby help protect against arthritis.

Dr. Hardin has served the Arthritis Foundation in multiple roles over the years including Chair of the Research Committee, participation on peer review study sections, and as a member of the New York Chapter Board of Directors.

He has a distinguished career in rheumatology, biomedical research, and medical administration. He is a graduate of the Medical College of Georgia, and received postdoctoral training at Strong Memorial Hospital in Rochester, NY, the National Institutes of Health, and the Massachusetts General Hospital. He was a member of the faculty of Yale University School of Medicine (1976-1991), Professor and Chairman of the Department of Medicine at the University of Georgia (1991-2000), and most recently Professor of Medicine, Albert Einstein College of Medicine, Bronx, NY and a Consultant to the National Institute of Arthritis and Musculoskeletal and Skin Diseases, Bethesda, MD. He has made numerous contributions to autoimmunity research, and published approximately 120 original articles, book chapters, and reviews.

Donate Blood for Research!



You can help advance arthritis research by donating a blood sample. By analyzing your blood in combination with your answers to the NDB questionnaires, we hope to discover biological reasons why some treatments work better and why some are more toxic to an individual.

As always, your privacy is protected and there is absolutely no cost to you. Your lab results will be available directly to you through a secured login on our website. You can also print out the lab results and take them with you to your next doctor appointment.

Blood collection takes place only at Quest Diagnostics laboratory sites, which are located in many cities across the US.

To donate blood, you must first sign a consent form, which we will mail to you. If you are interested in donating a blood sample, please contact Kimberly Harp by email at kim@arthritis-research.org or by phone at 1-800-323-5871 ext. 143.

**Our website for
rheumatology
questions, RheumMD.org**



On RheumMD.org we've brought together more than 20 volunteer experts to answer your questions about any rheumatic condition. You can also search existing questions and engage the doctors in discussions about the answers.

Here are some questions we've had on the site lately:

- *How safe is prednisone if you have a history of glaucoma and cataracts?*
- *How does a TENS unit help fibromyalgia?*
- *What effects do RA medications have on healing fractures?*

There are many more questions, and we invite you to ask your own at RheumMD.org.

**FOR MORE
INFORMATION
OR TO PARTICIPATE**

**Arthritis Research
Center Foundation, Inc.**

**1035 N. Emporia
Suite 288
Wichita, KS 67214**

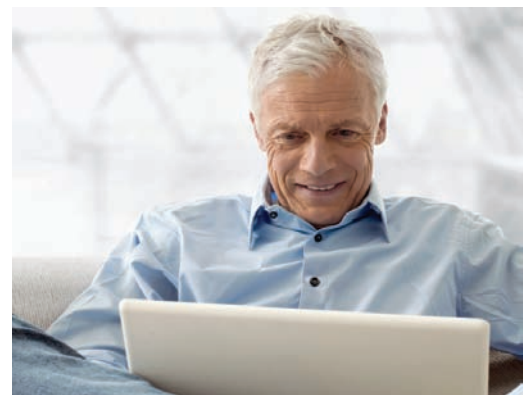
**Directors:
Frederick Wolfe, MD
Kaleb Michaud, PhD**

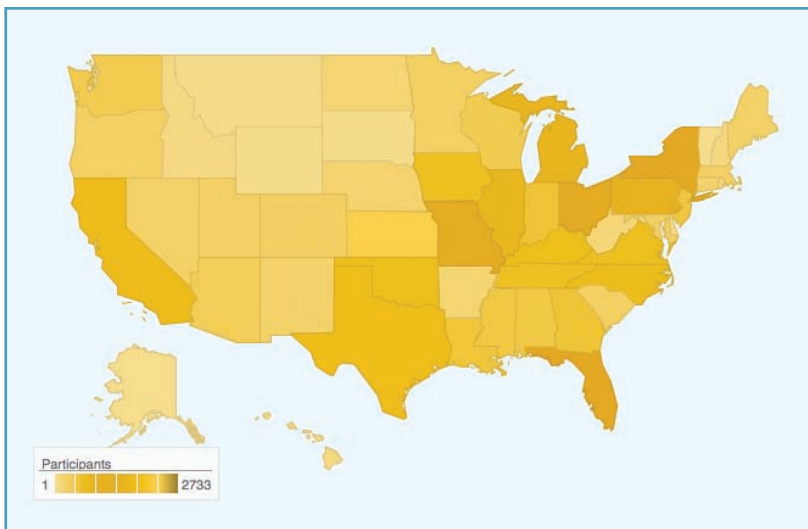
**Executive Director:
Rebecca Schumacher**

**Please call: 1-800-323-5871
or email:
info@arthritis-research.org**

WebQuest

WebQuest is the online version of our questionnaire. The questions are the same as what you get on the paper Questionnaire. People who are comfortable using computers should find it easier than the paper version. If you would like to try it, follow the links from our home page, www.arthritis-research.org and make the request, or send us an email at webquest@arthritis-research.org.





NDB Participants on the Map

We have a new item for those who have set up an account on our website—maps that show where participants are from and overall pain scores for each US state and also per specific diagnosis groups. The maps are set up for the following diagnosis groups: rheumatoid arthritis (RA), fibromyalgia, lupus, other inflammatory rheumatic diseases (which include psoriatic arthritis, ankylosing spondylitis, etc.) and non-inflammatory rheumatic diseases (which include osteoarthritis, osteoporosis, etc.).

You can view this map by logging into your account on our website or if you don't already have an account on our website, you can set one up by going to this page on the web: <https://www.arthritis-research.org/user/register>

Meet the Staff

Betty Pew

Betty has been working with Dr. Wolfe for over 30 years and has been around to see the very beginning of the NDB, which Dr. Wolfe first started with the patients he saw in his clinic.



Betty has had many jobs at the NDB and with the clinic, from being the Lab and Xray Director during clinic hours to currently the Xray/Lab Specimen Director and Research Assistant with the NDB. She is the person who processes all of the consent and clinic forms that we receive from various clinics throughout the United States. She makes sure that we get the new enrollees entered into the NDB and she also comes across some participants that we had lost through the years that have rejoined to participate again. She also works with certain clinics to obtain xray and other clinic data to incorporate with the 6-month questionnaire data that is used in various research projects.

Betty keeps herself busy when not at work by hiking in the mountains, riding bicycles and is on her city's Park and Tree Board.

Lottery Winners!

The research data bank can best contribute to research when the questionnaires are completed and returned as soon as possible. We conduct the lottery as a token of our gratitude in help with rheumatology research.

Our lottery drawings consist of:

2 drawings for \$1,000 each for those who complete a large questionnaire via mail, web or phone within the first 4 weeks.

2 drawings for \$500 each for those who complete a large questionnaire via mail, web or phone any time within the 5 ½ months.

4 drawings for \$50 each for those who complete a shorter questionnaire via mail or phone anytime within the 5 ½ months.

The \$1,000 winners from the last questionnaire were Carol Weiss, Paso Roble CA and Larry Meckley, Lititz PA. Winning smaller amounts were Virginia Neeley, Saint Ansgar IA; John Kratz, Orfordville WI; Sandra Gaines, Pasco WA; Daryl Callaway, Apple Valley CA; Josephine Crumb, Ozark AL; Catherine Bunker, Loveland, OH. Congratulations to all!

Support Rheumatic Disease Research with a Financial Donation

As a non-profit project conducting ongoing research to improve conditions for people with arthritis, fibromyalgia, lupus and other conditions, the NDB is an organization with ongoing financial needs.

If you would like to make a tax-deductible monetary donation to the NDB to help support this research, we would be very appreciative of your support.

If you would like to make your donation in memory of or honor of someone please let us know. We will send a card to the person of your choice to acknowledge your gift.

Donations should be payable to:
Arthritis Research Center Foundation Inc.

and sent to:
Arthritis Research Center Foundation Inc.
1035 N. Emporia, Suite 288
Wichita, KS 67214

Or you can donate online by visiting www.JustGive.org and type in Arthritis Research Center Foundation.

For more information please contact Rebecca Schumacher at 1-800-323-5871, ext. 119.

Thank you very much for considering a donation to support this important research.

Helping the NDB in other ways

Achieving the NDB's goals of telling the rheumatology community about patient experience depends on a large group of participants.

Available for your support group or arthritis, fibromyalgia or lupus meetings... our pamphlets explain what we do and how you and can help. Each one has a postage-paid postcard to request more information or an enrollment form to join the project. The pamphlets and a small table-top stand are available free from the NDB. Just contact us at info@arthritis-research.org or 800-323-5871 ext. 133. Thank you!



Reminders

While working on your questionnaire, if you have ANY questions about the questionnaire, please contact us right away by email or phone. These might be about technical difficulties or how to interpret a question. If you put your immediate questions in the comments section we probably won't see it in time to answer.

Please use the comments section for any information you think we should have that isn't covered in the questionnaire. This could be about a change in medication that needs explanation or information about other considerations of your condition that you think we need to know. You may also ask general questions that don't require an immediate answer.



Important Information about Email

For patients using WebQuest, email is our primary method of getting in touch with you. Even if you're not using WebQuest, we'd like to be able to send you important information by email.

We cannot emphasize enough how important it is for you to let us know whenever you change your email address.

To update your email address go to our website and look in the participant's links, or call us.

Here's a VERY IMPORTANT step you can take to make sure our email gets to you: Add us to your email address book. Our address is webquest@arthritis-research.org. This will ensure that our mail makes it through the spam blockers. You will need to do this every time you change your email address. Thank you!