

Notes from the Directors

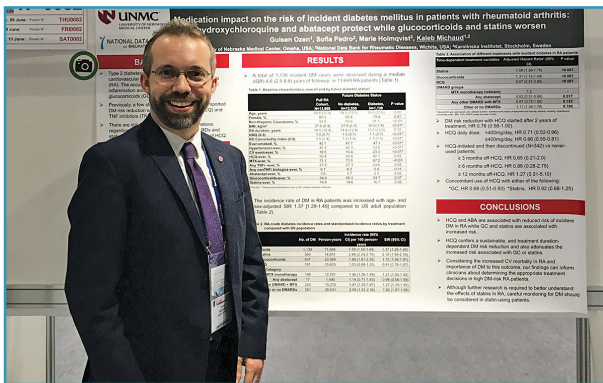
Kaleb Michaud, PhD

Real-life vs. Research

I have lots of big news to share—so, where to begin... First, remember last year when I wrote about my struggle to decide how to help my wrist? Well, working with my wife, we made a decision, and a few months ago I had my artificial wrist removed and then fused it completely using bone from my hip. The good news is now I don't have the wrist pain I had before (yay!), but I'm still gaining strength and getting used to the reduction in function as my fingers are having to flex and work harder than ever. And just like an old car in the garage, now that this "part" is working, my other wrist and knees are "hollering" that they may need work—even with my relatively low disease activity, it shows how the long-term effects of these diseases stick around.

of my DMARDs that years ago I was required to stop for months before my previous surgery—medicine is always changing!

The timing for my wrist surgery was greatly influenced by the news last fall of "we're going to have a baby!" If I wanted to hold my baby, I needed a fix quick. But first let me back up. Planning to have kids when you already have arthritis and/or an autoimmune disease is a big deal. When you're told that so much is genetic, there's the huge guilt if your kid were to get what you have. This was not something that we took lightly. Pros: We both wanted to have kids and there's not much research to show the hereditary aspects of my autoimmune disease (JIA), neither of us have any relatives with autoimmune diseases, and there are much better options now for kids who get JIA compared to when I got it (hot baths and aspirin).



Dr. Michaud presenting a research poster at the annual EULAR Meeting

In a twist of fate, I was invited to be on an expert panel working to devise recommendations on what to do with rheumatic disease treatments around joint replacement surgery. There are limited studies about this, and many surgeons ask you go off of many medications before and after surgery. The problem is, we, the patients, often suffer even more because our disease starts to flare and get worse right when we're having surgery and need to be healthy to heal. So 3 weeks before my surgery, I had access to ~20 world experts and heeded their mixed advice and worked with my rheumatologist and surgeon on my own modified and personal treatment plan. It was notable that I was kept on one

Getting pregnant while having a rheumatic disease is no small deal. Several of the DMARDs (Anti-Rheumatic Drugs) are known to be teratogenic (bad for baby!), while many others are still being studied in pregnancies. We ask in every questionnaire if you're pregnant (men, you won't get this question online). We also support the OTIS autoimmune disease in pregnancy study out of the University of California San Diego that you can read more about in this newsletter. Being the male part of this equation also has its unknowns. My doctor originally told me to go off my DMARDs for 6 months before trying to get pregnant. I was worried that going off my drugs would result in a lot more pain, possibly postponing any kids, or even hurting our marriage from me being lousy to be around. So I didn't go off my meds, and research came out a month later showing no side effects for men. **Whew!**

The wrist healing progressed well and I was told I could remove my brace whenever our baby arrived. And then it happened. Time truly stood still when my daughter was born. Zoom to the past when I was told several times that I'd never move without a wheelchair, that I wouldn't live to be middle age, and that it would all be a struggle without thought of offspring... and before me is my screaming, struggling, healthy, and most beautiful baby daughter. Such

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LATEST RESEARCH

Recently, at the Annual European League Against Rheumatism (EULAR) Meeting held June 2016, our Co-Director, Dr. Michaud, was invited to talk on “Statistics in Rheumatology Research” and NDB data was used in multiple presentations.

Here are some overviews of the research from the meeting:

Statistics in Rheumatology Research— How to Make the Best Use of It?

Dr. Kaleb Michaud spoke to a full room of EULAR attendees on understanding statistics used in Rheumatology research and how to review and understand the presented research at EULAR. He talked about a variety of statistics that trainees, clinicians, researchers, and physicians in rheumatology should understand, most notably about how the probability value (or more commonly p-value) is overused in interpreting results as significant or not.

Risk of Diabetes Mellitus Associated With Disease-Modifying Antirheumatic Drugs (DMARDs) and Statins in Rheumatoid Arthritis (RA)

We looked at 13,669 patients with RA to investigate the rate of diabetes and the impact of DMARD and statin treatments. We found that diabetes risk is generally higher (~20%) in patients with RA compared to non-RA population. After adjusting for the most important risk factors for diabetes, including weight and low exercise, we found hydroxychloroquine and abatacept to be associated with a reduced risk of diabetes and steroids and statins to be associated with an increased risk. There was no evidence of risk change from methotrexate or other synthetic or biological DMARDs. The greatest decreased risk of diabetes came from hydroxychloroquine in both high and low doses over 2 and 4-years of use, and this protection remained up to 6 months after stopping the drug.

Methotrexate Use in Rheumatoid Arthritis (RA): What 17 years and 22,621 Patients Can Teach Us

Besides steroids, methotrexate is the most commonly taken DMARD in rheumatic diseases and is often called the “anchor drug” at the conference. Following 22,621 patients with RA in the NDB, 73.5% had taken methotrexate at some time, 59.4% used it while in the NDB, and 11.4% started methotrexate before any other DMARD. Patients who were able to tolerate methotrexate when they started it, tended to use it for 6 to 12 years even while adding other DMARDs. RA patients who took methotrexate by injection (~20%) tended to have worse disease severity and higher weekly doses compared to those who took methotrexate orally.

Spotlight on Non-Profits and Organizations

We are always being asked “Where can I get help or find out information about my disease?” and we are now pleased to include in every newsletter Non-Profits or Organizations that may be of help to you.



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

MotherToBaby (<http://mothertobaby.org/>) is dedicated to providing up-to-date evidence based information on exposures during pregnancy and breastfeeding to women, healthcare providers, and the general public. Common questions that we receive are about over-the-counter or prescription medicines, alcohol and drugs, vaccines, infections, chemicals, and health conditions that a parent has.

Our service is *free* and *confidential*. You can get in touch with one of our counselors by calling 866-626-6847, texting 855-999-3525 or visiting our website to start a live chat or email-an-expert. We also provide free fact sheets (<http://mothertobaby.org/fact-sheets-parent/>) on many medications and other exposures during pregnancy and breastfeeding. We want women and their healthcare providers to have access to accurate and unbiased information so they can make the best decision for the health of both mom and baby.

In addition to providing information, MotherToBaby also studies the effects of certain medications and diseases in pregnancy through our MotherToBaby Pregnancy Studies (<http://mothertobaby.org/autoimmune-diseases/>) program. Conditions we are currently studying include rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, connective tissue disease, fibromyalgia, juvenile rheumatoid arthritis, and lupus.

Our studies never require a mother-to-be to take a medicine or do anything different from her normal routine. These studies add to the knowledge base of the effects in pregnancy of rheumatic conditions and the medications used to treat them, so we can help future moms and babies. If you are a pregnant woman living with a rheumatic condition, please consider sharing your experience with us, and help us find better answers for future moms and babies. And if you are a healthcare provider treating a pregnant woman who is living with rheumatic disease, patient referrals are welcome and appreciated!

MotherToBaby is a service of the non-profit Organization of Teratology Information Specialists (OTIS). MotherToBaby Pregnancy Studies are conducted by OTIS and coordinated by the University of California San Diego.

Ongoing Projects

University of California San Francisco (UCSF) RA and Lupus Cohorts

Ongoing collaboration efforts with Dr. Patricia Katz and UCSF have been successful in producing ongoing research with the help of the UCSF study patients continuing to participate in the NDB.

Our 6-month questionnaire has had some revisions with the help of Dr. Katz to help in testing different questions to find the best sets of items for researchers and health professionals to use in treating patients across all diseases including lupus.

International Dupuytren Data Bank (IDDB)

Progress on the International Dupuytren Data Bank



The International Dupuytren Data Bank launched in November 2015 as a collaboration between the Arthritis Research Foundation and the Dupuytren Foundation. The IDDB currently has over 1200 enrollees. Participants originate from 25 countries. The majority are from the United States, Canada, the United Kingdom and Australia.

Some of the demographics are different than prior research, which is expected for several reasons. Most reported studies are based on medical record reviews, which miss people without contracture. Contracture is not yet a problem for half of the current study enrollees. The study also includes people not under the care of a hand surgeon. Almost three quarters of enrollees found out about the IDDB online; less than one out of ten heard about the study from their doctor.

Compared to traditional studies, a higher percentage of IDDB enrollees are women—almost half. The

average age is 59, but spans from 17 to 88. On average, enrollees have lived with Dupuytren disease for 10 years.

Because Dupuytren disease behaves differently in each person, more enrollees are needed before these demographics will have much statistical certainty. It's important for the Dupuytren community (you!) to spread the word about this study and to encourage others with Dupuytren disease to enroll. The online shortcut link is easy: DupStudy.com. The first follow-up survey is about to go online to dig even deeper into the nature of Dupuytren disease.

Plans are underway for the other half of this study: finding a blood test for Dupuytren disease—a biomarker. The most promising tests are not done by standard laboratories. Some are very expensive. To keep costs down, this part of the study will be rolled out in stages as biomarkers are evaluated and the list narrowed down. More details will be released as the launch of the first stage nears.

This is all very exciting: a new era for Dupuytren research with the promise of new ways to evaluate Dupuytren disease and to speed up the process of developing preventative treatments.

As a study enrollee, your privacy is essential. Your contact information isn't shared with anyone, not even for the Dupuytren Foundation email newsletter. If you haven't received emails directly from the Dupuytren Foundation, you may be missing out on other Dupuytren related updates. Sign up now at Dupuytren.org/Newsletter.

Thanks for taking part of this important work. Because of your participation, there is hope to cure Dupuytren disease and related conditions.

Charles Eaton, MD
*Executive Director,
Dupuytren Foundation*

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a long path led to this miraculous little human. She's now only a few weeks old and still amazes me—but words can only do so much to communicate how I feel.



Our new addition to the family!

In regards to research on family, you may also recall that we announced an RA first-degree relative study from a couple years ago. Well, it's back and better than before thanks to several of you who participated. We'll be inviting some of you to participate again and for you to provide information on your biological relatives (parents, kids, and siblings) and invite from this list the adults that could also participate. It's a short questionnaire (~2 pages), and we're hoping to not only learn more about the hereditary aspects of RA (and likely other rheumatic diseases in the future), but also get blood samples from a few family members, too. This year the first ever study was launched to actually prevent RA! It's called Stop RA and it's based out of the University of Colorado with Dr. Kevin Deane. We're helping him recruit specific family members of patients with RA that have a certain biomarker that is commonly associated with getting RA in the future. It's the first test of what we hope will be more common—ways of tracking, testing, and preventing diseases like RA from ever happening!

Arthritis Internet Registry (AIR) News



AIR is a ground-breaking internet-based patient registry and biospecimen collection using the combination of the patient-study infrastructure of the NDB and the nation-wide availability of Quest Diagnostics blood collection sites. 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. We currently have had over 6,500 participants join and we have collected over 1,350 biospecimens on a variety of rheumatic diseases.

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.

Latest Research from AIR

Last year Dr. Stanley Naides had an article in our newsletter talking about Chikungunya virus infection, which causes a febrile illness with severe and painful joint symptoms. With the Zika virus and various other viruses, they can also cause severe and painful joint symptoms. Because these symptoms can continue from months to several years, we are starting to now also enroll patients with any type of viral arthritis.

With the data to be collected, along with the biospecimens, it will help provide a great data bank for researchers to help in preventing or shortening the severe and painful joint symptoms caused by these

viruses. If you know anyone that may have been diagnosed with Chikungunya, Zika, or another viral illness that caused severe and painful joint symptoms, please invite them to join to help with the research.

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

Kaleb Michaud, PhD
NDB and the University of Nebraska Medical Center

Peter Gregersen, MD
The Feinstein Institute for Medical Research

Stanley J. Naides, MD
Quest Diagnostics Nichols Institute

NDB Questionnaires & Primary Diagnosis

We have revised the name of our main questionnaire from "RA/Fib" to "Rheumatic Diseases" and thank those participants for commenting on the questionnaires over the years "Why did I get a questionnaire for RA/Fib, but my diagnosis is Psoriatic Arthritis (or another diagnosis)? As you may see on the cover of the paper questionnaires that are mailed out, it states a diagnosis on the cover, i.e. Rheumatic Diseases, OA, Lupus and Gout. But over the years, as the NDB has been able to work with experts in other diagnoses, we have added on other questionnaires geared to ask more specific questions for certain diagnoses. We wish we could have a questionnaire for each and every diagnosis, and might in the future, but currently we have the following questionnaires:

- **OA** is sent to people with osteoarthritis and asks the majority of the questions in the Rheumatic Diseases questionnaire and an extra set of questions that are used by rheumatologist's to help with OA patient care.
- **Lupus** is sent to people with lupus and includes some of the questions in the Rheumatic Diseases questionnaire, but also has many questions specifically about Lupus.
- **Gout** is sent to people with gout. Dr. Ted Mikuls and other researchers at the University of Nebraska Medical Center have helped to design this shorter and unique questionnaire specifically for patients with gout.
- **Rheumatic Diseases** is sent to all RA, fibromyalgia and other

diagnoses not listed above (i.e. psoriatic arthritis, ankylosing spondylitis, lower back pain, polyarthralgia, etc.). This questionnaire asks the questions that will help aid the researchers to see the entire view of how these diseases affect peoples' lives.

This is the reason we ask on the enrollment forms for your primary diagnosis, so we can make sure that we are sending you the correct questionnaire that will ask you the questions that would best reflect how your disease is affecting your life. Please let us know at any time if your primary disease changes or if you have any questions about this by emailing us at webquest@ndb.org or calling us at 1-800-323-5871.

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, in helping with 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.

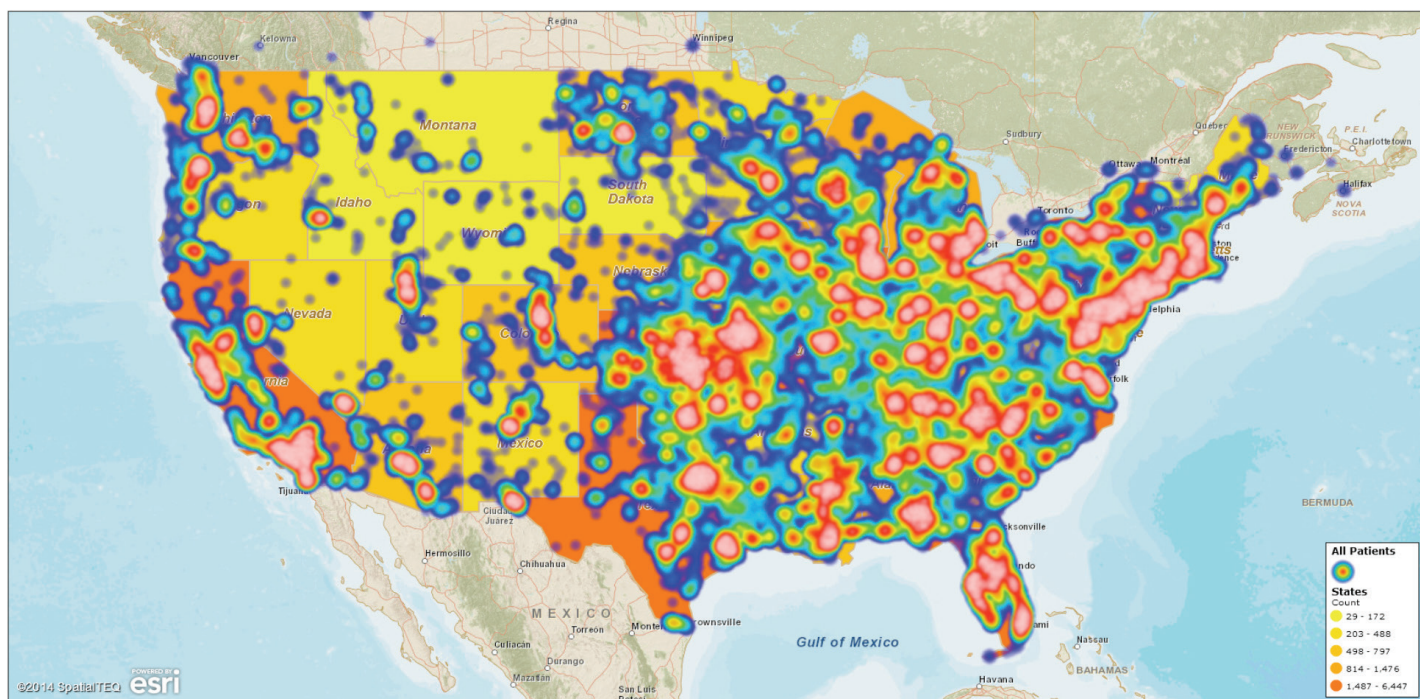
NDB Participants on the Map

Participants who have set up an account on our website will be able to see 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.ndb.org/user/register>



Reminders

While working on your questionnaire, if you have ANY questions about the questionnaire, please contact us right away by email (webquest@ndb.org) or phone (1-800-323-5871). These might be about technical difficulties or how to interpret a question. If you put your immediate questions in the comments section of the questionnaire we probably won't see it in time to answer.

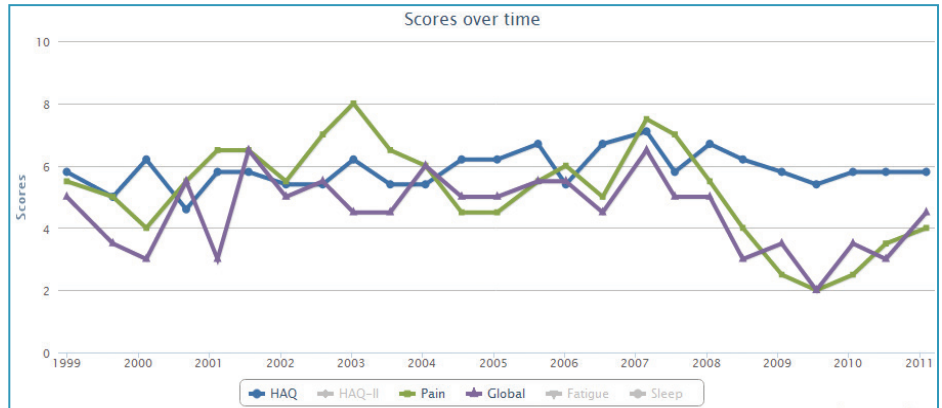
Please use the comments section for any information you think we should have that isn't covered in the questionnaire. This could be about a change in medication that needs explanation or information about other considerations of your condition that you think we need to know. You may also ask general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



WAIT! Do Not Throw This Survey Away!

We want your voice to be heard and the only way we can do this is with your help in filling out our questionnaires. We understand they may be overly long or repetitive for some, and so we want to hear from you on what we can do to improve your participation with us. We are a non-profit research organization with a staff of 16 that combines the experiences of thousands of patients over time for use by rheumatologists, nurses, immunologists, epidemiologists, and even health economists. We are the ONLY longitudinal research study that asks the level of detailed questions we have with so many people with rheumatic diseases, and we do this with a relatively small amount of grant funding. So before you decide to not participate, please let us know what we can do either by phone, email, or mail. We want to hear from you as we are passionate about helping fight these diseases and truly make a difference!

— 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: <https://www.ndb.org/user/register> Having an account keeps your information private 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@ndb.org if you have any questions about the website or your scores.

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 others 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@ndb.org or 800-323-5871 ext. 133. Thank you!

Prize Drawing Winners!

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

Our prize 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 prize drawing winners from the last questionnaire were:

Rosetta T., Nancy S., Christina S., Richard P., Anna H., Diane O., Carolyn M., and one other from across the 50 states. Congratulations to all!

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 Betty Pew by email at betty@ndb.org or by phone at 1-800-323-5871 ext. 143.



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

Join Us on Facebook & Twitter



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.



You can find us on Twitter as “@ndb_org”. We have added this for those that may be on Twitter but not on Facebook and we will be tweeting news items.



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

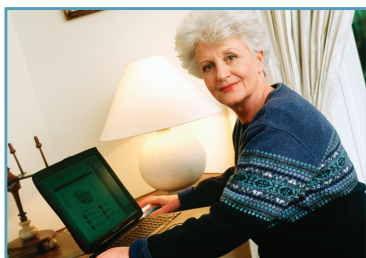
study. Go to <https://www.ndb.org/participate/tell-friend>

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.

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@ndb.org. This will ensure that our mail makes it through the spam blockers, and ends up in your Inbox and not your Spam or Junk folder. You will need to do this every time you change your email address.

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 email or call us. Thank you!



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 or Rebecca@ndb.org.

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

FOR MORE INFORMATION OR TO PARTICIPATE

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