Research Subject Information and Consent Form

Study Title:	Cross-sectional Observational Study Evaluating Clinical Specialty Setting as Determinant of Management in Patients with Psoriatic Arthritis
Study #:	H15-457
Sponsor:	AbbVie
Study Doctor:	Barry E. Shibuya MD
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Telephone Number:	(510) 791-1300
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California participants: Before you read this consent form, you should read and sign a copy of the California Experimental Subject's Bill of Rights. Ask the study staff for a copy of this document if you haven't already received one.

Before you can make an informed decision to participate in this research study, you should understand the possible risks and benefits of this study. This process is known as informed consent. Quorum Review IRB has approved the information in this consent and has given approval for the study doctor to do the study. An Institutional Review Board (IRB) is an independent committee made up of a group of independent experts and lay persons set up to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. It also does not mean the study is without risk. This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family, friends or anyone you choose before making your decision. If you decide to participate in this study, you will be asked to read and sign this consent form to confirm that you have had the study explained to you, and you have agreed to participate. You will receive a copy of the signed consent form.

Introduction

You have been asked to participate in this research study because you have either been diagnosed in the past with Psoriatic Arthritis (PsA), suspected to have PsA or newly diagnosed with PsA. AbbVie is the sponsor of this study. AbbVie is paying the study doctor to perform this study.

Being in this study does not replace your regular medical care.

Purpose of the Study

The purpose of this study is to evaluate the role of different physician specialties (Rheumatologist, Dermatologist, and Primary Care Physician) in the management of PsA.

Study Information

This study is being conducted at approximately 60 research centers in the US. Approximately 1040 patients with suspected or newly diagnosed PsA or PsA diagnosed in the past will participate in this study.

Your participation in this study will consist of 2 study visits. To ensure an accurate and complete evaluation of your disease, the research centers will cooperate in the study organized in dual units, meaning you will have one visit at a Rheumatology research center and one visit at a Dermatology research center. It is important to note that the Rheumatology study doctor and Dermatology study doctor may be located in different research centers. Your participation in the study will last approximately 6 weeks but could be longer depending on the time to complete PsA diagnostic testing and the availability of the study doctor for the second visit.

Procedures

Study Procedures

If you agree to be in this study, you will undergo the procedures and evaluations listed below over two separate visits.

Enrolling Visit (completed by either the Rheumatology research center or Dermatology research center) includes:

- Review and sign Informed consent (this form)
- Collect personal information, such as your name, year of birth, ethnicity, race, occupation, and educational level.
- Medical and surgical history (including PsA and Psoriasis history and treatments received for Psoriasis/PsA)
- Height and weight
- Blood pressure
- You will complete questionnaires about your well-being and the effect your condition has on your general health.

Additionally if you are enrolled by the Rheumatology research center or your second visit is with the Rheumatology center, you will undergo the following procedures/evaluations:

- Specific joints will be assessed for tenderness and swelling.
- Confirmation of your diagnosis of PsA
- Body surface area to measure the amount of area on the skin that has psoriasis
- Finger and toe assessments to count the number that are completely swollen
- Assessment for tenderness around the elbows, knees and ankles

Additionally if you are enrolled by the Dermatology research center or your second visit is with the Dermatology center, you will undergo the following procedures/evaluations:

- Your skin will be assessed for lesions through a Psoriasis Area Severity Index which will include an evaluation of your skin in four areas: head, arm, lower body, and legs. Each area will be examined for redness, thickness and scaling.
- Nails will be assessed for discoloration, dimples, and separation from the nail bed
- Body surface area to measure the amount of area on the skin that has psoriasis

Subject Responsibilities

In order for this study to provide good information, you will be expected to do the following:

- Follow the instructions of your study doctor. Come to your scheduled study visits and procedures.
- Fill out your health-based questionnaires completely and honestly. You will be given up to 6 different questionnaires during the study.
- Tell the study staff if you wish to stop being in the study.

If you have questions about your participation in this study or if you have any concerns or complaints about your participation in this study, contact the study doctor at the phone numbers listed on Page 1 of this Informed Consent Form.

If you have questions concerning your rights as a research subject, if you are not able to resolve your concerns with the study doctor or study staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you may contact Quorum Review or visit the Quorum Review website at www.quorumreview.com.

Quorum Review is located in Seattle, Washington.
Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.
Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

Risks and Discomforts

There are no physical risks associated with participating in this study. This study is intended to assess your disease and the management of it.

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

Costs

Some of the study's procedures are being performed only for study purposes and others may be performed even if you are not in the study. You will not be charged for procedures that are only being done for the study.

If you are suspected of having PsA or if you have been diagnosed with PsA in the past, the Rheumatology study doctor or the Dermatology study doctor may need to perform tests to

initially diagnose or confirm the diagnosis of PsA. These tests may include for example an x-ray (a picture scan of your bones), ultrasound (a scan of the inside of a section of your body), blood draw and/or skin biopsy. These procedures are not included as part of the study. As a result, if you need these tests, you will be billed for the cost of the tests (for example, you will have to pay the co-payments required by your insurance company or the out-of-pocket expenses that your insurance company would not cover). Before performing these tests, the study doctor will inform you if these tests are necessary.

Before you agree to be in this study, it is very important that you talk with the study doctor so you understand the potential cost for any necessary tests and with your health care payer/insurance company to see if your plan will cover these costs. It is also important that you understand that you are not required to undergo any testing, and you may withdraw your consent to participate in this study at any time and for any reason including if you feel that the costs will be unacceptable.

Patient Reimbursement of Travel Expenses

You will get a total of up to $78 if you finish the whole study. If you do not finish the whole study, you will get $78 for each study visit you finish. The study doctor or study staff can tell you more about when you will get paid.

In addition to payment for being in the study, you will be reimbursed for travel expenses for the study doctor's visit that you would not normally attend but for your participation in the trial. This means you will not receive reimbursement for travel and parking costs at your initial study doctor's visit (whether your doctor is a Rheumatologist or a Dermatologist) because this is part of your regular medical care. You will get a total of up to $50 for travel and parking costs if you finish the visit to the second, corresponding study doctor. Reimbursement will be paid at the end of that visit. The study doctor or study staff can tell you more about when you will be reimbursed for travel and parking costs.

Benefits

The information that is obtained during this study may be useful scientifically and thus be helpful to others with the same condition in the future. You may receive direct medical benefit from being in this study.

Alternatives to Participation

This study does not provide treatment for your condition. There will be no treatment provided for your participation in the study. In addition, you may discuss your options with your regular health care provider.

New Information

You will be informed in writing in a timely manner and will be asked to sign a new (revised) informed consent if new information that could affect your willingness to continue participation in this study becomes available.

Withdrawal/Voluntary Participation

Participation in this study is voluntary. You can stop participating in the study at any time. If you decide not to participate in the study or to withdraw from the study, the quality of your medical care or any benefits to which you are otherwise entitled will not be affected and there will be no penalty to you. Either of your study doctors may also end your participation in the study if he/she believes that it is in your best interest or if you are unable to follow the requirements of the study. In addition, AbbVie may end your participation in the study at any time without your consent. If you withdraw from the study for any reason, you should tell the study staff but will not need to return to the site for a final evaluation. If you leave the study, the study doctor and study staff will still be able to use your information that they have already collected.

What if I work for the study center? What if I am a family member of someone who works for the study center?

Study center employees and their family members do not have to be in this study. No one should influence or pressure you to be in this study. An employee's or his/her family member's decision to be in the study, or to leave the study early, will not affect the employee's job or job benefits.

Confidentiality

Data We Collect from You:

Your personal health information from your original medical records and all data resulting from your participation in this research will be collected during the course of this study. Your personal health information could include information pertinent to the diagnosis of PsA (e.g., blood testing, x-rays or other medical procedures). The Rheumatology study doctor or the Dermatology study doctor may ask you to sign a separate authorization to obtain some or all of your original medical records. You should understand that if you enroll under a Dermatology research center and have been diagnosed in the past with PsA, in order to participate in the study, you must sign a separate authorization to obtain some or all of your original medical records. The medical records will be provided to the Rheumatology study doctor to review and confirm the PsA diagnosis.

In addition, in order to participate in the study, you must agree to the sharing of your personal health information, including your study records, between the Rheumatology study doctor and Dermatology study doctor.

How Your Data Will Appear:

Your identity and contact details will not be disclosed except as described in this form, unless required by law. Rather, your identity and contact details will be replaced by a code, such as a number.

Why We Collect this Data:

Your personal health information will be used for clinical research purposes only. It may also be used in study reports or for scientific presentations, but in a way that will not identify you by name. Your personal health information will be kept confidential and, unless required by law, will not be made publicly available. After this study has been completed, it is possible that your coded health information will be used for future research concerning Psoriatic Arthritis or other arthritic diseases.

Who Will See Your Data:

The only people with access to your personal health information in identifiable form will be the Rheumatologist study doctor and the Dermatologist study doctor, personnel helping the study doctors conduct the study at the facilities, sponsor representatives who are checking that the study is conducted properly, IRB and regulatory authorities where required by law.

You may not participate in this study unless you give your permission to use and disclose your personal health information. By signing this document you are allowing the study doctors and personnel at the facilities to permit AbbVie and others described in this form to have access to your personal health information for the purpose of collecting data, verifying the data is correct, and checking that the study is conducted properly.

In order to complete the research, AbbVie, the study doctors and personnel at the facilities, Quorum Review and domestic and foreign regulatory

authorities responsible for overseeing research studies (including the US Food and Drug Administration [FDA], US Department of Health and Human Services, and/or equivalent government agencies in other countries) will have access to your coded health information.

Additionally, your personal health information may no longer be protected by HIPAA (Health Insurance Portability and Accountability Act) once it is disclosed to AbbVie and others as described in this form by the study doctors. However, AbbVie will take reasonable measures to keep your personal health information confidential. However, absolute confidentiality cannot be guaranteed. Your HIPAA authorization will expire 50 years from the date you sign it unless you revoke (cancel or withdraw) it sooner, since information collected for research purposes continues to be analyzed for many years. If the results of the study are published your identity will remain confidential.

Taking Back Your Permission to Use or Disclose Your Personal Health Information:

To take back your permission to use or disclose your personal health information you must write to the study doctor at the address listed on Page 1 of this consent form. If you do this, you will no longer be allowed to be in this study. Any information that has already been collected at the time you take back your permission will be kept and, where the law allows, your personal health information, will continue to be used by the study doctors or AbbVie or other parties involved with the study.

Rights to Your Data:

You may have the right to access, correct and make a copy of your medical and/or clinical study records as allowed by applicable privacy laws. You may ask to see your records by requesting such records from the study doctor(s) or the facility(ies) where the study is being conducted. However, to ensure the valid results of the study, you agree that you may not be able to review or make a copy of some of your records related to the study until after the study has been completed.

When you sign this document, you agree to the access, collection, processing and transfer of your personal health information as described in this informed consent document. If you do not sign this form, you cannot be in the study.

Signature of Participant _____ Date _____

Consent

I have read and understand this consent form and its contents were explained. My questions have been answered to my satisfaction. I consent voluntarily to participate in this research study and I will receive a signed and dated copy of this consent form for my records.

By signing this consent form, I am not giving up any of my legal rights.

By signing this informed consent form, I am authorizing access, use and transfer of my personal data as described in this informed consent.

Name of Subject (Printed) _____

Signature of Subject _____ Date _____

I attest that the subject named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

Name of Person Conducting Informed Consent Discussion
(Printed)

Signature of Person Conducting Informed Consent Discussion

Date