

RA-BRANCH

RA-BRANCH Feasibility Survey

Privacy Statement

* 1. What is the name of your institution/practice?

* 2. Name of person completing the survey

First and Last Name:

Title (Physician, Nurse, Study Coordinator, Office Manager, Research Manager etc.):

* 3. This survey is to be considered confidential, the information it contains is the property of Eli Lilly and Company ("Lilly") and HealthCore and must not be disclosed or used except as authorized in writing by Lilly and HealthCore. By accepting the terms of this agreement, you agree to maintain the material presented in complete confidentiality.

Please note by accepting these terms, you are indicating you are the person to whom the original correspondence was addressed or are acting as his or her representative.

The information you provide in the survey WILL REMAIN CONFIDENTIAL. Only those researchers associated with the study will have access to the information you provide. Your name and associated information will not be shared with anyone outside of the research teams and study sponsor.

I accept the terms of this agreement.

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PART 1. CONTACT INFORMATION

* 4. Please provide the Physician's/Principal Investigator's contact information:

First and Last Name:

Medical Degree and
Medical Specialty(ies):

Mailing Address/Street:

City:

State:

Zip code:

Office Phone Number:

Fax Number:

Cell Phone Number:

Email Address:

* 5. Please provide the contact information of the person who will assist with the study (e.g.: Study Coordinator/Nurse):

First and Last Name:

Degree or Title:

Phone Number:

Email Address:

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PART 2. PATIENT POPULATION

* 6. Estimated Patient Populations

Number of adult patients diagnosed with moderate to severe Rheumatoid Arthritis (RA):

Number of adult RA patients that have had an inadequate response or intolerance to a DMARD:

Number of these patients who are suitable to receive a targeted therapy (i.e. TNF/JAK inhibitor):

Number of these patients that have commercial insurance coverage:

* 7. Do you foresee any significant challenges/restrictions to recruitment for this RA study at your practice based on the eligibility criteria included in the study protocol synopsis?

No

Yes. (if YES, please specify below:)

* 8. Based on the eligibility criteria, how many patients do you estimate enrolling in this study per month?

Number of patients you estimate enrolling monthly:

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PART 3. EXPERIENCE

* 9. How many years of clinical trial experience does the Physician/Investigator have?

Number of years:

* 10. How many industry-sponsored clinical trials has the Physician/Investigator conducted in the last 5 years?

Number of clinical trials in
the last 5 years:

11. How many **actively enrolling** studies is the physician participating in?

* 12. About what percentage of the physician's time is spent on research activities?

* 13. How much time do you anticipate spending on this study per week?

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0-5 hours per week

5-10 hours per week

More than 10 hours per week

PI Time

SC Time

Other Staff Time

* 14. Does the Physician/Investigator have experience working on clinical trials with Lilly?

No

Yes (Please list the clinical trials the Physician/Investigator has worked with Lilly)

*15. Does your practice have experience conducting clinical trials in compliance with International Conference on Harmonisation (ICH) / Good Clinical Practice (GCP) Guidelines?

Yes

No

PART 4. REGULATORY

* 16. How many weeks are required for contract/budget to be finalized?

- 1-2 Weeks
- 3-4 weeks
- 6-8 weeks
- I'm not sure / Other (If selected, please clarify below)

* 17. Can your practice use Advarra (formerly Quorum) central Institutional Review Board?

- Yes, we can use a Advarra IRB
- No, we can only use our site's Local IRB
- We can use Advarra IRB with Local IRB's agreement
- Don't know

* 18. Is it possible to conduct IRB review in parallel with budget and contracting activities?

- Yes
- No
- Don't Know

* 19. Have you ever been audited by the FDA?

- Yes, but we were not cited
- Yes, Voluntary action indicated (VAI)
- Yes, we were issued an FDA Form 483
- No
- Other, (please specify):

* 20. Are there other questions, concerns, or issues that have not been addressed in this questionnaire?

Please return completed questionnaire to HealthCore via email or fax.
RA-BRANCH@healthcore.com; 855-847-4560

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