<u>COVER PAGE</u>

TITLE: <u>S</u>upporting <u>P</u>atient Care with <u>E</u>lectronic <u>R</u>esources in the United States (<u>SuPER-US</u>): Effectiveness of an Online Decision Aid for Patients Considering Biologic Therapy for Rheumatoid Arthritis

GRANT REQUEST ID: 17924525

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ABSTRACT

The proposed project aims **to improve rheumatoid arthritis (RA) care by advancing the process of making informed treatment decisions for biologics by RA patients with a shared decision-making approach through the use of online patient decision aids.** Patients who have used decision aids are more knowledgeable in general about the treatment (**through education** about the evidence and potential preference factors associated with available options), have more realistic expectations, and feel less conflicted with their decisions. Furthermore, decision aid use can lead to decisions that are 'right for them' and could eventually lead to improved medication adherence and RA outcome. The purpose of the **Supporting Patient Care with Electronic Resources in the United States (SuPER-US)** project is two-fold. First, we will evaluate the efficacy of an adapted version of the Animated, Self-serve, Web-based Research tool (ANSWER)-2 decision aid for biologics (developed by our Canadian Collaborators) among RA patients in the US (called the **US-ANSWER-2 decision aid**) in a randomized controlled trial (RCT). Second, we will develop an implementation strategy for US-ANSWER-2 through a collaboration with the Arthritis Foundation, as well as rheumatologist and patient communities. Central to this research is **engaging RA patients (i.e, our target population) throughout the research process** (from the initial planning and data collection steps to the interpretation and dissemination of findings) **to fully take into account the spectrum of consumer value-sensitive information**. Our anticipated findings and final decision aid tool can be **readily disseminated and implemented in different settings and facilities with various levels of resources.**

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RESPONSE TO REVIEWER COMMENTS

We thank the reviewers for their thoughtful comments on our letter of intent. To accommodate the page limit, please note that only comments requiring a response are included below.

Specific recommendations for your consideration

Portability: Please see our replies to **ERPM#4** below, which addresses the same issue.

Educational portion of this intervention: Our decision aid helps patients to make treatment decisions by educating them about the various treatment options and guiding them through the consideration of preference-sensitive evidence (e.g., benefits and risks, pros and cons of mode of administration). This will create a natural opportunity for the practice of "right" decision making and feedback through the ensuing discussions with care providers.

ERPM#3: Potentially different barriers to decision in the US versus Canada and Comments on the quality/simplicity of the educational instrument.

Reply: We agree. For example, barriers related to health care delivery and the insurance system are different between the US and Canada. As described in our letter of intent and Section 2.2.2 of this proposal, our patient decision aid (US-ANSWER-2) will be adapted specifically to the US health care setting based on rigorous criteria outlined in the International Patient Decision Aid Standards, which will ensure the quality and simplicity of our instrument.[1] The average completion time of ANSWER-2 is only 20 minutes, and a single page summary is produced (see **Appendix 1**) at the end of the session to help guide discussions with physicians.

ERPM#4: 'Institution specific needs assessment information' and more details on the study design, specifically its implementation to understand it's transferability to other settings.

Reply: The decision aid will be adapted so that it can be used by patients regardless of their place of residence in the US (i.e., different states). Obviously, presented information that pertains to biological effects (including the probabilities of benefits and side effects) will be universally applicable regardless of location, and these data are evidence-based from a recent Cochrane review and clinical practice recommendations. The only expected difference between different states is their insurance coverage of biologics. The US-ANSWER-2 decision aid will provide information about financial assistance programs for each of the biologic manufacturers in each individual state. We will also include a list of questions that patients can use to ask their insurance company about coverage for biologics.

ERPM#5: Request for details about the target audience and further development of dissemination and expansion of the project outcomes and interventional decision aid.

Reply: Our target audience is adult RA patients who are facing the decision to either initiate a biologic or switch to another biologic for anti-rheumatic treatment. The goal of the patient decision aid is to improve patients' decision quality; as such, our primary outcome measure is decisional conflict. Secondary outcomes include medication knowledge and self-efficacy. Other RA-related parameters are not relevant, as this study is designed to intervene at the point of decision for treatment; thus, we do not expect changes in RA disease activity measures soon after using a patient decision aid. RA patients currently faced with the decisions outlined above are eligible for inclusion into our study. Finally, with regard to the request to further develop the *dissemination and expansion of our project outcomes and interventional decision aid*, we have described our plan to construct an '**implementation toolkit**' to facilitate the use of the US-ANSWER-2 in rheumatology practices (**Section 2.2.4**) as well as our comprehensive plan for knowledge translation to the community (**Section 2.3.4**).

1.0 OVERALL GOAL & OBJECTIVES

The central goal of the project is to improve the management of rheumatoid arthritis (RA) by advancing the process of making informed treatment decisions by RA patients with a shared decision-making approach through the use of patient decision aids. Patients who have used decision aids are more knowledgeable about the treatment, have more realistic expectations, and feel less conflicted with their decisions compared to those in usual care.[2] Also, **decision aid users are more likely to reach a decision that is 'right for them',[2,3] eventually leading to improved medication adherence and outcomes.**

Few patient decision aids are available for patients with RA.[3] A common limitation of existing patient decision aids has been the lack of user-friendliness, which likely has contributed to poor uptake of this type of tool in patient care.[4] To address this issue, Arthritis Research Canada (ARC) investigators have successfully developed a patient decision aid called the Animated, Self-serve, Web-based Research tool (ANSWER) for patients considering methotrexate for RA.[5] ANSWER aimed to provide evidence-based information on the benefits and risks of methotrexate for RA and **to guide users through deciding whether this treatment is 'right for them' based on the provided information (i.e., the evidence) and their personal preferences.**[5] Central to this research was **engaging patients throughout the research process** (from the initial planning and data collection steps to the interpretation and dissemination of findings) **to fully take into account the spectrum of consumer value-sensitive information**. Evaluation of this tool showed that patients' decisional conflict and knowledge improved after using the ANSWER decision aid. Building upon the ANSWER experience, the same team of ARC investigators have recently developed another online decision aid, this time for those considering biologics (called **ANSWER-2**), and the tool has passed usability testing in a Canadian context. **No similar decision aids are currently available in the United States; in particular, none have been developed with consideration of the consumer perspective and the United States healthcare delivery system.**

The purpose of the **Supporting Patient Care with Electronic Resources in the United States (SuPER-US)** project is two-fold. First, we will **evaluate the effectiveness of an adapted version of ANSWER-2 for patients in the United States (US-ANSWER-2)**. Second, we will develop a US-ANSWER-2 **implementation strategy** through a collaboration with the Arthritis Foundation, as well as clinical and patient communities. Central to this research is our focus to engage patients throughout the research process, from the initial planning and data collection stages to the interpretation and dissemination of findings. The proposed study will employ state-of-the-art methods to adapt the US-ANSWER-2, evaluate its efficacy in a randomized controlled trial (RCT), and aim to develop a comprehensive implementation strategy involving both RA patients and rheumatologists. Our specific objectives are:

Objective 1. To **adapt the ANSWER-2 decision aid** to suit the US health care setting (i.e., **US-ANSWER-2**) and to assess the usability of this adapted decision aid for RA patients who are considering biologics or a switch to a different biologic. Of note, this objective will be conducted during the prefunding period prior to the beginning of the current project's funding period (see

Section 3.2) and will be funded by available non-industry sources to avoid a perceived conflict of interest.

Objective 2. To evaluate the **efficacy** of the US-ANSWER-2 decision aid in **reducing patients' decisional conflict** (i.e., the feeling of being uncertain, uninformed, unclear about values, and unsupported in decision-making).

Objective 3. To assess the extent to which the US-ANSWER-2 decision aid improves **patients' knowledge** about RA medications and their communication with health professionals.

Objective 4. To develop an '**implementation toolkit**' to facilitate the use of the US-ANSWER-2 decision aid in rheumatology practices.

Relevance to the Specific Intent of this RFP: Our research proposal includes the following attributes that are relevant to the Current FRP as below.

1. We propose to **improve the management of patients with RA** by employing evidence-and preference-based, user-friendly patient decision aids, as reflected in the title of our proposal "**Supporting Patient Care with Electronic Resources in the United States (SuPER-US)**". This approach holds great promise to lead to decisions that are 'right' for individual patients, eventually leading to improved medication adherence and RA outcomes.

2. Our decision aid to **improve RA patient care** has a clear **educational component,** as it helps patients to make treatment decisions by educating them about the various treatment options and guiding them through the consideration of preference-sensitive evidence (e.g., benefits and risks, pros and cons of mode of administration). This will create a natural opportunity for the practice of "right" decision making and feedback through the ensuing discussions with care providers. This may in turn lead to **future opportunities to make impactful system-wide changes to improve RA patient care**.

3. Our anticipated research findings and final decision aid are expected to be **readily disseminated and implemented in facilities with various levels of resources (including those with limited resources)**, as the decision aid will be used via the internet in their home or via other available computers over a span of approximately 20 minutes. To that effect, **our approach is largely free from the constraints of specific institutions, practices, or settings,** and the decision aid can be used by patients regardless of location and health care system.

Significance and Implications: Risk and uncertainty are ubiquitous in health care, including RA care; choosing an optimal biologic among many choices at a given stage of RA care has become a challenging task for both rheumatologists and RA patients alike. This treatment decision has both benefits and consequences, and involves certain levels of uncertainty and trade-offs. To that effect, a considerable gap exists in the communication and education of available evidence and different preference factors relevant to this key decision-making process in RA care. The **SuPER-US** study will directly address this unmet need by developing a state-of-the-art, patient-centered, and friendly decision aid that suits the US health care setting. Our carefully-crafted research plan (including a randomized trial) holds the remarkable potential to strengthen our knowledge about how to optimally communicate and facilitate the effective use of patient-centered outcomes research and comparative effectiveness research findings for both RA

patients and caregivers. Should our Objectives be achieved as proposed, the expected findings will be immediately useful to improving education and care of RA patients.

2.0 TECHNICAL APPROACH

2.1 Current Assessment of Need in Target Area

The proposed project aims to improve the process of making informed treatment decisions by patients with RA. Current treatment recommendations emphasize: 1) the need for early and aggressive treatment, and 2) the use of a 'treat-to-target' approach.[6] The latter involves a process whereby treatment is escalated until a target is reached and promptly modified when the target is no longer met.[6] The target of interest is to achieve and maintain remission, or low disease activity in cases of established long-standing disease. Patients typically start with one or a combination of conventional disease-modifying anti-rheumatic drugs (DMARDs), and if the target is not met then a biologic agent is considered. **However, patients often struggle with the decision to start these medications.[7] Among those who have used RA medications, the adherence rate is as low as 30%.[8] Current evidence indicates that patients are reluctant to adhere to RA medications due to: 1) a lack of health professional advice, 2) fear of side effects, 3) preference to avoid medications, and 4) a perceived lack of need.[7] Further, patients have perceived a shortage of credible and user-friendly information about treatment options.[9]**

To help improve this suboptimal level of patient education and adherence, chronic disease management has been moving toward a **shared decision-making approach** through the use of **patient decision aids** in recent years. Patient decision aids are evidence-based tools that are designed to help individuals choose between two or more treatment options.[3,10] Patients who have used decision aids are **more knowledgeable about the treatment, have more realistic expectations**, and feel less conflicted with their decisions compared to those in usual care.[2] **Also, decision aid users are more likely to reach a decision that is 'right for them',[2] meaning a decision that is informed by evidence and is congruent with the patient's preferences. This may eventually lead to improved medication adherence and disease outcomes.**

A few patient decision aids are available for patients with RA.[3] A common shortcoming of most existing decision aids is the limited effort in ensuring consumer engagement in their development (i.e., involving RA patients in the research process),[4] likely leading to the lack of user-friendliness. This in turn may have contributed to poor uptake of this type of tool in patient care.

To address this unmet need in the field, Arthritis Research Canada (ARC) investigators (led by Linda Li, PhD [collaborator of the current proposal] and Dr. John Esdaile [Co-Investigator]) (see **Sections 4.1.3 and 4.2**) have successfully developed an RA patient decision aid called the Animated, Self-serve, Web-based Research tool (ANSWER) for patients considering methotrexate for RA (http://answer.arccanada.org/).[5,11] ANSWER aimed to provide unbiased, evidence-based information on the benefits and risks of methotrexate for RA and to guide patients through deciding whether this is the "right" treatment for them based on the provided

information (i.e., the evidence) and their personal preferences.[5] Evaluation of this tool showed that patients' decisional conflict and knowledge improved after using the ANSWER decision aid. Interview findings further highlighted the power of patients' prior knowledge and experiences with RA on how they approach the information presented in a decision aid.[5]

Currently, there are no patient decision aids <u>on biologics</u> that take into account the full spectrum of consumer value-sensitive information by meaningfully involving RA patients in the development process (i.e., engaging patients throughout the research process). While evidence-based expected benefits and adverse profiles of individual biologic options should play a key role in the choice of biologics, other factors may considerably influence a patient's decision, particularly when risk benefit ratios are similar. For example, some biologics are administered by infusion in a hospital or infusion clinic, while some can be taken orally or by injection at home (or at a physician's clinic). Individuals may have different preferences for the mode of administration, which may affect their treatment preferences**.** Furthermore, patients' financial/insurance situation as well as the health care delivery system of their location can become relevant as well. As such, **patient decision aids on biologics that incorporate the full spectrum of these preferences would be valuable to improve patient-centered RA care.**

To fill this important gap in the field, Dr. Linda Li (a collaborator of this project) and colleagues at ARC have developed <u>another online decision aid for those considering biologics</u> in Canada (called ANSWER-2) through funding from the Canadian Institutes of Health Research (CIHR Funding Reference Number: CEH-126527). To date, the ANSWER-2 tool has passed usability testing in a Canadian context. **No similar decision aids are currently available in the United States; in particular, none have been developed with consideration of the United States healthcare delivery system.**

The purpose of the **Supporting Patient Care with Electronic Resources in the United States (SuPER-US)** project is two-fold. First, we will evaluate the effectiveness of an adapted version of the ANSWER-2 decision aid for patients in the US (called the **US-ANSWER-2 decision aid**). Second, we will develop a US-ANSWER-2 implementation strategy through a collaboration with the Arthritis Foundation, as well as clinical and patient communities (see attached Letters of Support). **Central to this research is our focus to engage patients throughout the research process, from the initial planning and data collection stages to the interpretation and dissemination of findings.** The proposed study will use state-of-the-art methods to adapt the US-ANSWER-2 decision aid, evaluate its efficacy in a randomized controlled trial (RCT), and aim to develop a comprehensive implementation strategy involving both RA patients and rheumatologists. In this proposal, we aim to evaluate a modified version of ANSWER-2 adapted to the US health care setting (i.e., **US-ANSWER-2**). The detailed project plan is described below.

2.2 Project Design and Methods

2.2.1 Overview

We propose to leverage our team's experience and expertise on **patient decision aid research** as well as a well-established RA clinical research setting (Massachusetts General Hospital and Brigham and Women's Hospital) to evaluate the US-ANSWER-2 decision aid and develop an implementation strategy in the US. First, we will adapt the US-ANSWER-2 decision aid (based on the original Canadian version) to suit the US healthcare setting and carry out usability testing of the adapted decision aid. This will be followed by an RCT to evaluate its efficacy among RA patients in the US. Finally, we will develop an 'implementation toolkit' to facilitate the use of this decision aid in rheumatology practices. Of note, our first objective (i.e., the adaptation and usability testing of US-ANSWER-2; see **Section 1.0 Objectives**) will be funded by available non-industry sources to avoid a perceived conflict of interest, as was done in the original development of ANSWER and ANSWER-2 in Canada.

Our target audience is comprised of patients who have been recommended by their rheumatologists to consider adding or switching to one of the available biologic agents. These include TNF inhibitors: infliximab, etanercept, adalimumab, certolizumab, golimumab; interleukin (IL)-1 antagonists: anakinra; IL-6 antagonists: tocilizumab; anti-CD28 drugs: abatacept; and anti-B cell drugs: rituximab; and a biologic alternative JAK inhibitor: tofacitinib. We aim to aid patients making the following 2 decisions: 1) adding/switching to biologic therapy as prescribed vs. continuing the current DMARD/biologic therapy, and if the patient chooses the former, then 2) taking the prescribed biologic agent vs. considering other options by discussing them with the physician. **We will present information from the recent Cochrane review[12] and clinical practice recommendations in a patient-friendly manner,[13] including the probability for favourable clinical outcomes and side effects. In addition, information that is important to patients (such as mode of administration and cost) will also be presented**.

To achieve our project goal, we have assembled an experienced and committed team of investigators with expertise in clinical research, decision aid development, qualitative research, and RCTs. The Principal Investigator (**Hyon K. Choi, MD, DrPH**, a leading rheumatologist and clinical epidemiologist with NIH grant support) has been the Principal Investigator of several studies of RA and many other rheumatic diseases, and has published extensively (including the papers in *NEJM, JAMA, Lancet, Nature, Nature Gen, Ann Int Med, BMJ, Circulation, Arch Int Med, Am J Med, Ann Rheum Dis, A&R,* and others). **John Esdaile, MD, MPH, FRCPC** (Co-Investigator), a rheumatologist-investigator specializing in RCTs in the context of rheumatic conditions, was closely involved in the development of ANSWER and its evaluation trial.[5] **Linda Li, PT, PhD** (Collaborator, see attached Letter of Support) was the Principal Investigator of both ANSWER and ANSWER-2 (both developed in Canada) and has unique expertise in patient decision aid science in rheumatic conditions. **Nancy Shadick, MD, MPH** (Collaborator, see attached Letter of Support), a rheumatologist-investigator, has served as the lead investigator of various RA projects (including RA education trials) and is the Principal Investigator of the Brigham and Women's Rheumatoid Arthritis Sequential Study. Thus, our team's collective

expertise and extensive experience in clinical research, decision aid development, qualitative research, and RCTs will ensure successful execution of the project and timely dissemination of findings.

2.2.2 Adaptation and Usability Testing of US-ANSWER-2 (Objective 1)

The US-ANSWER-2 will be adapted to the US health care setting based on the original ANSWER-2 decision aid, which was developed by employing **rigorous criteria outlined in the International Patient Decision Aid Standards**[1] and **the current best practice in developing online patient decision aids to ensure quality and practicality.**[14] As stated above, ANSWER-2 was developed at Arthritis Research Canada under the leadership of Dr. Linda Li (Collaborator of the current grant) and Dr. John Esdaile (Co-Investigator) to aid patients making the following two decisions: 1) adding/switching to biologic therapy as prescribed vs. continuing the current DMARD/biologic therapy, and if the patient chooses the former, then 2) taking the prescribed biologic agent vs. considering other options by discussing them with the physician. Prior to field testing, usability tests were conducted with RA patients who were considering biologic therapy to ensure user-friendliness of the ANSWER-2 prototype. Our investigators used the concurrent think-aloud method,[15] whereby participants were asked to verbalize their thoughts while using ANSWER-2. Sessions were audiotaped and field notes taken. At the end of the session, participants completed the System Usability Scale.[16,17] A content analysis was conducted to understand the user experience. Our investigators used an iterative testing protocol, whereby they: 1) conducted onsite testing with participants to identify usability issues with the prototype, 2) kept testing and modifying the prototype until no new issues were identified, and 3) repeated testing with the modified version. The testing continued until no usability issues were identified. Currently, ANSWER-2 has passed usability testing among Canadian patients.

In terms of **simplicity and practicality** of use, the average completion time of ANSWER-2 is 20 minutes, and a single page summary is produced (see **Appendix 1**) at the end of the session to help patients' ensuing discussions with their physicians.

The US-ANSWER-2 decision aid will be adapted from the original ANSWER-2 so that it can be used by patients regardless of their place of residence in the US (i.e., different states). Obviously, presented information that pertains to biological effects (including the probabilities of benefits and side effects) will be universally applicable regardless of location and health care system, and these data are evidence-based from a recent Cochrane review and clinical practice recommendations. The only expected difference between states is their insurance coverage of biologics. The US-ANSWER-2 decision aid will provide information about financial assistance programs for each of the biologic manufacturers in each state. We will additionally include a list of questions that patients can use to ask their insurance company about coverage for biologics. Although we fully expect the same level of usability in the US-ANSWER-2 decision aid given the minimal adaptions (i.e., the addition of state-specific insurance information to the US-ANSWER-2), we will confirm its usability among 20 RA patients recruited from Massachusetts General Hospital, using the iterative testing process described above.
Management of Potential Conflict of Interest:

Although the adaptation and subsequent usability testing of US-ANSWER-2 (i.e., **Objective 1**) is conducted in preparation for the rest of the Objectives (i.e., **Objectives 2-4**), this component has not been included in the budget of this grant and will be performed during the 2 month pre-funding period before the budgeted support begins (see **Section 3.2**). This is to avoid a perceived conflict of interest, as the decision aid helps patients to choose one biologic over others, as outlined above (see **Section 2.2.1 Outline**). As such, **Objective 1** will be strictly supported by internal, non-industry funding.

2.2.3 RCT to Evaluate the Efficacy of the Decision Aid (Objectives 2 and 3)

The final version of the US-ANSWER-2 (as developed in **Objective 1** above**)** will be evaluated in an RCT. The trial will evaluate the efficacy of US-ANSWER-2 among 80 rheumatologist-confirmed RA patients who are considering biologics (40 per trial arm) over 3 months. A schematic outlining the trial design is shown in **Figure 1**.
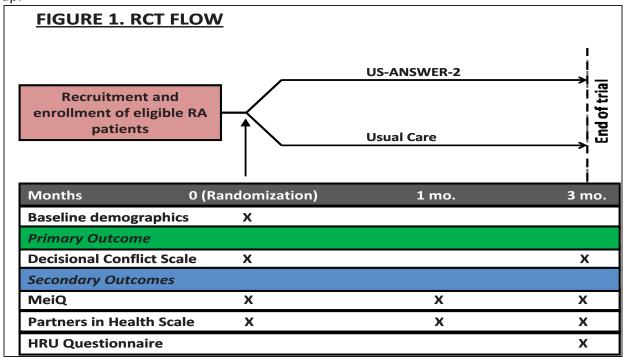
Eligibility:
Eligible individuals are those: 1) who have a rheumatologist-confirmed diagnosis of RA, 2) whose rheumatologists have recommended that they consider either starting a biologic or switching to another biologic, and 3) who have Internet access with a valid email address.
Recruitment:
The study will be conducted at two major Affiliate Hospitals of Harvard Medical School (i.e., Massachusetts General Hospital [the grant prime site] and Brigham and Women's Hospital [institution for additional recruitment]). Consecutive patients meeting the eligibility criteria will be recruited from the clinics of 50 rheumatologists in this catchment area (see Letters of Collaboration). All of these physicians are using Partners electronic medical records (EMRs), and regular searches of EMRs using relevant diagnoses (in this case, RA) and specific medications (e.g., conventional DMARDs) allows for rapid identification of eligible patients. For example, our EMR search of MGH rheumatologists alone has already revealed >200 biologic initiations or switches among RA patients in 2014. Furthermore, recruitment from Brigham and Women's Hospital would additionally help to achieve our recruitment target. As such, we will be able to screen over 200 RA patients and recruit our target of 80 patients over 20 months of recruitment (i.e., Month 1 to 20, see **Section 3.0 Detailed Work Plan**, below) without difficulty. In addition, we will use the **Partners** *Health Online for Patient Enrichment* **(HOPE) platform**, which was developed to facilitate patient recruitment in randomized trials. HOPE is an online patient community connected to the Partners Patient Gateway that enables Partners researchers to engage the patient community in the research process by posting up-to-date information about RCTs and other studies that are currently recruiting. Patients can easily join focused health areas (e.g., arthritis), allowing them to access information about IRB-approved studies that are directly relevant to their health.
RCT Procedure:
Participating rheumatologists (aided by the HOPE platform) will identify RA patients who are considering either starting a biologic or switching to another biologic. The study coordinator (see **Section 4.2.4 Project Staff**) will then contact these eligible and interested patients, guide them through the informed consent process, and provide them with simple instructions **to access and complete the US-ANSWER-2 decision aid on their home computers**.

Participants will complete the baseline measures and will then be randomly assigned to the **Intervention Group** or **Usual Care Group** using a 1:1 allocation ratio. Randomization will be performed using computer-generated random numbers in variable block sizes, which are necessary to ensure adequate allocation concealment. The use of stratified, permuted block randomization should result in a balance of known and unknown confounders. We will stratify by center to control for potential confounding by center, and will also use a permuted block design to prevent investigators from identifying the randomization sequence. Thus, the permuted block design will minimize potential selection bias due to investigator preference. Furthermore, to help minimize potential bias due to loss to follow-up, at the end of the follow-up period we will contact all participants to collect outcome data from the last date of follow-up.

FIGURE 1. RCT FLOW

Months	0 (Randomization)		1 mo.	3 mo.
Baseline demographics	X			
Primary Outcome				
Decisional Conflict Scale	X			X
Secondary Outcomes				
MeiQ	X		X	X
Partners in Health Scale	X		X	X
HRU Questionnaire				X

Intervention Group:

The Intervention Group will receive simple instructions to access the US-ANSWER-2 decision aid and complete the program **on their own computers** within two days. At the end of the session, a one-page summary will be produced (see **Appendix 1**) to help them discuss their questions, concerns, and preferred choices with their health care providers.

Usual Care Group:

The Usual Care Group will receive standard information about biologics from their rheumatologists or rheumatology nurses as per their current usual practice. This commonly includes introduction of a potential biologic (either a specific biologic or a class of biologics) followed by a short discussion. Patients are sometimes directed to brochures or other credible but generic resources.

RCT Outcome Measures:

Participants will complete the Decisional Conflict Scale[30] (**primary outcome**) before and after the intervention (**Figure 1**). The following **secondary measures** will be collected at baseline, 1

month, and 3 months: 1) Medication Education Impact Questionnaire (MeiQ),[31] and 2) Partners in Health Scale (**Figure 1**).[32] In addition, information on physician visits, medication use, and other healthcare resource use will be collected using the Health Resource Utilization (HRU) Questionnaire in 3 months.[33] Please see **Appendix 2** for all of these outcome measures.

The **primary outcome measure** will be the Decisional Conflict Scale, which measures personal perceptions of uncertainty in choosing options, factors contributing to uncertainty, and effective decision-making.[30] The short version has 10 questions and three response categories (yes/no/unsure). Both internal consistency and test-retest reliability exceed 0.78. Participants will complete the Decisional Conflict Scale[30] before and after the intervention (at baseline and 3 months).

The **secondary outcome measures** will be 1) Medication Education Impact Questionnaire (MeiQ)[31] (at baseline, 1 month, and 3 months), 2) Partners in Health Scale (at baseline, 1 month, and 3 months) , and 3) the Health Resource Utilization (HRU) Questionnaire (in 3 months).[32]

The **MeiQ** consists of six subscales and a total of 29 items. MeiQ was developed and tested in three different samples of patients with rheumatic conditions on their knowledge of medications. The internal consistency of each subscale was evaluated in a sample of 876 patients, with Cronbach's α ranging from 0.70 to 0.90. The questionnaire has demonstrated test-retest reliability (ICC = 0.68-0.87). The **Partners in Health Scale** is an 11-item measure, designed to assess self-efficacy, knowledge of RA and treatment, and self-management behaviours such as taking medication appropriately and adopting a healthy lifestyle.

Use of all healthcare resources will collected using the HRU questionnaire, which was developed for both self- and interviewer-administration in people with arthritis and other chronic conditions.[34] It consists of a series of open-ended questions about individuals' visits to health professionals, use of investigative tests, hospital visits, use of medications, purchases of adaptive aids, and estimated productivity loss incurred by the individual and their caregivers due to his/her health. Participants will be asked to report the use of all healthcare resources within the last three months.

Sample Size and Statistical Analysis:

Based on a recent Cochrane review report about sample size calculation on this topic, a total of **80** participants (n=40 per trial arm) will be required (α-level=0.05, 80% power, effect size difference between the group = 0.5, 20% dropout). Through our recruitment plan as described above, we will meet this over 20 months (i.e., Months 1 to 20).

An intention-to-treat analysis will be performed for the RCT. We will use analysis of covariance (ANCOVA) to compare between the Intervention Group and Usual Care Group over time, using the baseline measure as a covariate. Health resource utilization (total direct and indirect costs) will be calculated separately for participants in the Intervention Group and the Usual Care Group. A generalized liner model (GLM) approach with a log link function will be used to determine the relative contribution of the intervention to the total health-related costs. The following variables will be included in the multivariable analysis: 1) group assignment; 2) age; 3) sex; 4) education; and 5) number of comorbid conditions treated in the preceding year.

2.2.4 Development of an "Implementation Toolkit" (Objective 4)

The integration of new technologies in arthritis care is a complex process which requires an understanding from the user's perspective. Within one month after using the US-ANSWER-2 decision aid, the 40 participants in the Intervention Group will participate in a 1-hour telephone interview about their experience with using US-ANSWER-2 and their subsequent discussion with physicians about the preferred treatment option. It should be noted that the individual's willingness to participate in the interview is not an eligibility criteria for the RCT. In addition, we will interview 15 rheumatologists and their staff to further explore barriers/facilitators to integrating patient decision aids in clinical practice (see **Appendix 3**: Sample Interview Questions for Patients and Rheumatologists).

Qualitative Data Analysis. Guided by the grounded theory approach, we will conduct an iterative content analysis, whereby codes will be identified and revised as interviews are analyzed. We anticipate that this analysis will reveal barriers and facilitators to using the US-ANSWER-2 tool to assist in treatment decision-making and promoting patient-doctor communication. Findings will be used to develop a draft toolkit to guide health professionals through a series of questions that are key to consider in the implementation of the US-ANSWER-2 decision aid, such that they can make an informed decision regarding the resources for implementation. The draft tool kit will be presented to the 2014 ACR guideline development committee and our consumer collaborators for feedback. Revisions will be made based on this feedback prior to final dissemination of the toolkit to the clinical and patient communities.

2.3 Evaluation Design

2.3.1 Metrics for Needs Assessment and Expected Change

For Objectives 2 and 3, please refer to **Section 2.2.3** and **Appendix 2** for a description of our primary and secondary outcomes measures and Sample Size and Statistical Analysis; for our Objective 4, please refer to **Section 2.2.4.**

2.3.2 Engagement of Target Audience

The concept of this project (i.e., ANSWER in a Canadian context as well as subsequent adaptations) was originally refined through discussion with representatives from patient/consumer groups, including the Canadian Arthritis Patient Alliance, the Arthritis Patient Advisory Board, and the Arthritis Consumer Experts. Thus, **key to our activities is continued input from knowledge users, particularly arthritis consumers who will be engaged throughout the entire research process**.

To that end, the research team will continue to consult regularly with these patient-research collaborators (both Canadian patient groups who were involved in the development of the original ANSWER decision aids, as well as US patient groups from the Arthritis Foundation; see attached Letters of Support) to ensure that the patient perspective is clearly articulated in the US-ANSWER-2 decision aid. Further, our patient collaborators will assist in the development and execution of the study's extensive knowledge translation activities. We will use the 'FIRST'

model (*Facilitate, Identify, Respect, Support, and Train*) as a guiding framework for consumer-researcher collaborations.[18]   To date, all collaborators have participated in individual discussions with the researchers by e-mails, telephone calls, and/or face-to-face meetings, and have offered unique and constructive advice for developing this project.

2.3.3 Dissemination of Project Outcomes

An important component of this project is to ensure that the US-ANSWER-2 decision aid reaches the appropriate audiences (i.e., that the project results are appropriately disseminated), and that key findings from the pilot study are used to inform future knowledge translation research. For these reasons, we have developed a comprehensive end-of-grant knowledge translation plan that is guided by Lavis et al.'s 5 essential questions: (1.) What is the *message*? (2.) To whom (i.e*., target audience*)? (3.) By whom (i.e., *spokespersons*)? (4.) How (i.e., *knowledge translation activities*)? (5.) With what effect (i.e., *the impact*)?[19] The end-of-grant knowledge translation activities will also address Phases 6 and 8 of the Knowledge-to-Action Process.

Our dissemination goals are: (1) to increase awareness about US-ANSWER-2 and other arthritis-related decision aids for shared decision-making; and (2) to promote the practice of shared decision-making. It is premature to decide specific messages since we do not know the results; however, we can plan broadly around the anticipated content, which may include: (1) major outcomes of the US-ANSWER-2 pilot study; (2) the key components of shared decision-making; and (3) how the US-ANSWER-2 decision aid can be used to facilitate shared decision-making. We will work with representatives from various patient organizations, the Arthritis Foundation, and the American College of Rheumatology to refine the messages for these **target audiences** (i.e., people with RA, rheumatologists, primary care physicians, arthritis nurses and allied health professionals, policy makers, and researchers).   We anticipate that individuals elected to collaborate in this project will act as our **spokespersons**.

The **Knowledge Translation activities** will consist of presenting the results at public forums and writing plain language summaries in consultation with our patient/consumer collaborators. We will also post the US-ANSWER-2 tool and the pilot study findings on the Arthritis Foundation websites for public access (see attached Letter of Support) once the testing is completed. Members of the team will approach health professional associations (e.g., the American College of Rheumatology) to create a web link to the US-ANSWER-2. We will also share the results with the Massachusetts Department of Public Health through informal discussions (and presentations if requested). Finally, we will target researchers by presenting our findings at scientific conferences and publishing in peer-reviewed academic journals.

To **evaluate the impact** of the end-of-grant **Knowledge Translation** activities, we will monitor, over 12 months (including the post-funding period, see **Section 3.2 Schedule and Deliverables**), the use of the US-ANSWER-2 decision aid by collecting Arthritis Foundation website statistics and user satisfaction information using a short survey posted on the website (Step 6 of Graham's Action Cycle). In addition, we will conduct short (i.e., 20-minute) semi-structured interviews with representatives from the partner organizations at 12 months following the funding period to determine the uptake of the US-ANSWER-2 decision aid from their

perspectives and to understand their experience with this research collaboration. This post-grant evaluation activity will not be supported by the current grant, as it is beyond the scope of the allowable time frame and budget. Nevertheless, this critical research component will be conducted with internal funding support in order to provide the necessary and relevant evidence regarding the impact of the US-ANSWER-2 decision aid.

Finally, we recognise that further rigorous research will be warranted to advance the science of computerized decision aids for improving patients' engagement in the shared decision-making process, the ability to effectively use healthcare resources, and clinical outcomes. To this end, we plan to build on this project as well as the current and new partnerships born through execution of this project to develop further evaluations in this highly relevant area.

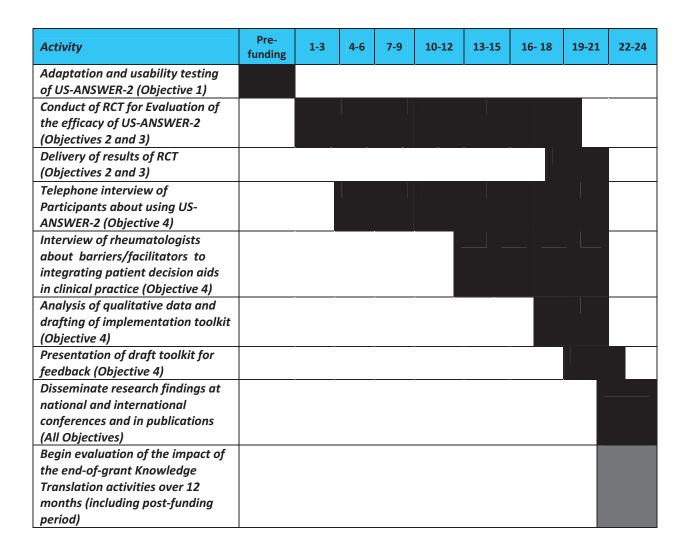## 3.0 DETAILED WORK PLAN AND DELIVERABLES SCHEDULE

3.1 Work Plan and Project Implementation

For our detailed **Work Plan and Project Implementation** for **Objectives 1-4**, please refer to **Sections 2.2.2, 2.2.3,** and **2.2.4** above.

3.2 Schedule and Deliverables

As depicted in the detailed project timeline below (see Section 3.3 on the next page), the pre-funding period (2 months) will be spent on the adaptation and usability testing of the US-ANSWER-2 decision aid (**Specific Objective 1**), whereas the following 20 months will be spent on **Specific Objectives 2 and 3** (i.e., conduct of a RCT). **Specific Objective 4** will coincide with execution of the RCT, although the rheumatologist interviews and qualitative data analysis will begin at Month 12 onward. **We will deliver our RCT results during Months 20-21**, and we will present our "implementation toolkit" to the 2014 ACR guideline development committee and involved consumer members for feedback between Months 19 and 22. We will present our study findings at major rheumatology meetings and publish our results at the end of the project period. **These presentations and resulting manuscripts will be our deliverables at the end of the project period.** Finally, we will begin the evaluation of the impact of the end-of-grant *Knowledge Translation* activities during the final two months of the grant period, although this process will be continued for a total of 12 months.

3.3 Detailed Project Timeline

Activity	Pre-funding	1-3	4-6	7-9	10-12	13-15	16- 18	19-21	22-24
Adaptation and usability testing of US-ANSWER-2 (Objective 1)	■								
Conduct of RCT for Evaluation of the efficacy of US-ANSWER-2 (Objectives 2 and 3)		■	■	■	■	■	■		
Delivery of results of RCT (Objectives 2 and 3)							■	■	
Telephone interview of Participants about using US-ANSWER-2 (Objective 4)			■	■	■	■	■		
Interview of rheumatologists about barriers/facilitators to integrating patient decision aids in clinical practice (Objective 4)						■	■	■	
Analysis of qualitative data and drafting of implementation toolkit (Objective 4)							■	■	
Presentation of draft toolkit for feedback (Objective 4)								■	
Disseminate research findings at national and international conferences and in publications (All Objectives)									■
Begin evaluation of the impact of the end-of-grant Knowledge Translation activities over 12 months (including post-funding period)									■

6.0 REFERENCES

1.   International Patient Decision Aid Standards (IPDAS) checklist (http://decisionaid.ohri.ca/methods.html#checklist). *Ottawa Health Research Institute.* 2008.
2.   O'Connor AM, Stacey D, Entwistle V, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst.Rev.* 2006 2006;3, 2006.
3.   Stacey D, Bennett CL, Barry MJ, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst.Rev.* 2011 2011(10).
4.   Legare F, Ratte S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. *Patient Educ Couns.* 2008;73(3):526-535.
5.   Li LC, Adam PM, Backman CL, Brooks S, Ellert G, Jones CA. A Proof-of-Concept Study of ANSWER, A Web-Based Methotrexate Decision Aid for Patients with Rheumatoid Arthritis. *Arthritis Care Res.* 2014;66(10):1472-1481.
6.   Smolen JS, Aletaha D, Bijlsma JW, et al. Treating rheumatoid arthritis to target: Recommendations of an international task force. *Ann.Rheum.Dis.* 2010 2010;69(4):631-637.
7.   Li LC, Townsend AF, Adam PM, et al. Crossing the threshold: Help-seeking for early symptoms in people with rheumatoid arthritis. *Arthritis Rheum.* 2009 2009;60(10 Suppl):S758.
8.   van den Bart BJ, Zwikker HE, Van den Ende CH. Medication adherence in patients with rheumatoid arthritis: a critical appraisal of the existing literature. *Expert Review of Clinical Immunology.* 2012 2012;8(4):337-351.
9.   Townsend A, Hunt K, Wyke S. Managing multiple morbidity in mid-life: a qualitative study of attitudes to drug use. *BMJ.* 10/11/2003 2003;327(7419):837.
10. O'Connor AM, Graham ID, Visser A. Implementing Shared Decision Making in Diverse Health Care Systems: the Role of Patient Decision Aids. *Patient Education and Counseling.* 6/2005 2005;57(3):247-249.
11. Li LC, Adam PM, Townsend AF, et al. Usability testing of ANSWER: A web-based methotrexate decision aid for patients with rheumatoid arthritis. *BMC Medical Informatics and Decision Making.* 2013;13:131.
12. Singh JA, Christensen R, Wells GA, et al. A network meta-analysis of randomized controlled trials of biologics for rheumatoid arthritis: a Cochrane overview. *Canadian Medical Association Journal.* 11/14/2009 2009;181(11):787-789.
13. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. [Review]. *Arthritis Care Res.* 5/2012 2012;64(5):625-639.
14. Hoffman AS, Volk RJ, Saarimaki A, et al. Delivering patient decision aids on the Internet: definitions, theories, current evidence, and emerging research areas. *BMC Medical Informatics and Decision Making.* 2013;13(Suppl 2):S13.

15. van den Haak M, de Jong M, Schellens PJ. Retrospective vs. concurrent think-aloud protocols: testing the usability of an online library catalogue. *Behaviour & Information Technology.* 2003 2003;22(5):339-351.

16. Brooke J. SUS: A "quick and dirty" usability scale. In: Jordan PW, Thomas B, Weerdmeester BA, McClelland IL, eds. *Usability Evaluation in Industry*. London: Taylor & Francis; 1996:189-194.

17. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the system usability scale. *International Journal of Human-Computer Interaction.* 2008 2008;24(6):574-594.

18. Hewlett S, de Wit M, Richards P, et al. Patients and Professionals as Research Partners: Challenges, Practicalities, and Benefits. *Arthritis & Rheumatism.* 2006;55(4):676-680.

19. JN JL, Robertson D, Woodside J, McLeod C, Abelson J, Milbank Q. Knowledge Transfer Study Group. How can research organizations more effectively transfer research knowledge to decision makers? . *Milbank Q.* 2003;81(2):221-248.

7.0 APPENDIX

Appendix 1: The current version of the single page summary produced for patients following completion of the decision aid

Appendix 2: Questionnaires (i.e., baseline measures, Medication Education Impact Questionnaire, Partners in Health Scale, and the Health Resource Utilization Questionnaire)

Appendix 3: Sample Interview Questions for Patients and Rheumatologists

	Report for Doctor	
CIHR IRSC / ARC	Rheumatoid Arthritis and Biologic Decision Aid	MGH 1811

Location of joint pain:

RIGHT   LEFT

This report is produced by the ANSWER-2 patient decision aid program. It summarises your patient's health and thoughts about taking biologics for rheumatoid arthritis. The report is intended to help your discussion with your patient.

ANSWER-2 was developed through funding from the Canadian Institutes of Health Research. For more information, please contact ANSWER@arthritisresearch.ca OR (604) 207-4007, toll-free: 1(877) 871-4575

Name: **Date Completed:**

My Health Assessment Questionnaire (HAQ) Score: _____ / 3
(0-3; high score = more severe disease)

My Arthritis Activity Rating	(0 = best; 10 = worst)

- In the past six months, I would rate the activity of my arthritis: _____ /10

- Today, I rate my joint tenderness and swelling: _____ /10

- Today, I rate my arthritis pain: _____ /10

- Today, my joints were stiff when I woke up. ☐ Yes ☐ No
  This joint stiffness lasted _____.

Check ☑ the best answer	**Yes**	**No**	**Not Sure**
1. At this point, I know enough about the benefits and side effects to make a decision about biologics.	☐	☐	☐
2. I am clear about which benefits and side effects matter the most to me.	☐	☐	☐
3. I have enough support and advice from others to make a choice.	☐	☐	☐
4. I feel sure about the best choice for me.	☐	☐	☐

5. Before making the final decision, I need to:

_____

_____

Thinking about what is most important to me, I prefer to:

☐ Continue with DMARD therapy   ☐ Take (NAME of BIOLOGIC)

Questions for my doctor:
1. _____
2. _____
3. _____
4. _____

Version 1

MASSACHUSETTS
GENERAL HOSPITAL

HARVARD
MEDICAL SCHOOL

BASELINE QUESTIONNAIRE

Information about You

1. **What is your year of birth?** ☐☐☐☐

2. **Are you:** ☐₁ Male ☐₂ Female

3. **What is the highest level of education you have <u>completed</u>?** (Please check (✓) one box).

    ☐₁   Grade 8 or lower

    ☐₂   Grade 9 to 10

    ☐₃   Grade 11 to 13 (including GED–General Education Diploma)

    ☐₄   Trades certificate, vocational school diploma, apprenticeship

    ☐₅   Non-university certificate below Bachelor's level

    ☐₆   Bachelor's degree

    ☐₇   University degree, certificate or diploma above Bachelor's degree

4. **To identify the general region you live in, enter the first 3 digits in your postal code**

    _____

5. **What is your total household income per year before taxes?**

    ☐₁   Under $12,000

    ☐₂ $12,001 – $24,000

    ☐₃ $24,001 – $40,000

    ☐₄ $40,001 – $60,000

    ☐₅ $60,001 – $80,000

☐6 $80,001 – $100,000

☐7   Over $100,000

☐8   No answer

6. Which of the following best describes your current marital status:

☐1   Married / Common Law

☐2   Separated / Divorced

☐3   Widowed

☐4   Never married

☐5   Other *(please specify):* _____

7. Which of the following best describes your current living arrangements?

☐1   Living alone in a house or apartment (i.e. independent)

☐2   Living in a house or apartment with your spouse or significant other

☐3   Living in a house or apartment with your relatives or with others

☐4   Living in a house or apartment with dependants (children)

☐5   Living in a house or apartment with elderly relatives whom you take care of

☐6   Living in a nursing home or other residential care facility

☐7   Other (please specify): _____

We would like to know about your overall health. Health refers not only to the absence of disease or injury, but also physical, mental and social wellbeing.

8. What is your current height and weight?   **Height** ___ ft ____ in **or** ____cm   **Weight** _____ lbs **or** ____ kg

9. In general, would you say your health is: (Please check (✓) one box).

☐1	☐2	☐3	☐4	☐5
Excellent	Very good	Good	Fair	Poor

10. <u>**Compared to one year ago**</u>**, how would you rate your health in general <u>now</u>?** (Please check (✓) one box).

☐1	☐2	☐3	☐4	☐5
Much better now	Somewhat better now	About the same	Somewhat worse now	Much worse now

YOUR MEDICAL HISTORY

This section asks about your general health. Please check the appropriate boxes.

Health Problem	Do you have it?		Have you been treated in the last year (saw doctor, took pills)?	To what degree does it affect your health?
a. Rheumatoid arthritis	Yes □ →→ No □ ↓		Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
b. Osteoarthritis	Yes □ →→ No □ ↓		Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
c. Fibromyalgia/Fibrositis	Yes □ →→ No □ ↓		Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
d. High blood pressure (Hypertension)	Yes □ →→ No□ ↓		Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
e. Heart problems (such as angina, heart attack, heart failure, heart valve problems)	Yes □ →→ No □ ↓		Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
f. Circulation problems (such as hardening of arteries, varicose veins, claudication, foot or leg ulcers, others)	Yes □ →→ No □ ↓		Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
g. Digestive system problems (such as inflammatory or irritable bowel disease, colitis, Crohn's disease, hiatus hernia, gall stones, pancreatitis, gastritis, others)	Yes □ →→ No □ ↓		Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
h. Ulcer problems (such as stomach ulcers, or peptic ulcer disease)	Yes □ →→ No □ ↓		Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
i. Allergies (such as hay fever, dermatitis, eczema, allergies to medication, food allergy, others)	Yes □ →→ No □ ↓		Yes □ No □	Not at all □ Mild □ Moderate □ Severe □

Health Problem	Do you have it?	Have you been treated in the last year (saw doctor, took pills)?	To what degree does it affect your health?
j. Diabetes	Yes □ →→ No □ ↓	Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
k. Breathing problems (such as asthma, emphysema, bronchitis, fibrosis, lung scarring, TB, pneumonia, infection, common cold, others)	Yes □ →→ No □ ↓	Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
l. Liver problems (such as cirrhosis, hepatitis or serious liver damage)	Yes □ →→ No □ ↓	Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
m. Kidney, bladder or urinary problems (such as kidney failure, nephritis, kidney stones, urinary tract infection, prostate problems, bladder control problems, others)	Yes □ →→ No □ ↓	Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
n. Cerebrovascular problems (such as stroke, blood clot or bleeding in the brain, cerebrovascular accident, or transient ischemic attach [TIA])	Yes □ →→ No□ ↓	Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
o. Neurological problems (such as epilepsy, seizures, multiple sclerosis, Parkinson's, paraplegia, quadriplegia, paralysis, Alzheimer's, dizziness, others)	Yes □ →→ No □ ↓	Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
p. Skin problems (such as eczema, others)	Yes □ →→ No □ ↓	Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
q. Psoriasis (excluding of the scalp)	Yes □ →→ No □ ↓	Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
r. Headaches (such as migraine, tension, stress, sinus, others)	Yes □ →→ No□ ↓	Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
s. Mental or emotional problems (such as depression, anxiety, substance abuse: alcohol, drugs, others)	Yes □ →→ No □ ↓	Yes □ No □	Not at all □ Mild □ Moderate □ Severe □
t. Gynaecological problems	Yes □ →→	Yes □	Not at all □ Mild □

Health Problem	Do you have it?		Have you been treated in the last year (saw doctor, took pills)?	To what degree does it affect your health?
	No □ ↓		No □	Moderate □ Severe □
u. Osteoporosis	Yes □	→→	Yes □	Not at all □ Mild □
	No □ ↓		No □	Moderate □ Severe □
v. Cancer	Yes □	→→	Yes □	Not at all □ Mild □
	No □ ↓		No □	Moderate □ Severe □
w. Blood problems	Yes □	→→	Yes □	Not at all □ Mild □
	No □ ↓		No □	Moderate □ Severe □
x. Other problems *(please list:_____* *_____)*	Yes □	→→	Yes □	Not at all □ Mild □
	No □ ↓		No □	Moderate □ Severe □

1	Do you smoke? Yes □ →→ No □ ↓	a.	How many years have you smoked? _____ Years →→	b.	On average, how many cigarettes do you smoke *per day (1 pack equals 25 cigarettes)*? ____ cigarettes per day
2	Have you ever smoked? Yes □ →→ No □	a.	How many years did you smoke? _____ Years →→	b.	On average, how many cigarettes did you smoke *per day (1 pack equals 25 cigarettes)*? ____ cigarettes per day

DECISIONAL CONFLICT SCALE

The following questions ask about your treatment decisions. Please check the appropriate boxes.

		Yes	No	Unsure
1	Do you know which options are available to you?	☐	☐	☐
2	Do you know the benefits of each option?	☐	☐	☐
3	Do you know the risks and side effects of each option?	☐	☐	☐
4	Are you clear about which benefits matter most to you?	☐	☐	☐
5	Are you clear about which risks and side effects matter most to you?	☐	☐	☐
6	Do you have enough support from others to make a choice?	☐	☐	☐
7	Are you choosing without pressure from others?	☐	☐	☐
8	Do you have enough advice to make a choice?	☐	☐	☐
9	Are you clear about the best choice for you?	☐	☐	☐
10	Do you feel sure about what to choose?	☐	☐	☐

MEDICATION EDUCATION IMPACT QUESTIONAIRE

The following statements relate to the most recent medication/s you started taking for your health problem and the information you were given about them.

Please indicate how strongly you disagree or agree with the following statements by checking the response which best describes you. When answering these questions think about the information and care you received at the time you started the most recent medication for your condition.

Answer each question thinking about the most recent medication you started for your condition.

Check a box by crossing it: ☐ ☐ ☐ ☒ ☐ ☐

disagree strongly   disagree   disagree slightly   agree slightly   agree   agree strongly

Q1.	The information I received about this medication was easy to understand	☐ ☐ ☐ ☐ ☐ ☐
Q2.	I feel comfortable about asking my doctors for more information	☐ ☐ ☐ ☐ ☐ ☐
Q3.	I have "had a say" in choosing this medication	☐ ☐ ☐ ☐ ☐ ☐
Q4.	I understand that it is important that I get treatment for my condition	☐ ☐ ☐ ☐ ☐ ☐
Q5.	It is up to me to report any problems from the medication to my doctors	☐ ☐ ☐ ☐ ☐ ☐
Q6.	I have a realistic understanding of the positives and negatives of this medication	☐ ☐ ☐ ☐ ☐ ☐
Q7.	I am able to have good discussions with my doctors about my treatment	☐ ☐ ☐ ☐ ☐ ☐
Q8.	I feel I have been fully informed about this medication	☐ ☐ ☐ ☐ ☐ ☐
Q9.	It is my job to know when and how to take my medication	☐ ☐ ☐ ☐ ☐ ☐
Q10.	I know what I need to do to improve my condition	☐ ☐ ☐ ☐ ☐ ☐
Q11.	Overall I feel that I am able to ask my doctors questions	☐ ☐ ☐ ☐ ☐ ☐

Answer each question thinking about the most recent medication you started for your condition

Check a box by crossing it: ☐ ☐ ☐ ☒ ☐ ☐

		disagree strongly	disagree	disagree slightly	agree slightly	agree	agree strongly
Q1.	I know what to expect with this medication	☐	☐	☐	☐	☐	☐
Q2.	I have the support I need from health professionals to take this medication safely	☐	☐	☐	☐	☐	☐
Q3.	I have come to terms with having to take medication	☐	☐	☐	☐	☐	☐
Q4.	I know I need to manage my illness	☐	☐	☐	☐	☐	☐
Q5.	I am confident that I know enough to make decisions about my treatment	☐	☐	☐	☐	☐	☐
Q6.	The information I was given covered the areas that I wanted to know about	☐	☐	☐	☐	☐	☐
Q7.	I feel that I can tell my doctors if I do not understand what they are saying	☐	☐	☐	☐	☐	☐
Q8.	I need to understand my medicines so I can take them the right way	☐	☐	☐	☐	☐	☐
Q9.	I am confident that I can recognise side effects caused by my medication	☐	☐	☐	☐	☐	☐
Q10.	I have received the help I need to manage my condition	☐	☐	☐	☐	☐	☐
Q11.	The information I was given about this medication was easy to use	☐	☐	☐	☐	☐	☐
Q12.	I feel I have enough knowledge to choose between treatment options	☐	☐	☐	☐	☐	☐
Q13.	I know what to do if my condition gets worse	☐	☐	☐	☐	☐	☐
Q14.	I have a role in making sure my condition is treated successfully	☐	☐	☐	☐	☐	☐
Q15.	I have been given enough help to be able to manage my medication	☐	☐	☐	☐	☐	☐
Q16.	I feel that I am able to make an educated decision about taking this medication	☐	☐	☐	☐	☐	☐
Q17.	I am willing to live with minor side effects if the medication is helping my condition	☐	☐	☐	☐	☐	☐

Q18.	I am confident in my ability to communicate with my doctors	☐ ☐ ☐ ☐ ☐ ☐
Q19.	I am able to assess how well I am responding to treatment	☐ ☐ ☐ ☐ ☐ ☐
Q20.	I know I can rely on the information I was given	☐ ☐ ☐ ☐ ☐ ☐
Q21.	My health is my responsibility	☐ ☐ ☐ ☐ ☐ ☐
Q22.	I have come to terms with the diagnosis of my condition	☐ ☐ ☐ ☐ ☐ ☐
Q23.	I understand the risks of taking this medication	☐ ☐ ☐ ☐ ☐ ☐
Q24.	I know I have the back up I need if I have problems with my medication	☐ ☐ ☐ ☐ ☐ ☐
Q25.	There was enough detail for me to understand the information I was given	☐ ☐ ☐ ☐ ☐ ☐
Q26.	It is my responsibility to make sure I take my medication safely	☐ ☐ ☐ ☐ ☐ ☐
Q27.	I feel motivated to take this medication	☐ ☐ ☐ ☐ ☐ ☐
Q28.	I am clear about the potential benefits of this medication	☐ ☐ ☐ ☐ ☐ ☐
Q29.	I feel that the information I received about this medication met all of my needs	☐ ☐ ☐ ☐ ☐ ☐

PARTNERS IN HEALTH SCALE

Please circle the number that most closely fits your answer

1. My knowledge of my condition is:

0	1	2	3	4	5	6	7	8
Very good				Satisfactory				Poor

2. My knowledge of the treatment of my condition is:

0	1	2	3	4	5	6	7	8
Very good				Satisfactory				Poor

3. My ability to share in decisions made about the management of my condition is:

0	1	2	3	4	5	6	7	8
Very good				Satisfactory				Poor

4. My ability to arrange appointments as recommended by my Doctor or Health Service Provider is:

0	1	2	3	4	5	6	7	8
Very good				Satisfactory				Poor

5. My attendance at appointments is:

0	1	2	3	4	5	6	7	8
Very good				Satisfactory				Poor

6. My ability to take my medication as directed by my doctor is:

0	1	2	3	4	5	6	7	8
Very good				Satisfactory				Poor

7. My understanding of why I need to observe, measure and record symptoms is:

0	1	2	3	4	5	6	7	8
Very good				Satisfactory				Poor

8. My ability to observe, measure and record my symptoms is:

0	1	2	3	4	5	6	7	8
Very good				Satisfactory				Poor

9. My understanding of what to do when my symptoms get worse is:

0	1	2	3	4	5	6	7	8
Very good				Satisfactory				Poor

10. My ability to take the right action when my symptoms get worse is:

0	1	2	3	4	5	6	7	8
Very good				Satisfactory				Poor

11. My progress towards adopting habits that improve my health is:

0	1	2	3	4	5	6	7	8
Very good				Satisfactory				Poor

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Office visits to health professionals (any type) during THE PAST 3 WEEKS

1. Please indicate any visits you have made to see health professionals (e.g. family physician, physician, specialist, physiotherapist, chiropractor, acupuncturist, nurse practitioner) **during the last 3 month**. If you visited the same health professional more than once, please indicate each visit separately.

    ☐ Check here if you did **NOT** see any health professionals during the last 3 month

Example: Type of Health Professional	Reason for visit
Family Doctor	Pain in my hands, hips, knees, and feet
no treatment: ☐	**Most important treatment prescribed**
	Increased the dosage of methotrexate
no procedure/service: ☐	**Most important procedure/service that was performed**
	Referred to home care

a) Type of Health Professional
Reason for visit

no treatment: ☐
Most important treatment prescribed

no procedure/service: ☐
Most important procedure/service that was performed

b) Type of Health Professional
Reason for visit

no treatment: ☐
Most important treatment prescribed

no procedure/service: ☐
Most important procedure/service that was performed

c) Type of Health Professional
Reason for visit

no treatment: ☐
Most important treatment prescribed

no procedure/service: ☐
Most important procedure/service that was performed

d) Type of Health Professional
Reason for visit

no treatment: ☐
Most important treatment prescribed

no procedure/service: ☐
Most important procedure/service that was performed

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Test and Investigations

2. Please indicate any **test or investigations you had** (e.g. x-rays, blood work) **during the last 3 months.**

☐ Check here is you did **NOT** have any tests or investigations during the last 3 months.

Example:	
Type of test or investigation: Blood work	**Site:** ☐Hospital ☐Physician's Office ☐Clinic ☐Home

a. Type of test or investigation:

Site: ☐Hospital ☐Physician's Office

☐Clinic ☐Home

b. Type of test or investigation:

Site: ☐Hospital ☐Physician's Office

☐Clinic ☐Home

c. Type of test or investigation:

Site: ☐Hospital ☐Physician's Office

☐Clinic ☐Home

d. Type of test or investigation:

Site: ☐Hospital ☐Physician's Office

☐Clinic ☐Home

Hospital Visits

3. Please indicate any **visits, admissions or procedure you had in a hospital department** (e.g. General Ward, Emergency, Day Surgery) during **the last 3 month.**

☐ Check here is you did **NOT** have any procedures done in a hospital during **the last 3 months.**

Example:

Type of hospital department (see above)

Day Surgery

Reason for visit

Bronchoscopy

Length of Stay

0   [days]

Most Important tests/procedure performed

Check here if no tests/procedures: ☐

---

a.   **Type of hospital department**

Reason for visit

Length of Stay

[days] no tests/procedures: ☐

Most Important tests/procedure performed

---

b.   **Type of hospital department**

Reason for visit

Length of Stay

[days] no tests/procedures: ☐

Most Important tests/procedure performed

---

c.   **Type of hospital department**

Reason for visit

Length of Stay

[days] no tests/procedures: ☐

Most Important tests/procedure performed

---

d.   **Type of hospital department**

Reason for visit

Length of Stay

[days] no tests/procedures: ☐

Most Important tests/procedure performed

Appendix (Questionnaires)   15

Medications (prescribed and over the counter)

4. Please indicate **any medications** (such as painkillers, aspirin/Tylenol, anti-inflammatory drugs, antacids/stomach medications, anti-hypertensives, etc.) **you took during the last 3 months, the reason you took them, and how long you have used them.**

☐ Check here if there was no change to your medication in the last 3 months.

Item (Name, reason(s) for taking the medication)	Dosage:	How long have you used it?
e.g. Tylenol	200 mg/week	1 year
a.		
b.		
c.		
d.		
e.		
f.		
g.		
h.		

Adaptive aids, devices, household items

5. Please indicate any equipment, i.e. aids or devices (e.g. bathroom equipment, wheelchair ramp, splints, canes, or walkers) you acquired during **the last 3 months**. Please indicate whether the costs were reimbursed by an outside agency (e.g. government programs, extended health insurance), and the amount of money you contributed out of your own pocket.

☐ Check here if you did **NOT** purchase any adaptive aides or devices during **the last 3 months.**

Item	Reimbursed?	Your costs, if any:
e.g. A cane	☐Yes ☐No	$20
a.	☐Yes ☐No	$
b.	☐Yes ☐No	$
c.	☐Yes ☐No	$
d.	☐Yes ☐No	$
e.	☐Yes ☐No	$

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Community Services or Resources

6. Please indicate the type and amount of community services you received or utilized during the **last 3 months**, (i.e. transportation, home maker from homecare, meals on wheels).

☐ **Check here if you did NOT use any community services or resources during the last 3 months**

Type of Service	How often did you use it?	Costs (monthly):
e.g. Handydart	5 times a week	$ 40
a.		$
b.		$
c.		$
d.		$
e.		$

Time off from paid employment or volunteer activities

7. During the **last 3 months** did you take **time off from paid employment or volunteer activities** to attend medical or therapy appointment?

☐ Yes ☐ No **(Skip to question X)**

Your time lost: ⬜ [days] ⬜ [hours

8. During the **last month** did your main support person (i.e. spouse, relatives or friends) **take time off from paid employment or volunteer activities** because of *your* health problems?

☐ Yes ☐ No **(Skip to question X)**

Caregiver's time lost: ⬜ [days] ⬜ [hours]

Caregiver's Gender: ☐F ☐M   Age: ⬜ years

Difficulty Working

9. During the **last 3 months** did you have **difficulty working at your paid job or participating in volunteer activities** because of your health problems?

☐Yes ☐No **(Skip to question X)** ☐Not applicable **(Skip to question X)**

How many days or hours did you have difficulty working (paid or volunteer work):

[days] [hours]

Difficulty with Leisure Activities

10. During the **last 3 months** did you have **difficulty participating in leisure activities** because of your health problems?

☐Yes ☐No **(Skip to question X)**

How many days or hours did you have difficulty participating in leisure activities:

[days] [hours]

We welcome your comments. Please use the space below for any suggestions you would like to make.

Thank you for taking the time to answer these questions!

SuPER: Interview Questions for Patients

Preamble: Thank you for taking part in this study. Now that you have had a chance to use the US-ANSWER-2, I would like to know your opinion about the process.

1. **As you may recall, in this study we asked you to use the US-ANSWER-2 decision aid and complete a set of questions online. What do you think about this process to help you decide about using a biologic agent?**

   Probes:
   - What do you like about this process? Can you explain?
   - What don't you like about the process? Should anything be changed about the decision aid?
   - Anything else you can think of?

2. **Have you talked to anyone regarding your decision about biologic after using the US-ANSWER-2?**

   Probes:
   - If so, please tell me about it.
   - If not, please tell me why.

3. **How did you feel about getting information on biologics from the US-ANSWER-2 website?**

   Probes:
   - Did you trust the information from US-ANSWER-2?
   - Did it help you make the decision about using a biologic?
   - What was the most useful feature in US-ANSWER-2? Can you explain why that is?
   - What part of the US-ANSWER-2 that was the least helpful? Can you say a bit more about that?
   - Was it unclear/boring/unrealistic? Did you already have that knowledge or was the information hard to understand?
   - Do you think we should change anything in the website?

4. **A month ago, when you finished using the US-ANSWER-2, you chose to (*take the medication / discuss with your doctor about other treatment options*). Please tell me what action have you taken since then.**

   Probes:
   - Have you changed their minds?
   - If you choose to take a biologic, are you still on the medication?
   - Are you happy with your decision?

5. **What do you think would make decision aids like this successful in arthritis care? What do you think might prevent people using decisions aids?**

   Probes:
   - Was there anything about the US-ANSWER-2 that has raised your concerns? Please tell me more about it.
   - Would you recommend US-ANSWER-2 to other people with rheumatoid arthritis? Why?
   - Anything else you can think of?

6. **Just before we finish, can you tell me about why you chose to take part in this study?**

End of Interview: Thanks very much for your time helping us with this project and telling us what you think.

Preamble: Thank you for taking part in this study. Now that you and your patients have had a chance to use the US-ANSWER-2, I would like to know your opinion about the process.

1. **As you may recall, in this study we asked your patients to use the US-ANSWER-2 decision aid and complete a set of questions online. What do you think about this process to help your patients while considering a biologic agent?**

   Probes:
   - What do you like about this process? Can you explain?
   - What don't you like about the process? Should anything be changed about the decision aid?
   - Anything else you can think of?

2. **Have you talked to your patient regarding the decision about biologic after using the US-ANSWER-2?**

   Probes:
   - If so, please tell me about it.
   - If not, please tell me why.

3. **How did you feel about your patients getting information on biologics from the US-ANSWER-2 patient decision aid?**

   Probes:
   - Did you trust the information from US-ANSWER-2?
   - Did it help you and your patients come to a decision about using a biologic?
   - What was the <u>most useful feature</u> in US-ANSWER-2? Can you explain why that is?
   - What part of the US-ANSWER-2 that was the least helpful? Can you say a bit more about that?
     - ➢ Was it unclear/boring/unrealistic? Did you already have that knowledge or was the information hard to understand?
   - Do you think we should change anything in the website?

4. **What do you think would make decision aids like this successful in arthritis care? What do you think might prevent people using decisions aids?**

   Probes:
   - Was there anything about the US-ANSWER-2 that has raised your concerns? Please tell me more about it.
   - Would you recommend US-ANSWER-2 to other people with rheumatoid arthritis? Why?
   - Anything else you can think of?

5. **In your view, what would be the barriers to using patient decision aids in clinical practice?**
   a. Could you give an example?
   b. What can be done to make it easier for patient decision aids to be used in clinical practice?

End of Interview: Thanks very much for your time helping us with this project and telling us what you think.