Capturing Patient Reported Outcomes in RA
To Improve Quality of Care & Outcomes
in Real-World Settings

Abstract: We will develop a national, highly-generalizable software platform to electronically capture patient reported outcome (PRO) data for RA patients. This tool will be used by clinicians to improve process of care and outcomes in the management of RA. Our proposed work builds on past and ongoing research and electronic clinical tool development at the University of Alabama (UAB) in rheumatoid arthritis (RA), provider-patient activation in the context of evidence implementation trials, health information technology (HIT), and our current relationship with CreakyJoints, the largest arthritis patient community in the world. Seeking to effect tangible improvement in RA patients' outcomes and better quality of care consistent with national guidelines, many of which we have developed in partnership with the American College of Rheumatology (ACR), we will build on existing relationships collaborations to bring together researchers with expertise in rheumatology, epidemiology, bioinformatics, statistics, risk communication and medical decision-making. We will leverage our past work at UAB building electronic PRO data capture tools. This system is complementary to but not redundant with an electronic health record (EHR) and can be used with paper-based medical records systems. The main objectives of this project are to implement and rigorously test the deployment of practical, real-world tools in routine clinical practice to measure Patient Reported Outcomes (PROs) and RA disease activity.

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C.1 Goals and Objectives: To implement practical, real-world tools in routine clinical practice to measure Patient Reported Outcomes (PROs) and RA disease activity. We will accomplish this goal by achieving the following objectives:

1. In partnership with Creakyjoints (CJ), one of the largest arthritis patient networks in the world with more than 50,000 members, to a) determine barriers to PRO data capture in routine clinical practice and at home; and b) examine patient perspectives regarding using PROs to resolve discordance in patient-provider assessments as it relates to decision-making in achieving RA treat-to-target (T2T) goals
2. Demonstrate the feasibility and usefulness of electronically capturing patient reported outcome (PRO) data at patients' homes and in rheumatology clinics
3. Using Internet and mobile (e.g. Smartphone) technology, quantify the effect of this PRO data collection on patients-provider communication, RA treatment changes, and attainment of improved PROs and better RA disease activity states (low disease activity or remission). These outcomes are consistent with the American College of Rheumatology (ACR) 2012 RA guidelines (developed at UAB).

Summary: We will develop a national, highly-generalizable software platform to electronically capture patient reported outcome (PRO) data for RA patients. This tool will be used by clinicians to improve process of care and outcomes in the management of RA. Our proposed work builds on past and ongoing research and electronic clinical tool development at the University of Alabama (UAB) in rheumatoid arthritis (RA), provider-patient activation in the context of evidence implementation trials, health information technology (HIT), and our current relationship with CreakyJoints, the largest arthritis patient community in the world. Seeking to effect tangible improvement in RA patients' outcomes and better quality of care consistent with national guidelines, many of which we have developed in partnership with the American College of Rheumatology (ACR), we will build on existing relationships collaborations to bring together researchers with expertise in rheumatology, epidemiology, bioinformatics, statistics, risk communication and medical decision-making. We will leverage our past work at UAB building electronic PRO data capture tools. This system is complementary to but not redundant with an electronic health record (EHR) and can be used with paper-based medical records systems.

C.2.1. Needs Assessment: As described in the RFP, there are several validated measures and instruments to measure PROs in RA, but few are used in real-world clinical settings. Paper-based tools suffer from limitations as they must be scored by hand, and missing data makes calculations problematic. Longitudinal PRO data must be available at the point of care so as to enable real-world decision-making. A small group of electronic tools exist, but most are impractical and require appreciable time from clinicians to collect, record, longitudinally track, and be useful to make decisions in real time. Single centers, practices, or health systems may have such tools, but these are not easily exportable outside of those contexts to a national audience. We will address these barriers in the proposed project to demonstrate the feasibility and usefulness of collecting PROs using validated instruments in a highly generalizable way that improves outcomes for RA patients in diverse health care settings across the country.

Based upon 2006-9 data focused on RA disease activity related to quality of care, we found that few U.S. practices collect RA disease activity using any tool (1). The data supporting this national need and under-capture of RA disease activity was derived from national U.S. Medicare data collected at a person-level. Using national data from the CORRONA RA registry, we found that the publication of the ACR guidelines recommending measurement of RA disease activity and PROs, with the goal of achieving low disease activity or remission, had a negligible impact on treatment (2). This finding underscores the need for more practical tools deployed via evidence implementation programs like ours. Finally, to support our needs assessment, a national survey of U.S. rheumatologists conducted by Jack Cush (presented at the ACR 2008 meeting) found that at most, only about one-third of U.S. rheumatologists collected any quantitative disease activity measures. With Dr. Cush, we are currently updating this national survey to reassess this, with results available within the next 6 months.

Despite the relative dearth of information and tools to capture PROs in diverse practice settings described above, patients themselves have even fewer options to capture PRO data and use it in a meaningful way. Given ever-increasing time pressures on physician office visits, maximizing the efficiency of clinical encounters with rheumatologists is imperative, and determining methods that engage patients in capturing their own PROs offers considerable efficiencies. For that reason, the primary audience for this project is RA patients. This project will empower patients by providing them with a set of flexible electronic tools to capture existing, validated PROs and then facilitating their sharing of this information with their doctor. Our proposed assessments in this project will include not only field-testing of the approach and patient interface but also assessment of the impact of deployment of these tools on both process and outcome measures.

C2.2. Summary: First, we will deploy and evaluate novel methods for systematic data collection using direct, patient-provided data using healthcare information technology that collects PROs via a patient-facing, smartphone/Internet-based system (RheumPRO) coupled with a companion in-office iPad-based system (READY2). Either system can be used independently, but they are anticipated to be most effective when used together. Moreover, this platform has high potential for downstream integration to EHR data. We will enable use of these tools based upon input from multiple stakeholders collected as part of this project. Beta versions of these tools already have been developed through R01 funding from the Agency for Health Research and Quality (PI: Curtis), the National Institutes of Health (1P60AR064172-01, Project 2; PI: Curtis) and UAB institutional funds. These leveraged resources have enabled initial development of these electronic PRO capture tools. However, they have not yet been subjected to large scale evaluation or deployment from patients providing PRO data at home, as we now propose.

Following this formative work to refine the PRO data collection approach (Aim 1), these methodologic advances will be applied to evaluating the feasibility and usability of the enhanced electronic tools (Aim 2). Finally, this innovation will be tested in a randomized controlled evidence implementation study that will rigorously evaluate the impact on quality of RA care and associated outcomes (Aim 3). Overall, we will evaluate an approach that enables longitudinal PRO data captured in real-time to facilitate shared decision-making and personalized approaches consistent with patients' values and goals; provides real-time decision

support to encourage treatment changes without being prescriptive; is able to provide a better context for specific PROs in light of symptoms (e.g. pain) and concomitant comorbidities (e.g. depression, fibromyalgia) that may impact the interpretation of RA disease activity; and is feasible at home and in busy rheumatology clinic settings. This platform of tools can be widely adopted at the point-of-care by a diverse group of arthritis patients and their treating clinicians, including those not ordinarily able to support complex computational infrastructures (e.g. community physicians, with or without an EHR). To our knowledge, there is no other system that exists that can provide these capabilities that can scale easily to a national rheumatology audience. Our research findings will have immediate direct impact on RA quality of care and also will be a significant incremental improvement in PRO methodology in RA.

C.2.3 Technical Approach

***Program Design & Methods*:**

Aim 1: we will convene two sets of RA patient focus groups, both in-person and online for two key domains. The first domain covered by the focus groups is patients' interest, needs, and barriers/facilitators around PRO data collection. The second domain that will be discussed in the focus groups will be patients' perceptions of the need, goals, and concerns regarding applying PRO data to RA treatment decisions in light of T2T disease activity targets. There will be 4 patient focus groups: 2 online and 2 in-person, one set for each of the two domains. The focus groups will consist of Creakyjoints members with RA (for the online groups) and RA patients at the UAB RA clinic (for the in-person focus groups). A fifth focus group will be conducted online and consist of rheumatologists who treat RA patients to assess their perspectives on PRO data as it relates to RA treatment decisions and T2T goals (Domain 2).

Each focus group will be 10-12 people each. The two sets of focus groups will be run by Dr. James Willig, who has extensive experience in PRO data collection in diverse settings and in conducting qualitative research. By way of example, Dr. Willig initially led a similar effort at UAB with HIV+ patients and subsequently has extended this type of interaction to patients with other chronic diseases and conditions (e.g. geriatric patients, those receiving hospice). The groups will be presented key questions for the 2 relevant domains, and dialogue can "piggy-back" on the comments of other group members and can enrich the discussion in ways that could not be achieved through one-on-one interviews. Our expectation is that two focus groups for each of these two topics will be sufficient to achieve saturation for key major themes. In the event that the group moderator feels that saturation has not been achieved, we will conduct additional focus groups as necessary.

Examples of the themes to be discussed as part of these focus groups for Domain 1 include motivation, barriers and concerns (e.g. privacy, security) to collection and adoption of PROs at home and in clinician office settings. We also will explore how the impact of comorbidities and patients' own health goals relate to which specific PROs are most important to patients to capture and share with their physician. Following completion of the Domain 1 topics, a second round of focus groups for Domain 2 will be conducted and will explore barriers/facilitators, motivations, and concerns regarding how to best visually present PROs to patients and clinicians to facilitate shared decision-making to achieve the RA disease activity targets recommended in national guidelines.

As the third and final task for Aim 1, we will use the themes obtained from the focus groups to develop and deploy a national survey. We will assess the prevalence and generalizability of the various motivations, barriers, and concerns around PRO data capture that emerged from the focus groups to better understand these issues on a broader scale. Major themes will be abstracted using standard commercial software available for this purpose (e.g. NVivo, which allows for qualitative and mixed-methods research; it supports data collected from focus groups as well as large social media-based discussions (which we will use for this aim). The survey will be deployed online to the Creakyjoints membership and in person (using iPad tablets deployed in the waiting room of the UAB RA Clinic) to collect the same data from the pool of 2,000+ RA patients who are not part of the Creakyjoints online membership. The incorporation both of an online RA patient community as well as in-person at the UAB RA clinic will ensure that the results from Aim 1 are highly generalizable to all RA patients, not only those who are part of an online arthritis community. From within the UAB population, we will oversample RA patients who are non-Caucasian, those with low socioeconomic status, and lower education.

As the second component of this sub-aim, we will use the survey to ask patients to rank various existing, validated PRO instruments chosen by patients in the focus groups with respect to their importance, feasibility, and relevance to RA. We will include RA-specific measures derived solely from patients (e.g. RAPID3, RAPID4, SF-12, pain visual analog scale, Multidimensional Health Assessment Questionnaire, fatigue) and those that incorporate some physician data (e.g. Clinical Disease Activity Index [CDAI](3)). We will also present our patient partners with options to rank several of the instruments relevant to RA that are part of the NIH Patient Reported Outcomes Measurement Information System (PROMIS). PROMIS consists of precise, customizable instruments to capture domains that are likely very important to patients. While not disease specific, these are often impacted by RA. Examples of relevant PROMIS domains include depression, psychosocial impact, anxiety, pain intensity, sleep dysfunction, social roles, and peer relationships.

Aim 2: In this aim, we will demonstrate the feasibility and usefulness of electronically capturing the PROs that were most highly prioritized as a result of the Aim 1 findings. The UAB Mobile Application lab will work with the rest of the project team, including reknown RA patient advocates Seth Ginsberg, Amye Leong, and other arthritis patients that are part of Creakyjoints or the UAB RA clinic to evaluate electronic representation of PRO data that will be incorporated into the RheumPRO mobile application that has been developed at UAB. We will obtain patients' feedback on use of the tool deployed both for at-home data collection, as well as collected in the waiting rooms at rheumatology clinics. The Questionnaire for User Interaction Satisfaction (QUIS) (4) will be used for this purpose.

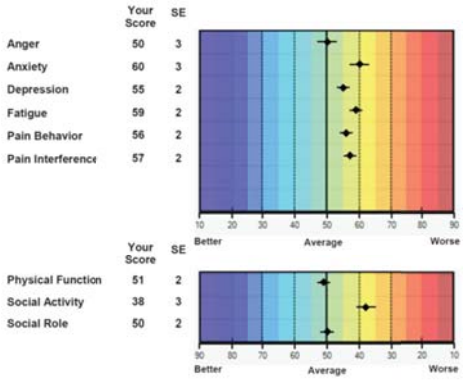

Figure 1: Heat Map representation of PROs across multiple domains

As part of this Aim, we will test different ways of displaying quantitative information around PROs and obtain patients' perceptions of the understandability, importance, and usefulness of the presentation of the results of the PRO instruments that were most highly ranked by participants in Aim 1. For example, the NIH PROMIS measures typically display the results of the PRO instruments as a number ranging from 0 to 100, normalized to a mean of 50. We will test alternative representations, such as with a 'heat map' (Figure 1). Variations on this display would include allowing patients to 1) pick which PROs they feel are most relevant to them, and most helpful to talk about with their doctor; 2) compare themselves with the other RA patients ('benchmarking'), using data collected by the tool; 3) prioritize which of the various PROs they want to discuss with their physician at the next clinic visit; and 4) decide on an intervention threshold, meaning the level of the PRO at which they feel that they would want to do something different with respect to their RA treatment approach. This will help stimulate patients to consider their interest and readiness to make treatment changes, using an instrument such as the Stages of Change questionnaire derived from Prochaska.

Although the focus of the evaluation is on PROs, the benefits of RA treatment and their impact on PROs must be considered in light of potential risks. For that reason, we will also examine patients understanding and perception of safety risks and associated presentation of information (e.g. risk of serious infection, displayed as a pictograph [Figure 2]. Presentation of this information will be tailored in light of patients' graphical and numeric literacy, which will also be captured as part of this aim using existing instruments.

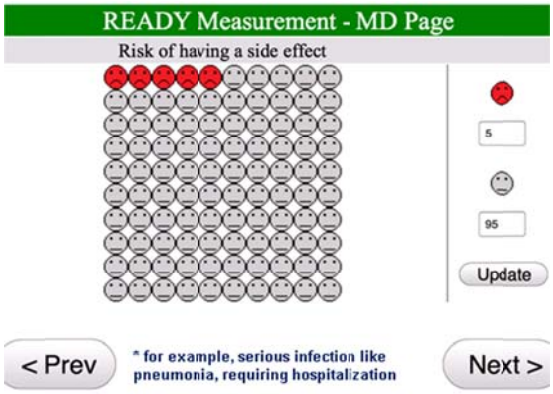

Figure 2: Icon Array showing Safety Risks for Serious Infections (5/100 patient-years)

At the conclusion of this Aim, we will have a field-tested electronic PRO data capture tool. It will allow patients to pick the PRO instruments of highest relevance to them, yet maintain a 'core set' of PRO instruments (e.g. RAPID3) commonly used in RA. Thus, for analysis purposes, there will always be a standard, stable core foundation of PRO instruments collected by all patients, yet customization will let patients additionally choose from a set of existing, validated instruments to capture the PRO domains of highest relevance to them.

Aim 3:

Following Aims 1 and 2, we will scale RheumPRO to be available for distribution within the Apple App store (for Apple-based devices, like the iPhone and iPad), Google Play (for Android-based devices), and via the Internet (through a browser). We will enable connectivity to READY2 so that the PRO data can be integrated between the two systems. We then will engage twelve rheumatology clinics in both university and private practice settings to enable their RA patients who have either at-home Internet access, and/or own Smartphones, to collect PROs. To select sites, we will leverage our ongoing relationships with many rheumatologists with interest in this topic including the extensive site network of CORRONA (more than 80 sites), the 42 sites participating in the TEAR trial (PI: Curtis), and the 12 site VARA registry (which UAB

investigators are part of). Preliminary discussions with a number of these sites indicate that many have high interest in participating in such a program. We will evaluate effectiveness and efficiency of the tool platform in these real world settings at 6 months after deployment at each site.

Of note, we have found that although many clinical sites report that they are already adopting T2T treatment strategies, there is wide variability as to what this actually means. Typically, many clinical sites collect a RAPID3 or MDHAQ on paper, with no specified use of the data, nor any means to know whether the PROs or other quantitative information (e.g. CDAI) is being used in treatment decision making. This type of site will be eligible to be selected for our project. Moreover, we will help each site understand that this project is not enforcing and evaluating a rigid T2T treatment strategy but rather seeks to collect and incorporate patient-derived PRO data into real-world encounters and RA treatment decisions.

C.2.4 Design of Outcomes Evaluation: The main outcomes to be assessed as part of Aim 3 are whether the PROs data is discussed at the clinic visit, and whether changes in RA therapies were made. These outcomes will be assessed over the 6 month study period. A secondary outcome is the proportion of RA patients in each physician's practice who achieve low disease activity or remission at 1 year, measured using validated instruments based on their established cutpoints (e.g. CDAI < 10 [0-76 scale], RAPID3 < 6 [0-30 scale]).

As part of this latter evaluation, we will cross-classify (i.e. stratify) achieving the recommended disease activity targets by CDAI against other PROs (e.g. pain, fatigue, sleep, function measured by MDHAQ) to examine the impact on improvement or worsening on those scales. This addresses a concern whereby RA patients may be improving in certain ways (e.g. fatigue) that traditional measures of RA disease activity (e.g. CDAI) fail to capture, or conversely, fail to improve in domains that patients care about the most, despite improving in RA disease activity measures (5). Through capture of key patient and clinician-reported comorbidities (derived from the formative work in Aim 1), we will assess PRO data in light of symptoms or problems that may not be related directly to RA-associated inflammation yet impact PROs and perceptions of RA treatment benefits.

We will evaluate the two main outcomes of the study: 1) time (in minutes) that the patient and clinician spend discussing PRO data at clinic visits; and 2) RA treatment changes. We will assess these outcomes upon data collected via both RheumPRO and READY2. We will collect the amount of time that was spent discussing PROs based upon patients' perspectives, and their medications and medication changes. For the outcome of time spent with the clinician discussing PROs, we will test the hypothesis that the time spent is significantly different from zero (i.e. H_0: PROs were not discussed, i.e. 0 minutes). We will also use RheumPRO and READY2 to assess whether patients' RA medications were changed (either non-biologic DMARDs, and/or biologics) during the 6 month study period compared to the 6 months prior to the intervention start, a within-person, pre-post comparison, testing the hypothesis that RA medications were more likely to be changed during the study period than immediately prior to it. As part of this analysis, we will examine discussion of PROs as a mediating factor that increased the likelihood of medication change.

The third study outcome (a secondary endpoint), will examine changes in RA disease activity using both the RAPID3 and the CDAI (for sites who collect CDAI), testing the hypothesis

that the within-person change in these measures is significantly different than 0. Finally, the amount of engagement with PRO data collection will be quantified both as how much the tool is used by patients (quantified by their frequency of PRO data input), and within physician practices at each of the 12 sites. Finally, we will qualitatively obtain feedback and satisfaction with electronic PRO data capture from clinicians, staff & patients following the conclusion of Aim 3 of the project based upon the Agency for Healthcare Research and Quality Health Information Technology Evaluation Toolkit.

The number of sites was chosen based upon the goal of having at least 80-90% power to show significant differences in the two main outcomes described above. The assumptions made in these calculations assume that there are 50 RA patients/site who are willing and able to use the RheumPRO tool (based upon having at-home Internet access, and/or a Smartphone), and alpha = 0.05. For RA medication treatment changes during the 6 month study period, we have assumed a 20% 'background' rate of DMARD/biologic changes, based upon our past work and using CORRONA data (6) . These calculations also allow for sufficient power even assuming the presence of within-site clustering using an intra-class correlation of 0.05. For the dichotomous outcomes of RA medication changes and proportion achieving remission/LDA, we have used a 10% improvement over baseline (i.e. pre-intervention) to represent a clinically significant change, and we have based our hypothesis testing on these assumptions.

C.3 Workplan and Deliverables

Each Period (P) represents 6 month periods beginning 1/2014 (P1) and extending through 7/2016 (P5)

Description of Task & Deliverables	P1	P2	P3	P4	P5
Obtain IRB approval	X				
Aim 1: Patient focus groups for Domain 1 (barriers, preferences, concerns for PRO data collection)	X	X			
Aim 1: Patient focus groups for Domain 2 (barriers, preferences, goals, concerns for achieving T2T goals, informed by PRO data)		X	X		
Aim 1 Deliverable: Results from patient focus groups and patient surveys			X		
Aim 2: Enhancement of mobile application PRO platform, informed by Aim 1, with assessment of usability and user interface		X	X	X	
Aim 2 Deliverable: Results from beta-tested version of patient-facing mobile application, evaluated by the Creakyjoints membership and UAB RA Clinic patients				X	
Aim 3: Deployment and evaluation of PRO application to 12 clinic sites and their RA patients				X	X
Aim 3 Deliverable: Results from evaluation of PRO data collection on process measures (discussion around PRO data; RA treatment changes) and outcome measures (RA disease activity)					X

C.4. Dissemination: We will publish our results in the peer reviewed literature based upon the Deliverables described above, under the leadership of Dr. Curtis. Also, we will include hands-on demonstration of the electronic PRO data collection at an ACR workshop at the ACR annual meeting (based upon interest on the part of the ACR meeting planning committee and Registry committee, of which Dr. Curtis is a member) and through other rheumatology regional and national meetings. The tools also will be available in the iTunes App store and Google Play, facilitating easy of acquisition by RA patients across the U.S. Seth Ginsberg, the president and founder of Creakyjoints, will also facilitate dissemination of the study results and PRO tools as part to the Creakyjoints member community via Facebook, Twitter, the Creakyjoints arthritis community website, and bi-weekly newsletters.

C.5. Limitations and Alternative Approaches

Engagement of Creakyjoints and online arthritis patient communities. Our Creakyjoints RA patient partners represent a convenient, highly-accessible, motivated, and willing set of patient participants to help with the formative work described in Aim 1, and the electronic PRO data capture assessment for Aim 2. However, this group is by no means the only large group of patients with RA. Indeed, Dr. Curtis has established relationships with other large RA patient groups (e.g. RA Warrior, at www.rawarrior.com; recent joint presentation at the ACR, and Rheumatoid Awareness Day Twitter chat, sponsored by the Rheumatoid Patient Foundation). Irrespective of an RA patients' membership in an online RA patient community, based upon results from the most recent Pew Internet survey, over 50% of Americans currently have access to smartphone technology. Nevertheless, we recognize that some RA patients are not currently members of any such community, nor do they have Internet access or smartphone technology (e.g. iPhone)., Our intent is that the PRO data collection tools will be generalizable to a national audience, at a minimum through in-office PRO data collection through READY2 or a similar system. For that reason, the formative work and technology evaluation described in Aims 1 and 2 also will engage UAB RA Clinic patients (numbering more than 2,000 overall) to ensure that patients' views and comfort with PRO data collection represent not only those with Internet access but also include RA patients contributing PRO data in rheumatologists' offices. While in this project, in-office PRO data capture will be accomplished via the READY2 iPad tool, we will maximize generalizability by clearly delineating our results related to PRO data capture through any means (electronic or paper) as distinct from the operational aspects of electronic PRO data capture we will use for this project (Aim 2). Thus, our results regarding barriers/facilitators, concerns, and use of PRO data will generalize to data capture deployed via other electronic tools or even on paper (e.g. MDHAQ, RAPID3, or NIH PROMIS paper-based short forms).

Interface between RheumPRO (at-home PRO data collection), READY2 (in-office data collection), and Electronic Health Record (EHR) Systems.

As part of Aim 3, we will evaluate PROs collected at home via Internet and Smartphone technology (RheumPRO), coupled with in-office data collection via READY2. This set of tools will be provided to 12 rheumatology clinics and all of their RA patients. The two tools are most efficient when used together, because they allow at-home PRO data collection to flow to the physician 'automatically' to enable point-of-care use of PRO data, facilitate real-time clinical

decision support for T2T targets, and facilitate providers' RA-related data collection (e.g. Swollen Joint Count, CDAI) to flow back to patients to address discordance between patient and provider perceptions of RA disease activity (7).

However, outside of the context of this project, we recognize that not all physicians will use the READY2 tool. For that reason, we will enable the RheumPRO application to allow patients to capture their PROs and provide the information to their doctors (even if they do not use READY2) to discuss their PRO measures through a 'PRO summary sheet' that can be printed at home and brought to the office visit, or shown to the physician in the office setting (for mobile devices brought to the encounter).

Finally, although both these tools can be used as standalone systems or work together, they need to and will often be used in the context of an existing EHR. For that reason, these tools will not replace or be redundant with information that clinicians will already be inputting into their EHR. Rather, the PRO scores (e.g. RAPID3, MDHAQ, CDAI) will be easily available to simply input the resulting scores into a template EHR-note, saving the clinician time. [This is how we most efficiently use READY2 with the UAB EHR]. In the future, this system is expected to be able to interface with the ACR's Rheumatology Information System for Effectiveness (RISE) registry, enabling EHR and PROs data to be used in an integrated fashion.

Link between PRO Data Capture and Attainment of the T2T Targets of Remission/Low Disease Activity.

Despite our high expectation that longitudinal capture of PROs will facilitate discussions between patients and their clinicians and promote shared decision-making, it is possible that this interaction may not lead to a higher likelihood of RA medication changes nor attainment of T2T disease activity goals. While this possibility exists, this end result may be warranted for RA patients who have other concerns besides minimizing RA disease activity. Moreover, patients may have comorbidities (e.g. malignancy, cardiovascular disease, osteoporotic fractures, fibromyalgia) that reflect adversely on PRO measurement independent of RA disease activity. While this possibility exists, the data capture that is part of this project will enable efficient characterization of the phenotype of patients who do desire to improve and provide tools to help patients communicate with their physician about their own RA treatment goals.

D. Organizational Detail

The UAB School of Medicine and Health System provide a vibrant, collegial, interactive environment that benefits our faculty, patients, students and community stakeholders alike. The UAB Division of Clinical Immunology and Rheumatology has been listed as one of the best clinical Rheumatology programs in the country by *US News & World Report* for 19 consecutive years and is internationally recognized for its dedication to pursuing new knowledge and translating research findings into more effective diagnosis and treatment of patients with rheumatic diseases. As one of the largest academic rheumatology units in the nation, the division's clinical program employs 17 rheumatology clinicians and is responsible for the care of more than 2,000 RA patients.

Key clinical leaders of the proposed project team include Drs. Jeff Curtis, MD (PI) and Kenneth Saag. Drs. Curtis and Saag are rheumatologists, outcomes researchers and are coauthors of the ACR 2008 and 2012 ACR Recommendations for the management of RA (PI and senior author: Dr. Saag). Their long-standing expertise in evidence implementation and adherence research will serve as core strengths of this QI project. Moreover, as Director (Saag) and Co-Director (Curtis) of the UAB Center for Education and Research on Therapeutics (CERTs) of Musculoskeletal Disorders, their main areas of research interest are in comparative effectiveness, medication adherence and safety, evidence implementation and quality of care. Dr. Curtis will be responsible for all aspects of the project.

Other UAB co-investigators include Dr. Tony Skjellum and Larry Owens in the UAB Division of Computer Science and Information systems. They have extensive experience in developing and working with secure information systems, managed services, mobile application development, and large database optimization. Dr. Ragib Hasan is expert in data security, encryption, and systems architecture and will provide expertise in verifying that the tools being used conform to the highest standards of HIPAA privacy and security. Sheila Moore will provide expertise (as a consultant) in patient privacy and consent matters. As former head of the UAB IRB, Ms. Moore will provide technical input into the development of language describing the data collection tools to patients and ensuring that the information can be used for outcome assessment. Dr. Lang Chen, the UAB lead statistician for the UAB CERTs, will be responsible for data integrity and analysis. Dr. James Willig will work with Dr. Curtis to be responsible for the focus groups and survey development described in Aim 1, as well as the usability assessment that is part of Aim 2.

Our patient partners for this work include members of Creakyjoints (CJ), part of the non-profit Global Healthy Living Foundation (GHLF) (http://www.ghlf.org). CJ is a patient network that is a 501(c)(3) non-profit organization, based in New York, with the mission to improve the quality of life for people with chronic illness. The GHLF accomplishes this by advocating nationally for improved access to care and by educating the community about the importance of diagnosis, early and innovative medical intervention, long-term lifestyle improvement, and therapeutic compliance. Co-founded in 1999 by arthritis patient and advocate Seth Ginsberg, the GHLF includes several disease-specific communities, the most visible being CreakyJoints (www.CreakyJoints.org) [CJ], a network of approximately 56,000 patients and caregivers in all 50 states. Approximately half of these patients have rheumatoid arthritis (RA), and ~1/4 have another inflammatory arthritis (e.g. spondyloarthritis). CJ represents vibrant online

communities for patients with chronic conditions with an active presence on Facebook, Twitter, YouTube, and other social media tools, as well as an electronic newsletter sent every 2 weeks that is read by more than 60% of members on its distribution list. The current impact of GHLF/CJ is profound; annually, it has more than 20,000 one-on-one interactions with patients through community-based education and advocacy events; partners with more than 400 other advocacy/community groups throughout the U.S.; has an active online presence with 19 million unique website hits across its seven sites; 100 million “impressions” from traditional media; >250,000 YouTube views; and relationships with numerous U.S. Congress and State legislatures. The CreakyJoints Facebook (www.facebook.com/creakyjoints) page is by far the most popular arthritis page with between 10,000 and 30,000 conversations per week.

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