



**Therapy Selection in RA:  
From Clinical Trials to Effectiveness in Practice**

Educational Grant Request – Pfizer Grant ID 10179979

**Collaborators**

University of California, San Diego & Medscape

**Abstract**

A blended-learning educational initiative designed by the University of California, San Diego under the leadership of Dr. Arthur Kavanaugh, Professor of Clinical Medicine in the Division of Rheumatology, Allergy, and Immunology and the Director for the Center for Innovative Therapy at the UC San Diego School of Medicine, that will enable practicing rheumatologists and other clinicians involved in the care of patients with RA to select appropriate treatments based on better comprehension and application of evidence-based data on effectiveness of DMARDs in real-life practice settings. The 4-part initiative includes both live and web-based interventions that will address identified loco-regional and national clinician educational needs with the aim of improving knowledge and self-reported performance in the clinical care for patients with RA.

Perspectives from community-based practitioners will contribute to the common themes that will be integrated within each activity in the curriculum. In this manner, learners participating in all or select interventions are exposed to foundational knowledge and clinical-practice application techniques.

Advanced assessment of activities will measure improvement in individual learners' ability to apply disease activity measures in practice for frequent monitoring and assessment of RA patients, and identify practical strategies to achieve target goals of therapy using available DMARDs.

**TABLE OF CONTENTS**

**1. OVERALL GOALS AND OBJECTIVES..... 3**

**2. TECHNICAL APPROACH ..... 3**

**A. CURRENT ASSESSMENT OF NEED..... 3**

**B. INTERVENTION DESIGN AND METHODS..... 6**

**C. EVALUATION DESIGN ..... 12**

**3. DETAILED WORKPLAN AND DELIVERABLES SCHEDULE ..... 14**

**4. ORGANIZATIONAL DETAIL..... 15**

**5. DETAILED BUDGET ..... 17**

**APPENDIX A: RHEUMATOID ARTHRITIS TREATMENT SURVEY QUESTIONS ..... 20**

**APPENDIX B: CONFLICT OF INTEREST AND DISCLOSURE POLICY ..... 23**

**APPENDIX C: REFERENCES..... 24**

## 1. OVERALL GOALS AND OBJECTIVES

The overall goal of this educational initiative is to enable community-based practicing rheumatologists and other clinicians involved in the care of patients with rheumatoid arthritis (RA) to select appropriate treatments (mono- and combination therapies) based on critical appraisal and application of data on effectiveness of disease-modifying anti-rheumatic drugs (DMARDs) in real-life practice settings. The curriculum is designed by the University of California, San Diego (UC San Diego) under the leadership of Dr. Arthur Kavanaugh, Professor of Clinical Medicine in the Division of Rheumatology, Allergy, and Immunology and the Director for the Center for Innovative Therapy at the UC San Diego School of Medicine. This program utilizes carefully integrated educational interventions to maximize the transfer of clinical information into practical strategies for community practitioners. The insights gained through participation in the interventions will help build clinician confidence and competence and support use of the learnings in clinical practice, thereby contributing to improved management and outcomes of patients with RA.

*Objectives:* The aim of the educational initiative is to improve clinician knowledge and performance with the following aspects of clinical care for patients with RA:

- Synthesize and analyze factors for the benefits and risks of mono- versus combination DMARD therapy in the management of patients with RA
- Interpret recent evidence-based data from patient registries and pragmatic clinical trials in RA regarding mono- vs combination strategies to inform decision-making in practice
- Identify practical strategies for monitoring disease activity and for achieving target goals of therapy using available DMARDs in patients with RA

## 2. TECHNICAL APPROACH

### A. CURRENT ASSESSMENT OF NEED

According to the American College of Rheumatology, the overall goal of therapy for patients with RA is to achieve low disease activity or remission and to prevent or control joint damage, prevent loss of function, and decrease pain.[Singh 2012] However, many patients with RA do not have the disease adequately controlled, and only a minority attain consistent remission.[Prince 2012] The Comparative Effectiveness Review of the Agency for Healthcare Research and Quality (AHRQ), *Drug Therapy for Rheumatoid Arthritis in Adults*, was designed to assist clinicians in making treatment decisions,[Donahue 2012] but data from an online survey of US-based rheumatologists reveal that:

- 45% of respondents had not read the report;
- 70% of participants were not familiar with the findings and recommendations of the report;
- Only 20% had used the reported data on therapies for adults with RA in their own clinical practices; and
- 27% identified the barrier that it is not clear how to translate comparative effectiveness reports into patient care in practice.

Increasing evidence suggests that using a treat-to-target strategy can achieve remission or low disease activity in RA.[Cardiel 2013; Ruderman 2012; Vermeer 2011] To successfully treat to target, rheumatologists need reliable measures of disease activity and the knowledge and competence to switch and/or escalate therapy to achieve and maintain therapeutic targets.[Gilek-Seibert 2013]

UC San Diego has noted that the available guidelines provide broad recommendations and clinical trials offer supportive data, but rheumatology healthcare professionals have difficulty selecting from treatment choices for RA in the real world practice setting. Differences in study design, dosing regimens, and data from defined and specific patient populations pose challenges to clinicians who treat patients with diverse characteristics and needs. Because clinical trial results are not easily translated into real-life clinical practice (due to strict inclusion and exclusion criteria), there is a need to synthesize evidence from all sources, including meta-analyses of clinical trial data, data from patient registries in RA (eg, CORRONA, CATCH, ARTIS), and results of pragmatic trial designs (eg, TICORA, BeST, SWEFOT, TEAR). This synthesis would enable rheumatology healthcare professionals to more easily compare the effectiveness and safety of RA treatment strategies as experienced in real-life practice settings. Analysis of data from several patient registries and pragmatic clinical trials can provide direction for treatment selection at point of care using mono- and combination DMARD therapies, monitoring and assessment, considerations of potential toxicities, impact on adherence, patient preferences, and optimization of outcomes for patients at various stages of RA. Community rheumatologists and other clinicians may benefit from education and expert guidance to appropriately evaluate and apply these data for the improved care of their patients with RA.

The need for this specific education to provide optimal care for patients with RA has been further noted and documented through local experience by Course Director, Arthur F. Kavanaugh, MD, surveys, and substantiated by gap data derived from previous educational activities available to clinicians nationwide.

Responses to an October 2013 survey conducted by UC San Diego among Southern California rheumatologists underscored regional educational needs in the treatment of patients with RA. A total of 27 rheumatology specialists (21 physicians, 1 PA, 3 NP, 1 RN, and 1 non-identified) responded, 48% noting they are private practice. In designing the questionnaire, Dr. Kavanaugh noted that collecting self-reported data from a survey of regional practitioners was more informative of practice trends in comparison to an analysis of claims data, which could reflect treatment biases based on reimbursement.

#### Regional Survey results

- When asked about their ability to synthesize rheumatoid arthritis (RA) data from the literature into practice to make informed treatment choices, only 19% of responders indicated that they were Very Confident in performing this task.

- Only 19% of survey participants reported that they were aware of available data from RA registries, pragmatic trials, and real-world data but did not know how to incorporate this into daily clinical practice.
- Thirty-nine percent of survey respondents indicated a lack of knowledge on the evidence for mono- versus combination-therapy in managing RA, while only 19% noted that they Fully Understood.
- Seventy-four percent of participants indicated that their greatest area of educational need is practical recommendations for mono- versus combination-therapy in RA.
- Seventy percent of survey participants indicated they would like more education on the comparison of effectiveness and safety of RA treatment strategies in real-life practice settings.
- Synthesized evidence from clinical trials in RA (59%) and practice points for disease activity monitoring and treatment modification (67%) were also highly valued as future educational areas of need.

Leveraging UC San Diego’s partnership with Medscape Education Rheumatology, this same survey was then issued by Medscape in November reaching rheumatologists practicing across the US. A total of 52 rheumatology MD specialists responded, with 59% in private practice.

Survey results found the following:

- While 41% of respondents felt very confident in their ability to synthesize data from clinical trials, 48% of respondents still indicated a need for and interest in additional education on this topic.
- Similarly, 48% of respondents were interested in education on practical recommendations for mono- versus combination therapy in RA and 69% were interested in education that offered a comparison of effectiveness and safety of RA treatment strategies in real-life practice settings.

Additional gap analysis data from online activities developed by Medscape Education Rheumatology show that approximately 25% of rheumatologists could not identify appropriate therapy selection in a patient demonstrating suboptimal response for first-line DMARD; 30% of rheumatologists could not identify the impact of discontinuing DMARD therapy; and 22% of rheumatologists did not know how best to treat patients experiencing secondary failure or toxicity from combination DMARD therapy.

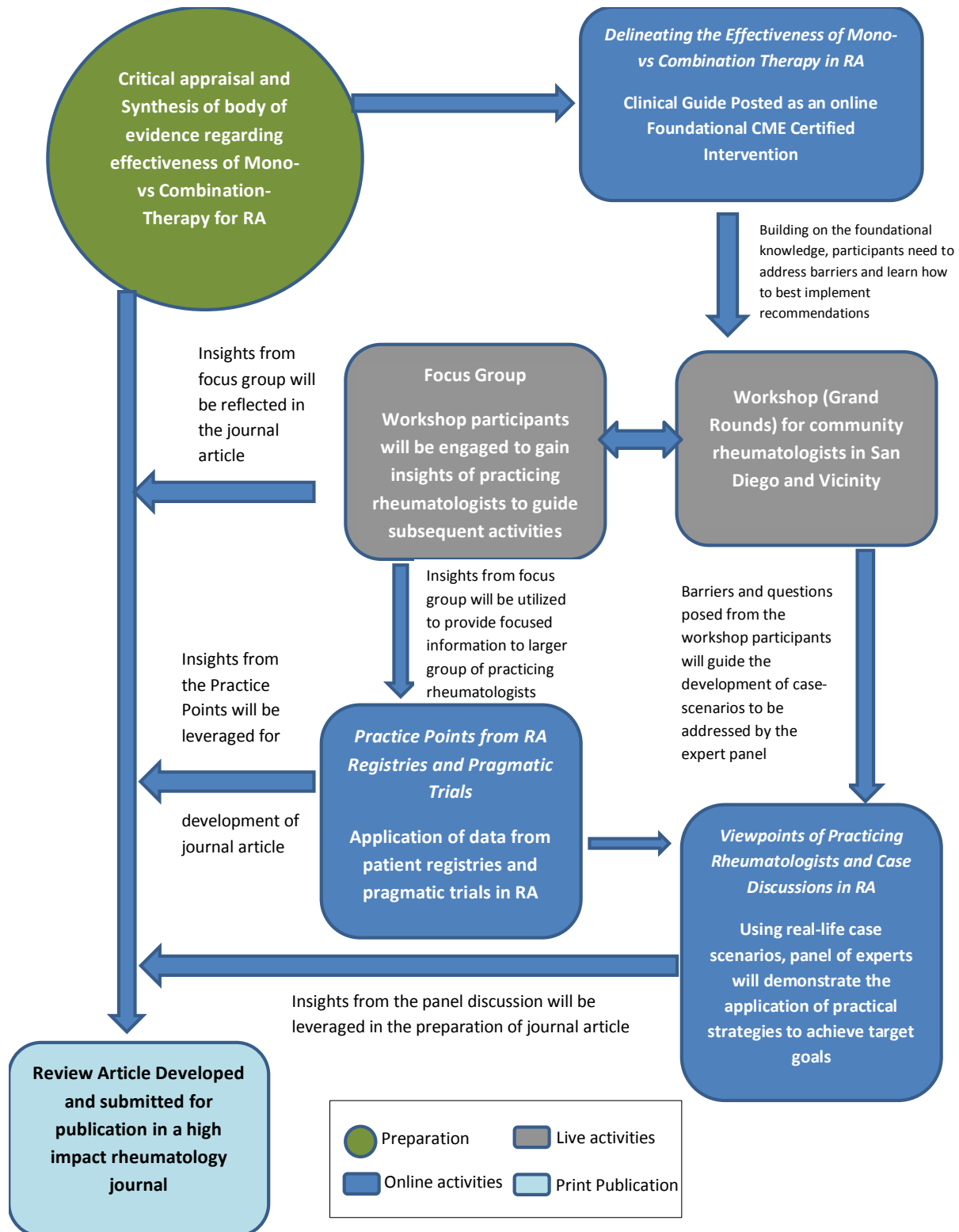
Thus, this survey was useful in determining the current regional and national practitioner knowledge base as well as specific areas and topics practicing rheumatologists would select for additional continued education and professional development. Accordingly, the interventions within this initiative are intended to highlight these areas of interest and provide updated clinical trials findings and practical applications to clinical practice.

## B. INTERVENTION DESIGN AND METHODS

To address knowledge and clinical practice gaps in therapy selection for RA at the community level, UC San Diego, in collaboration with Medscape Education Rheumatology, will develop a blended-learning initiative using live and online educational interventions. Leveraging the wealth of experience and novel educational techniques and approaches developed by the faculty at UC San Diego, in conjunction with instructional design experts at Medscape, the education partners will develop instructional modules outlining the decision-making process for treatment selection in RA that will move rheumatology healthcare professionals along a progressive continuum from awareness of real-life data on mono- and combination-therapy for RA, to performance. **Common themes will be integrated within each activity as the content focus progresses from foundational knowledge to clinical application, with material and results from each activity informing the content of subsequent activities.** Dr. Arthur F. Kavanaugh will guide the development of all content, in collaboration with other renowned faculty in RA. (Figure 1)

This initiative will provide community-based practitioners with the unique opportunity of networking and learning from an expert in the field of RA, with the aim of improving knowledge, competence and performance in determining when mono- or combination therapy is appropriate. The education builds upon and adds to the well-respected and long-standing RA educational curriculum offered by the UC San Diego Division of Rheumatology, Allergy and Immunology, which has reached an engaged population of rheumatology specialists practicing within the UC San Diego region. Inclusion of this regional clinician network will allow for direct follow-up and feedback on the Self-Reported Performance Improvement questionnaire, which will be distributed to the clinicians who participate in the live event in the form of pre-, post-, and follow-up activity assessments.

The intended learner audience for the live workshop includes practicing rheumatologists in the UC San Diego local and regional community. To ensure that the education for community rheumatologists also reaches largest group of practicing rheumatologists, UC San Diego, through the partnership with Medscape, will reach an additional 3,590 active rheumatologist Medscape members by leveraging the Medscape web platform to host education developed within this initiative. To further ensure that the education within this initiative is distributed to the clinicians who can most benefit from the lessons, UC San Diego will engage Medscape's database cross-referencing capabilities using ICD codes on administrative health claims to identify physician members specifically providing care to patients with RA.



**Figure 1: Integrated curriculum of activities.**

## **Description of Educational Interventions**

The educational interventions within this initiative will be implemented in the following sequence, to allow progression of education from foundational knowledge through practical strategies for optimal selection of therapy for patients with RA:

1. **CME-certified Clinical Guide (online activity): *Delineating the Effectiveness of Mono- vs Combination Therapy in RA***  
1.0 AMA PRA Category 1 Credit™  
*Teaching aim:* Improve foundational knowledge and acquire skills to synthesize data from multiple sources

The Clinical Guide is designed as a comprehensive 5000-word review of research findings and therapeutic advances, with the aim of synthesizing diverse data (from patient registries, clinical trials, and pragmatic trials) into material that will clarify and guide treatment of RA. The text will be organized to distill detailed information into easily digestible segments and is designed to provide point-of-care context and perspective. The article features multiple embedded, interactive, practice- or knowledge-based polling questions that assess confidence, barriers, attitudes, and other unmet needs of learners. Immediate peer-response feedback deepens learner engagement. The Clinical Guide is an effective format for establishing a foundation for subsequent practice-related education; aggregating and synthesizing a large body of evidence; analyzing how recent research has influenced the standard of care; and clarifying complex therapeutic issues.

This activity will be authored by Dr. Arthur Kavanaugh, a well-respected local and nationally recognized leader in the field of rheumatology. The content will focus on the current evidence base on the effectiveness of mono- and combination treatment strategies for patients at various stages of RA. The text will evaluate the relevance and impact of comparative effectiveness data on clinical practice for patients with RA and appraise and analyze factors for the benefits and risks of mono- versus combination DMARD therapy. The content of the Clinical Guide will serve as a basis for subsequent educational activities in the curriculum.

2. **CME-certified Live Workshop**

Up to 3.0 AMA PRA Category 1 Credits™

*Teaching aim:* Improve foundational knowledge and develop ability to apply knowledge

A live educational workshop will include foundational material and case-based discussion between a practicing clinician expert, Dr. Arthur F. Kavanaugh, and a community-based rheumatologist. This live educational activity will be made available to rheumatology healthcare professionals practicing onsite at UC San Diego as well as to clinicians practicing locally at affiliate hospitals and independent practices in the Southern California region. A nominal registration fee will help ensure commitment of participation. Through the real-world case presentation, clinician participants will learn about practical strategies for treatment selection and monitoring of disease activity. Upon registration and again with



confirmation of attendance, participants will be invited to share personal case studies to gain expert and peer consultation.

To prime the learner for the discussion to be presented within the live workshop, registrants will be given a pre-activity assignment to view the online Clinical Guide activity (curriculum activity 1). At the conclusion of the workshop, clinicians will also be made aware of the upcoming online activities to be developed within this initiative.

**Focus Group:** Workshop participants will be invited to engage in a focus group held immediately following the live activity. It is anticipated that 10 clinicians will be convened during a moderated 45-minute session that will probe for the community practitioner's perspective regarding barriers to optimal treatment of RA and effective modes of communication to best disseminate evidence-based data. This information will further contribute to refinement of content for the remaining online and print interventions to be developed within this curriculum.

3. **CME-certified Video Curbside Consult (online activity): *Practice Points from RA Registries and Pragmatic Trials***

0.25 AMA PRA Category 1 Credit™

*Teaching aim:* Develop ability and competency to apply knowledge in practice

Emulating the style of the live workshop, the Curbside Consult is designed as a 10- to 15-minute case-based online video discussion between 2 experts in the clinical management of RA. As with the live workshop, 1 presenter will provide the academic expert perspective and the other will represent the community practitioner perspective. The discussion will include 1-2 interactive, multiple-choice, intra-activity questions to deepen learner engagement and provide immediate peer feedback. This structure of the activity permits for succinct delivery of practical clinical information and recommendations for patient care. A transcript with embedded slides and a downloadable deck will be available for future reference and serve as supplemental learning tools.

Seminal teaching points from the live workshop and the focus group session will inform the discussion between the 2 expert faculty about how appropriate examination of data from patient registries and pragmatic trial designs can impact treatment decisions in real-life practice. The faculty will interpret recent evidence base from patient registries and landmark clinical trials in RA with regard to mono- vs combination strategies and will demonstrate the application of treatment recommendations in individual patients with RA for optimal outcomes.

4. **Video Panel Discussion (online activity): *Viewpoints of Practicing Rheumatologists and Case Discussions in RA***

0.5 AMA PRA Category 1 Credit™

*Teaching aim:* Reinforce foundational concepts and strategize approaches for clinical application

This online roundtable panel discussion features a 30-minute video of a moderated dialogue. Questions posed during the focus group discussion and the workshop will be deliberated by a panel of expert academic and community-based rheumatologists who will also review real-life patient cases to highlight when mono- or combination therapy is appropriate. Panelists will demonstrate how application in practice of disease activity measures can help with frequent monitoring and assessment of RA patients to inform treatment decisions, and will identify practical strategies to achieve target goals of therapy using available DMARDs in patients with RA.

Interactive, multiple-choice, intra-activity questions will deepen learner engagement and provide immediate peer feedback. A transcript with embedded slides and a downloadable deck will be available as supplemental learning tools.

5. **Review Article.** The synthesis of established literature, content from the live workshop and learnings from the focus group and project outcomes will be used to develop an article that will be submitted for consideration of publication in RA-specific peer-reviewed journals. The content focus for this article will be to serve as a practical guide that can easily be referenced by rheumatologists at point of care. In addition, results from this initiative will be submitted for presentation to professional and scientific meetings, including the American College of Rheumatology Annual Conference and the Alliance for Continuing Education in the Health Professions (ACEHP) Annual Conference.

### **Faculty**

UC San Diego Office of Continuing Medical Education uses a multifaceted approach to identify and secure faculty for all CME initiatives, including a review of current literature and discussions with current and previous faculty contributors and education partners. The goals are to ensure that all potential faculty contributors have an appropriate level of expertise in the therapeutic area, an understanding of the identified audience, a familiarity with adult learning principles, and a willingness to disclose and resolve all potential conflicts of interest.

Dr. Arthur Kavanaugh, Professor of Clinical Medicine in the Division of Rheumatology, Allergy, and Immunology and the Director for the, Center for Innovative Therapy at the UC San Diego School of Medicine, will be the Course Director for this initiative and will direct the development of content for all activities and will be involved at all stages of program planning and execution. Additionally, Dr. Kavanaugh will lead the presentation for the live workshop and participate in the video presentations.

### **Accreditation**

The activities within this initiative will be planned and implemented in accordance with the Essentials and Standards of the Accreditation Council for Continuing Medical Education (ACCME). UC San Diego CME has been awarded Accreditation with Commendation by the ACCME to provide CME for physicians. UC San Diego CME will award AMA Physician's

Recognition Award Category 1 Credit™ to physicians and other healthcare providers who complete these activities.

In the development and presentation of the educational initiative, UC San Diego CME and Medscape will adhere to all rules, regulations, and guidelines of the ACCME, AMA, Association of American Medical Colleges, FDA, and Office of the Inspector General that govern the conduct of accredited CME activities. All scientific materials presented will be objective and show fair balance with regard to the range of therapeutic modalities.

### **Learner Generation Plan**

Custom awareness and recruitment tactics will be used to reach a targeted and active audience of practicing rheumatologists. UC San Diego CME will recruit participants from its membership and participant databases and through the CME website. Email and Web-based notifications will be sent to UC San Diego CME subscribers and past participants. As noted previously, due to the success of Dr. Kavanaugh's past courses in the region, UC San Diego CME has access to a dedicated learner base in the field of rheumatology in the Southern California region.

The activities will also be advertised on the CME California learning portal (<http://www.CMECalifornia.com>), a collaborative project of the 5 University of California medical schools (San Diego, Los Angeles, Davis, Irvine, and San Francisco). CME California provides a comprehensive catalog presented by the schools in the consortium and offers healthcare professionals a unique place to research course offerings and to participate in e-learning and other continuing education activities, along with simplified tracking of course participation to meet re-licensure and professional organization requirements. The reach of CME California includes all current and past participants of the University of California CME programs (national). Activities are searchable by users of other portals on the CECity Centricity Network; anticipated reach is more than 400,000 users.

UC San Diego CME has extensive experience in the development of educational activities with the UC San Diego Division of Rheumatology, Allergy, and Immunology. The Department's annual regional meeting, Update in Rheumatology meeting is its 9<sup>th</sup> year, and sells-out its registration capacity each year. Many of these learners attend the annual course every year, and have been continuously engaged with relevant coursework developed by UC San Diego CME. This meeting reaches an average of 100 regionally located rheumatologists and rheumatology healthcare professionals each year. Additionally, UC San Diego CME has been involved in nationally distributed rheumatology activities, including an 8 city series and subsequent newsletters reaching more than 1,000 participants.

### **Enhanced Recruitment Strategy with ICD Cross-Matching**

Online activities will be distributed by Medscape Education through an active promotion campaign. To ensure that the education within this initiative is distributed to the clinicians who can most benefit from the lessons, Medscape will use administrative health claims to identify those physician members specifically providing care to patients with RA. In the past 12 months, Medscape rheumatologists had 379,335 diagnostic or therapeutic interactions with patients

who have RA. An *International Classification of Diseases, 9th Revision (ICD-9)* analysis of Medscape membership also found that, in addition to rheumatologists, 85,000 practicing member physicians have seen patients with RA over the last 12 months. These Medscape members will receive custom emails that will generate awareness of each activity and invite participation in the curriculum.

The enduring activities will build upon the success of several online activities previously launched by Medscape Rheumatology, which have addressed the management of patients with RA. A sampling of 3 recent activities reached more than 2500 practicing rheumatologists.

### **C. EVALUATION DESIGN**

The outcomes measures of the live workshop will be threefold. First the **Post-Conference Evaluation** will include measurements of objectives, perceived barriers to implementing change, confidence, self-report of knowledge gain, and self-report of intent to change. Participants are asked to identify specific professional changes they intend to make in their practice as a result of participating in the activity, barriers they perceive in implementing these changes, and how they plan to address specified barriers.

Secondly, following the workshop, via e-mail UC San Diego will issue a **Self-Reported Performance Improvement questionnaire** to all physician participants. This survey will assess improvements in knowledge and application of the education with the clinician's individual practice. It is expected that participants will express greater confidence in 1) knowing when to change RA therapies; 2) evaluate the benefits vs risks of mono- and combination therapies; and 3) identify which treatment strategies to apply in real-life practice settings.

Thirdly, a **follow-up survey** will be distributed via e-mail 6 weeks post activity for measures of confidence, competence, self-report of barriers to implementing change, self-report of knowledge gain, self-report of performance; objective measurements of knowledge gain (repeat of knowledge and competence based post-test questions from evaluation). Pertinent data collected on the Post-Conference Evaluation and Self-Reported Performance Improvement Questionnaire will be shared in this follow up, including participant identified goals, changes they intended to make in their practice, tools and tips, and specific suggestions attendees made to overcome barriers to change. Participants will also report on the impact specific information imparted in the activity had on their practice as well as changes in clinical behaviors/procedures they have actually made in their practice at this stage. This reinforcement of goals and suggestions made by colleagues is helpful in supporting long term retention of knowledge and commitment to change. Participants will also be able to view the responses they gave on their evaluation, specifically the goals they identified immediately upon completion of the activity, and reflect on if they actually made those changes. Not only does this approach reinforce the learning objectives of the activity, but also reminds individuals of the specific goals they themselves set for themselves and encourages long term change. A summative report will provide an analysis of the results from these surveys.

UC San Diego will partner with Medscape to measure the online activities to assess educational effectiveness at the following levels: participation (monthly participation statistics), satisfaction (CME evaluations forms), and medical knowledge and competence (CME post-tests). In addition, the online Panel Discussion activity will be further assessed to measure **performance-level outcomes via a Performance Linked Learning Assessment**. A representative sample of rheumatologists will be assessed via a case-based instrument of up to 6 questions to measure clinical practice improvement and analyze barriers to optimal care. Each multiple-choice question, which will align to the workshop post-activity survey, will map to a learning objective, and will be derived from performance measures, guidelines, and current evidence-based citations. The generation of a Performance-Based Linked Learning Assessment and Report will measure improvement in individual learners' ability to apply disease activity measures in practice for frequent monitoring and assessment of RA patients, and identify practical strategies to achieve target goals of therapy using available DMARDs.

Participant responses to the same instrument will be collected pre-exposure, immediately post-exposure and 30-60 days after exposure (follow up) to the educational activity. Feedback on correct responses will be provided at the post-exposure and follow-up periods only. Reassessment 30-60 days after the activity and retrieval of that information, especially with feedback, serves the dual purpose of measuring the impact of learning experience, and strongly facilitating new learning, thus benefitting the learner and supporting the outcome evaluation. This capture of baseline, post-participation, and follow-up responses—with learners serving as their own controls—allows for a determination of the overall effect of the intervention, and an assessment of performance on a per-learner and an overall specialty-specific basis.

The Performance-Based Linked Learning Assessment Report, delivered as a PDF and slide presentation 4 months post activity launch, will contain a summary of the methods, study design, main findings and conclusions illustrating the participants' evidence-based, clinical diagnostic, and therapeutic choices, as well as the barriers to best practice in the treatment of RA. The report will provide a response-driven assessment of audience needs to identify clinical gaps and recommendations for future education. The report will determine the degree of educational impact of the activity and provide a confirmation of the number of learners who improved or reinforced their baseline level of knowledge or competence, and those who were unaffected by the educational activity. Based on past performance, it is anticipated that 20%-40% of participants will improve their level of competence from the pre-activity survey.

### 3. DETAILED WORKPLAN AND DELIVERABLES SCHEDULE

A critical appraisal/synthesis of the established body of clinical information is key to the development of this initiative, and the first online activity will explore the current landscape and provide the foundation for subsequent activities. Dr. Kavanaugh will serve as Course Director for all initiative activities, and his expertise and commitment will add immeasurable value to the focus of the education. To address knowledge and clinical practice gaps at the community level, UC San Diego will design and host a **live educational workshop** that will include a foundational and case-based discussion between Dr. Kavanaugh and a community-based rheumatologist. A focus group of community-based practitioners attending the workshop will provide practical feedback regarding community-based barriers in the management of RA and will inform the content of the 2 subsequent online activities and the review article.

All educational content will be reviewed by Dr. Kavanaugh, UC San Diego, with support from the Medscape Education Scientific Director, and will undergo compliance review by an external reviewer with no conflicts of interest to ensure fair balance. If there are any concerns regarding the content, a leading expert in the field will conduct additional peer review.

#### DELIVERABLES SCHEDULE AND PROJECT TIMELINE

Task	Month
Educational planning commences	January 2014
Launch of curriculum online activity #1: Clinical Guide	April 2014
Live Workshop (activity #2) and outcomes assessment development; CME review	April 2014
Conduct Live Workshop (Activity #2): Live Workshop-Immediate Post-test/outcomes assessment	May 2014
Posting of online curriculum activity #3: Curbside Consult	December 2014
Posting of online curriculum activities #4: video roundtable discussion, initiation of performance analysis	January 2015
Analysis of outcomes data from video Roundtable is completed	March- April 2015
Preliminary publication of outcomes findings	April 2015
Preparation (preliminary publication) of Clinical Guide review article	May 2015

## **4. ORGANIZATIONAL DETAIL**

### **Leadership and Organizational Capability**

#### ***University of California San Diego Continuing Medical Education***

The mission of UC San Diego CME is to provide needs-based education for physicians and healthcare providers to improve knowledge, competence, and performance and enable the optimal provision of healthcare.

UC San Diego CME uses numerous strategies to achieve our educational mission, including:

- Supporting members of our target audience in point-of-care learning and specific practice improvements;
- Employing additional strategies to support physician learning and positive change (self-assessments, pre-/post-tests, reminders, feedback);
- Participating in a system-wide process-based quality improvement platform;
- Collaborating with stakeholders that support our mission, including hospital-based quality assurance organizations, medical societies, federal and state organizations, advocacy groups, medical schools, and other health organizations;
- Researching and applying current adult education principles and CME literature; and
- Participating in national organizations committed to improving CME.

UC San Diego CME is committed to providing innovative education that impacts healthcare providers' knowledge and behavior, with the ultimate goal of improved patient care. UC San Diego CME has expertise in numerous educational interventions that can be utilized to optimize learning, support behavior change, and document outcomes. UC San Diego CME certifies more than 300 conferences, mini-residencies, home-study programs, and grand-rounds/case conferences annually and was granted Accreditation with Commendation by the ACCME for a 6-year term in 2010. UC San Diego CME is a partner in the CMECalifornia.com learning portal, which reaches more than 100,000 subscribers.

UC San Diego CME has been selected by the Association of American Medical Colleges (AAMC) to be their accredited provider for CME activities. UC San Diego CME was selected by the AAMC review committee due to our streamlined processes, web-based systems, focus on customer service, and faculty leadership. The AAMC represents all 134 accredited U.S. and 17 accredited Canadian medical schools, approximately 400 major teaching hospitals and health systems, and nearly 90 academic and scientific societies.

#### ***UC San Diego Division of Rheumatology, Allergy and Immunology***

The UC San Diego Division of Rheumatology, Allergy and Immunology offers outstanding clinical care, cutting edge clinical and basic research, and training for the next generation of rheumatologists and allergists. The highly-regarded subspecialty training programs in

rheumatology and in allergy/immunology are designed to produce outstanding physicians and scientists that treat patients and develop new treatments to improve the health of our community.

The UC San Diego Health System currently ranks number 1 among San Diego's hospitals for adults, and is among the elite "America's Best Hospitals" for several years running, according to U.S. News and World Report. In 2013, the UC San Diego Health System was recognized in 10 out of 16 specialties in *U.S. News and World Reports 24th annual America's Best Hospitals* issue., Moreover, in 2010, The UC San Diego Health System was recognized as one of the top 15 teaching hospitals in the country, with more than 80 of the physicians on staff named as the best physicians in the region by their colleagues.

### ***Medscape Education***

Medscape, LLC is the leading online source for medical education, with more than 1 million US healthcare provider visits per month.

High quality medical education is effective only if it actually reaches those healthcare professionals who need it. Medscape Rheumatology provides unmatched online reach to rheumatologists and other physicians who may treat patients with RA. Membership includes more than 3500 registered and AMA database-validated rheumatologists. Membership also includes more than 1400 registered rheumatology nurse practitioners (NPs), physician assistants (PAs), and nurses..

In the past 12 months, Medscape rheumatologists had 379,335 diagnostic or therapeutic Interactions with patients who have RA. ICD-9 analysis of Medscape membership also found that, in addition to rheumatologists, 85,000 practicing physicians have seen patients with RA over the last 12 months.



## **Staff Capacity**

Project Manager will be involved in all aspects of this initiative, from program planning to distribution and outcomes analysis. She will coordinate with all collaborators both within and outside of the University to ensure that timelines are followed, deadlines are met, and that the final project is of high quality and meets the overall program goals. Additionally, she will ensure that all ACCME guidelines are followed in the development and execution of this program and handle all aspects of accreditation and related tasks.

Program Manager will oversee and manage the program through to completion, while maintaining established timelines within an At-task project database system. She has expertise in managing web-based video and text projects across a variety of therapeutic areas in the medical education field, but primarily in the rheumatology area and has executed more than 3000 print, online and live media programs during her tenure at Medscape. In her 7 year career at Medscape she has managed programs with many partners including the American College of Cardiology, American Gastroenterological Association, Duke University School of Medicine and University of Texas Southwestern Medical Center. She serves as the primary point of contact for the project team, and implements project timelines to ensure successful execution of the program, within budget and meeting the goals and objectives. She will organize status meetings and collaborate with both internal scientific editorial teams and external partners during the program's development as needed. She will create and maintain the program's At-task database timeline providing the strategic tasks required to successfully develop the program for integration onto Medscape.org. She will manage the development of content, in collaboration with UC San Diego, based on the input from the Course Director and presenting faculty.

## **5. DETAILED BUDGET**

UC San Diego and its partner, Medscape Education Rheumatology, seek a grant in the amount of \$495,400 to support the development and production of this initiative. The project will commence development in January 2014 to ensure posting of the Clinical Guide by April 2014.

The full budget template is submitted as a separate attachment.

## APPENDIX A: RHEUMATOID ARTHRITIS TREATMENT SURVEY QUESTIONS

**Target specialty: Rheumatology**

**Title: *Treatment Selection in Rheumatoid Arthritis***

**Teaser: Rheumatoid Arthritis - What are your challenges in treatment selection?**

1. What is your profession? (Select only one response)
2. What is your primary specialty? (Select only one response)
3. Please rank your level of confidence in synthesizing data from clinical trials in RA to inform treatment choices:  
1 – Not At All Confident      2                      3                      4                      5- Very Confident
4. What is your level of understanding of the evidence for mono- versus combination-therapy in managing RA?  
1 – Do Not Understand      2                      3                      4                      5- Fully Understand
5. Do you incorporate data from RA registries, pragmatic trials, and real-world data in your clinical decision making?
  - Not aware of such data
  - Don't know where to find real-world data
  - Aware, but don't know how to incorporate in practice
  - Sometimes use for clinical decision making
  - Always use such data to make treatment decisions
6. Please select your areas of educational need related to management of RA: (select all that apply)
  - Synthesized evidence from clinical trials in RA
  - Comparison of effectiveness and safety of RA treatment strategies in real-life practice settings
  - Practical recommendations for mono- versus combination-therapy in RA
  - Impact of therapy selection on adherence and patient preferences
  - Practice points for disease activity monitoring and treatment modification
7. Please identify your clinical practice setting:
  - Academic teaching hospital/clinic
  - Community hospital
  - Community public clinic
  - Private practice
  - Other: Open comment field.

## **APPENDIX B: CONFLICT OF INTEREST AND DISCLOSURE POLICY**

UC San Diego CME is dedicated to ensuring balance, independence, objectivity, and scientific rigor in all CME/continuing education initiatives. Planning must be free of the influence or control of a commercial entity and promote improvements or quality in healthcare. All recommendations in CME activities involving clinical medicine must be based on evidence accepted within the medical profession. All scientific research used to support patient care recommendations must conform to generally accepted standards of experimental design, data collection, and analysis.

Conflict of interest is created when individuals in a position to control the content of CME, or their spouses/partners, have a relevant personal financial relationship with a commercial interest within the past 12 months that benefits the individual in any financial amount and therefore may bias their opinions and teachings. This may include receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (eg, stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research and clinical trials), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities for which remuneration is received or expected.

It is the policy of the UC San Diego School of Medicine (accredited provider) to ensure balance, independence, objectivity, and scientific rigor. All persons involved in the selection, development, and presentation of content are required to disclose any real or apparent conflicts of interest. All conflicts of interest will be resolved before an educational activity is delivered to learners through one of the following mechanisms: (1) altering the financial relationship with the commercial interest, (2) altering the individual's control over CME content about the products or services of the commercial interest, and/or (3) validating the activity content through independent peer review. All persons are also required to disclose any discussions of off-label/unapproved uses of drugs or devices. Persons who refuse or fail to disclose will be disqualified from participating in the CME activity.

## APPENDIX C: REFERENCES

Bykerk VP, Keystone EC, Kuriya B, Larché M, Thorne JC, Haraoui B. Achieving remission in clinical practice: lessons from clinical trial data. *Clin Exp Rheumatol*. 2013;31:621-632.

Cardiel MH. Treat to target strategy in rheumatoid arthritis: real benefits. *Reumatol Clin*. 2013;9:101-105.

Donahue KE, Jonas D, Hansen RA, et al. Drug Therapy for Rheumatoid Arthritis in Adults: An Update: Comparative Effectiveness Review. April 2012. Executive Summary No. 55 (AHRQ Pub. No. 12-EHC025-1).

[http://effectivehealthcare.ahrq.gov/ehc/products/203/1042/CER55\\_DrugTherapies-rheumatoidarthritis\\_execsumm.pdf](http://effectivehealthcare.ahrq.gov/ehc/products/203/1042/CER55_DrugTherapies-rheumatoidarthritis_execsumm.pdf) Accessed October 15, 2013.

Casebeer L, Brown JJ, Roepke N, Grimes C, Henson B, Palmore R, Granstaff S, Salinas G. Evidence-Based Choices of Physicians: A Comparative Analysis of Physicians Participating in Internet CME and Non-participants. *BMC Med Educ*. 2010;10:42.

Casebeer L, Engler S, Bennett N, et al. A controlled trial of the effectiveness of internet continuing medical education. *BMC Med*. 2008;6:37.

Cook DA, Levinson AJ, Garside S, et al. Internet-based learning in the health professions: a meta-analysis. *JAMA*. 2008;300:1181-1196.

de Jong PH, Hazes JM, Barendregt PJ, et al. Induction therapy with a combination of DMARDs is better than methotrexate monotherapy: first results of the tREACH trial. *Ann Rheum Dis*. 2013;72:72-78.

Ellison JA, Hennekens CH, Wang J et al. Low Rates of Reporting Commercial Bias by Physicians Following Online Continuing Medical Education Activities. *Am J Med*. 2009;122:875-878.

Gilek-Seibert K, Prescott K, Kazi S. Outcome assessments in rheumatoid arthritis. *Curr Rheumatol Rep*. 2013;15:370.

Isik M, Halacli B, Atmaca O, et al. Triple DMARD combination for rheumatoid arthritis resistant to methotrexate and steroid combination: a single-center experience. *Rheumatol Int*. 2013;33:1425-1427.

Medscape Education Survey. Effective Management of Rheumatoid Arthritis. [.pdf file]. December 27, 2011. Accessed October 15, 2013.

Prince FH, Bykerk VP, Shadick NA, et al. Sustained rheumatoid arthritis remission is uncommon in clinical practice. *Arthritis Res Ther.* 2012;14:R68.

Ruderman EM, Nola KM, Ferrell S, Sapir T, Cameron DR. Incorporating the treat-to-target concept in rheumatoid arthritis. *J Manag Care Pharm.* 2012;18:1-18.

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. *Arthritis Care Res (Hoboken).* 2012;64:625-639.

Vermeer M, Kuper HH, Hoekstra M, et al. Implementation of a treat-to-target strategy in very early rheumatoid arthritis: results of the Dutch Rheumatoid Arthritis Monitoring remission induction cohort study. *Arthritis Rheum.* 2011;63:2865-2872.