**Health Care Quality Improvement & Education in Rheumatoid Arthritis:**

**Bringing Rheumatologists and Primary Care Providers Together to Improve Rheumatoid Arthritis Outcomes**


Grant Proposal - Grant ID 41504

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Submitted to Pfizer, Inc.


An educational grant request from The NYU Post-Graduate Medical School and

Intelligent Medical Decisions, Inc.


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# Contents

**Overall Goals and Objectives**

The Hospital for Joint Diseases at New York University (NYU) Langone Medical Center (HJD) is ranked among the nation's top 10 in rheumatology, and the Division of Rheumatology is a nationally-known center for the diagnosis and treatment of rheumatologic disorders. This educational collaborative will bring together rheumatologists and primary care providers (PCPs) from NYU and the New York, NY metro area with the goal of demonstrating successful interdisciplinary team building to better address appropriate diagnosis, timely referral and CVD risk assessment in patients with rheumatoid arthritis (RA).

The objectives of this initiative are to:

1. Establish a broad baseline of patient- and system-level data on how NYU rheumatologists and PCPs work together to manage patients with RA, with a focus on diagnosis, referral and CVD risk assessment;

2. Analyze the baseline results to develop data-driven educational interventions for a broad audience that identify best practices, persistent gaps, and actionable processes that can result in an overall improvement in RA management between and amongst rheumatologists and PCPs;

3. Broadly re-assess the percentage of adults receiving optimal RA management and CVD risk assessment after the interventions to identify successful strategies and persistent challenges to optimal care;

4. Disseminate the findings to a national audience (via publications and online educational offerings) focusing on all issues – from policy to patient – that positively or negatively impact the management of patients with RA.

These objectives work together serially with the expected outcome of improving diagnosis, timely referral, disease management and guideline-based CVD risk management in patients with RA, as well as fostering a more efficient relationship between rheumatologists and PCPs.

This innovative marriage of quality-improvement (QI) strategies and continuing professional development will result in education that supports and improves the level of care provided to patients with RA. This initiative will involve thousands of patients and providers, and will generate tens of thousands of valuable data points toward a better understanding of population-level outcomes and the impact of CME and QI interventions on RA management. New York University - through the Hospital for Joint Diseases and a partnership with Intelligent Medical Decisions, Inc. (iMD) - is uniquely positioned to bring rheumatologists and PCPs together to guarantee participation, rigorous data collection/analysis, data-driven CME, successful QI implementation, and publication of results.

**Current Assessment of Need in Target Area**

A study of patients with RA in a national health plan show that recommended processes of care specific to RA management were performed only 62% of the time. Through a broader assessment of need (i.e., discussions with expert rheumatologists, a review of NYU-specific educational and quality needs, and a review of the current literature as summarized in the Pfizer RFP document, national and regional guidelines, and quality-of-care measures), we have identified several key areas toward improving appropriate diagnosis, timely referral, disease management and CVD risk assessment in patients with RA.

The project starting point is to establish a regional baseline at NYU and surrounding practices using quality measures defined by this assessment of need and the overall goals & objectives of this initiative. Several sources of quality measures (i.e., The NCQA/PCPI/ACR RA Physician Performance Measure Set, ACR/EULAR classification criteria, and CVD risk assessment measures) will be applied. This will be accomplished by looking at patients in both the Division of Rheumatology and Department of General Internal Medicine at NYU according to the protocol outlined below. Where available, actual baseline data from NYU has been provided to support the needs identified in the broader assessment; however, due to power outages related to Hurricane Sandy, some of the data intended for this proposal were unavailable in time for submission.

**Baseline Assessment Design:** The baseline will be established using two separate groups of patients.

1. ~2000 patients with RA seen in the NYU Division of Rheumatology
2. ~8000 *consecutive* patients (age > 18) seen in NYU General Internal Medicine

In group 1, we will assess ~2000 patients with RA against measures derived from the NCQA/PCPI/ACR RA Physician Performance Measure Set, ACR/EULAR classification criteria, and several CVD risk assessment metrics as listed below. Patients in both Group 1 and 2 will be assessed using the CVD risk assessment metrics*.

| | |
|---|---|
| ✓ RA Functional Status Assessment | ✓ *Blood Sugar Assessment and Management |
| ✓ RA Disease Prognosis | ✓ *Blood Pressure Assessment and Management |
| ✓ Glucocorticoid Use | ✓ *Blood Lipid Assessment and Management |
| ✓ RA Remission Criteria | ✓ *Smoking Status and Cessation Management |
| ✓ Tuberculosis Screening | ✓ RA Disease Activity Assessment |

In group 2, we will assess ~8000 *consecutive* patients seen in the primary care setting against the CVD risk assessment metrics above*, and unique metrics to determine the diagnostic and screening procedures used to identify and refer patients with RA. The goal is to identify patients with joint pain persisting more than 6-8 weeks in which the following referral indicators have been applied (or more importantly, were *not* applied, indicating a gap in the diagnosis and referral process). By assessing a large number of consecutive patients we will establish an accurate baseline measuring the prevalence of RA symptoms and CVD risk assessment in the primary care setting, and be able to examine how PCPs act (or don't act) when patients present with these actionable criteria.

| ✓ Joint Swelling | ✓ Morning Stiffness ≥ 30 Minutes |
|---|---|
| ✓ MCP/MTP Involvement | ✓ Constitutional Complaints |
| ✓ Elevated Inflammatory Markers | ✓ Positive Rheumatoid Factor |

**Baseline Assessment Methods:** NYU faculty – with representation from both the Division of Rheumatology and the Department of General Internal Medicine – will convene to develop a rigorous protocol and determine the quantitative metrics to abstract from patient charts based on the measures described above, as well as qualitative information to describe current RA and CVD risk management processes at NYU (i.e., EMR capabilities, CVD risk assessment tools, RA referral protocols from PCPs to rheumatologists, provider attitudes & beliefs toward CVD risk assessment and RA diagnosis & management).

Data will be obtained through an electronic medical records audit performed by trained NYU departmental assistants. Though some data me be extracted via EMR output procedures (i.e. lab values, CVD risk markers, patient demographics), many of the key data points toward establishing the baseline will require trained personnel evaluating each record to obtain the level of detail required for this project.  iMD will provide its Mobile Medical Outcomes™ platform - a secure & HIPAA compliant electronic data-management and analysis platform - to conduct this initiative.

**Regulatory & Legal:** The U.S. Department of Health and Human Services (HHS) views certain quality improvement activities differently in relation to regulations for human research subject protections.  Therefore the HHS regulations for the protection of human subjects do not always apply to quality improvement activities that meet specific criteria; if these criteria are met, there is no requirement under these regulations for such activities to undergo review by a national IRB, or for these activities to be conducted with provider or patient informed consent.

This study will be designed to meet HHS criteria of a true quality improvement activity therefore not requiring additional regulatory considerations at the national level.  Details regarding HHS policy on QI vs. human subject research activities can be found at **http://answers.hhs.gov/ohrp/categories/1569**. The educational collaborative will fulfill NYU's IRB and legal requirements to ensure the QI protocol and plan for dissemination of findings is in line with University policy and regulations.

**Historical Baseline Data from NYU:**  The Division of Rheumatology performed an assessment of 1400 patients with rheumatoid arthritis toward developing abstracts for the 2011 American College of Rheumatology.  While this analysis was not powered to look specifically at RA quality measures or CVD risk assessment, a broad look at the data set revealed significant gaps in the these areas.  The data are summarized below:

**CVD Risk Outcomes:**
*LDL-C goal attainment in patients with RA:* **25% not at goal** (does not take into account varying LDL goals based on additional risk factors)
- Numerator: Patients with LDL > 130 mg/dL (N=200)
- Denominator: Patients (men ≥45 years; women ≥55 years) with diagnosis of RA (N=800)

*Blood pressure goal attainment in patients with RA:* **31% not at goal** (does not take into account varying BP goals based on additional risk factors)
- Numerator: Patients with BP > 140/90 mmHg (N=250)
- Denominator: Patients (men ≥45 years; women ≥55 years) with diagnosis of RA (N=800)

*LDL-C and BP goal attainment in patients with RA ("All or None"):* **89% not goal** for both LDL and BP (does not take into account varying goal levels based on additional risk factors)
- Numerator: Patients with LDL < 130 mg/dL AND Patients with BP < 140/90 mmHg (N=150)
- Denominator: Patients with a diagnosis of RA (N=1400)

*Smoking Cessation:* **73% of smokers** without a documented discussion/plan toward smoking cessation
- Numerator: Patients who smoke AND who have smoking cessation plan/discussion documented in chart (N=50)
- Denominator: Patients with a Diagnosis of RA AND who smoke (N=300)

**RA Outcomes:**
*RA Disease Prognosis Assessment:* **36% of patients** without a documented prognosis assessment over 12 months
- Numerator: Patients with at least one documented assessment and classification (good/poor) of disease prognosis utilizing clinical markers of poor prognosis within 12 months (N=900)
- Denominator: Patients with a diagnosis of rheumatoid arthritis (RA) (N=1400)

*RA Functional Status Assessment:* **36% of patients** without a functional status assessment over 12 months
- Numerator: Patients for whom a functional status assessment was performed at least once within twelve months (N=900)
- Denominator: Patients with a diagnosis of rheumatoid arthritis (RA) (N=1400)

*RA Disease Activity Assessment:* **36% of patients** without a disease activity assessment over 12 months
- Numerator: Patients with disease activity assessed by a standardized descriptive or numeric scale or composite index and classified into one of the following categories: low, moderate or high, at least once within 12 months (N=900)
- Denominator: Patients with a diagnosis of rheumatoid arthritis (RA) (N=1400)

**Intended Audience:** This activity is intended to foster an interdisciplinary approach to RA management between rheumatologists and primary care providers (including NPs, PAs and allied health professionals). The pre-agreement from NYU to participate in this initiative provides the critical audience of both NYU rheumatologists and primary care providers.

**Intervention Design and Methods**

**Deliverables:** This 2-year, structured QI-CME initiative will include multiple integrated delivery methods as summarized below.  Timelines for each deliverable are described in the *Work Plan and Deliverables* section later in the proposal.

1. Baseline Assessment & Program Development
    a. ~2000 patients with RA seen in the NYU Division of Rheumatology
    b. ~8000 *consecutive* patients (age > 18) seen in NYU General Internal Medicine
    c. Qualitative data related to EMR capabilities, CVD risk assessment tools, RA referral protocols from PCPs to rheumatologists, provider attitudes & beliefs toward CVD risk assessment and RA diagnosis & management
2. Formal Data Review & Discussion - NYU Division of Rheumatology
    a. 20 rheumatologists, 10 allied health providers, 10 medical assistants and 8 fellows
3. Content Development Meeting - NYU Division of Rheumatology and Department of General Internal Medicine
4. Live Meeting #1: *From Data to Insight: The Rheumatoid Arthritis Landscape in New York City*
    a. 150-200 participants (80% PCPs, 20% rheumatologists)
    b. All live-meeting attendees will complete a survey examining attitudes toward RA diagnosis, referral and CVD risk assessment
5. Live Meeting #2: *Beyond Medical Knowledge: Addressing Real-World Barriers to Optimal RA Diagnosis, Referral and CVD Risk Assessment*
    a. 150-200 participants regionally (80% PCPs, 20% rheumatologists)
6. Improvement Plan Implementation & Comparative Assessment: Patients will be assessed according to the same protocol followed during the baseline assessment and the results compared to baseline to quantify change in outcomes.
7. Live Meeting #3: *Impact & Implications: Assessing Improvement and Identifying Persistent Barriers in Rheumatoid Arthritis Management*
    a. 150-200 participants regionally (80% PCPs, 20% rheumatologists)
8. Publication of Results: Both a white paper and peer-reviewed manuscript(s) will be authored and published:
    a. A white paper summarizing the methods and results of this initiative will be authored and distributed to subscribers of *Bulletin of the NYU Hospital for Joint Diseases,* a peer-reviewed clinical journal.
    b. Manuscript(s) will be submitted to multiple peer-reviewed publications including those in the field of rheumatology, primary care, QI, and continuing medical education.
9. Individualized PI-CME Activity for Non-NYU Providers: A streamlined set of performance measures will be applied to the existing data management platform and allow non-NYU providers to participate in an AMA-standardized 3-stage PI-CME activity.
10. Online CME Activity: All live meetings will be audio and video captured and converted into interactive online CME activities.  Participants from any activity (live or web) can seamlessly participate in the PI-CME activity, assess their patients with RA against national goals, and contribute to the overall outcomes assessment.
    a. 1000-2000 participants nationally

**Baseline Assessment & Program Development:** The measures and methods for the baseline assessment are described in detail in the prior section (*Current Assessment of Need*). Once all data are collected, iMD will extract, transform, and integrate the raw data for final statistical analysis within the reporting templates created during the development phase. iMD will then facilitate delivery of these reports to NYU faculty for the content development meeting.

**Formal Data Review & Discussion:** The NYU Division of Rheumatology will convene formally to review the baseline assessment with a focus on addressing the outcomes specific to RA disease management. While these data are of critical importance toward closing gaps in RA care, they are not as relevant to a primary care audience. During this meeting:
- Faculty will present evidence-based content on the importance of appropriate assessment and medical management in patients with RA
  - This will include an update on new and emerging treatment options
- Faculty will present strategies for a focused group improvement plan with the goal of overcoming the identified gaps and barriers
- Attendees will share their own ideas and strategies and leave the discussion prepared to implement a group improvement plan focused on improving outcomes in patients with RA

**Content Development Meeting:** Representatives from the NYU Division of Rheumatology, Department of General Internal Medicine, Office of Continuing Medical Education and iMD will convene formally to review the baseline assessment during a live half-day meeting held at NYU. The data will be used toward developing content for 3 live meetings that bring together rheumatologists and PCPs toward improving care quality in patients with RA. These live meetings will present the findings to a large audience (to include NYU providers as well as regional PCPs and rheumatologists) and will engage participants in an active discussion toward identifying gaps demonstrated in the data.

**Live Meeting #1:** *From Data to Insight: The Rheumatoid Arthritis Landscape in New York City*

Providers will participate in 3 live meetings where expert faculty and a health-system champion will lead attendees in evaluating care-quality gaps identified through the baseline data and developing steps to implement a focused improvement plan. Each data-driven meeting will be 90 minutes in length and will occur on NYU Campus, with a participation goal of 150-200 providers per meeting. Expert faculty and NYU providers will develop content. All meetings will be audio and video recorded and transcribed so that key points can be highlighted in the final analysis and reports as well as used to create a web-based enduring activity. All participants will take a survey designed to examine attitudes toward RA management (a validated survey will be used if available).

The first meeting will be designed to engage providers by presenting data that are directly relevant to improving patient care, and to foster an open discussion toward identifying gaps leading to suboptimal outcomes.

| 30 Minutes | Defining Quality in Rheumatoid Arthritis Diagnosis, Referral and CVD Risk Management |
|---|---|
| | - Faculty will raise awareness on RA diagnostic criteria and the importance |

of early referral

- A nationally known faculty member will present content to update attendees on current and emerging RA treatment options and the role of early treatment in reducing progression

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| **30 Minutes** | **The Truth is in the Data: Baseline Review**<br>• Faculty presentation of NYU provider baseline patient data based on the protocol described in prior sections, with a focus on RA diagnosis, referral and CVD risk assessment<br>• Brief review of value of PI and participation requirements for non-NYU providers interested in enrolling |
| **30 Minutes** | **Mind the Gaps: An Open Discussion to Identify Barriers to Optimal RA Diagnosis, Referral and CVD Risk Management**<br>• Faculty and health-system champions will lead a moderated discussion with attendees to identify clinical and system-based barriers and gaps preventing optimal diagnosis and referral of patients with RA. A primary care faculty member from NYU will help moderate this discussion.<br>• Assignments will be given to attendees to prepare practical improvement-plan strategies for the next meeting |

**Live Meeting #2:** *Beyond Medical Knowledge: Addressing Real-World Barriers to Optimal RA Diagnosis, Referral and CVD Risk Assessment*

The second meeting carries forward the barriers and gaps identified in the first meeting and leads providers through a planning session toward addressing these barriers and gaps with real-world solutions.

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| **30 Minutes** | **Shared Goals, Shared Challenges: CVD Risk Management in the Patient with Rheumatoid Arthritis**<br>• Faculty will present evidence-based content on current and emerging treatment options and the importance of addressing CVD risk in patients with RA and other at-risk populations, and the importance of an interdisciplinary approach between PCPs and rheumatologists |
| **30 Minutes** | **The Elephant in the Room: Tackling the System to Improve Communication and Outcomes**<br>• Faculty will present strategies for a focused group improvement plan with the goal of overcoming the identified gaps and barriers from *Live Meeting #1*, with a focus on issues related to fostering an interdisciplinary approach to care and health system-level complexities |
| **30 Minutes** | **Bridge the Gaps: An Open Discussion to Identify Actionable Steps Toward Quality Improvement in Rheumatoid Arthritis Management**<br>• Attendees will share their own ideas and strategies and leave the meeting prepared to implement a group improvement plan after identifying specific process-based areas in which to improve |

**Improvement Plan Implementation & Comparative Assessment:** After the 2nd live meeting, NYU leadership will work with their respective departments toward implementing specific improvement plans as discussed during the meetings. While this is happening "behind the scenes," it represents the most important and most time consuming part of this initiative. The educational collaborative will monitor progress and note successes and challenges for discussion at the 3rd and final live meeting. Four to Six months after 2nd meeting, NYU Departmental Assistants will perform another chart audit of patients in the Division of Rheumatology and the Department of General Internal Medicine according to the same protocol used in the baseline assessment. A special focus will be given to shared patients (i.e. those patients see in both settings at NYU) to assess changes in the interdisciplinary approach to care.

**Live Meeting #3:** *Impact & Implications: Assessing Improvement and Identifying Persistent Barriers in Rheumatoid Arthritis Management*

The third meeting presents the results of the initiative and allows attendees to reflect on successes and continued challenges.

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| 30 Minutes | **Leverage Your Resources: Practical Steps for Achieving Better RA Outcomes**<br>• Faculty will present practical solutions to challenging problems in RA management and CVD risk assessment, with a focus on leveraging outside resources such as patient educators, pharmacists, and community health workers |
| 30 Minutes | **Extreme Makeover: How Did We Do?**<br>• Faculty and health-system champion review of the comparative assessment<br>• Interactive discussion to identify methods that led to improvement and continued challenges |
| 30 Minutes | **Close the Gaps: An Open Discussion to Review Successes and Challenges in Achieving Higher Quality in RA Diagnosis, Referral and CVD Risk Management**<br>• Faculty and health-system champion discussion of implications, both immediate and projected, of the outcomes:<br>   o Discuss successes that improved processes for patient care quality<br>   o Ongoing barriers and gaps to achieving optimal outcomes |

**Publication of Results:** Utilizing the aggregate outcomes data, NYU rheumatology faculty will develop a white paper for distribution in the Bulletin of the NYU Hospital for Joint Diseases, a peer-reviewed clinical journal with a quarterly circulation of 2000 subscribers. NYU expert faculty, in collaboration with iMD's data analysis team, will also develop a rigorous manuscript summarizing the methods and results of the program for submission to one of several journals, possibly including:

✓ Rheumatology
✓ American Family Physician

✓ Journal of Primary Care & Community Health
✓ Journal of Continuing Education in the Health Professions

**Individualized PI-CME Activity:**  The data management platform developed by iMD will also allow for providers outside of NYU to participate in this quality-focused initiative by collecting data on their own patients with RA.  This activity will follow the AMA 3-Stage model and examine performance measures as described throughout this request.  Participants will be asked to collect data on 15-20 patients with RA.  While the educational collaborative recognizes that many attendees will opt not to participate in a PI-CME activity, there are several reasons we feel this opportunity should be extended to all providers:

1. The infrastructure will already be developed for the NYU-based quality assessment and will not incur additional development costs.
2. Any data obtained will only help strengthen the educational outcomes.
3. By using actual data throughout the meetings, we hope to motivate participants by demonstrating the value of practice data and the QI process itself.

iMD's Mobile Medical Outcomes platform uses categorical data-entry fields for maximum efficiency, and functions on most popular smart phones and tablets, as well as through any computer with an internet connection.

**Online CME Activity:**  All live meetings that are part of this educational initiative will be captured and posted online as standalone web-based enduring CME activity. These activities will provide an on-demand option for learning at the provider's convenience and allows dissemination of the educational programming to a broader, national audience.  iMD will use its existing online platform to create this initiative (for an example please visit http://acm2011.adacourses.com).  NYU and iMD will manage a multi-tiered recruitment campaign with the goal of 1000-2000 completers of the online course.

The online activity will present webcasts of the live meetings (slides and audio), the survey used in the first meeting, allow users to post questions and feedback, and a pre and post test for knowledge assessment.  The final assessment in the form of the white paper will also be posted online.  This unique aspect gives online users the ability not only to take part fully in the initiative by attending the meetings and engaging in the QI process, but to also reflect on the results of the initiative as a whole.  It is via the publications and online activity that we intend to share the benefits of this educational initiative to a broad audience outside of the New York, NY area.

**Evaluation Design**

The outcomes evaluation plan is built into the framework of this QI-CME initiative and will effectively examine provider performance and patient/population outcomes. The outcomes plan will primarily measure change from baseline in the quality metrics defined throughout the proposal – expected/desired change from baseline are detailed in the table below.

| Quality Measure | Desired Outcome |
|---|---|
| **For Rheumatologists – RA Management** | |
| Tuberculosis Screening | The goal will be to improve these process measures to near 100% after establishing the baseline and understanding the barriers and gaps toward goal achievement throughout the initiative. Additional clinical goals will be established by the NYU Division of Rheumatology during program development. |
| Functional Status Assessment | |
| Disease Prognosis | |
| Glucocorticoid Use | |
| Remission Criteria | |
| Disease Activity Assessment | |
| **For Primary Care Providers – Referral and Diagnosis of RA** | |
| Joint Swelling | A baseline for diagnosis and referral of RA by PCPs will be determined by looking at 8000 consecutive patients seen in the PCP setting as described earlier. This is a unique and central component of this initiative and the desired outcome will be to greatly improve diagnosis and timely referral of patients with RA from baseline. |
| Morning Stiffness ≥ 30 Minutes | |
| MCP/MTP Involvement | |
| Constitutional Complaints | |
| Elevated Inflammatory Markers | |
| Positive Rheumatoid Factor | |
| **For ALL Providers – CVD Risk Assessment & Management** | |
| Blood Sugar Assessment and Management | 5-10% improvement in the % of RA patients at goal,100% of RA patients with documented blood sugar assessment |
| Blood Pressure Assessment and Management | 5-10% improvement in the % of RA patients at goal, 100% of RA patients with documented BP assessment |
| Blood Lipid Assessment and Management | 5-10% improvement in the % of RA patients at goal, 100% of RA patients with documented blood lipid assessment |
| Smoking Status and Cessation Management | 100% of patients with RA who smoke with a documented cessation plan/discussion |

**Additional Sources of Data:** In addition to the patient-level data and assessment of quality measures through the baseline and comparative assessments, we will also examine the therapeutic options used by NYU providers for the management of RA and for CVD risk management. This goes above and beyond most quality improvement programs toward developing a true therapeutic landscape in this established patient population. These data will be analyzed to glean a better understanding of current practices and change in behavior as a result of this initiative.

Other sources of qualitative data will be used to compile the final evaluation and outcomes assessment and are listed below:

- Provider & staff survey results looking at attitudes and beliefs surrounding RA management
- Qualitative data describing current RA and CVD risk management processes at NYU (i.e., EMR capabilities, CVD risk assessment tools, RA referral protocols from PCPs to rheumatologists, provider attitudes & beliefs toward CVD risk assessment and RA diagnosis & management)
- Departmental meeting and live meeting highlights (via audio recordings and transcripts)
    - Barriers and gaps identified during the moderated discussions and in departmental meetings
        - Individuals participating in the PI-CME initiative will also report barriers and gaps
    - The clinic and system-level improvement plans discussed and implemented based on the meetings
        - Feedback from NYU leadership and providers during the implementation phase will be included in the final assessment
- Attendee feedback via evaluations
- Pre and post test data
- Participation metrics

**Data Collection and Analysis:** NYU Departmental Assistants will perform chart audits of patients that match the inclusion criteria as described in prior sections. iMD's data-analysis team will deploy a password-protected, data-collection questionnaire-management software system to handle the collection, management, reporting, and storage of research and patient data. All statistical analyses will be conducted using R Statistical Package v.2.13.1. Performance outcomes will be calculated as the percentage of eligible patients at goal, after accounting for patient inclusion and exclusion criterion for each measure. Group outcomes will be calculated as a mean ± SEM of all individual outcomes. Changes between baseline and comparative assessment will be assessed using a paired, one-tailed t-test at 95% power. P-value of .05 will be used to evaluate statistical significance. Qualitative data such as barrier analysis and proposed practice changes will be indexed according to a combination of preset and emergent categories, and plotted as a percentage of frequency. The phi coefficient will be used to measure correlation between binary variables. In an observational study in which the administration of an intervention does not affect the covariate (e.g., same practice measured before and after implementing a plan), the variables predicated to be affected by the intervention are known as outcomes. Therefore, the baseline assessment within this activity serves as the control from which change is measured against.

**Data Management:** Mobile Medical Outcomes™, from iMD, is a password-protected, data-collection, questionnaire-management software system used by patients, physicians and researchers worldwide. Mobile Medical Outcomes™ handles the collection, management, reporting, and storage of research and patient data.

Mobile Medical Outcomes™ was specifically designed to meet and exceed the industry standards for Internet data security and Institutional Review Board (IRB) standards for the protection of research participants.

**Data Security and Privacy:** Clinic Champions, physicians & staff or trained QI monitors will enter a study-specific Mobile Medical Outcomes™ website by using a unique UserID and Password. For security Mobile Medical Outcomes™ uses HTTPS/SSL.  HTTPS/SSL encrypts the data while it is being transferred from the physicians' or patients' computer to the central server. This prevents interception of any content. HTTPS is the standard for securing financial transactions and all private transactions across the Internet.

Data is stored in a Microsoft SQL database with a private password. Access to the data is only available to authorized users of the study through a secure connection to the server and database.

iMD complies with applicable security and confidentiality requirements, including The Health Insurance Portability and Accountability Act (HIPAA). Additionally iMD is registered as a Safe Harbor with the United States Department of Commerce. This means that iMD has met certain guidelines for the adequate protection of confidential information as defined by the European Union's Directive on Data Protection.

**Physical Security:** A professionally managed Internet Service Provider (ISP) hosts Mobile Medical Outcomes™ and provides firewall protection, antivirus software, automatic daily backups of data and secured, restricted access to facilities.  Severs are stored in a locked, well-ventilated room in locked server cabinets. The server room is in a building with 24/7/365 alarm security. Protection of servers from remote attacks is accomplished with firewalls with data auditing. Suspicious packets of data are blocked.

The ISP uses top-of-the-line UPS (Uninterruptable Power Supply) for protection against power spikes and outages and it implements complete network redundancy all key points to ensure uninterrupted connections.

**Data Validation:** Validation (edit) checks and derivation procedures will be developed by iMD. The validation specifications will be developed by taking into account the requirements of the analysis plan, a review of the protocol, and general experience.

**Auditing:** iMD will carry out a 100% review of all key variables to ensure accuracy.

**Reporting:** NYU will provide quarterly progress reports to all supporters of this initiative, and welcomes requests from supporters for status updates at any time during program development and implementation.

**Workplan and Deliverables:**

The table below provides additional detail toward implementing the project described in this grant request and includes timelines for each deliverable.

| Deliverable | Additional Workplan Details | Timeline |
|---|---|---|
| Baseline Assessment & Program Development | During the development phase NYU faculty and iMD will determine the detailed study protocol and satisfy all institutional requirements toward implementing the project, which includes IRB submission and staffing considerations. iMD will train departmental assistants and provide technical support.<br><br>NYU Office of CME will begin the development of recruitment materials while content is being developed for the live meetings. | Jan 2013 to May 2013: Data Collection<br><br>May 2013 to Jun 2013: Data Analysis |
| Formal Data Review & Discussion - NYU Division of Rheumatology | NYU Division of Rheumatology leadership will determine the schedule and guarantee commitment of faculty and staff to participate in this meeting | Jul/Aug 2013 |
| Content Development Meeting | While content is being developed for the live meetings, a combination of e-mail blasts and print brochures will be distributed to more than 22,500 rheumatologists, internists, PCPs, and family practitioners within the tri-state area to encourage non-NYU providers to participate in the live meetings and PI-CME initiative. The CME course calendar, internal web calendars, and intranet will also be used to make participants aware of this program. | Aug/Sep 2013 |
| Live Meeting #1 | NYU leadership will work together to determine the optimal scheduling for the live meetings. Meetings will be held on NYU campus - a light meal will be provided at each meeting. | Sep/Oct 2013 |
| Live Meeting #2 | As described. | Oct/Nov 2013 |
| Improvement Plan Implementation & Comparative Assessment | During this time period NYU providers will be implementing the improvement plans determined during the live meetings. Sufficient time must be allowed for these plans to take effect and to show impact on patient outcomes before reassessment. | Nov 2013 – Feb/Mar 2014: Data Collection & Analysis |
| Live Meeting #3 | As described. | Mar/Apr 2014 |
| Publication of Results | NYU faculty and iMD will compile and analyze all data toward the development of the white paper and publications. NYU faculty will be the lead | Apr 2014 to Aug 2014 |

| | authors on all publications. | |
|---|---|---|
| Individualized PI-CME Activity for Non-NYU Providers | This initiative will launch on the date of the first live meeting and be available for attendees of the live meetings as well as the online activity. | Sep/Oct 2013 to Jan 2014 |
| Online CME Activity | The online activity implementation will be longitudinal and coincide with the live meetings, with time given after each meeting for post-production editing and deployment.  All participants of the online activity will be encouraged to participate in the PI-CME initiative thus providing their patient and practice data toward a broader educational outcomes assessment. | Sep 2013 to Jan 2014 |

**Disclosure of Conflicts of Interest:** The NYU Post-Graduate Medical School adheres to ACCME Essential Areas and Policies, including the Standards for Commercial Support regarding industry support of continuing medical education. In order to resolve any identified conflicts of interest, disclosure information is provided during the planning process to ensure resolution of any identified conflicts. Disclosure of faculty and commercial relationships as well as the discussion of unlabeled or unapproved use of any drug, device or procedure by the faculty will be fully noted at the meeting.

**Accreditation:** This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the NYU Post-Graduate Medical School and Intelligent Medical Decisions, Inc. The NYU Post-Graduate Medical School is accredited by the ACCME to provide continuing medical education for physicians.

**Credit Designation:**

The NYU Post-Graduate Medical School designates each of the live meetings and resulting webcasts from this activity individually for a maximum of 1.5 *AMA PRA Category 1 Credits™*. The NYU Post-Graduate Medical School designates each completed stage of the PI-CME initiative (i.e., Stage A, Stage B, Stage C) for a maximum of 5 *AMA PRA Category 1 Credits™* with an additional 5 *AMA PRA Category 1 Credits™* for participating.

The NYU Post-Graduate Medical School designates a fully completed PI-CME initiative for a maximum of 20 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

**Special Needs:** The NYU Post-Graduate Medical School, in compliance with the legal requirements of the Americans with Disabilities Act, requests any participant of this Continuing Medical Education course who is in need of accommodation to submit a written request to our office at least one month prior to the course date.