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TITLE: Evaluation of a New Strategy for Protocolized Antibiotic Care for Severe Open Fractures

PRINCIPAL INVESTIGATOR: Michael Bosse, MD

CONTRACTING ORGANIZATION: Atrium Health, Charlotte, NC

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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14. ABSTRACT

Background. Infection remains the most common and significant complication following high-energy open fractures, with rates ranging from 15-40%. Up to 15% of recent combat casualties develop osteomyelitis. At present, antibiotics are delivered in an empiric fashion, as the surgeon does not know the bacterial profile of the open fracture wound at the time of injury or at the time of wound coverage/closure. Building on conclusions from a prospective observational study that evaluated the bioburden of severe lower extremity wounds sampled at the time of final wound coverage or closure, this project will study the impact of a new antibiotic delivery treatment strategy compared to the existing standard of care antibiotic prophylaxis strategy to evaluate the impact on deep SSI. **Objective**. The overall objective of the proposed study is to perform a PRCT in order to compare the antibiotic and infection related outcomes of a new antibiotic strategy for use in the care of severe open extremity fractures to the current standard of care. **Study Design**. This study will be conducted in 30 established METRC level 1 trauma centers. The patients will be randomized as close to admission as possible to either 1) Standard of Care (SOC) prophylactic open fracture protocol or 2) experimental protocol (SEXTANT) that will direct a wound bioburden targeted systemic and topical vancomycin powder and tobramycin powder antibiotic treatment at the time of final wound closure/coverage. The study will compare results of the current SOC prophylactic coverage to the SEXTANT protocol. As of 9/25/23, 145 participants have been enrolled in the study. There are 32 sites certified, 28 sites actively screening, and other participating sites status can be found in the attachment. The study team is actively engaged with providing regular summary reports and data queries to the participating sites.

15. SUBJECT TERMS
Orthopaedic trauma; surgical site infection; local antibiotics

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
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Unclassified	Unclassified	Unclassified	Unclassified	23	**19b. TELEPHONE NUMBER** *(include area code)*

TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose, and scope of the research.*

Background. Infection remains the most common and significant complication following high-energy open fractures, with rates ranging from 15-40%. Up to 15% of recent combat casualties develop osteomyelitis. At present, antibiotics are delivered in an empiric fashion, as the surgeon does not know the bacterial profile of the open fracture wound at the time of injury or at the time of wound coverage/closure. Building on conclusions from a prospective observational study that evaluated the bioburden of severe lower extremity wounds sampled at the time of final wound coverage or closure, this project will study the impact of a new antibiotic delivery *treatment strategy* compared to the existing standard of care antibiotic *prophylaxis strategy* to evaluate the impact on deep SSI.
Objective. The overall objective of the proposed study is to perform a PRCT in order to compare the antibiotic and infection related outcomes of a new antibiotic strategy for use in the care of severe open extremity fractures to the current standard of care.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Orthopaedic trauma; surgical site infection; local antibiotics

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

The specific aims of the study are as follows:

- Specific Aim 1: To compare the infection rates of the current severe open fracture prophylactic antibiotic strategy to a revised SEXTANT treatment strategy designed to address the modern wound bioburden at the time of wound closure.
- Specific Aim 2: To compare the terminal bioburden of the wounds at the time of definitive closure/coverage as sampled by standard tissue microbiology.
- Specific Aim 3: To compare rates of antibiotic-related serious adverse events (SAEs) of the two treatment groups.
- Exploratory Aim 4: To pilot the use of available and emerging rapid PCR platforms for wound pathogen identification in a sub-cohort of patients.

The tasks and milestones set forth to meet the aims of the project, as stated in the approved scope of work, are shown in the table below. Items not yet completed and marked with an asterisk (*) in the status column below have additional information specifically addressed in other sections of this report.

	Timeline	Status
Major Task 1: Study Initiation	Months	
Refine eligibility criteria, exclusion criteria, and screening protocol	1-6	Completed

Finalize consent form & human subjects protocol	1-6	Completed
Develop case report forms (CRFs) for data capture, program, and pilot test REDCap	1-6	Completed
Coordinate with Sites for IRB protocol submission	15-20	Started (95%)*
Coordinate with Sites for Advarra IRB review	15-20	Started (90%)*
Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO)	15-20	Started (90%)*
Submit amendments, adverse events, and protocol deviations as needed	As Needed	
Coordinate with Sites for annual IRB report for continuing review	Annually	
Milestone Achieved: Local IRB approval and Advarra	40	
Milestone Achieved: HRPO approval for all protocols	30	
Major Task 2: Training Research Staff		
Develop and conduct training for Research Coordinators on procedures for screening and consenting patients, study procedures, and data collection/reporting.	6-8	Completed
Certify sites to begin screening and enrolling patients	15-20	Started (90%)*
Conduct study initiation calls with each site to ensure procedures are in place	15-20	Started (95%)*
Milestone Achieved: Research Staff Trained	20	
Major Task 3: Microbiology and PCR Processing		
Establish agreement with central laboratory to process tissue samples and provide microbiology culture results	1	Completed
Establish agreement with central laboratory to perform "real time" PCR sequencing for a subset of cases associated with Exploratory Aim #4	1	Completed
Develop sampling framework to identify the appropriate cases for Exploratory Aim #4.	1	Completed
Establish site procedures for appropriate tissue sampling, storage and shipping.	6	Completed
Tissue samples collected and sent to appropriate laboratories	15-40	Started
Milestone Achieved: PCR Results Available for Subset of Cases (Exploratory Aim #4)	39	
Milestone Achieved: Culture Results Available for All Tissue Samples	40	
Major Task 4: Conduct Study		
Clinical site Research Coordinators will screen and enroll eligible study patients	15-40	Started*
Generate and distribute monthly enrollment and follow-up reports; provide ongoing training and support to address problems with enrollment as they are identified	15-46	Started
Generate and distribute data quality reports to monitor data completeness; check for errors and inconsistencies	15-46	Started
Milestone Achieved: All patients enrolled	40	
Milestone Achieved: All patient follow up complete	52	
Major Task 5: Data Analysis and Report Writing		
Develop final analysis files	40-46	
Conduct analysis and write final reports and peer-reviewed publications	52-60	
Disseminate results publication in peer reviewed journals and presentation at professional and scientific meetings	52-60	
Milestone Achieved: Report findings from final analysis	60	

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting

As of September 25, 2023, 740 patients screened, and 145 participants have been enrolled. Please refer to the end of the report (pages 17-23) on the screening/enrollment and follow-up progress of the study. As the number of the certified sites increased over the past year, the number of enrollments has been increasing.

There are twenty-eight actively screening and enrolling patients out of the thirty-two sites certified. There are two sites pending certification after receiving HRPO submission. Two sites are waiting for HRPO approval after receiving local IRB and sIRB approvals. We are continuing to work through the process of reliance agreements, local cede reviews and central IRB submissions with three other participating sites.

The coordinating center is sending out regular summary reports which includes screening/enrollment and follow-up progress and data queries to the participating sites. Also, monthly site research coordinator meetings have been held since February 2022 to address any study questions.

The study adjudication committee is reviewing the early discontinuation cases in real-time and all cases have been reviewed up to date. The specimen sample culture test results are being reviewed every two weeks during the study team meetings.

The study team finalized the adjudication process for the potential primary outcome (determination of infection) and the adjudication panel is reviewing the potential cases now.

The original study grant period ended on September 29, 2023, and the prime site (CMC) is currently waiting for an official memo from DoD to provide to the finance office to begin the extension process.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to report

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

The next reporting period will be focused on enrollment, data collection, and gaining the necessary approvals to begin enrollment at the rest of the participating sites. Key activities will include:

1. IRB: We will continue to add sites to Advarra IRB and develop reliance agreements.
2. Adjudication: Adjudication committee will continue reviewing new early discontinuation cases with enrolled patients. The committee will also begin reviewing the potential study outcomes.
3. Site management: Administrative tasks associated with securing site participation will continue.
4. Screening and enrollment: Sites will begin screening and enrollment once they are certified.
5. Data quality checks: Data quality checks, including site data queries, will be programmed and implemented. Also, weekly screening, enrollment, and follow-up reports will be shared with the sites.
6. Monthly check-in meetings: The coordinating center will continue monthly check-in calls to address any questions as the sites are implementing the study.
7. Bioburden data: We will continue reviewing Bioburden data and develop SOP.
8. Infection Disease (ID) Steering Committee: ID steering committee will adjudicate site's ID protocol and antibiograms and address questions on participating site's antibiotic protocol.
9. Manuscript: We will begin drafting the methods manuscript
10. Specimen sample: We will continue monitoring the results of the sample culture tests.
11. NCE: The prime site (CMC) will provide extension to JHU (and all participating sites) after DoD provides an official NCE memo.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Clinical research shut down or slow down at many sites in 2020 and 2021 related to COVID restrictions delayed the entire project for an estimate of 12 months. The new requirement for a single IRB has also led to some delays. Because the use of a sIRB is fairly new to most of our participating sites, it is slowing down the both local and central IRB submission processes. We are working with the last group of the sites (n=5) and providing additional meetings and communications to follow-up on individual sites' sIRB policy and submission process when compared with other studies that do not require a sIRB.

There will be delay of providing extension to JHU from the prime site (CMC) as the prime site is waiting for official NCE memo from DoD. Once JHU receives the extension, they will be able to provide extensions to all sites. The sites may not willing to move forward with administrative approval process or enrollment/data collection activities until they receive the extension.

Due to a misunderstanding, the BSPH MCC never filed an application to become a pSite themselves, thinking that we were covered by the original single IRB application. The Sextant study was among the first METRC studies to require a single IRB, and for budgetary reasons, the PI chose to route this study through an external IRB, Advarra. The research manager at Carolinas Medical Center completed an application with Advarra sIRB. In this application, the protocol clearly listed Renan Castillo as a co-investigator, and the BSPH MCC as the data coordinating center. The study was approved, and pSite applications were approved for the 32 sites where data collection activities will take place, and reliance agreements were executed for data collection. The requirement for a reliance agreement, the responsibility of which rests with the study PI, was not fully understood, and never clarified by any of the external IRB, our subcontracts office, or our sponsor. In terms of corrective action, we have applied and have an approval for reliance between BSPH IRB and Advarra IRB now. We are currently waiting to hear from BSPH IRB's response on this unanticipated event.

Another issue that the study came across in the past month is that the central lab (AHN) processing all wound samples collected from the participating sites will not able to continue to be a part of the study. The Sextant study team held a meeting with the central lab personnels. The study PI is planning on reaching out to the DoD science officer to discuss this issue prior to a meeting with the directors of the lab.

Changes that had a significant impact on expenditures
Desribe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report

- **Website(s) or other Internet site(s)**
List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report

- **Technologies or techniques**
Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report

- **Inventions, patent applications, and/or licenses**
Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Example:

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Name:	Katherine Frey
Project Role:	MCC Principal Investigator
ORCID ID:	0000-0003-0473-5891
Effort:	0.04
Contribution:	

	Dr. Frey contributed to the development of protocol and statistical planning as well as led all project efforts at the METRC Coordinating Center.
Name: Project Role: ORCID ID: Effort: Contribution:	Anthony Carlini MCC Co-Investigator 0000-0003-1419-4515 0.30 Mr. Carlini has organized all project efforts across institutions and has developed/drafted study documents and reports.
Name: Project Role: ORCID ID: Effort: Contribution:	Richard Thompson Biostatistician 0000-0001-8378-4426 0.15 Dr. Thompson has oversight and expertise on all project matters related to statistical planning.
Name: Project Role: ORCID ID: Effort: Contribution:	Suna Chung MCC Project Director Not Available 0.30 Ms. Chung has organized all project efforts across institutions and has developed/drafted study documents and reports.
Name: Project Role: ORCID ID: Effort: Contribution:	Susan Collins MCC Study Manager Not Available 0.60 Ms. Collins corresponded with participating centers, organized site survey responses, and drafted the consent documents and case report forms.
Name: Project Role: ORCID ID: Effort: Contribution:	Elias Weston-Farber Programmer Not Available 0.15 Mr. Weston-Farber supports the analysis of the data under the supervision of the study investigators.
Name: Project Role: ORCID ID: Effort: Contribution:	Paige Sullivan Programmer Not Available 0.15 Ms. Sullivan supports the programming of the REDCap database under the supervision of the study investigators.
Name: Project Role: ORCID ID: Effort: Contribution:	Christina Owens Financial Analyst Not Available 0.08 Ms. Owens set up the study account and prepared subaward paperwork for participating centers.

Name: Project Role: ORCID ID: Effort: Contribution:	TBD Data Analyst Not Available 0.45 TBD supports the analysis of the data under the supervision of the study investigators.
Name: Project Role: ORCID ID: Effort: Contribution:	Rachel Seymour Co-Investigator 0000-0002-9203-8297 0.60 Dr. Seymour supervises the research team at Carolinas Medical Center and meets bi-weekly with Dr. Reider and Ms. Wysocki at the MCC.
Name: Project Role: ORCID ID: Effort: Contribution:	Christine Churchill Research Manager Not Available 0.33 Ms. Churchill supervises all screening, enrollment, and follow-up at Carolinas Medical Center. She also works closely with the METRC Coordinating Center on regulatory for all enrolling sites.
Name: Project Role: ORCID ID: Effort: Contribution:	Kate Hickson Research Coordinator Not Available 0.24 Ms. Hickson is responsible for screening, enrollment and follow-up of patients at Carolinas Medical Center.
Name: Project Role: ORCID ID: Effort: Contribution:	Enosh Ishman Research Coordinator Not Available 0.24 Mr. Ishman is responsible for screening, enrollment and follow-up of patients at Carolinas Medical Center.
Name: Project Role: ORCID ID: Effort: Contribution:	Catherine Young Research Coordinator Not Available 0.24 Ms. Young is responsible for screening, enrollment and follow-up of patients at Carolinas Medical Center.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or

if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Dr. Rachel Seymour has updates to active other support. The projects listed below are now active.

- Primary Subtalar Arthrodesis for Calcaneal Fractures to Optimize Performance: A Randomized Clinical Trial (1.8 CM)
- A Randomized, Multi-Center, Double-Blind, Parallel Study to Examine the Effect of Lipogems Processed Microfragmented Adipose Tissue in Comparison to Corticosteroid for the Treatment of Knee Osteoarthritis (1.44 CM Y1, 1.2 CM Y2, 0.6 CM Y3)
- Single Implant Versus Dual Implant Fixation of Distal Femur Extra Articular and Complete Articular Fractures (1.8 CM)

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*

Nothing to report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI*

and research site. A report shall be submitted to ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

An updated Quad Chart is included as Attachment 1.

9. **APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc*

TABLE 1a: Screening, Eligibility, and Enrollment by Site

	Last 14 Days			Average per week		Cumulative, to date							
Clinical Site	Screened	Eligible	Enrolled	Screened	Enrolled	Screened	Eligible (% screened)	Refused (% eligible)	Non-enrolled for 'other' reasons (% eligible)	Discontinued, pre-enrollment (% eligible)	Consented & Randomized (% eligible)	Discontinued, pre-r0 (% randomized)	Eligible & Enrolled (% randomized)
AGY	0	0	0	0.05	0	4	0 (0%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
CMC	2	2	0	0.91	0.15	111	36 (32%)	14 (39%)	4 (11%)	0 (0%)	18 (50%)	0 (0%)	18 (100%)
DAR	0	0	0	0.14	0.07	10	6 (60%)	0 (0%)	1 (17%)	0 (0%)	5 (83%)	0 (0%)	5 (100%)
ESK	0	0	0	0.04	0.02	2	2 (100%)	1 (50%)	0 (0%)	0 (0%)	1 (50%)	0 (0%)	1 (100%)
GRT	0	0	0	0.07	0	2	0 (0%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
HCM	0	0	0	0.08	0.06	8	6 (75%)	0 (0%)	0 (0%)	0 (0%)	6 (100%)	0 (0%)	6 (100%)
HOU	1	0	0	0.89	0.18	116	59 (51%)	4 (7%)	28 (47%)	2 (3%)	25 (42%)	2 (8%)	23 (92%)
HRV	0	0	0	0.15	0.08	11	7 (64%)	0 (0%)	0 (0%)	0 (0%)	7 (100%)	1 (14%)	6 (86%)
IFH	0	0	0	0.26	0.16	10	8 (80%)	1 (13%)	0 (0%)	0 (0%)	7 (88%)	1 (14%)	6 (86%)
JAM	0	0	0	0.17	0.11	12	8 (67%)	0 (0%)	0 (0%)	0 (0%)	8 (100%)	0 (0%)	8 (100%)
LSU	2	0	0	0.25	0.06	8	3 (38%)	1 (33%)	0 (0%)	0 (0%)	2 (67%)	0 (0%)	2 (100%)
LUB	0	0	0	0.09	0.09	3	3 (100%)	0 (0%)	0 (0%)	0 (0%)	3 (100%)	0 (0%)	3 (100%)
MET	2	0	0	0.37	0.04	27	5 (19%)	1 (20%)	1 (20%)	0 (0%)	3 (60%)	0 (0%)	3 (100%)
MTH	3	1	0	0.6	0.13	47	22 (47%)	8 (36%)	0 (0%)	0 (0%)	14 (64%)	4 (29%)	10 (71%)
OSU	0	0	0	0.13	0	8	1 (13%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	0 (.%)	0 (.%)
RIH	1	1	1	0.22	0.04	15	9 (60%)	1 (11%)	3 (33%)	0 (0%)	5 (56%)	2 (40%)	3 (60%)
STM	0	0	0	0.03	0	2	0 (0%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
STN	0	0	0	0.29	0	15	0 (0%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
TMP	0	0	0	0.37	0.37	1	1 (100%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	1 (100%)
UCH	0	0	0	0.17	0.13	4	3 (75%)	0 (0%)	0 (0%)	0 (0%)	3 (100%)	0 (0%)	3 (100%)
UMD	3	1	1	1.08	0.27	61	22 (36%)	2 (9%)	5 (23%)	0 (0%)	15 (68%)	0 (0%)	15 (100%)
UMS	0	0	0	1.15	0.17	115	34 (30%)	6 (18%)	8 (24%)	0 (0%)	20 (59%)	3 (15%)	17 (85%)
UOK	1	0	0	0.81	0.06	63	13 (21%)	3 (23%)	2 (15%)	0 (0%)	8 (62%)	3 (38%)	5 (63%)
USF	1	0	0	0.3	0.01	21	3 (14%)	1 (33%)	1 (33%)	0 (0%)	1 (33%)	0 (0%)	1 (100%)
UVA	0	0	0	0.01	0	1	0 (0%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
VCU	0	0	0	0.07	0.04	5	4 (80%)	0 (0%)	0 (0%)	0 (0%)	4 (100%)	1 (25%)	3 (75%)
VMC	0	0	0	0.31	0.08	24	11 (46%)	1 (9%)	1 (9%)	1 (9%)	8 (73%)	2 (25%)	6 (75%)
WFU	0	0	0	0.48	0	35	1 (3%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	0 (.%)	0 (.%)
TOTAL	**16**	5	2	.	.	**741**	**267 (36%)**	**44 (16%)**	**56 (21%)**	**3 (1%)**	**164 (61%)**	**19 (12%)**	**145 (88%)**

TABLE 1b: Screened patients with pending screening/enrollment status (studystat=99)

TABLE 2a: Reasons for Ineligibility by Site

			Ineligibility Reason (% screened)						
Clinical Site	Screened, to date	Ineligible, to date (% screened)	Failed Facture criteria	Failed age criteria	Failed fracture closure/graft/ coverage inclusion criteria	Language (no English or Spanish)	In therapy for wound/implant/ infection	Pregnant or lactating	Follow-up concerns
AGY	4	4 (100%)	1 (25%)	0 (0%)	0 (0%)	0 (0%)	1 (25%)	0 (0%)	2 (50%)
CMC	111	75 (68%)	16 (14%)	4 (4%)	69 (62%)	0 (0%)	1 (1%)	0 (0%)	1 (1%)
DAR	10	4 (40%)	3 (30%)	1 (10%)	2 (20%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
ESK	2	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
GRT	2	2 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (100%)
HCM	8	2 (25%)	0 (0%)	0 (0%)	1 (13%)	0 (0%)	0 (0%)	0 (0%)	1 (13%)
HOU	116	57 (49%)	2 (2%)	14 (12%)	9 (8%)	1 (1%)	15 (13%)	0 (0%)	18 (16%)
HRV	11	4 (36%)	0 (0%)	0 (0%)	3 (27%)	0 (0%)	0 (0%)	0 (0%)	1 (9%)
IFH	10	2 (20%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (10%)	0 (0%)	1 (10%)
JAM	12	4 (33%)	1 (8%)	0 (0%)	3 (25%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
LSU	8	5 (63%)	2 (25%)	2 (25%)	1 (13%)	0 (0%)	1 (13%)	0 (0%)	1 (13%)
LUB	3	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
MET	27	22 (81%)	2 (7%)	5 (19%)	13 (48%)	1 (4%)	0 (0%)	0 (0%)	8 (30%)
MTH	47	25 (53%)	2 (4%)	6 (13%)	6 (13%)	0 (0%)	0 (0%)	0 (0%)	14 (30%)
OSU	8	7 (88%)	2 (25%)	1 (13%)	5 (63%)	0 (0%)	0 (0%)	0 (0%)	2 (25%)
RIH	15	6 (40%)	0 (0%)	1 (7%)	3 (20%)	0 (0%)	0 (0%)	1 (7%)	1 (7%)
STM	2	2 (100%)	0 (0%)	0 (0%)	1 (50%)	0 (0%)	0 (0%)	0 (0%)	1 (50%)
STN	15	15 (100%)	10 (67%)	6 (40%)	13 (87%)	0 (0%)	0 (0%)	0 (0%)	1 (7%)
TMP	1	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
UCH	4	1 (25%)	1 (25%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
UMD	61	39 (64%)	8 (13%)	5 (8%)	28 (46%)	2 (3%)	2 (3%)	0 (0%)	2 (3%)
UMS	115	81 (70%)	57 (50%)	5 (4%)	16 (14%)	0 (0%)	5 (4%)	0 (0%)	9 (8%)
UOK	63	50 (79%)	0 (0%)	5 (8%)	35 (56%)	2 (3%)	6 (10%)	0 (0%)	3 (5%)
USF	21	18 (86%)	2 (10%)	1 (5%)	12 (57%)	0 (0%)	0 (0%)	0 (0%)	4 (19%)
UVA	1	1 (100%)	1 (100%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
VCU	5	1 (20%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (20%)
VMC	24	13 (54%)	5 (21%)	5 (21%)	6 (25%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
WFU	35	34 (97%)	12 (34%)	0 (0%)	27 (77%)	0 (0%)	1 (3%)	0 (0%)	4 (11%)
TOTAL	**741**	**474 (64%)**	**127 (17%)**	**61 (8%)**	**254 (34%)**	**6 (1%)**	**33 (4%)**	**1 (0%)**	**79 (11%)**

TABLE 2b: Reasons for Refusal by Site

			Reason for Refusal to Participate (% refused)												
Clinical Site	Screened, to date	Refused, to date	General lack of interest	Specific treatment arm avoidance	Specific treatment arm preference	Fear of side effect/harm caused by treatment	Uncomfortable with randomization process	Preferred that physician select treatment	Family or cultural disagreement	Overwhelmed physically or emotionally	Fear of being experimented on/participating in research	Financial concern regarding participation in the study	No reason given	Other	Don't know
AGY	4	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
CMC	111	14	4 (29%)	0 (0%)	1 (7%)	1 (7%)	0 (0%)	1 (7%)	0 (0%)	2 (14%)	2 (14%)	0 (0%)	0 (0%)	3 (21%)	0 (0%)
DAR	10	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
ESK	2	1	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
GRT	2	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
HCM	8	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
HOU	116	4	1 (25%)	1 (25%)	0 (0%)	1 (25%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (25%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
HRV	11	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
IFH	10	1	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
JAM	12	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
LSU	8	1	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
LUB	3	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
MET	27	1	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
MTH	47	8	1 (13%)	0 (0%)	0 (0%)	1 (13%)	0 (0%)	2 (25%)	0 (0%)	2 (25%)	0 (0%)	0 (0%)	0 (0%)	1 (13%)	1 (13%)
OSU	8	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
RIH	15	1	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
STM	2	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
STN	15	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
TMP	1	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
UCH	4	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
UMD	61	2	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (50%)	0 (0%)	1 (50%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
UMS	115	6	2 (33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (17%)	0 (0%)	0 (0%)	0 (0%)	3 (50%)	0 (0%)
UOK	63	3	1 (33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (67%)
USF	21	1	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
UVA	1	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
VCU	5	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
VMC	24	1	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)
WFU	35	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
TOTAL	**741**	**44**	**9 (20%)**	**1 (2%)**	**1 (2%)**	**5 (11%)**	**1 (2%)**	**4 (9%)**	**2 (5%)**	**6 (14%)**	**4 (9%)**	**0 (0%)**	**0 (0%)**	**8 (18%)**	**3 (7%)**

TABLE 5a: Week 2 Follow-up Status by Site

				Week 2 CRF12 (Clinical Follow-up) Status							Week 2 PROMIS Pain Interference Survey Status		Week 2 PROMIS Pain Intensity Survey Status		Week 2 CRF15 (HRQL) Status	
Clinical site	Eligible & Enrolled	DWC complete	Due	Complete (% due)	Incomplete (% due)	Not Started, =<30 days (% due)	Not Started, >30 days (% due)	Missed (% due)	*Early (% complete)*	*Late (% complete)*	Complete (% due)	Missed (% due)	Complete (% due)	Missed (% due)	Complete (% due)	Missed (% due)
CMC	18	18	17	17 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*1 (6%)*	*0 (0%)*	17 (100%)	0 (0%)	17 (100%)	0 (0%)	17 (100%)	0 (0%)
DAR	5	5	5	5 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	0 (0%)	4 (80%)	0 (0%)	4 (80%)	4 (80%)	1 (20%)
ESK	1	1	1	1 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	0 (0%)	1 (100%)	0 (0%)	1 (100%)	1 (100%)	0 (0%)
HCM	6	5	5	4 (80%)	0 (0%)	0 (0%)	1 (20%)	0 (0%)	*0 (0%)*	*0 (0%)*	0 (0%)	4 (80%)	0 (0%)	4 (80%)	4 (80%)	0 (0%)
HOU	23	23	23	20 (87%)	1 (4%)	1 (4%)	1 (4%)	0 (0%)	*4 (20%)*	*0 (0%)*	19 (83%)	1 (4%)	19 (83%)	1 (4%)	20 (87%)	2 (9%)
HRV	6	6	6	5 (83%)	0 (0%)	0 (0%)	0 (0%)	1 (17%)	*0 (0%)*	*0 (0%)*	4 (67%)	2 (33%)	4 (67%)	2 (33%)	4 (67%)	2 (33%)
IFH	6	6	6	6 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	6 (100%)	0 (0%)	6 (100%)	0 (0%)	6 (100%)	0 (0%)
JAM	8	0	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
LSU	2	1	1	1 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	1 (100%)	0 (0%)	1 (100%)	0 (0%)	1 (100%)	0 (0%)
LUB	3	0	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
MET	3	3	3	3 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*1 (33%)*	*0 (0%)*	2 (67%)	1 (33%)	2 (67%)	1 (33%)	3 (100%)	0 (0%)
MTH	10	7	7	7 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	7 (100%)	0 (0%)	7 (100%)	0 (0%)	7 (100%)	0 (0%)
RIH	3	2	2	2 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	2 (100%)	0 (0%)	2 (100%)	0 (0%)	2 (100%)	0 (0%)
TMP	1	1	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
UCH	3	3	3	3 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	1 (33%)	2 (67%)	1 (33%)	2 (67%)	1 (33%)	2 (67%)
UMD	15	13	12	11 (92%)	0 (0%)	1 (8%)	0 (0%)	0 (0%)	*2 (18%)*	*0 (0%)*	10 (83%)	0 (0%)	10 (83%)	0 (0%)	10 (83%)	0 (0%)
UMS	17	16	16	15 (94%)	0 (0%)	0 (0%)	0 (0%)	1 (6%)	*0 (0%)*	*0 (0%)*	14 (88%)	2 (13%)	14 (88%)	2 (13%)	14 (88%)	2 (13%)
UOK	5	3	3	2 (67%)	0 (0%)	0 (0%)	0 (0%)	1 (33%)	*1 (50%)*	*0 (0%)*	2 (67%)	1 (33%)	2 (67%)	1 (33%)	2 (67%)	1 (33%)
USF	1	0	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
VCU	3	3	3	3 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	3 (100%)	0 (0%)	3 (100%)	0 (0%)	3 (100%)	0 (0%)
VMC	6	6	6	6 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	6 (100%)	0 (0%)	6 (100%)	0 (0%)	6 (100%)	0 (0%)
TOTAL	**145**	**122**	**119**	**111 (93%)**	**1 (1%)**	**2 (2%)**	**2 (2%)**	**3 (3%)**	***9 (8%)***	***0 (0%)***	**94 (79%)**	**18 (15%)**	**94 (79%)**	**18 (15%)**	**105 (88%)**	**10 (8%)**

TABLE 6a: Month 3 Follow-up Status by Site

				Month 3 CRF12 (Clinical Follow-up) Status							Month 3 PROMIS Pain Interference Survey Status		Month 3 PROMIS Pain Intensity Survey Status		Month 3 CRF15 (HRQL) Status	
Clinical site	Eligible & Enrolled	DWC complete	Due	Complete (% due)	Incomplete (% due)	Not Started, =<30 days (% due)	Not Started, >30 days (% due)	Missed (% due)	*Early (% complete)*	*Late (% complete)*	Complete (% due)	Missed (% due)	Complete (% due)	Missed (% due)	Complete (% due)	Missed (% due)
CMC	18	18	15	13 (87%)	0 (0%)	1 (7%)	1 (7%)	0 (0%)	*2 (15%)*	*1 (8%)*	13 (87%)	0 (0%)	13 (87%)	0 (0%)	13 (87%)	0 (0%)
DAR	5	5	4	3 (75%)	0 (0%)	0 (0%)	1 (25%)	0 (0%)	*3 (100%)*	*0 (0%)*	0 (0%)	3 (75%)	0 (0%)	3 (75%)	3 (75%)	0 (0%)
ESK	1	1	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
HCM	6	5	4	4 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*3 (75%)*	*0 (0%)*	1 (25%)	3 (75%)	1 (25%)	3 (75%)	4 (100%)	0 (0%)
HOU	23	23	17	17 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*2 (12%)*	*0 (0%)*	16 (94%)	1 (6%)	16 (94%)	1 (6%)	16 (94%)	1 (6%)
HRV	6	6	5	2 (40%)	0 (0%)	0 (0%)	0 (0%)	3 (60%)	*2 (100%)*	*0 (0%)*	2 (40%)	3 (60%)	2 (40%)	3 (60%)	2 (40%)	3 (60%)
IFH	6	6	6	5 (83%)	0 (0%)	0 (0%)	1 (17%)	0 (0%)	*0 (0%)*	*0 (0%)*	5 (83%)	0 (0%)	5 (83%)	0 (0%)	5 (83%)	0 (0%)
JAM	8	0	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
LSU	2	1	1	1 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	0 (0%)	1 (100%)	0 (0%)	1 (100%)	0 (0%)	1 (100%)
LUB	3	0	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
MET	3	3	3	3 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*2 (67%)*	*0 (0%)*	2 (67%)	0 (0%)	2 (67%)	0 (0%)	3 (100%)	0 (0%)
MTH	10	7	5	4 (80%)	0 (0%)	0 (0%)	0 (0%)	1 (20%)	*0 (0%)*	*0 (0%)*	4 (80%)	1 (20%)	4 (80%)	1 (20%)	4 (80%)	1 (20%)
RIH	3	2	2	2 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	1 (50%)	1 (50%)	1 (50%)	1 (50%)	1 (50%)	1 (50%)
TMP	1	1	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
UCH	3	3	2	2 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
UMD	15	13	10	10 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*7 (70%)*	*0 (0%)*	10 (100%)	0 (0%)	10 (100%)	0 (0%)	10 (100%)	0 (0%)
UMS	17	16	16	11 (69%)	0 (0%)	0 (0%)	0 (0%)	5 (31%)	*0 (0%)*	*0 (0%)*	11 (69%)	5 (31%)	11 (69%)	5 (31%)	11 (69%)	5 (31%)
UOK	5	3	3	2 (67%)	0 (0%)	0 (0%)	0 (0%)	1 (33%)	*2 (100%)*	*0 (0%)*	2 (67%)	1 (33%)	2 (67%)	1 (33%)	2 (67%)	1 (33%)
USF	1	0	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
VCU	3	3	3	3 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	1 (33%)	1 (33%)	0 (0%)	2 (67%)	3 (100%)	0 (0%)
VMC	6	6	6	5 (83%)	0 (0%)	0 (0%)	0 (0%)	1 (17%)	*2 (40%)*	*0 (0%)*	5 (83%)	1 (17%)	5 (83%)	1 (17%)	5 (83%)	1 (17%)
TOTAL	**145**	**122**	**102**	**87 (85%)**	**0 (0%)**	**1 (1%)**	**3 (3%)**	**11 (11%)**	*25 (29%)*	*1 (1%)*	**73 (72%)**	**21 (21%)**	**72 (71%)**	**22 (22%)**	**82 (80%)**	**14 (14%)**

TABLE 7a: Month 6 Follow-up Status by Site

				Month 6 CRF12 (Clinical Follow-up) Status							Month 6 PROMIS Pain Interference Survey Status		Month 6 PROMIS Pain Intensity Survey Status		Month 6 CRF15 (HRQL) Status	
Clinical site	Eligible & Enrolled	DWC complete	Due	Complete (% due)	Incomplete (% due)	Not Started, =<30 days (% due)	Not Started, >30 days (% due)	Missed (% due)	*Early (% complete)*	*Late (% complete)*	Complete (% due)	Missed (% due)	Complete (% due)	Missed (% due)	Complete (% due)	Missed (% due)
CMC	18	18	11	10 (91%)	0 (0%)	0 (0%)	1 (9%)	0 (0%)	*4 (40%)*	*0 (0%)*	11 (100%)	0 (0%)	11 (100%)	0 (0%)	11 (100%)	0 (0%)
DAR	5	5	3	3 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*1 (33%)*	*0 (0%)*	1 (33%)	2 (67%)	1 (33%)	2 (67%)	3 (100%)	0 (0%)
ESK	1	1	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
HCM	6	5	4	3 (75%)	0 (0%)	0 (0%)	0 (0%)	1 (25%)	*2 (67%)*	*0 (0%)*	0 (0%)	4 (100%)	0 (0%)	4 (100%)	3 (75%)	1 (25%)
HOU	23	23	15	11 (73%)	0 (0%)	1 (7%)	3 (20%)	0 (0%)	*1 (9%)*	*0 (0%)*	12 (80%)	0 (0%)	12 (80%)	0 (0%)	12 (80%)	0 (0%)
HRV	6	6	5	1 (20%)	1 (20%)	0 (0%)	0 (0%)	3 (60%)	*0 (0%)*	*0 (0%)*	2 (40%)	3 (60%)	2 (40%)	3 (60%)	2 (40%)	3 (60%)
IFH	6	6	1	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	*0 (.%)*	*0 (.%)*	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
JAM	8	0	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
LSU	2	1	1	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	*0 (.%)*	*0 (.%)*	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
LUB	3	0	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
MET	3	3	2	2 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*1 (50%)*	*0 (0%)*	0 (0%)	2 (100%)	0 (0%)	2 (100%)	2 (100%)	0 (0%)
MTH	10	7	5	4 (80%)	0 (0%)	0 (0%)	1 (20%)	0 (0%)	*0 (0%)*	*0 (0%)*	4 (80%)	0 (0%)	4 (80%)	0 (0%)	4 (80%)	0 (0%)
RIH	3	2	1	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	*0 (.%)*	*0 (.%)*	0 (0%)	1 (100%)	0 (0%)	1 (100%)	0 (0%)	1 (100%)
TMP	1	1	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
UCH	3	3	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
UMD	15	13	6	6 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*6 (100%)*	*0 (0%)*	6 (100%)	0 (0%)	6 (100%)	0 (0%)	5 (83%)	0 (0%)
UMS	17	16	16	8 (50%)	0 (0%)	0 (0%)	4 (25%)	4 (25%)	*0 (0%)*	*0 (0%)*	8 (50%)	4 (25%)	8 (50%)	4 (25%)	8 (50%)	4 (25%)
UOK	5	3	3	0 (0%)	0 (0%)	0 (0%)	1 (33%)	2 (67%)	*0 (.%)*	*0 (.%)*	0 (0%)	2 (67%)	0 (0%)	2 (67%)	0 (0%)	2 (67%)
USF	1	0	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	*0 (.%)*	*0 (.%)*	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
VCU	3	3	2	2 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*0 (0%)*	*0 (0%)*	0 (0%)	2 (100%)	0 (0%)	2 (100%)	2 (100%)	0 (0%)
VMC	6	6	5	5 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*1 (20%)*	*0 (0%)*	5 (100%)	0 (0%)	5 (100%)	0 (0%)	5 (100%)	0 (0%)
TOTAL	**145**	**122**	**80**	**55 (69%)**	**1 (1%)**	**1 (1%)**	**12 (15%)**	**11 (14%)**	***16 (29%)***	***0 (0%)***	**49 (61%)**	**20 (25%)**	**49 (61%)**	**20 (25%)**	**57 (71%)**	**11 (14%)**

TABLE 8a: Month 12 Follow-up Status by Site

				Month 12 CRF09 (MRR) Status		Month 12 CRF11 (12MOFU) Status		Month 12 CRF12 (CFU) Status		Month 12 PROMIS Pain Interference Survey Status		Month 12 PROMIS Pain Intensity Survey Status		Month 12 CRF15 (HRQL) Status	
Clinical site	Eligible & Enrolled	DWC complete	Due	Complete (% due)	Missed (% due)	Complete (% due)	Missed (% due)	Complete (% due)	Missed (% due)	Complete (% due)	Missed (% due)	Complete (% due)	Missed (% due)	Complete (% due)	Missed (% due)
CMC	18	18	10	2 (20%)	0 (0%)	9 (90%)	0 (0%)	9 (90%)	0 (0%)	9 (90%)	0 (0%)	9 (90%)	0 (0%)	9 (90%)	0 (0%)
DAR	5	5	3	1 (33%)	0 (0%)	2 (67%)	0 (0%)	3 (100%)	0 (0%)	2 (67%)	0 (0%)	2 (67%)	0 (0%)	3 (100%)	0 (0%)
ESK	1	1	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
HCM	6	5	4	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (25%)	0 (0%)	1 (25%)	0 (0%)	1 (25%)	0 (0%)
HOU	23	23	8	4 (50%)	0 (0%)	6 (75%)	0 (0%)	6 (75%)	0 (0%)	4 (50%)	0 (0%)	4 (50%)	0 (0%)	5 (63%)	0 (0%)
HRV	6	6	5	0 (0%)	0 (0%)	3 (60%)	0 (0%)	1 (20%)	0 (0%)	1 (20%)	0 (0%)	1 (20%)	0 (0%)	1 (20%)	0 (0%)
IFH	6	6	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
JAM	8	0	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
LSU	2	1	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
LUB	3	0	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
MET	3	3	2	2 (100%)	0 (0%)	1 (50%)	0 (0%)	2 (100%)	0 (0%)	1 (50%)	0 (0%)	1 (50%)	0 (0%)	1 (50%)	0 (0%)
MTH	10	7	3	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
RIH	3	2	1	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
TMP	1	1	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
UCH	3	3	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
UMD	15	13	2	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (50%)	0 (0%)	1 (50%)	0 (0%)	1 (50%)	0 (0%)	0 (0%)	0 (0%)
UMS	17	16	12	4 (33%)	0 (0%)	6 (50%)	0 (0%)	6 (50%)	0 (0%)	5 (42%)	0 (0%)	5 (42%)	0 (0%)	5 (42%)	0 (0%)
UOK	5	3	2	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
USF	1	0	0	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)
VCU	3	3	2	2 (100%)	0 (0%)	2 (100%)	0 (0%)	2 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (100%)	0 (0%)
VMC	6	6	5	2 (40%)	0 (0%)	2 (40%)	0 (0%)	3 (60%)	0 (0%)	3 (60%)	0 (0%)	3 (60%)	0 (0%)	3 (60%)	0 (0%)
TOTAL	**145**	**122**	**59**	**17 (29%)**	**0 (0%)**	**31 (53%)**	**0 (0%)**	**33 (56%)**	**0 (0%)**	**27 (46%)**	**0 (0%)**	**27 (46%)**	**0 (0%)**	**30 (51%)**	**0 (0%)**