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

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**CONTRACTING ORGANIZATION: Atrium Health, Charlotte, NC**

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<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> <b>Background.</b> 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. <b>Objective.</b> 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. <b>Study Design.</b> 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 9/26/22, 82 participants have been enrolled in the study. There are twenty-six 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.					
<b>15. SUBJECT TERMS</b> Orthopaedic trauma; surgical site infection; local antibiotics					
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## 1. INTRODUCTION:

**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:

Orthopaedic trauma; surgical site infection; local antibiotics

## 3. ACCOMPLISHMENTS:

**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
<b>Major Task 1: Study Initiation</b>	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 (80%)*
Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO)	15-20	Started (80%)*
Submit amendments, adverse events, and protocol deviations as needed	As Needed	
Coordinate with Sites for annual IRB report for continuing review	Annually	
<i>Milestone Achieved: Local IRB approval and Advarra</i>	40	
<i>Milestone Achieved: HRPO approval for all protocols</i>	30	
<b>Major Task 2: Training Research Staff</b>		
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 (65%)*
Conduct study initiation calls with each site to ensure procedures are in place	15-20	Started (65%)*
<i>Milestone Achieved: Research Staff Trained</i>	20	
<b>Major Task 3: Microbiology and PCR Processing</b>		
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
<i>Milestone Achieved: PCR Results Available for Subset of Cases (Exploratory Aim #4)</i>	39	
<i>Milestone Achieved: Culture Results Available for All Tissue Samples</i>	40	
<b>Major Task 4: Conduct Study</b>		
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
<i>Milestone Achieved: All patients enrolled</i>	40	
<i>Milestone Achieved: All patient follow up complete</i>	52	
<b>Major Task 5: Data Analysis and Report Writing</b>		
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	
<i>Milestone Achieved: Report findings from final analysis</i>	60	

**What was accomplished under these goals?**

As of September 26, 2022, 338 patients screened, and 82 participants have been enrolled. Please refer to the end of the report (pages 15-20) 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 and our goal is to reach 100 participants by the end of fall 2022.

There are twenty sites actively screening and enrolling patients out of the twenty-six sites certified. There is one site pending certification after receiving HRPO submission. Two sites are preparing for HRPO submission 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 other participating sites. There are 4 sites preparing Advarra sIRB submission, 7 sites with local IRB, and 4 new sites are in preparation stage.

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 specimen sample culture test results are being reviewed every two weeks during the study team meetings. The study adjudication committee is reviewing the early discontinuation cases in real-time. Most recent DSMB meeting was held on August 30, 2022 and the board members found that the study is safe and ethical to continue.

**What opportunities for training and professional development has the project provided?**

Nothing to report

## How were the results disseminated to communities of interest?

Nothing to report

## What do you plan to do during the next reporting period to accomplish the goals?

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. FDA: We plan to submit an information amendment to the FDA addressing items that were not part of the clinical hold.
2. IRB: We will continue to add sites to Advarra IRB and develop reliance agreements.
3. Adjudication: Adjudication committee will continue reviewing new cases with enrolled patients.
4. Site management: Administrative tasks associated with securing site participation will continue.
5. Screening and enrollment: Sites will begin screening and enrollment once they are certified.
6. 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.
7. Monthly check-in meetings: The coordinating center will continue monthly check-in calls to address any questions as the sites are implementing the study.
8. Bioburden data: We will begin developing SAP and SOP.
9. Infection Disease (ID) Steering Committee: ID steering committee will hold meetings and communicate via emails to review and address questions on participating site's antibiotic protocol.
10. Manuscript: We will begin drafting the methods manuscript.
11. Specimen sample: We will continue monitoring the results of the sample culture tests.

**4. IMPACT:**

**What was the impact on the development of the principal discipline(s) of the project?**

Nothing to report

**What was the impact on other disciplines?**

Nothing to report

**What was the impact on technology transfer?**

Nothing to report

**What was the impact on society beyond science and technology?**

Nothing to Report

**5. CHANGES/PROBLEMS:**

**Changes in approach and reasons for change**

Nothing to report.

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

The delay caused by the new requirement for a single IRB is continuing to impact the certification timeline of the sites. Because the use of an sIRB is fairly new to most of our participating sites, it is slowing down both local and central IRB submission processes. We are providing extra time and effort for additional meetings and communications as our plan is to certify as many sites as possible before the next technical report.

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.

**Changes that had a significant impact on expenditures**

Nothing to Report

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

**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:**

- **Publications, conference papers, and presentations**  
**Journal publications.**

Nothing to Report

**Books or other non-periodical, one-time publications.**

Nothing to Report

**Other publications, conference papers and presentations.**

Nothing to Report

- **Website(s) or other Internet site(s)**

Nothing to Report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Nothing to Report

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

**What individuals have worked on the project?**

Name: Project Role: ORCID ID: Effort: Contribution:	Renan Castillo MCC Principal Investigator 0000-0003-0473-5891 0.04 Dr. Castillo 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:	Susan Collins MCC Study Manager

ORCID ID: Effort: Contribution:	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:	Chris Witczak Financial Analyst Not Available 0.08 Mr. Witczak set up the study account and prepared subaward paperwork for participating centers.
Name: Project Role: ORCID ID: Effort: Contribution:	Christopher Pierce Data Analyst Not Available 0.45 Mr. Pierce supports the analysis of the data under the supervision of the study investigators.

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

Nothing to report

**What other organizations were involved as partners?**

Nothing to report

**8. SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:**

**QUAD CHARTS:**

**An updated Quad Chart is included as Attachment 1.**

**9. APPENDICES:**

**SEXTANT Monthly Report Tables for 20220926**

TABLE 1: Screening, Eligibility, and Enrollment by Site

Clinical Site	Last 14 days			Cumulative, per week		Cumulative, to date						
	Screened	Eligible	Enrolled	Screened	Enrolled	Screened	Eligible	Refused	Non-enrolled for 'other' reasons	Early discontinuation (pre-enrollment)	Potential Early discontinuation (pre-enrollment)	Consented & Randomized
AGY	0	0	0	0.19	0.00	4	0	0	0	0	0	0
CMC	1	0	0	0.77	0.19	54	22	9	2	0	0	11
DAR	0	0	0	0.29	0.16	6	3	0	0	0	0	3
ESK	1	1	1	1.75	1.75	1	1	0	0	0	0	1
HCM	0	0	0	0.16	0.12	7	5	0	0	0	0	5
HOU	0	0	0	0.44	0.25	34	24	0	14	1	0	9
HRV	0	0	0	0.34	0.29	7	6	0	0	0	0	6
JAM	2	2	2	0.67	0.75	12	8	0	0	0	0	8
MET	2	0	0	0.79	0.10	17	3	0	1	0	0	2
MTH	0	0	0	0.42	0.21	11	4	0	0	0	0	4
OSU	1	0	0	0.50	.	4	0	0	0	0	0	0
RIH	4	3	1	0.63	0.25	10	5	1	2	0	0	2
STM	0	0	0	0.11	0.00	2	0	0	0	0	0	0
UMD	2	1	1	1.75	0.45	8	2	0	0	0	0	2
UMS	4	3	2	1.70	0.34	81	22	2	4	0	0	16
UOK	0	0	0	1.57	0.37	40	5	0	1	0	0	4
USF	2	0	0	0.53	.	9	1	1	0	0	0	0
VCU	0	0	0	0.19	0.19	3	3	0	0	0	0	3
VMC	2	2	2	0.60	0.33	15	7	1	0	0	0	6
WFU	1	0	0	0.59	0.00	12	0	0	0	0	0	0
<b>TOTAL</b>	<b>23</b>	<b>12</b>	<b>9</b>	<b>.</b>	<b>.</b>	<b>338</b>	<b>121 (36%)</b>	<b>14 (12%)</b>	<b>24 (20%)</b>	<b>1 (&lt;1%)</b>	<b>0 (0%)</b>	<b>82 (68%)</b>

TABLE 2: Reasons for Ineligibility by Site

Clinical Site	Screened, to date	Ineligible, to date	Failed fracture inclusion criteria	Failed age criteria	Failed fracture closure/graft/coverage inclusion criteria	Pregnant or lactating	Language (no English or Spanish)	In therapy for wound/implant/infection	Follow-up concerns
AGY	4	4	1	0	0	0	0	1	2
CMC	54	32	8	1	30	0	0	0	1
DAR	6	3	3	1	2	0	0	0	0
ESK	1	0	0	0	0	0	0	0	0
HCM	7	2	0	0	1	0	0	0	1
HOU	34	10	1	1	0	0	0	1	7
HRV	7	1	0	0	1	0	0	0	0
JAM	12	4	1	0	3	0	0	0	0
MET	17	14	1	3	10	0	0	0	4
MTH	11	7	2	1	1	0	0	0	5
OSU	4	4	1	0	2	0	0	0	2
RIH	10	5	2	1	2	1	0	0	1
STM	2	2	0	0	1	0	0	0	1
UMD	8	6	4	2	3	0	0	0	0
UMS	81	59	43	5	12	0	0	2	7
UOK	40	35	18	2	26	0	0	6	2
USF	9	8	2	0	4	0	0	0	2
VCU	3	0	0	0	0	0	0	0	0
VMC	15	8	5	1	6	0	0	0	1
WFU	12	12	5	0	9	0	0	0	2
<b>TOTAL</b>	<b>338</b>	<b>217 (64%)</b>	<b>98</b>	<b>18</b>	<b>114</b>	<b>1</b>	<b>0</b>	<b>10</b>	<b>38</b>

TABLE 3: Discontinuations by Site

Clinical Site	Consented & Randomized, to date	Discontinuations, pre-t0			Discontinuations, post-t0			
		Inappropriate Enrollment	Late Ineligible	Late Refusal	Eligible & Enrolled	Participant Withdrawal	Physician Withdrawal	Death
CMC	11	0	0	0	11	0	0	1
DAR	3	0	0	0	3	0	0	0
ESK	1	0	0	0	1	0	0	0
HCM	5	0	0	0	5	0	0	0
HOU	9	0	0	0	9	0	0	0
HRV	6	0	1	0	5	0	0	0
JAM	8	0	0	0	8	0	0	0
MET	2	0	0	0	2	0	0	0
MTH	4	1	0	0	3	0	0	0
RIH	2	0	0	0	2	0	0	0
UMD	2	0	0	0	2	0	0	0
UMS	16	0	3	0	13	0	0	0
UOK	4	0	0	0	4	0	0	0
VCU	3	0	0	1	2	0	0	0
VMC	6	0	0	0	6	0	0	0
<b>TOTAL</b>	<b>82</b>	<b>1</b>	<b>4</b>	<b>1</b>	<b>76</b>	<b>0</b>	<b>0</b>	<b>1</b>

TABLE 4: Week 2 Follow-up

Clinical Site	Enrolled & Eligible	DWC complete	DUE	Week 2 Clinical follow-up Status						HRQOL status		
				Complete	Incomplete	Not started	missed	early	late	Complete	Incomplete	Not started
CMC	11	11	11	10	0	0	1	0	0	10	0	1
DAR	3	3	3	3	0	0	0	0	0	3	0	0
ESK	1	0	0	0	0	0	0	0	0	0	0	0
HCM	5	4	4	3	0	1	0	0	0	3	0	1
HOU	9	8	8	8	0	0	0	1	0	7	1	0
HRV	5	2	2	2	0	0	0	0	0	2	0	0
JAM	8	0	0	0	0	0	0	0	0	0	0	0
MET	2	2	2	2	0	0	0	0	0	2	0	0
MTH	3	3	3	3	0	0	0	0	0	3	0	0
RIH	2	2	1	0	0	1	0	0	0	0	0	1
UMD	2	2	1	1	0	0	0	0	0	1	0	0
UMS	13	11	11	10	0	1	0	0	0	10	0	1
UOK	4	3	3	3	0	0	0	2	0	3	0	0
VCU	2	2	2	2	0	0	0	0	0	2	0	0
VMC	6	6	4	3	0	1	0	0	0	3	0	1
<b>TOTAL</b>	<b>76</b>	<b>59</b>	<b>55</b>	<b>50</b>	<b>0</b>	<b>4</b>	<b>1</b>	<b>3</b>	<b>0</b>	<b>49</b>	<b>1</b>	<b>5</b>

TABLE 5: Month 3 Follow-up

Clinical Site	Enrolled & Eligible	DWC complete	DUE	Month 3 Clinical follow-up Status						HRQOL status		
				Complete	Incomplete	Not started	missed	early	late	Complete	Incomplete	Not started
CMC	11	11	10	8	0	1	1	2	0	8	0	2
DAR	3	3	3	3	0	0	0	3	0	3	0	0
ESK	1	0	0	0	0	0	0	0	0	0	0	0
HCM	5	4	3	2	0	0	1	2	0	1	1	1
HOU	9	8	5	4	0	1	0	0	0	4	0	1
HRV	5	2	2	0	1	1	0	0	0	1	0	1
JAM	8	0	0	0	0	0	0	0	0	0	0	0
MET	2	2	1	1	0	0	0	1	0	1	0	0
MTH	3	3	2	0	0	2	0	0	0	0	0	2
RIH	2	2	0	0	0	0	0	0	0	0	0	0
UMD	2	2	0	0	0	0	0	0	0	0	0	0
UMS	13	11	8	8	0	0	0	0	0	8	0	0
UOK	4	3	0	0	0	0	0	0	0	0	0	0
VCU	2	2	0	0	0	0	0	0	0	0	0	0
VMC	6	6	2	1	0	1	0	0	0	1	0	1
<b>TOTAL</b>	<b>76</b>	<b>59</b>	<b>36</b>	<b>27</b>	<b>1</b>	<b>6</b>	<b>2</b>	<b>8</b>	<b>0</b>	<b>27</b>	<b>1</b>	<b>8</b>

TABLE 6: Month 6 Follow-up

Clinical Site	Enrolled & Eligible	DWC complete	DUE	Month 3 Clinical follow-up Status						HRQOL status		
				Complete	Incomplete	Not started	missed	<i>early</i>	<i>late</i>	Complete	Incomplete	Not started
CMC	11	11	6	3	2	1	0	<i>1</i>	<i>0</i>	5	0	1
DAR	3	3	0	0	0	0	0	<i>0</i>	<i>0</i>	0	0	0
ESK	1	0	0	0	0	0	0	<i>0</i>	<i>0</i>	0	0	0
HCM	5	4	3	0	0	3	0	<i>0</i>	<i>0</i>	0	0	3
HOU	9	8	3	0	0	3	0	<i>0</i>	<i>0</i>	0	0	3
HRV	5	2	0	0	0	0	0	<i>0</i>	<i>0</i>	0	0	0
JAM	8	0	0	0	0	0	0	<i>0</i>	<i>0</i>	0	0	0
MET	2	2	0	0	0	0	0	<i>0</i>	<i>0</i>	0	0	0
MTH	3	3	0	0	0	0	0	<i>0</i>	<i>0</i>	0	0	0
RIH	2	2	0	0	0	0	0	<i>0</i>	<i>0</i>	0	0	0
UMD	2	2	0	0	0	0	0	<i>0</i>	<i>0</i>	0	0	0
UMS	13	11	6	4	0	2	0	<i>0</i>	<i>0</i>	4	0	2
UOK	4	3	0	0	0	0	0	<i>0</i>	<i>0</i>	0	0	0
VCU	2	2	0	0	0	0	0	<i>0</i>	<i>0</i>	0	0	0
VMC	6	6	0	0	0	0	0	<i>0</i>	<i>0</i>	0	0	0
<b>TOTAL</b>	<b>76</b>	<b>59</b>	<b>18</b>	<b>7</b>	<b>2</b>	<b>9</b>	<b>0</b>	<b><i>1</i></b>	<b><i>0</i></b>	<b>9</b>	<b>0</b>	<b>9</b>

**AWARD NUMBER: W81XWH-19-2-0062**  
**Annual Progress Report SEXTANT STUDY Y3Q4**  
**Participating Site Status**

<b>Site name</b>	<b>HRPO assigned #</b>	<b>Target required for clinical significance</b>	<b>Local IRB submission status</b>	<b>Submitted/ approved by Advarra sIRB</b>	<b>Submitted/ approved by DoD HRPO</b>	<b># of subjects screened/original planned target</b>	<b># of patients enrolled/original planned target</b>
Carolinas Medical Center	E00881.1b	96	N/A	Submitted 12/8/20 Approved 12/15/20	Submitted 2/24/21 Approved 3/8/21	54/96	11/96
Hennepin County Medical Center	E00881.1c	16	Approved	Submitted 6/8/21 Approved 7/2/21	Submitted 7/6/21 Approved 7/28/21	7/16	5/16
University of Mississippi Medical Center	E00881.1d	16	Approved	Submitted 6/8/21 Approved 6/23/21	Submitted 7/16/21 Approved 7/28/21	81/16	16/16
Ohio State University	E00881.1e	16	Approved	Submitted 7/27/21 Approved 8/4/21	Submitted 9/13/21 Approved 9/22/21	4/16	0/16
Methodist Hospital, Indiana University	E00881.1f	16	Approved	Submitted 8/5/21 Approved 8/20/21	Submitted 9/13/21 Approved 9/23/21	11/16	4/16
McGovern Medical School at UTHealth Houston	E00881.1g	16	Approved	Submitted 8/4/21 Approved 8/17/21	Submitted 9/14/21 Approved 9/28/21	34/16	9/16
Dartmouth Hitchcock Clinic	E00881.1h	16	Approved	Submitted 7/30/21 Approved 9/22/21	Submitted 10/4/21 Approved 12/15/21	6/16	3/16
MetroHealth Medical Center	E00881.1i	16	Approved	Submitted 8/24/21 Approved	Submitted 10/7/21 Approved	17/16	2/16

Site name	HRPO assigned #	Target required for clinical significance	Local IRB submission status	Submitted/ approved by Advarra sIRB	Submitted/ approved by DoD HRPO	# of subjects screened/original planned target	# of patients enrolled/original planned target
				9/14/21	10/13/21		
University of California at San Francisco	E00881.1j	16	Approved	Submitted 8/16/21 Approved 9/10/21	Submitted 10/18/21 Approved 11/19/21	9/16	0/16
University of Colorado Department of Orthopaedics	E00881.1l	16	Approved	Submitted 9/13/21 Approved 10/21/21	Submitted 11/11/21 Approved 11/19/21	0/16	0/16
Wake Forest University Baptist Medical Center	E00881.1m	16	Approved	Submitted 10/6/21 Approved 11/4/21	Submitted 12/10/21 Approved 12/20/21	12/16	0/16
Allegheny General Hospital	E00881.1n	16	Approved	Submitted 11/9/21 Approved 12/10/21	Submitted 12/17/21 Approved 12/29/21	4/16	0/16
Rhode Island Hospital, Brown University	E00881.1o	16	Approved	Submitted 10/14/21 Approved 12/16/21	Submitted 1/12/22 Approved 1/19/22	10/16	2/16
Jamaica Hospital Medical Center	E00881.1p	16	Approved	Submitted 11/23/21 Approved 12/17/21	Submitted 1/20/22 Approved 2/3/22	12/16	8/16
St. Mary's Medical Center	E00881.1q	16	Approved	Submitted 8/7/21 Approved 1/6/22	Submitted 2/13/22 Approved 2/22/22	2/16	0/16
Virginia Commonwealth University	E00881.1r	16	Approved	Submitted 2/2/22 Approved 2/9/22	Submitted 2/16/22 Approved 2/23/22	3/16	3/16
Vanderbilt University Medical Center	E00881.1s	16	Approved	Submitted 2/10/22 Approved	Submitted 2/16/22 Approved	15/16	6/16

Site name	HRPO assigned #	Target required for clinical significance	Local IRB submission status	Submitted/ approved by Advarra sIRB	Submitted/ approved by DoD HRPO	# of subjects screened/original planned target	# of patients enrolled/original planned target
				2/15/22	2/23/22		
University of Oklahoma	E00881.1t	16	Approved	Submitted 11/29/21 Approved 2/18/22	Submitted 2/22/22 Approved 2/23/22	40/16	4/16
Eskenazi Health	E00881.1u	16	Approved	Submitted 2/10/22 Approved 3/10/22	Submitted 3/16/22 Approved 3/17/22	1/16	1/16
Harvard Orthopaedic Trauma Services	E00881.1v	16	Approved	Submitted 3/9/22 Approved 3/18/22	Submitted 3/22/22 Approved 4/1/22	7/16	6/16
Temple University Hospital	E00881.1w	16	Approved	Submitted 4/1/22 Approved 4/5/22	Submitted 4/18/22 Approved 4/20/22	0/16	0/16
University of Maryland, Shock Trauma Center	E00881.1x	16	Approved	Submitted 12/13/21 Approved 1/14/22	Submitted 5/3/22 Approved 6/4/22	8/16	2/16
Texas Tech University Health Sciences Center	E00881.1y	16	Approved	Submitted 2/8/22 Approved 3/17/22	Submitted 6/14/22 Approved 6/27/22	0/16	0/16
Louisiana State University	E00881.1z	16	Approved	Submitted 4/12/22 Approved 5/10/22	Submitted 6/16/22 Approved 6/30/22	0/16	0/16
Spectrum Health System	E00881.1aa	16	Approved	Submitted 4/1/22 Approved 5/10/22	Submitted 7/5/22 Approved 7/29/22	0/16	0/16
Stanford University Medical Center	E00881.1bb	16	Approved	Submitted 2/23/22 Approved	Submitted 7/1/22 Approved	0/16	0/16

Site name	HRPO assigned #	Target required for clinical significance	Local IRB submission status	Submitted/ approved by Advarra sIRB	Submitted/ approved by DoD HRPO	# of subjects screened/original planned target	# of patients enrolled/original planned target
				3/24/22	7/29/22		
University of Virginia Medical Center	E00881.1cc	16	Approved	Submitted 2/23/22 Approved 4/5/22	Submitted 8/10/22 Approved 9/6/22	3/16	0/16
Inova Fairfax Hospital	Not assigned yet	16	Approved	Submitted 8/19/22 Approved 9/27/22	Pending		
Boston Medical Center	Not assigned yet	16	Approved	Pending	Not available yet		
Grant Medical Center	Not assigned yet	16	Approved	Submitted 3/1/22 Approved 3/30/22	Pending		
UCLA	Not assigned yet	16	Approved	Pending	Not available yet		
Walter Reed National Military Medical Center	Not assigned yet	16	Approved	Pending	Not available yet		
Mission Hospital	Not assigned yet	16	Pending	Not available yet	Not available yet		
Emory University School of Medicine	Not assigned yet	16	Approved	Pending	Not available yet		
University Hospitals Cleveland	Not assigned yet	16	Approved	Pending	Not available yet		
University of Michigan	Not assigned yet	16	Approved	Pending	Not available yet		
University of Texas Southwestern Medical Center	Not assigned yet	16	Approved	Submitted 7/27/22	Not available yet		
Beth Israel Beacon Medical Center	Not assigned yet	16	Submitted	Not available yet	Not available yet		
NYU Lagone	Not assigned yet	16	Submitted	Submitted 1/7/22 Approved 1/18/22	Pending		

<b>Site name</b>	<b>HRPO assigned #</b>	<b>Target required for clinical significance</b>	<b>Local IRB submission status</b>	<b>Submitted/ approved by Advarra sIRB</b>	<b>Submitted/ approved by DoD HRPO</b>	<b># of subjects screened/original planned target</b>	<b># of patients enrolled/original planned target</b>
Loyola University	Not assigned yet	16	Submitted	Not available yet	Not available yet		
Dignity Health	Not assigned yet	16	Submitted	Not available yet	Not available yet		
University of North Carolina	Not assigned yet	16	Submitted	Not available yet	Not available yet		