



TASK ORDER NUMBER: W81XWH-15-9-0001-0005

MTEC RESEARCH PROJECT NUMBER: MT17002.18

EGS NUMBER: MT17002.18

TITLE: ELECTROCEUTICAL TECHNOLOGY AGAINST BACTERIAL DRUG RESISTANCE.

PRINCIPAL INVESTIGATOR: Sashwati Roy, PhD

PERFORMING ORGANIZATION: Indiana University School of Medicine, Indianapolis, IN

CONTRACTING ORGANIZATION: Medical Technology Enterprise Consortium (MTEC)

REPORT DATE: October 25, 2021

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PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

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6. AUTHOR(S) PI: Sashwati Roy Co-I: Chandan K. Sen, PhD, Gayle M Gordillo, MD, Savita Khanna, Mohamed El Masry, MD, Post Doc: Nandini Ghosh, PhD E-Mail: Roysa@iu.edu			5d. PROJECT NUMBER MT17002.18		
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14. ABSTRACT The objective of this work is to develop EDT _{lo} and EDT _{hi} wound dressings against bacteria and fungal biofilm infections as MTEC Technology for prototype acceleration. Resilience, DoD). Two sp aims have been proposed: Aim 1 . Specific Aim 1. To determine the ability of optimized electroceutical EDT dressings to eliminate mixed species, multi-drug resistant infection in an in vitro assay and porcine burn infection model. Aim 2 . . Test whether wound closure in a pair-matched setting is improved using optimized EDT treatment compared to standard of care (SoC) in biofilm/MDR-infected porcine burn wounds. Aim 3 . To determine the ability of optimized electroceutical EDT dressings to eliminate Candida albicans infection: Aim 3a . An in vitro biofilm assay and Aim 3b . In a porcine burn infection model.					
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a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code)
Unclassified	Unclassified	Unclassified	Unclassified		

Standard Form 298 (Rev. 8-98)



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Final Technical Status Report for
Electroceutical technology against bacterial drug resistance

Research Project No. MTEC-17-02-PA-18
EGS#MT17002.18

Reporting Period: Effective Date
Mar 19, 2019 - Oct 24, 2021

MTEC Research Project Awardee

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Submitted: 12.20.2021

1. Project Status

a. Accomplishments

The Table below indicates the status of all milestone within the past year.

MTEC Milestone #	Significant Event/ Accomplishments	Due Date	Milestone Status
1	In vitro testing of EDT on the viability of the drug resistant strains tested either in planktonic or biofilm mode of growth used independently or in combination with antibiotic.	6/21/2019	Complete
2	DoD ACURO submission	04/30/2019	Complete
3	Quarterly Reports 1 (March-June, Technical and Business Reports)	7/25/2019	Complete
4	Quarterly Report 2 (July-September, Technical and Business Reports)	10/25/2019	Complete
5	Receive DoD ACURO approval	7/30/2019	Complete
6	Preclinical porcine wound studies testing efficacy of EDT on the persistence of infection in wounds infected by drug resistant strains in planktonic/biofilm mode.	10/29/2019	Complete
7	Preclinical porcine wound studies testing efficacy of EDT as compared to SoC on wound closure of burn wounds infected by drug resistant strains in planktonic/biofilm mode.	11/29/2019	Complete
8	Quarterly Report 3 (September-Dec, Technical and Business Reports)	1/25/2020	Complete
9	Data analysis	2/29/2020	Complete

10	Annual Report	4/25/2020	Complete
11	In vitro testing of the efficacy of EDT on the planktonic and on biofilm mode for candida albicans	5/29/2020	Complete
12	Quarterly Report 4 (March-June, Technical and Business Reports)	7/25/2020	Complete
13	Quarterly Report 5 (June-Sept, Technical and Business Reports)	10/25/2020	Complete
14	Quarterly Report 6(Sept-Dec, Technical and Business Reports)	1/25/2021	Complete
15	Annual Report	4/25/2021	Complete
16	Quarterly Report 7 (April – June, Technical and Business Reports)	7/25/2021	Complete
17	Preclinical porcine wound studies testing efficacy of EDT on the persistence of infection in wounds infected by CA infection.	7/30/2021	Complete
18	Data analysis	08/31/2021	Complete
19	Pre submission meeting with FDA and Preparation/submission of FDA 510(k) application	09/29/2021	Complete
20	Final Reports	10/25/2021	Complete

b. Reportable Outcomes

1. The porcine studies for Biofilm infection and wound closures studies have concluded. A significantly improved wound closure and attenuation in biofilm infection was noted in EDT treatment group as compared to placebo treated group. These experiments are now complete with all the proposed pigs (n=5) are complete. The data indicate a favorable outcome of EDT treatment on

- a. Biofilm infection control
- b. wound closure and reepithelialization/vascularization

These studies are part of the FDA IND application for a clinical study.

A manuscript is in preparation for reporting the findings of the studies described above. The tentative submission date is March 2022.

2. The studies to determine the ability of optimized electroceutical EDT dressings to eliminate *Candida albicans* biofilm infection has concluded. The potential synergy of EDT and ketoconazole in the management of ketoconazole-resistant *Candida albicans* biofilm infection was also tested. Visualization of biofilm aggregate architecture using Scanning Electron Microscopy (SEM) revealed biofilms hyphal morphologies within 24 h. Such structures were abundant in untreated cells, cells treated with placebo and Ag-only control. In biofilm-forming cells treated with ketoconazole, the filamentation appeared after 48 h. In EDT treated cells, hyphal morphology was absent suggesting a beneficial effect of EDT on *Candida albicans* biofilm infection in invitro model.

3. The studies were finalized and reported:

Khona DK, Roy S, Ghatak S, Huang K, Jagdale G, Baker LA, Sen CK Ketoconazole resistant *Candida albicans* is sensitive to a wireless electroceutical wound care dressing. *Bioelectrochemistry*. 2021 Dec;142:107921.

c. Progress Detail

All milestones are complete, the details have been reported below:

Milestone 1 (complete). *In vitro* testing of EDT on the viability of the drug resistant strains tested either in planktonic or biofilm mode of growth used independently or in combination with antibiotic. To determine efficacy of the EDT dressings against

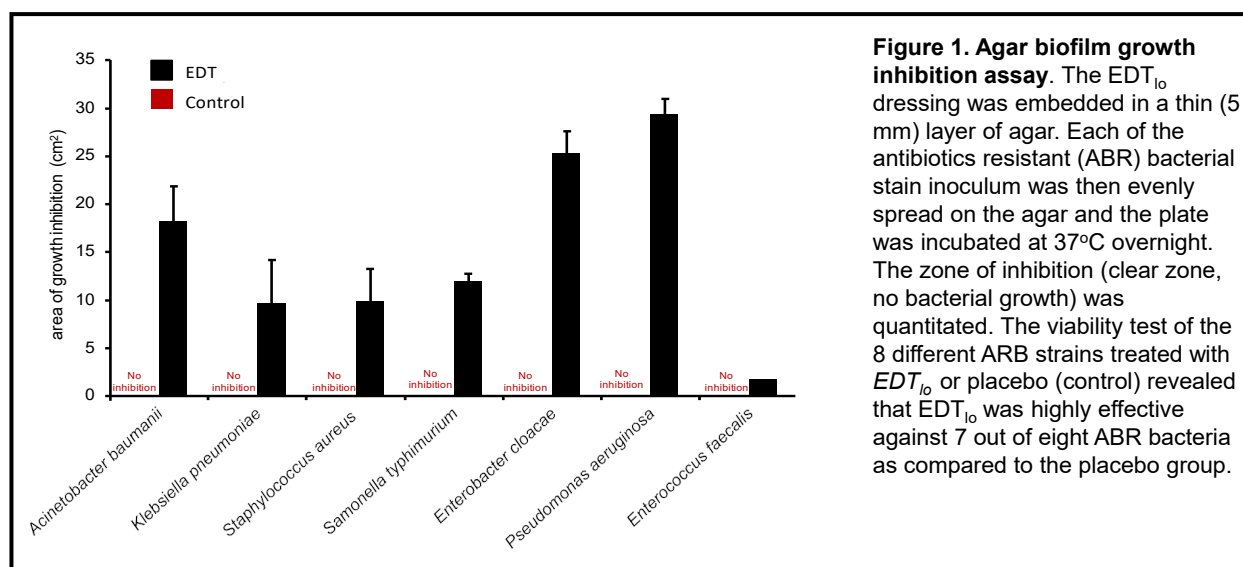


Figure 1. Agar biofilm growth inhibition assay. The EDT₁₀ dressing was embedded in a thin (5 mm) layer of agar. Each of the antibiotics resistant (ABR) bacterial stain inoculum was then evenly spread on the agar and the plate was incubated at 37°C overnight. The zone of inhibition (clear zone, no bacterial growth) was quantitated. The viability test of the 8 different ABR strains treated with EDT₁₀ or placebo (control) revealed that EDT₁₀ was highly effective against 7 out of eight ABR bacteria as compared to the placebo group.

antibiotic resistant (ABR) bacteria, an agar biofilm growth inhibition assay was performed. The EDT dressing was embedded in a thin (5 mm) layer of agar. Each of the ABR resistant bacterial strain inoculum was then evenly spread on the agar and the plate was incubated at 37°C overnight. The zone of inhibition (clear zone, no bacterial growth) was quantified. The viability test of the 8 different ARB strains treated with EDT or placebo (control) revealed that EDT was highly effective against 7 out of eight ABR bacteria as compared to the placebo group. The data for *in vitro* studies testing efficacy of EDT against ABR Data attached as **Figure 1**.

Milestones 2-5 (Complete). DoD ACURO submission; Quarterly Reports 1 & 2; receive DoD ACURO approval

Both reports were submitted on respective due dates.

Milestone 6 (Complete). Preclinical porcine wound studies testing efficacy of EDT on the persistence of infection in wounds infected by drug resistant strains in planktonic/biofilm mode.

For the studies, domestic Yorkshire female pigs were wounded and infected to establish chronic wound biofilm model as described by us. In brief, eight full thickness burn wounds (2 x 2 inch) were created on the dorsum of pigs. On day 3 post-burn,

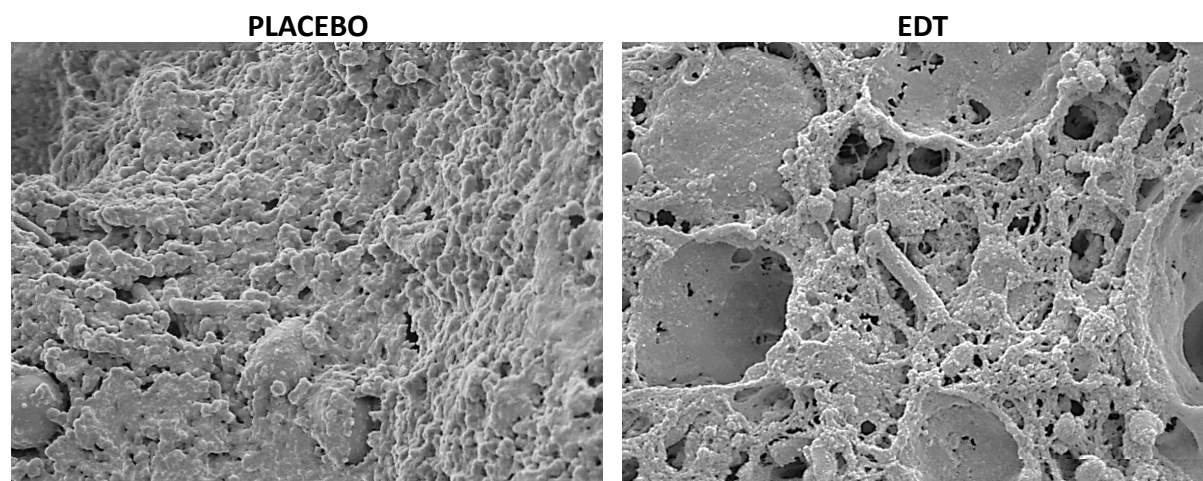
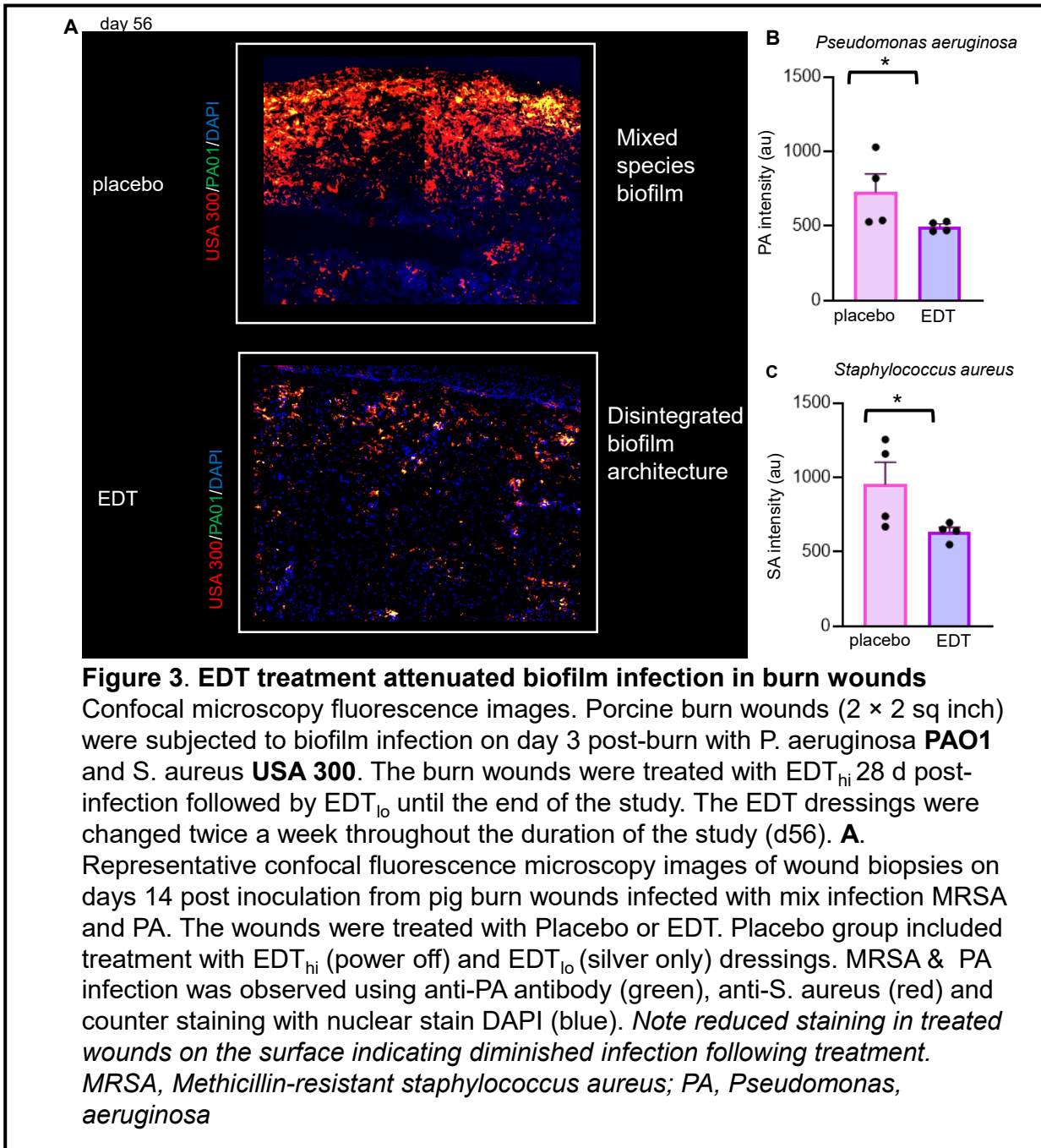


Figure 2. Scanning electron microscopy images of wound biofilm. Porcine burn wounds (2 × 2 sq inch) were subjected to biofilm infection on day 3 post-burn with *P. aeruginosa* PAO1 and *S. aureus* USA 300 (MRSA). The burn wounds were treated with EDT_{hi} 28 d post-infection followed by EDT_{lo} until the end of the study. The EDT dressings were changed twice a week throughout the duration of the study (d56). Scanning electron microscope (SEM) images of wound biopsies on days 14 post inoculation from pig burn wounds infected with mix biofilm infection MRSA and PA. The wounds were treated with Placebo or EDT. Note the thick aggregates of bacteria (cocci) encased in extrapolymeric matrix (EPS) characteristic of bacterial biofilm in placebo group, such thick biofilm was not observed in EDT treated group. Placebo group included treatment with EDT_{hi} (power off) and EDT_{lo} (silver only) dressings.

MRSA, Methicillin-resistant staphylococcus aureus; PA, Pseudomonas, aeruginosa.

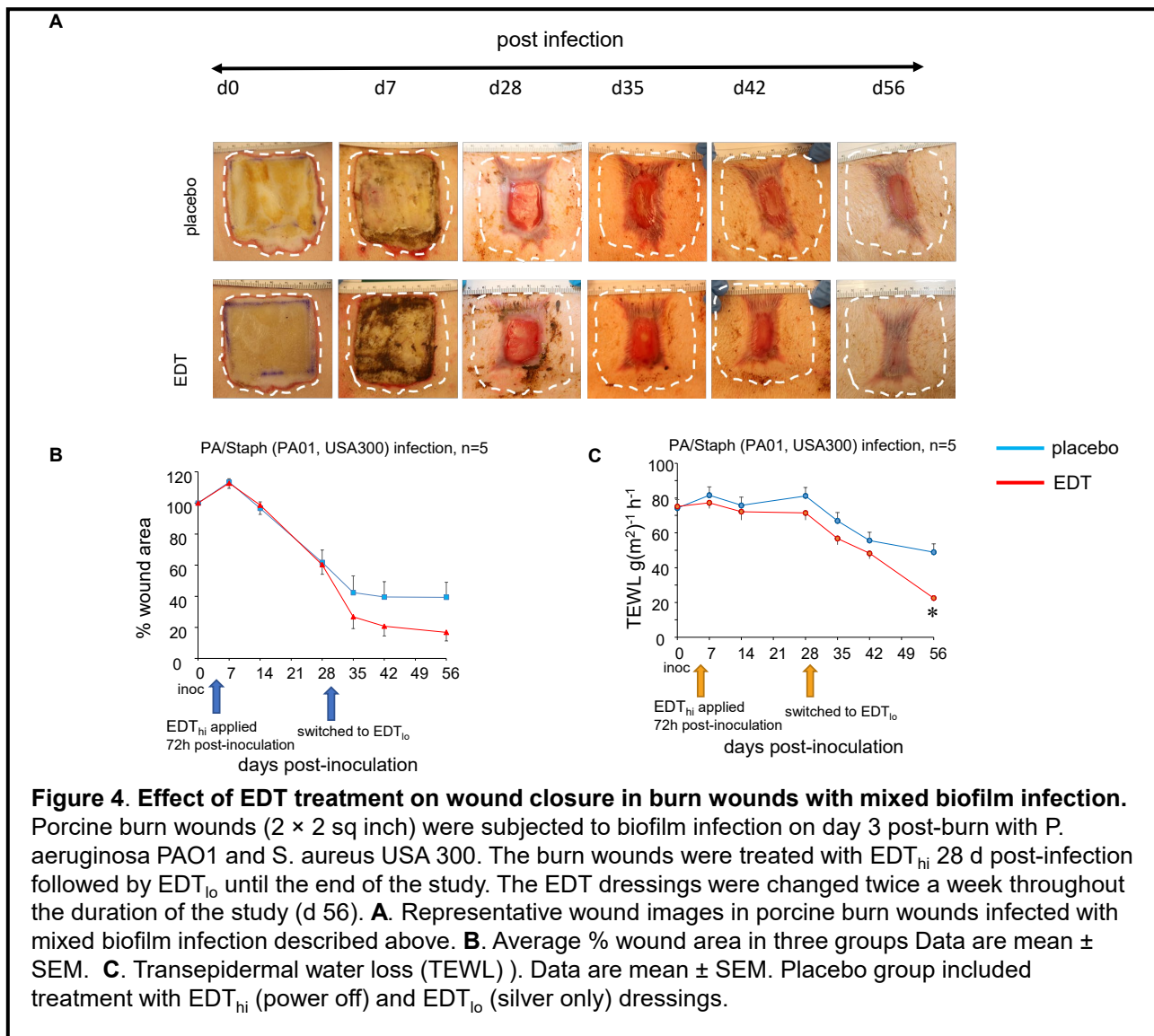
wounds were inoculated with infection with mixed bacterial species consisting of *Pseudomonas aeruginosa* (PA01, CFU 10^8 /ml), and *Staphylococcus aureus* (USA300, CFU 10^8 /ml). Bacteria were allowed to form biofilm in the wounds and the dressings were applied post 72h of inoculation. Dressings were changed twice a week and treatment with EDT_{hi} was switched to EDT_{lo} on d28 post inoculation. Control wounds were treated EDT_{hi} (OFF) and then switched to silver only on d28 post inoculation.



Wounds were followed up to 56 days post inoculation. Biopsies were collected on day 7, 14, 28 and 56 post-bacterial inoculation. The pigs were euthanized at day 56 post inoculation. Biopsies were collected using a 6 mm sterile disposable punch biopsy tool. TEWL, HUSD and LSI measurements were taken on pre burn and post burn day and

on days 0, 7, 14, 28, 35, 42 and 56 post inoculation. A total of 7 pigs were used for PA01/USA300 infection and 5 pigs were used for the *Candida albicans* infection. Note the thick aggregates of bacteria (cocci) encased in extrapolymeric matrix (EPS) characteristic of bacterial biofilm in placebo group, such thick biofilm was not observed in EDT treated group. Placebo group included treatment with EDT_{hi} (power off) and EDT_{lo} (silver only) dressings. Biofilm infection data (SEM and confocal) has been presented in **Figures 2 & 3**.

Milestone 7 (Complete). Preclinical porcine wound studies testing efficacy of EDT as compared to SoC on wound closure of burn wounds infected by drug resistant strains in planktonic/biofilm mode. Wound closure, as determined by digital planimetry displayed that EDT treatment significantly improves wound closure as compared to the placebo treatment (**Figure 4A-B**). Wound closure is primarily aimed at re-establishment of barrier function of the defective skin. Measured by **TEWL**, skin barrier function represents a functional descriptor of wound healing. A significant improvement in TEWL was noted in EDT treated wounds indication improved re-establishment of barrier function following treatment (**Figure 4C**).



Day 56

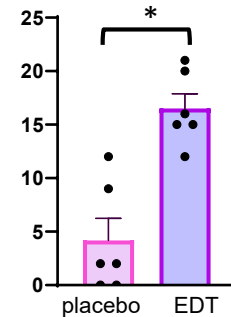
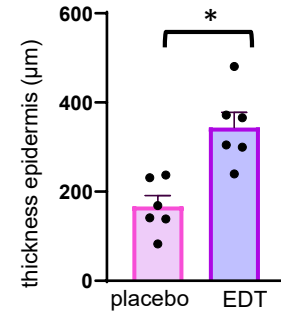
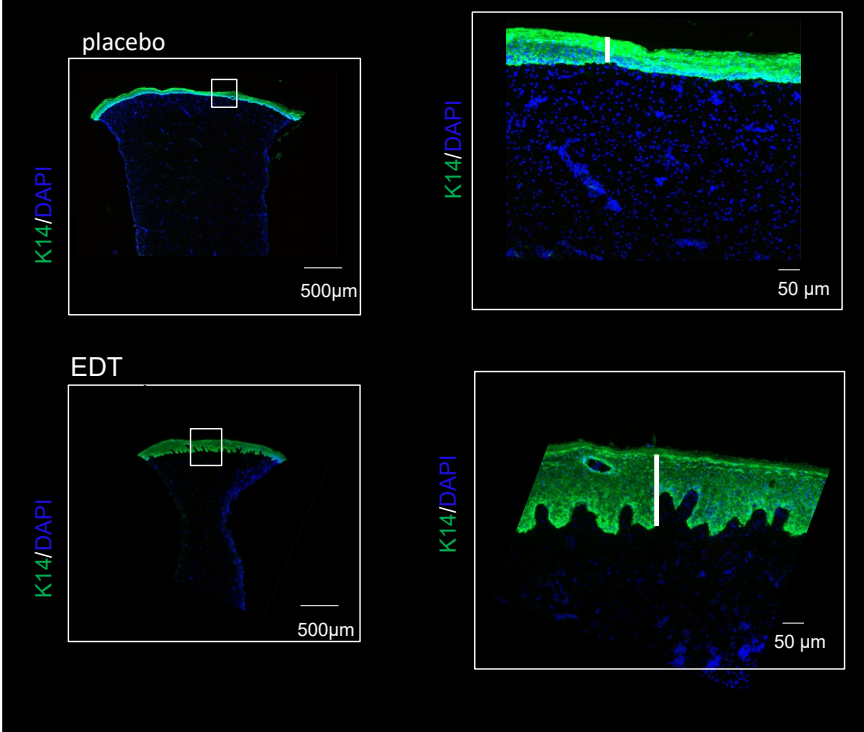


Figure 5. Effect of EDT treatment on wound reepithelialization in burn wounds with mixed biofilm infection. A. Representative K14 (Keratinocytes/epidermis, green) and DAPI (nuclear, blue) micrographs from wound sections on d56 post infection. Placebo group included treatment with EDT_{hi} (power off) and EDT_{lo} (silver only) dressings.

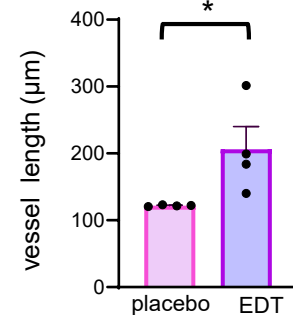
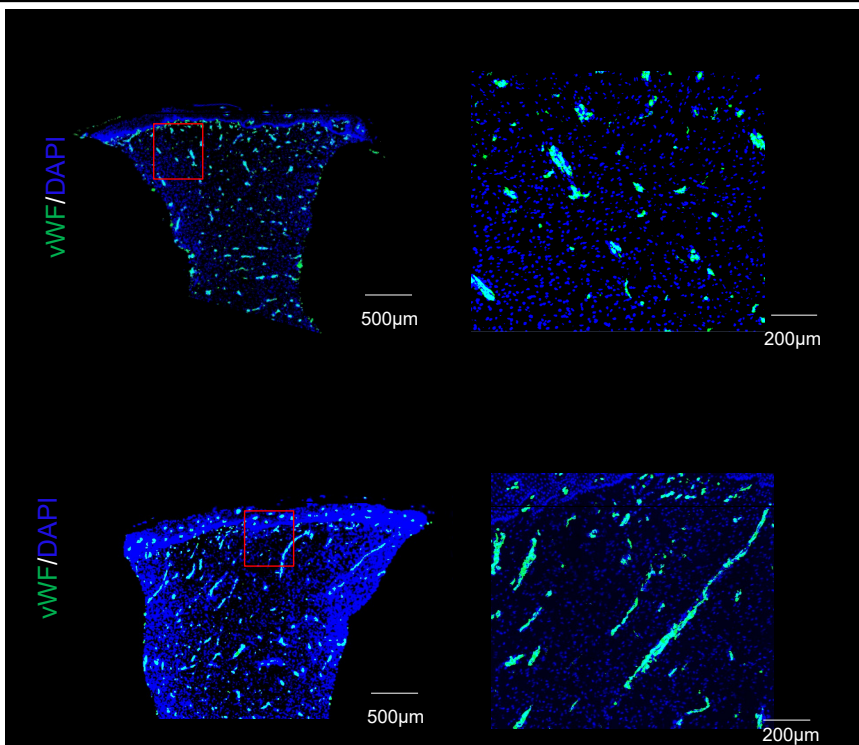


Figure 6. Effect of EDT treatment on wound neovascularization in burn wounds with mixed biofilm infection. A. Representative vWF (endothelial cells/vessels, green) and DAPI (nuclear, blue) wound micrographs d56 post infection. Placebo group included treatment with EDT_{hi} (power off) and EDT_{lo} (silver only) dressings.

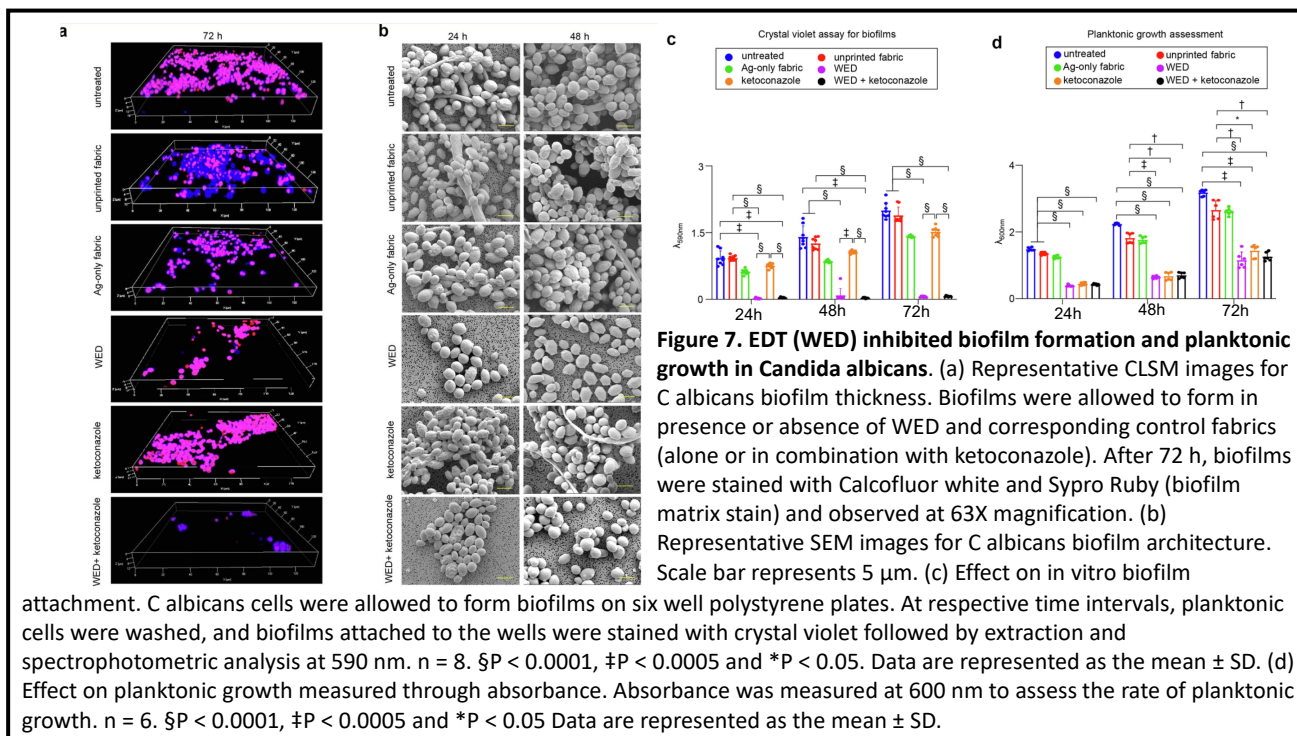
The wound reepithelialization and neovascularization was assessed using histological approaches. Consistent with wound closure data, an significantly improved re-

epithelialization and wound vascularization was noted EDT treated wounds as compared to placebo group (**Figures 5&6**).

Milestones 8-10 (Complete). Quarterly Report 3 (September-Dec, Technical and Business Reports); Data analysis; Annual report Y1.

The reports were submitted on respective due dates. All data analysis for in vitro and porcine biofilm infection studies are complete (**See Figures 2-6**).

Milestone 11 (Complete). In vitro testing of the efficacy of EDT on the planktonic and on biofilm mode for *Candida albicans*. EDT inhibited *Candida albicans* biofilm formation and planktonic growth of ketoconazole-resistant yeast *Candida albicans*. Unlike ketoconazole, the EDT inhibited yeast to hyphal transition. The objective of the following experiment was to test whether EDT can attenuated/ eradicate ketoconazole-resistant *Candida albicans* biofilm infection. The potential synergy of EDT and ketoconazole in the management of ketoconazole-resistant *Candida albicans* biofilm infection was also tested.



Confocal laser scanning microscopy analyses of biofilm formation demonstrated no change of biofilm formation in response to ketoconazole, Placebo EDT or Ag-only control.

Significant reduction in biofilm thickness was noted when cells were exposed to EDT alone or in combination with ketoconazole (**Figure 7**). Akin to the outcome of ketoconazole alone, addition of the drug to WED did not cause any further difference in biofilm outcome.

Visualization of biofilm aggregate architecture using SEM revealed biofilms hyphal morphologies within 24 h (**Figure 7**). Such structures were abundant in untreated cells, cells treated with placebo and Ag-only control. In biofilm-forming cells treated with ketoconazole, the filamentation appeared after 48 h. In EDT treated cells, hyphal morphology was absent.

The studies were finalized and reported:

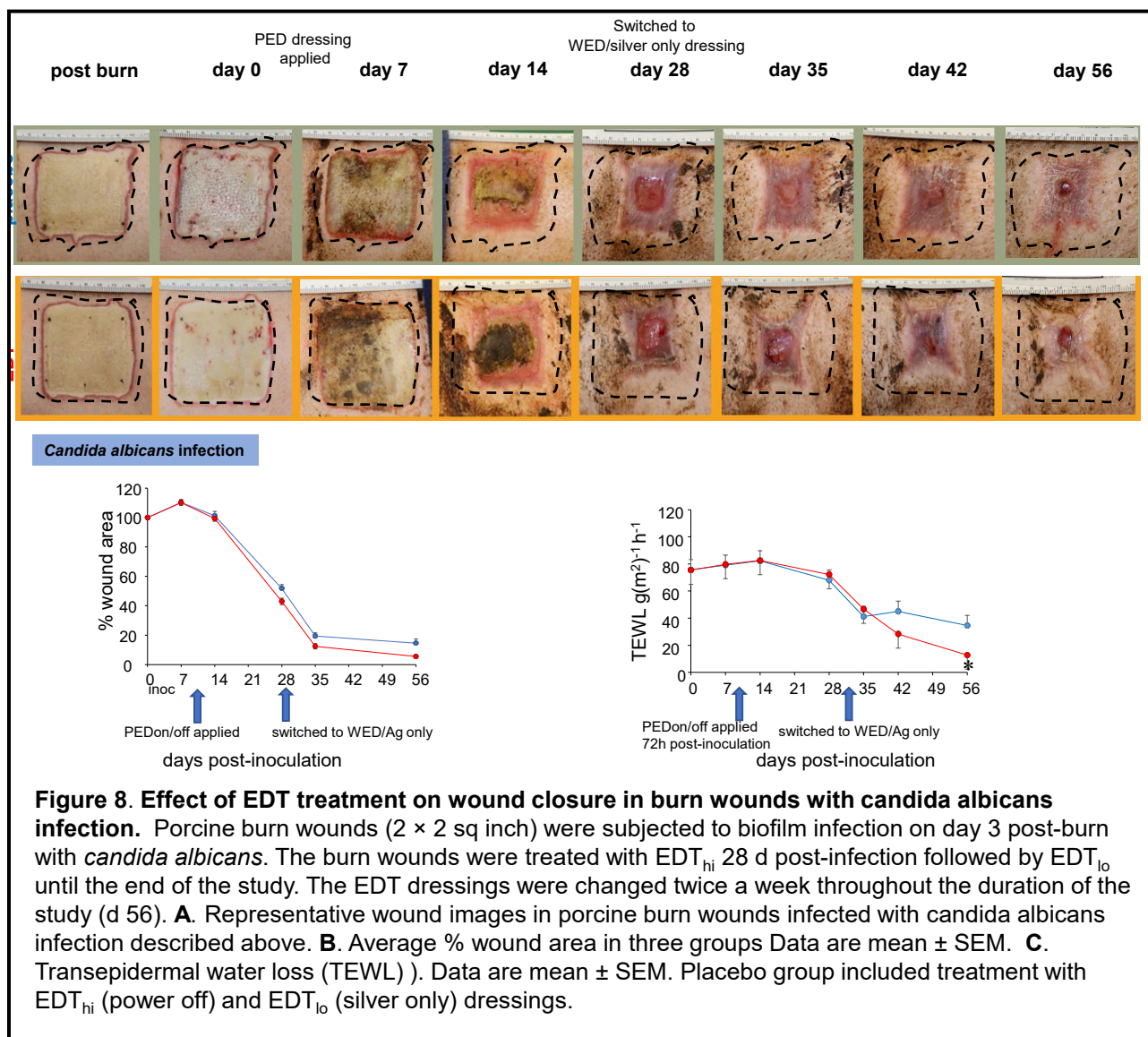
Khona DK, Roy S, Ghatak S, Huang K, Jagdale G, Baker LA, Sen CK Ketoconazole resistant *Candida albicans* is sensitive to a wireless electroceutical wound care dressing. *Bioelectrochemistry*. 2021 Dec;142:107921.

Milestones 12-16 (Complete). Quarterly Report 4-7 & Annual Report Y2

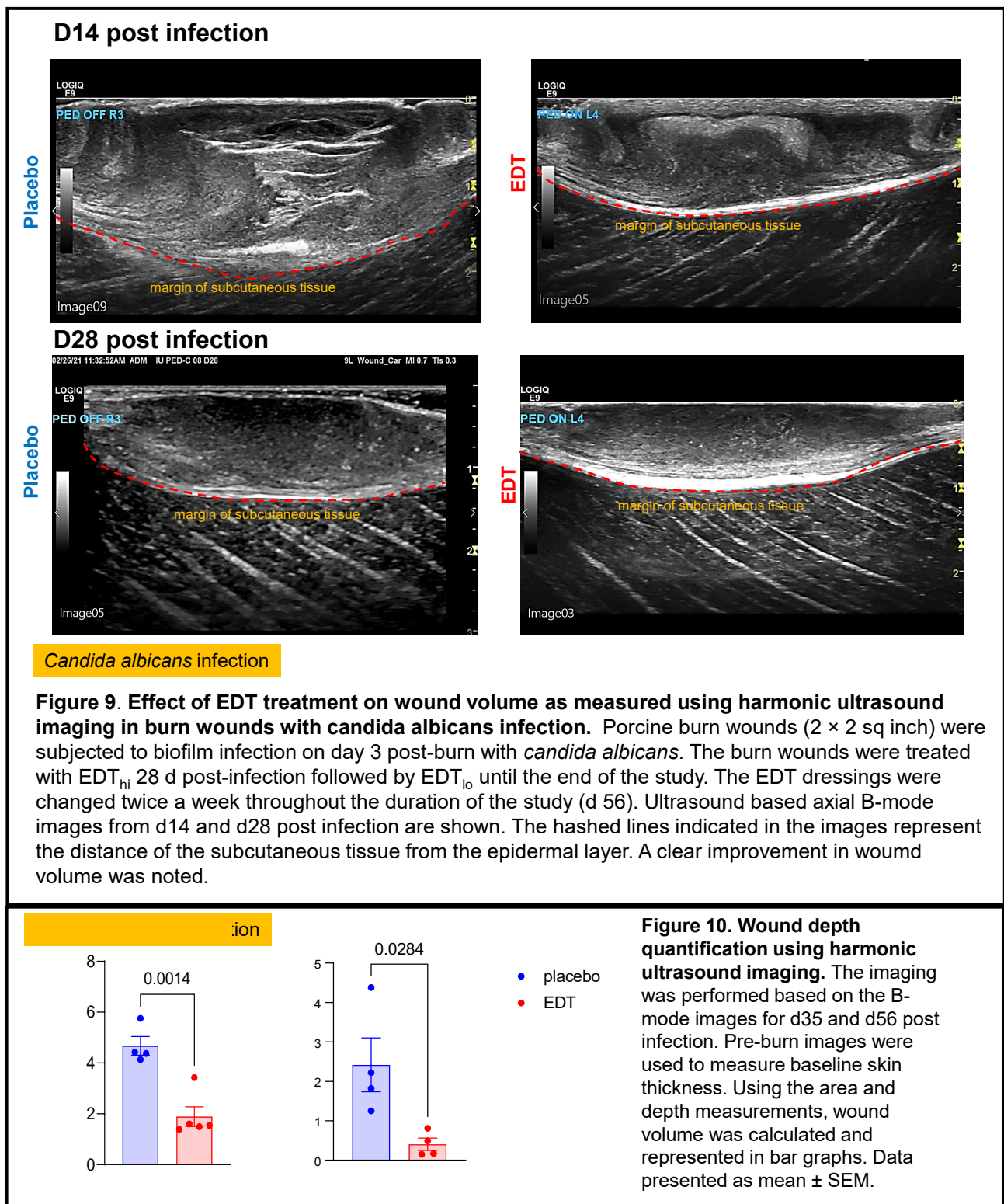
All reports were submitted per due date.

Milestones 17-18 (Complete). Preclinical porcine wound studies testing efficacy of EDT on the persistence of infection in wounds infected by CA infection; Data Analysis

For the studies, established pre-clinical porcine chronic wound model as described above in Figure 4 was utilized. The burn wounds were infected with *C. albicans* (ATCC 64124) followed by treatment with placebo or EDT. Wound closure was determined using digital



planimetry, TEWL and harmonic ultrasound imaging (Figures 8-10).



Milestones 19 (Complete). Pre submission meeting with FDA and Preparation of FDA 510(k) application.

We have recruited Pearl Pathways, a consulting firm for EDT FDA Q-submission meeting services and 510(k) regulatory services to assist in achieving FDA clearance of EDT. All the

data from the project has been finalized and submitted to Pearl Pathways for FDA clearance.

Milestones 20 (Complete). Final Reports

Report preparation and submission complete.

2. Problems / Issues

Covid-19 pandemic was a significant challenge during performance period. A No cost extension of the project was requested to mitigate the problem.

3. Financial Health

The project was on track with budget except for the NCE period due to COVID 19. The NCE resulted in additional personnel cost incurred that was covered via PI's Institutional funds. No major equipment was purchased on this award for last year.

4. Personnel Effort

Provide names of current staff along with their roles and percent effort of each on this project. Add additional rows if necessary to list the complete team. If there is more than one project on this award, breakdown according to each project (one table per project).

Personnel	Role	Percent Effort
Principal Investigator	PI	5%
Chandan K. Sen	Co-I	5%
Gayle Gordillo	Co-I	1%
Shomita Steiner	Project Manager	30%
Savita Khanna	Co-I	5%
Suman Santra	Post Doc	30%
Nandini Ghosh	Post Doc	25%
Dolly Khona	Post Doc	60%
Mahadeo Gorain	Post Doc	10%
Vinoj Gopalakrishnan	Post Doc	20%
Jessica Smith	Research Tech	10%

5. Protocol and Activity Status

For awards involving the use of human subjects, use of human cadavers, and/or use of animal subjects, prepare a summary in accordance with the following subsections. For all other awards, including those involving the use of human anatomical substances (such as tissue or cells or identifiable private information), mark as directed below.

a. Human Use Regulatory Protocols

TOTAL PROTOCOLS: State the total number of human use protocols required to complete



this project (e.g., 5 human subject research protocols will be required to complete the Statement of Work.”). If not applicable, write “No human subjects research will be performed to complete the Statement of Work.”

Not applicable – no human subjects proposed

PROTOCOLS: List all human use protocols to be performed to complete the project, an include approved target number for clinical significance, followed by type of submission and type of approval with associated dates, and performance status for each.

Protocol [HRPO Assigned Number]:

Title:

Target required for clinical significance:

Target approved for clinical significance:

Submitted to and Approved by:

Provide bullet point list of protocol development, submission, amendments, and approvals (include IRB in addition to HRPO).

STATUS: Provide bullet point list of performance and/or progress status relating to the above protocol and discuss recruitment number, enrollment number, drop outs, disqualified, etc. Discuss any administrative, technical, or logistical issues that may impact performance or progress of the study (e.g. slow enrollment, large dropouts, or adverse events) for the above HPRO approved protocol.

b. Use of Human Cadavers for RDT&E, Education or Training

“Cadaver” is defined as a deceased person or portion thereof, and is synonymous with the terms "human cadaver" and "post-mortem human subject" or "PMHS." The term includes organs, tissue, eyes, bones, arteries or other specimens obtained from an individual upon or after death. The term "cadaver" does not include portions of an individual person, such as organs, tissue or blood, that were removed while the individual was alive (for example, if a living person donated tissue for use in future research protocols, that tissue is not considered a "cadaver" under this policy, regardless of whether the donor is living or deceased at the time of tissue use).

TOTAL ACTIVITIES: State the total number of RDT&E, education or training activities that will involve cadavers. If not applicable, write “No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW).”

ACTIVITIES: Provide the following information in a bulleted list for all RDT&E, education or training activities involving human cadavers conducted or supported during the quarter:

- Title of the RDT&E, education or training activity
- SOW task/aim associated with the activity
- Date the activity was conducted
- Identification of the organization’s responsible individual (e.g., PI or individual primarily responsible for the activity’s conduct)
- Brief description of the use(s) of cadavers in the activity and the total



number of cadavers used during the reporting period

- Brief description of the Department of Army organization's involvement in the activity
- Status of document submission and approvals
- Problems encountered in the procurement, inventory, use, storage, transfer, transportation and disposition of cadavers used for RDT&E, education or training. Examples of problems include but are not limited to: loss of confidentiality of cadaveric donors, breach of security, significant deviation from the approved protocol, failure to comply with state laws and/or institutional policies and public relations issues.

c. Animal Use Regulatory Protocols

TOTAL PROTOCOLS: State the total number of animal use protocols required to complete this project (e.g., 2 animal use research protocols will be required to complete the Statement of Work.). If not applicable, write "No animal use research will be performed to complete the Statement of Work."

PROTOCOLS: List all animal use protocols to be performed to complete the project, include approved target number for statistical significance, followed by type of submission and type of approval with associated dates, and performance status for each.

Protocol [ACURO Assigned Number]: **MT17002.18**

Title: **Electroceutical Technology Against Bacterial Drug Resistance**

Target required for statistical significance: n=5

Target approved for statistical significance: n=5

Submitted to and Approved by: Submitted to ACURO and approved by ACURO USAMRDC Proposal Number MT17002.18 entitled, on July 23rd, 2019

Provide bullet point list of protocol development, submission, amendments, and approvals (include IACUC in addition to ACURO).

IACUC approved protocol # 18048 - Tilted - Dermal wound healing treatment

STATUS: Provide bullet point list of performance and/or progress status relating to the above protocol and discuss any administrative, technical, or logistical issues that may impact performance or progress of the study (e.g. animal use protocol need revision to minimize animal suffering, animal protocol modification to include additional staff) for the above ACURO approved protocol.

No administrative, technical, or logistical issues anticipated.



Final Business Status Report for

Electroceutical technology against bacterial drug resistance

Research Project No. MTEC-17-02-PA-18

EGS#MT17002.18

Reporting Period: Effective Date

Mar 19, 2019 - Oct 24, 2021

MTEC Research Project Awardee

Sashwati Roy, PhD

Co-I

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Post Doc

Nandini Ghosh, PhD

Research Project Technical POC

Sashwati Roy

Indiana University School of Medicine

444A MRLB; 975 Walnut Street

Indianapolis, IN

Tel: 317-278-2706

Email: roysa@iu.edu

Submitted: 12.20.2021



1. CURRENT STAFF

Personnel	% of Effort on project
Program Manager (Toto)	none
Principal Investigator/Co-I (Roy, Sen Gordillo/Khanna)	Cumulative 11%
Project Manager (Steiner)	30%
Project Management Officer	None
Contracting	None
Management Assistant (Nandini Ghosh, Victoria Wehman)	Cumulative 70%

2. CURRENT EXPENDITURES

DIRECTIONS: FILL OUT TABLE A OR B DEPENDING ON CONTRACT TYPE. TABLE A IS FOR COST REIMBURSABLE CONTRACTS AND TABLE B IS FOR FIX PRICED CONTRACTS.

A. Cost Reimbursable Contracts: Complete only if your contract is Cost Reimbursable or Cost Plus Fixed Fee.

Expenditures should be reflective of cost incurred to date, not exceeding awarded project ceiling. Expenditures should coincide with the latest invoice for the reporting period. For cost reimbursable contracts please use the table below.

Contract Expenditures	<i>Cumulative To Date Expenditures</i>
Labor (Personnel and Fringe)	\$
Supplies/Materials	\$
Travel	\$
Equipment	\$
Subcontractors and Consultants	\$
Other Direct Costs	\$
Indirect Costs	\$
Total	\$

B. Fixed Priced Contracts: Complete only if your contract is Fixed Priced.

Expenditures should be reflective of milestones that are **100% complete** and **invoiced** for. Milestones reported below should correspond to the Milestone Payment Schedule in the Project Award. **Milestones can only be invoiced for if they are 100% Complete.** Expenditures should coincide with the latest invoice for the reporting period. For fixed priced contracts please use the table below.

MTEC Milestone #	Significant Event/ Accomplishments	Due Date	Government Funds
1	In vitro testing of EDT on the viability of the drug resistant strains tested either in planktonic or biofilm mode of growth used independently or in combination with antibiotic.	6/21/2019	41,985.00
2	DoD ACURO submission	04/30/2019	
3	Quarterly Reports 1 (March-June, Technical and Business Reports)	7/25/2019	
4	Quarterly Report 2 (July-September, Technical and Business Reports)	10/25/2019	
5	2 Receive DoD ACURO approval	7/30/2019	
6	Preclinical porcine wound studies testing efficacy of EDT on the persistence of infection in wounds infected by drug resistant strains in planktonic/biofilm mode.	10/29/2019	69,545.00
7	Preclinical porcine wound studies testing efficacy of EDT as compared to SoC on wound closure of burn wounds infected by drug resistant strains in planktonic/biofilm mode.	11/29/2019	41,820.00
8	Quarterly Report 3 (September-Dec, Technical and Business Reports)	1/25/2020	
9	Data analysis	2/29/2020	31,100.00

10	Annual Report	4/25/2020	
11	In vitro testing of the efficacy of EDT on the planktonic and on biofilm mode for candida albicans	5/29/2020	75,000
12	Quarterly Report 4 (March-June, Technical and Business Reports)	7/25/2020	
13	Quarterly Report 5 (June-Sept, Technical and Business Reports)	10/25/2020	
14	Quarterly Report 6(Sept-Dec, Technical and Business Reports)	1/25/2021	
15	Annual Report	4/25/2021	
16	Quarterly Report 7 (April – June, Technical and Business Reports)	7/25/2021	
17	Preclinical porcine wound studies testing efficacy of EDT on the persistence of infection in wounds infected by CA infection.	7/30/2021	85,000
18	Data analysis	08/31/2021	27,500
19	Pre submission meeting with FDA and Preparation/submission of FDA 510(k) application	09/29/2021	15,549.00
	Final Reports	10/25/2021	387,499.00

C. Cost Share Contributions: Complete only if you're reporting Cost Share:

Cost sharing includes any costs a reasonable person would incur to carry out (necessary to) proposed projects' statements of work not directly paid for by the Government. There are two types of cost sharing: **(1) Cash:** Outlays of funds to perform the proposed project. Cash includes labor, materials, new equipment, and relevant subcontractor efforts. Sources include new IR&D



funds, profit or fee from another contract, overhead or capital equipment expense pool. **(2) In-Kind:** Reasonable value of in-place equipment, materials or other property used in performance of the proposed project. All cash or in-kind cost sharing availability must be clearly and convincingly demonstrated by the Offeror. The Offeror will be required to provide financial reporting with appropriate visibility into expenditures of Government funds vs. private funds.

Funding Source (Cash)	This Period	Cumulative to Date
Cash	\$0.00	\$0.00
Labor Dollars	\$0.00	\$20,496
Indirect Labor Rates (Overhead/Fringe Benefits)	\$0.00	\$8,789
Travel	\$0.00	\$0.00
General & Administrative Services	\$0.00	\$10,000
Equipment (New)	\$0.00	\$0.00
Material	\$0.00	\$31,715
Other Direct Costs	\$0.00	\$0.00
Other *	\$0.00	\$0.00
Sub-Total	\$0.00	\$0.00
Funding Source (In-Kind)	This Period	Cumulative to Date
Use of Existing Equipment (Estimated fair market value)	\$0.00	\$29,000
Use of Existing Software (Estimated fair market value)	\$0.00	\$0.00
Intellectual Property (Estimated fair market Value)	\$0.00	\$0.00
Space (Land or buildings)	\$0.00	\$0.00
Sub-Total	\$0.00	\$100,000
Cost Share Total	\$0.00	\$100,000

3. STATUS OF MILESTONES – FILL OUT FOR ALL CONTRACT TYPES (all project milestones are to be included)

All project milestones from the Milestone Payment Schedule, in the project award, should be accounted for below.

MTEC Milestone Number	Milestone Description	Due Date	Cumulative % Complete
1	In vitro testing of EDT on the viability of the drug resistant strains tested either in planktonic or biofilm mode of growth used independently or in combination with antibiotic.	6/21/2019	100%
2	DoD ACURO submission	04/30/2019	100%
3	Quarterly Reports 1 (March-June, Technical and Business Reports)	7/25/2019	100%
4	Quarterly Report 2 (July-September, Technical and Business Reports)	10/25/2019	100%
5	Receive DoD ACURO approval	7/30/2019	100%
6	Preclinical porcine wound studies testing efficacy of EDT on the persistence of infection in wounds infected by drug resistant strains in planktonic/biofilm mode.	10/29/2019	100%
7	Preclinical porcine wound studies testing efficacy of EDT as compared to SoC on wound closure of burn wounds infected by drug resistant strains in planktonic/biofilm mode.	11/29/2019	100%
8	Quarterly Report 3 (September-Dec, Technical and Business Reports)	1/25/2020	100%
9	Data analysis	2/29/2020	100%
10	Annual Report	4/25/2020	100%

11	In vitro testing of the efficacy of EDT on the planktonic and on biofilm mode for candida albicans	5/29/2020	100%
12	Quarterly Report 4 (March-June, Technical and Business Reports)	7/25/2020	100%
13	Quarterly Report 5 (June-Sept, Technical and Business Reports)	10/25/2020	100%
14	Quarterly Report 6(Sept-Dec, Technical and Business Reports)	1/25/2021	100%
15	Annual Report	4/25/2021	100%
16	Quarterly Report 7 (April – June, Technical and Business Reports)	7/25/2021	100%
17	Preclinical porcine wound studies testing efficacy of EDT on the persistence of infection in wounds infected by CA infection.	7/30/2021	100%
18	Data analysis	08/31/2021	100%
19	Pre submission meeting with FDA and Preparation/submission of FDA 510(k) application	09/29/2021	100%
20	Final Reports	10/25/2021	100%

4. DEVIATION FROM PROJECT PLAN

There are no deviations from the project plan during the project period.

Please name this final report file as EGS#_Final Report (For example MT160001.01_Final Report)

Please submit as a PDF file.

Please make sure to fill in the page number on page 3 Table of Contents.

Don't forget to submit the final Quad Chart as well. Please name the Quad chart file as EGS#_Quad Chart_Final