Surgical Critical Care Initiative (SC2i): Leveraging iRODS to Accomplish Multi-Site Data Collection, Harmonization, and Analytics to Generate Clinical Decision Support Tools

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# Surgical Critical Care Initiative (SC2i)

<table>
<thead>
<tr>
<th>FUNDING SOURCE – STRUCTURE – REPORTING</th>
<th>DUAL FOCUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funded by DOD</td>
<td>Leveraging clinical and -omics data to develop ‘precision’ CDSTs in the acute care space</td>
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<tr>
<td>Launched in 2013 and designated as a USU Center in 2016</td>
<td>Improving outcomes and lowering costs in both military and civilian systems</td>
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<tr>
<td>A Federal / Non-Federal partnership</td>
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<tr>
<td>Biannual Oversight Meetings</td>
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Leveraging clinical and -omics data to develop ‘precision’ CDSTs in the acute care space

Improving outcomes and lowering costs in both military and civilian systems
Gap Addressed in Critical Care

• **Problem:** Management of battle injured and civilian trauma and surgical patients remains largely dependent upon traditional (visually-guided) clinical decision-making.

• **Solution:** Develop decision support tools using evidence-based clinical data together with cutting-edge science in the understanding of physiological, psychological, and physical factors that govern the body’s response to trauma to guide management of surgical care.
Standardize Data Collection

Critically ill patient
• Complications of critical injury or illness
• Stably injured
• Acutely injured

Event and Time-Driven Collection
- T0
- T1
- T3
- T7
1/week until discharge if 'no event'

Serum:
• Cytokines
• Chemokines
• Proteases
• DAMPs / TLRs
• FACS, PAXgene

Tissue biopsy:
• Wound healing associated genes
• Osteogenesis
• Pathogen specific PCR
• Quantitative bacteriology
• Pathogen Sequencing
• RNA Sequencing

Wound effluent:
• Cytokines
• Chemokines
• Proteases
• RNA Sequencing

Protein Expression
Gene Expression
ProCalcitonin
Flow Cytometry
Sequencing
Data Workflow

BIO-BANK
- Freezer Storage
- Reverified Metadata Entry
- Automated Quality Assessments
- Environment Control Alerts
- Secure Facilities
- 24/7 Facility Support

DEVELOPMENT
- Reproducible Methods
- GCLP Standards
- Progression
- Consistent Reverification
- Thorough Documentation
- DNA / RNA
- Cytokines
- Microbiome
- Clinical Data
- Participant Data and Sample Acquisition
- Alignment and Quality Control

METADATA
- Performance Consistency Studies
- Data Usage Statistics
- Methods Effectiveness Studies
- Refined Development Methods
- Improved Predictive Modeling
- Expert Analysis
- Testing & Refinement
- PEER REVIEW
- Model Design
- Machine Learning
- AWS

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Clinical Decision Support Tools

- **MTP app guideline developed**
  - In-use @ Duke & Emory/Grady
  - Deploying @ Upenn
  - Building database to track clinical utility

- **In JTS-CPGs / In-use @ WRNMMC**
  - Used on 22 combat traumas
  - Building database to track clinical utility

- **Deployed @ Emory**
  - Deploying @ Grady
  - Building database to track clinical utility

### CDSTs in-development

<table>
<thead>
<tr>
<th>DSSTs in-development</th>
<th>Anticipated deployment</th>
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<tbody>
<tr>
<td>Appendectomy</td>
<td>FY21</td>
</tr>
<tr>
<td>WoundX™</td>
<td>FY23</td>
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<tr>
<td>OA Dx</td>
<td>FY23</td>
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<tr>
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<td>ARDS Dx</td>
<td>FY25</td>
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<tr>
<td>SBO Dx</td>
<td>FY25</td>
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</table>
Amazon Web Services GovCloud Architecture

Public Internet

user requests

AWS firewall

CDR VPC

GovCloud

EC2 VMs

iRODS

ETL

Databases

Elastic Block Storage

RDS

Duke IdM

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iRODS Authentication

- Users are authenticated with Shibboleth with two factor authentication
- Once authenticated via Shibboleth, users are automatically created in iRODS.
iRODS Authorization

- Users are assigned to groups in Grouper (https://www.internet2.edu/products-services/trust-identity/grouper/)
- When a user logs into CloudBrowser, groups in iRODS are created or updated as needed for each study/site combination.
- Users belong one or more groups in the following categories:
  - Studies (example: WounDx, TDAP, OpenAbdoment, ...)
  - Sites (Duke, Emory, WalterReed, NavalMedicalResearchCenter)
- Authorization on iRODS objects requires access to a study and site.
- iRODS groups were created for each combination of site/study.

Examples:
- TDAPDuke
- WounDxEmory
Example Authentication/Authorization

1. User Accesses URL

2. Redirect to IDP

3. User Authenticates

4. Return Groups: Duke, TDAP, WounDx

5. Create User (If Necessary)

6. Modify Groups: DukeTDAP and DukeWounDx

7. User Provided Access to CDR / Cloud Browser
iRODS Rules

- Python rules perform the following tasks:
  - Determine if ingested files are of interest (based on file name and location)
  - Validates and loads input data to a back end database
  - Periodic delay rule determines if new output generation is required; validates and generates new output files
  - Policy enforcement points are used to log all interactions for auditing purposes.
iRODS Metadata

• Progress of data loads is stored in metadata. This includes:
  • The validation and load status for input files
  • Time of last input data submission and output generation (for each study)
  • Progress of output file generation and validation