Integration of AI/ML into clinical workflows

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Overview of the Surgical Critical Care Initiative (SC2i)

FUNDING SOURCE STRUCTURE REPORTING
Funded by DOD
Launched in 2013 and designated as a USU Center in 2016
A Federal / Non-Federal partnership
Biannual Oversight Meetings

DUAL FOCUS
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

CDSTs in development	Anticipated deployment
AISE/AIDEx	FY23
WounDx™	FY24
VTE Dx	FY24
Pneumonia Dx	FY24
AKI Dx	FY24
OA Dx	FY25
Bacteremia Dx	FY25
sTBI Dx	FY25
HO Dx	FY26
ARDS Dx	FY26
SBO Dx	FY26

SC2i clinical research supported by:

- 2,400 + patients enrolled
- 86 million data elements
- 14.6 million molecular assay measurements
- 88,000 + biobank specimens

SC2i research products include at least 11 in-development and 3 deployed CDSTs, including AIDEx 1.0, MTP, and IFI

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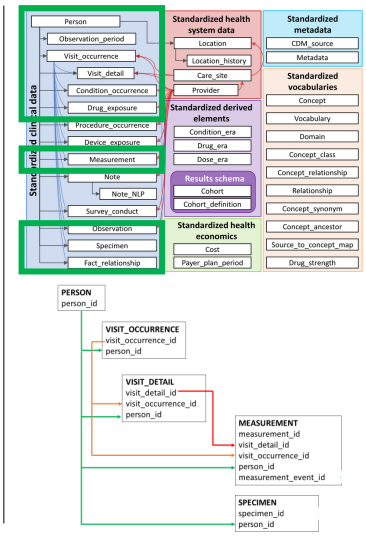
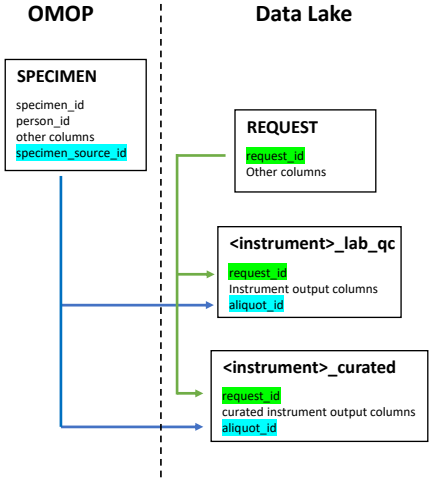
To efficiently utilize all of this information, the data must be in a common format

- In the process of converting our databases into a relational data in OMOP format
  - Large flat files are an inefficient way of storing data
  - Observational Medical Outcomes Partnership (OMOP) Common Data Model is a standardized way to structure data
    - Will allow for more easy integration of new datasets
- Developing a data lake for assay results
  - Will allow for the integration of new assay results into our datasets

OMOP Structure





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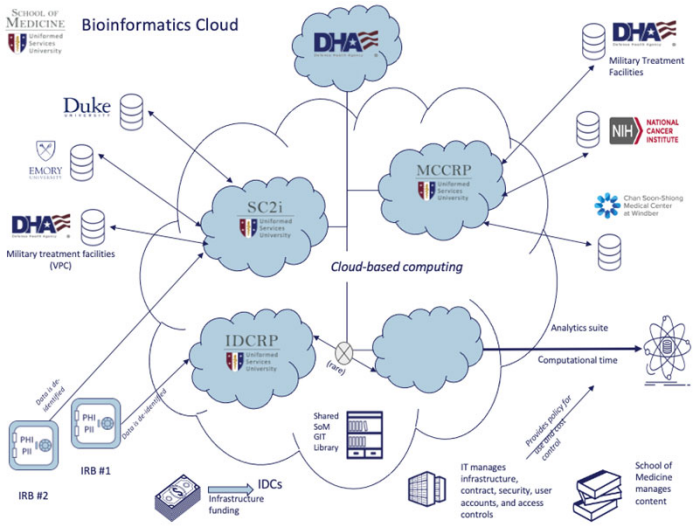
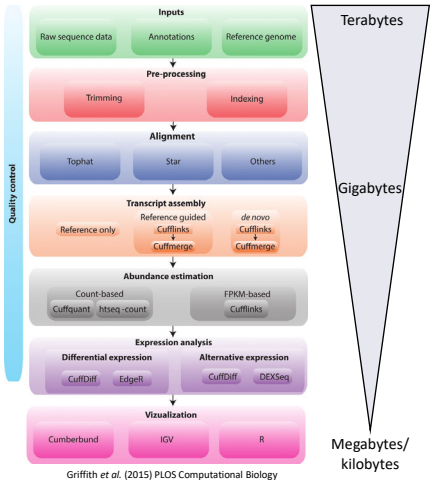
Cloud solutions are being implemented to analyze the increasingly larger biological datasets





Griffith *et al.* (2015) PLOS Computational Biology

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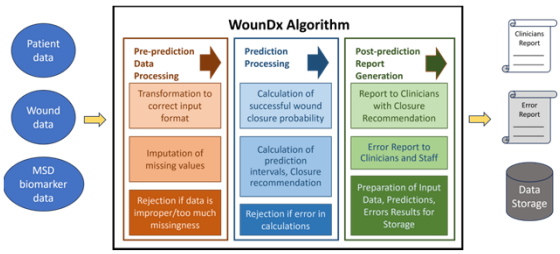
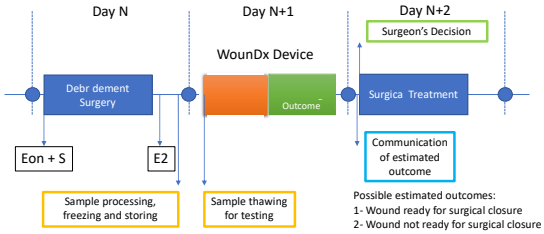
WounDx™ Purpose and Process

- WounDx™ is a device intended to assist surgeons in making decisions related to the timing of closure for traumatic extremity wounds
  - Following consultations with the FDA, this device classified as class II (moderate risk)
- WounDx™ is a combination product
  - Biomarkers (Cytokine Panel: IL-5, IL-7, IL-15, IL-17A, IL12/IL23p40, GMSCF)
  - Clinical factors (Wound size measurements, wound location, wound type)
  - Predictive algorithm
- Initial wound effluent samples collected upon enrollment + 12~24 hours prior to each debridement
- WounDx™ provides clinicians with a binary recommendation of whether the wound should be closed in the next 24 to 72 hour prior to next debridement





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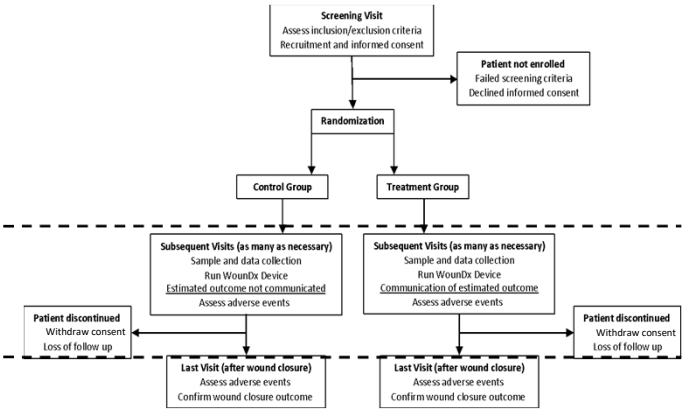
WounDx Trial Study Design/Phases

- Screening, enrollment:
  Randomization
  (blinding of CRT)
- All wound surgeries:
  Samples, data and pictures
  (documentation and transfer)
- Confirming wound closure:
  (30 days post closure)



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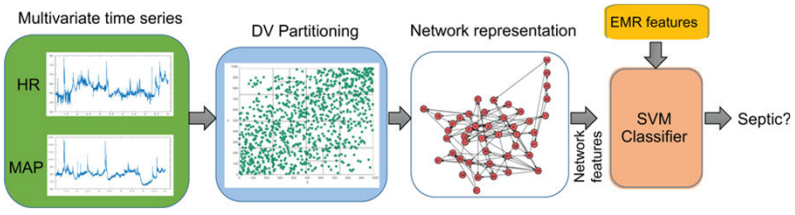
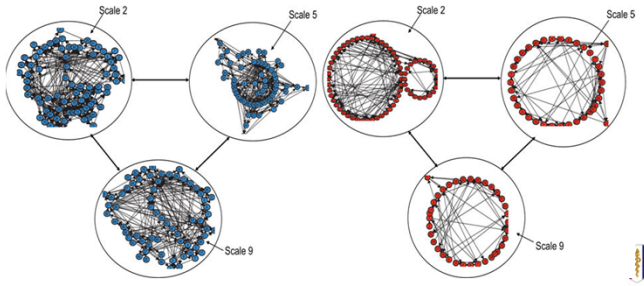
Using multivariate data to predict sepsis occurrence

Proposed Schematic of Algorithm/Workflow



Difference in network topology can be seen in control (blue) and pre-septic (red) patients



Shashikumer *et al.* 2018 Physiol Meas.

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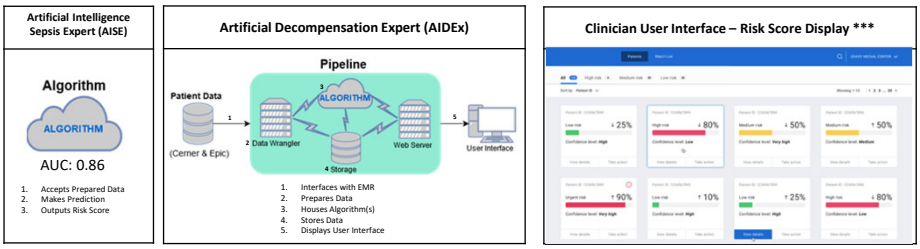
AIDEx in the MHS

- Artificial Intelligence Decompensation Expert (AIDEx) is a clinical decision support tool that identifies patients with sepsis on average 4-8 hours prior to clinician suspicion
  - Received DNA funding for integration at ten level 5 MTFs*
- AIDEx is composed of two key components:
  1. A location & EHR agnostic pipeline
     - Interfaces with a health system's EHR to provide the algorithm with real-time patient data; Provides clinicians with a user interface for interpreting the algorithm's predictions
  2. A machine-learning based sepsis prediction algorithm**



* 10 MTFs: WRNMMC, NMCSD, MAMC, SAMMC, NMCP, Tripler, Lejeune, Bliss, Gordon, and Travis
** Additional predictive algorithms are under development, with supervision from Dr. Gari Clifford (Emory DBMI)
*** User Interface is shown for illustrative purposes, and may change significantly based on feedback

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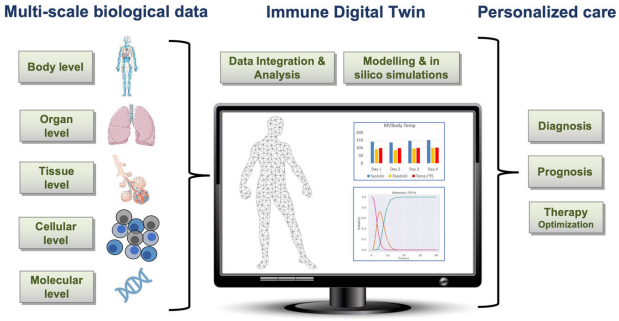
Limitations with AI/ML Modeling of Real World Data to predict hospital complications

- Machine Learning and Artificial Intelligence are being used for prediction of various complications including sepsis and multiple organ failure yet there are challenges to these approaches
  - Improving the actual predictive performance
  - Future robustness of models
  - One way to improve performance is generating more data for the selected features to train these models but the actual amount of data is limiting
- Synthetic datasets could be used to aid in training of the models
  - Has been done previously in image recognition/generation and text analysis/recognition
- Propose the need to generate synthetic multiplexed mediator time series data coincides with the advent of the concept of medical digital twins
  - Specifically related to interpretations of medical digits twins that hew closely to the original description and use of industrial digit twins
    - Involves generating multiple digital twins from a common computation model specification



Laubenbacher *et al.* 2022 npj Digital Medicine

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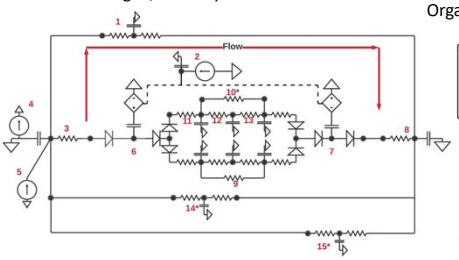
Plans to create a Post-Burn Sepsis Digital Twin to augment the development of ML-models to predict sepsis and MODS

Circuit Diagram designed that incorporates organ/tissue systems of interest

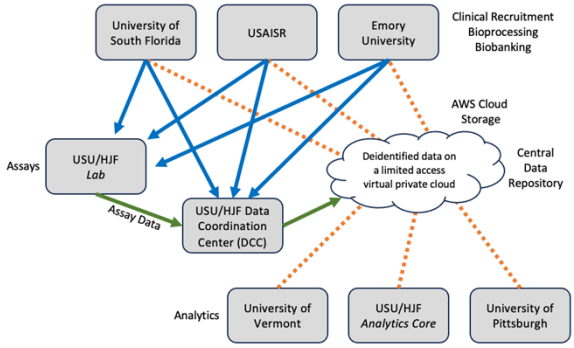


Overview of Arrangement of Organ Configuration

Labeled Points of Interest on Circuit Diagram

Number	Description	Number	Description
1	Myocardium	9	Shunt
2	Pericardium	10	Pulmonary Circulation
3	Vena Cava	11	Arteries
4	Bleeding	12	Capillaries
5	IV	13	Veins
6	Right Heart	14	Liver
7	Left Heart	15	Kidney
8	Aorta		

Sites Involved in Study



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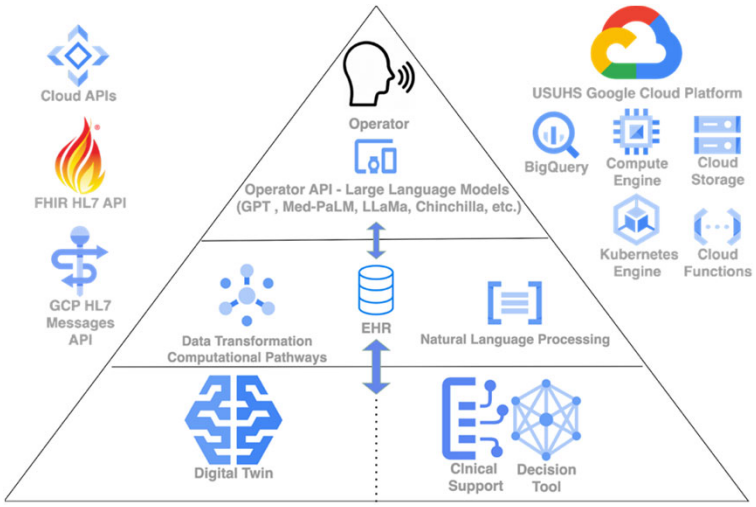
SC2i's innovations allow for the consortium to address complex questions in critical care using novel methods and infrastructure



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SC2i Scientific Meeting
Bethesda, MD
(2019)

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