**RESEARCH OBJECTIVES**

Develop an approach to reducing interoperability failures in medical devices, specifically, the software upgrade process of medical devices.

- Identify stakeholders affected by upgrade process risks which become failures.
- Identify a Qualitative Model of the process which identifies failures at each PPTONE level.
- Identify data sources to provide Quantitative values for the probability and severity of these failures, and for performance indicators and benchmarking.
- Identify risk mitigations, performance indicators and benchmark sources for each failure.
- Suggest an approach to Health IT system integration which will supply data for decision making for benchmarking and analyzing risk mitigations.

**METHODS AND MODEL**

**Level**

- **Patient Population**
  - Failure: No notification of an Adverse Event is generated.
  - Stakeholder: Patient is exposed to an adverse event.
- **Team**
  -Failure: Tracking System is not updated.
  - Stakeholder: Identifies the device failure, Updates Tracking System.
- **Organization**
  -Failure: Tracking System is not updated.
  - Stakeholder: Develops and tests device changes.
- **Network**
  -Failure: Tracking Systems.
  - Stakeholder: Records and issues a safety alert for the Adverse Event.
- **Environment**
  -Failure: Tracking Systems.
  - Stakeholder: Does not issue a Safety Alert for an Adverse Event.

**METHODOLOGY**

- Collection and aggregation of retrospective data from the identified sources.
- The application of this methodology to a prospective risk analysis tool (i.e. FMEA).
- The application of the methods to a specific type of failure in the healthcare domain.