The biotech startup Theranos has been all over headlines in recent years. At first the company made news for its ambitious goals of running comprehensive laboratory testing on just a few drops of blood. The company has claimed to have created a handheld medical device (nicknamed Edison) that uses only a finger stick of blood and makes blood testing less painful, faster and cheaper. Theranos' young and compelling founder Elizabeth Holmes has been featured in multiple magazines, gave a popular Ted talk and has even been compared to Steve Jobs and Bill Gates. In 2014, the company was valued at $9 billion.

Lately, the type of headlines the company has made have changed as the company has been embroiled in controversy. Regulators ask hard questions about blood testing startup

**Problem Outline**

- **What**
  - Problem(s): Inaccurate lab results, deficiencies found in lab
  - Lab results inaccurate?
  - Blood tests

- **When**
  - Date: Inspections performed August through September 2015

- **Where**
  - Facility, site: Labs in CA and Arizona

- **Impact to the Goals**
  - Patient Safety: Potential for patients to receive inadequate care
  - Compliance: Potential loss of license
  - Patient Services: Lab results inaccurate?
  - Regulatory: Potential for lawsuits
  - Economics: Potential for fines, loss of revenue
  - Labor/Time: Investigation/inspections

**Analysis - Intermediate Level Cause Map**

- **Patient Safety Goal Impacted**
  - Potential for patients to receive inadequate care
  - Evidence: Findings from FDA inspections

- **Compliance Goal Impacted**
  - Potential loss of license
  - Evidence: Findings from FDA inspections

- **Economics Goal Impacted**
  - Potential for fines, loss of revenue

- **Labor/Time Goal Impacted**
  - Investigation/inspections

- **Patient Services Goal Impacted**
  - Lab results inaccurate?
    - Evidence: Findings from FDA inspections
    - New device being used to test blood samples
      - Evidence: Nanotainer did not receive appropriate level of scrutiny
      - Evidence: Theranos developed a new proprietary blood testing device called Edison

- **Regulatory Goal Impacted**
  - Company subject of criminal investigation
    - Evidence: No formal charges have been made against the company, but federal officials are conducting a criminal investigation into claims made by the company about its technology.

- **Solution**
  - Needs to raise capital?