UNIVERSITY OF MARYLAND

M-CERSI

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ANALYZING DEVICE RISK USING TEXTUAL DATABASES

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M-CERSI Symposium

Wealth of Data

Adverse Event
or Recall

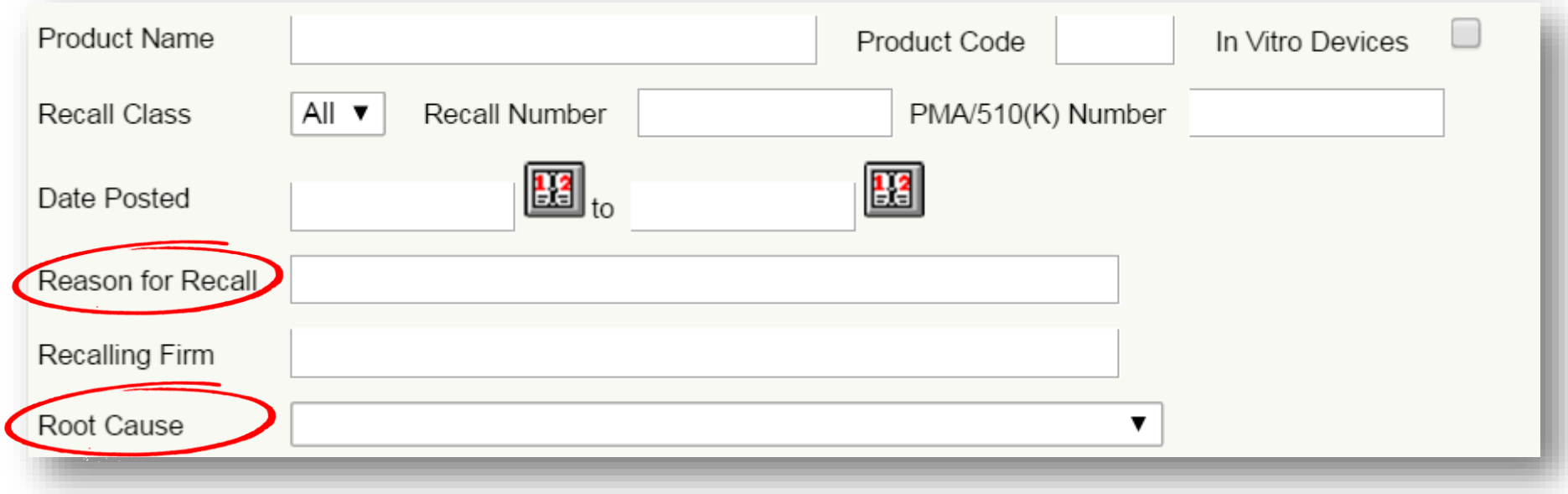
Date Posted

Manufacturer

FDA Review Panel

Etc…

Wealth of Data



Textual Coding

- FDA Device Problem Code Hierarchy (multi-level hierarchy)
  1. Device Operational Issue
  2. Physical Property Issue
  3. Facilities Issue
  4. Human Factors Issue

Subset: Device Issue

- **Device Operational Issue - LEVEL 1** - *Issue associated with any deviations from specifications relating to device operations (e.g. deployment, connection, electrical, computer software, infusion/flow, output, protective measure, and incompatibility issues).*
  - **Device Operates Differently than Expected C62955; FDA 2913** - *Issue associated with any deviations from expected performance while operating and using the device.*
    - **Device displays error message C63205; FDA 2591** - *Issue associated with a device prompting user with an error message in order to indicate a device problem*

Textual Coding

- FDA Component Code Hierarchy
  - Alphabetized list of components and sub-components

Subset: Device Component or Accessory

- Absorber C50372; FDA 3028
  - Absorber (CO2) C49804; FDA 401
  - Sound Absorber C49805; FDA 968
- Accumulator C49806; FDA 548
- Actuator C49807; FDA 402
- Adapter (Adaptor) C49808; FDA 431
  - Socket Adaptor C49809; FDA 966

Textual Coding

2012 Recall

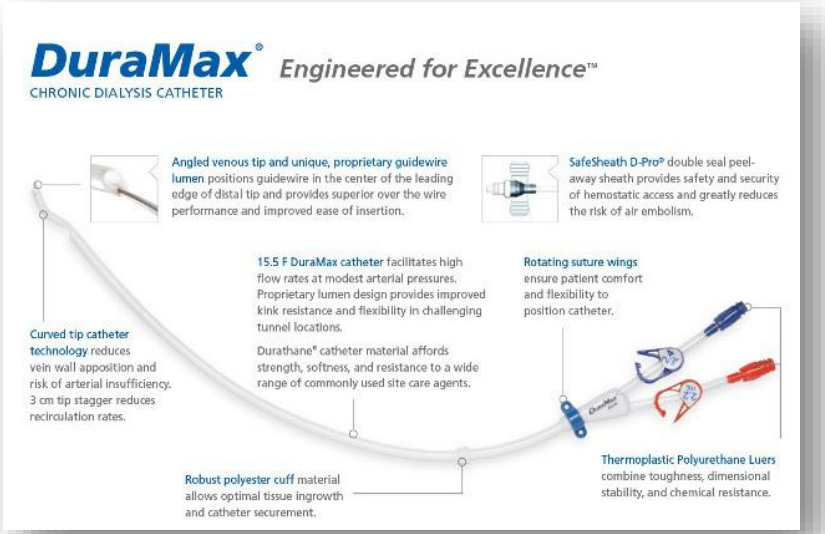
Reason for Recall

"The securement cuff on the hemodialysis catheter has the potential to detach from the shaft."

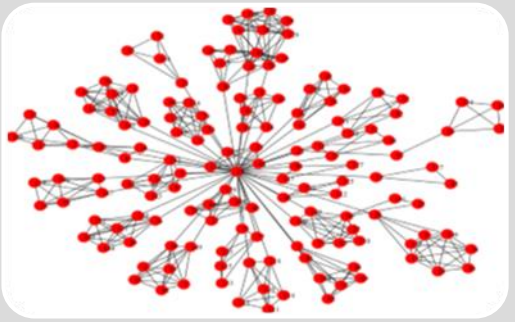
Textual Coding

- **Reason for Recall**
  - *"The securement cuff on the hemodialysis catheter has the potential to detach from the shaft."*

- Problem Code Hierarchy
  - Level 1: Operational Issue
    - Level 2: Connection Issue
      - Level 3: Decoupling
      - Level 3: Disconnection
- Component Code Hierarchy
  - Cuff, catheter, shaft



Quantifying the Qualitative Data



TEXT PARSING

Quantifies the input text and proves a list of parsed terms with corresponding metrics

TEXT FILTER

Filter out unwanted terms from the database

TEXT CLUSTER

Statistical clustering of textual data to identify groupings

FDA Device Recall Textual Mining Study

Notable aggregate 11 year results (2002-2012)

- Major Manufacturers
  - Boston Scientific, Guidant, Medtronic and St. Jude Medical
- Major Device Problem Codes
  - Physical Property Issue (56%)
  - Device Operational Issue (37%)
- Major Review Panel
  - Cardiovascular (42%)

FDA Device Recall Textual Mining Study

- Major Cardiovascular Devices
  - Defibrillators (26%) and Stents (14%)
  - All PMA defibrillators were recalled with the exception of four Implantable Cardio Defibrillators (LWS)
- Major Reliability-Related Defibrillator Problem Codes
  - Electrical (19%)
  - Software (11%)

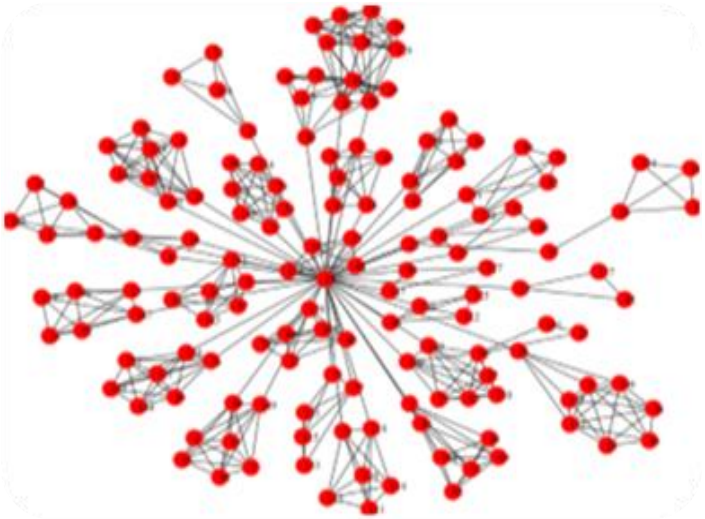
Current Research Directions

- Probabilistic modeling of textual data

Significant Textual Themes

Events

	Short Reason Txt
1	ConMed received complaints of some units exhibiting inaccurate or inconsistent flow rates. It was determined that certain units were assembled with an incorrect component which could result in the devices exhibiting a different flow rate and might reduce the ability of the user to regulate the device at low flow rates.
2	Low measurements of Troponin I in the MAS CardioImmune XL Control which were outside the published control ranges.
3	Currently there is a possibility, at the start of the perimetry examination, for the background illumination of the cupola not to turn on. If no illumination of cupola occurs, data obtained from the examination could provide the doctor with results that would appear to be better than actual.
4	Retaining pins in handle assembly may disengage and fall into surgical field or compromise handle unlatching.
5	Eyezone have distributed soft color lens while on FDA hold and were later found to be misbranded.



Quantified thematic variables for each event

Recommendations

- There is room for improvement in providing industry with structured expectations for reliability tests
  - Standardized requirements for non-clinical tests
- More structured textual reporting framework to facilitate textual mining risk analysis
  - Field entry and pre-coding
  - High resolution digitization of submission packages

THANK YOU

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