FDA recalls database: publicly available collection of medical device recalls since 2002.

Recalls: Voluntary actions, taken by manufacturers to correct or remove medical devices that violate the FDA laws.

Several hundred recalls are reported each year, but only a fraction are related to computer-based medical devices.

**EXAMPLE RECALL RECORD**

<table>
<thead>
<tr>
<th>Device Information</th>
<th>Device type</th>
<th>Class</th>
<th>Reason for Recall</th>
<th>Action</th>
<th>Date</th>
<th>Product Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardware</td>
<td>Computer</td>
<td>Software</td>
<td>Application software, function, code, version</td>
<td>patches</td>
<td>2021-01-01</td>
<td>SoftwareX</td>
<td>ManufacturerX</td>
</tr>
</tbody>
</table>

**GOALS AND CHALLENGES**

- Study of recalls data provides valuable insights on past failures of medical devices and how their future designs could be improved.
- Important fields in the recall records, including Product Name, Reason for Recall, and Action, are in unstructured text format.
- Identification of causes and impacts of failures requires semantic interpretation of the natural language text.
- Manual review of several thousands records require significant amount of human effort, and simple keyword searching might not provide accurate results.

**PROPOSED APPROACH**

Recalls Data Analysis Flow:

- Collection of data from online databases
- Extraction of unique recall events and calculating number of affected devices
- Identification of computer-related recalls

**RESULTS**

Classification accuracy:
- Training set: 5,354 recall events (2006-2011)
- 10-fold cross-validation on the training set: 
  - Sensitivity 87%, specificity 88%, and F-Score 77%
- Testing on new recall data (2012 – 2013) manually verified: 
  - Sensitivity 93.8% and specificity 95.8%

**CONCLUSIONS**

- A total of 16,881 records were submitted during 2007-2013.
- About 6,864 (40.7%) unique recall events were identified.
- A total of 1,678 (24.4%) of recall events were computer-related.
- Computer-related recalls affected around 18,189,751 devices.