FDA BI Research Weekly Report

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**Question 1. How many BI records are found?**

For this question, please see the following file:

1\_Total\_BI\_Report\_Number\_List.txt

2\_BI\_Report\_Number\_By\_Text\_Mining.txt

3\_FWM\_Report\_Number.txt

4\_FTR\_Report\_Number.txt

Answer: 26,584 BI related records are found. 25,787 records have matched report number.

Method 1: Use text mining to identify

Data source: MAUDE database [foitext.zip, foitextadd.zip, foitextchange.zip, foitextthru1995.zip, foitext(1996-2016).zip] (25 files in total), use column “FOI\_TEXT”

Word List 1: ['breast pain', 'breast swelling', 'breast cyst', 'breast calcification', 'capsular contracture', 'lymph node enlargement', 'firmness of breast', 'breast implant', 'breast augmentation', 'breast enlargement', 'mammary implant', 'mammary augmentation', 'mammary enlargement', 'mammary swelling', 'breast prosthesis', 'mammary prosthesis']

Word List 2: ['hematoma', 'mass', 'lump', 'rupture', 'deflated', 'infection', 'abscess', 'leukopenia', 'nodules', 'skin discoloration', 'skin lesion', 'seroma', 'effusion', 'fluid']

Fuzzy Match Rate: 95%

If one record contains at least one word in Word List 1, or it contains “breast/mammary” **and** at least one word in Word List 2, then it would be considered as BI related record.

In this method, 10,980 BI related records are found with 10689 distinct report number.

Method 2: Use product code to identify

Data source: MAUDE database [foidev.zip, foidevadd.zip, foidevchange.zip, foidevthru1997.zip, foidev(1998-2016).zip] (23 files in total), use column “DEVICE\_RECORD\_PRODUCT\_CODE”

Product Code List: [‘FWM’, ‘FTR’]

If one record whose product code equals to one of the list, it would be considered as BI related record.

In this method, 26,604 BI related records are found. (FWM = 11097, FTR = 15507)

Combination of two methods

The union of two methods has 27,475 distinct BI records.

If time criteria set to 01/01/1994 – 02/01/2017, 26,584 records are found. (The data from MAUDE are from 1992 to 2017/06)

Finally, 25787 records have matched report number.

**Question 2. How many ALCL records are found?**

For this question, please see the following file:

5\_ALCL\_Number\_List.txt

Answer: 197 ALCL related records are found with 152 distinct report keys. 121 records have matched report number with 106 distinct report number.

We search all these 152 distinct report keys in BI record in Question 1, and 151 report keys are found. So, we have a strong belief that all ALCL records are related with breast implant in MAUDE database.

Method: Use text mining to identify

Data source: MAUDE database [foitext.zip, foitextadd.zip, foitextchange.zip, foitextthru1995.zip, foitext(1996-2016).zip] (25 files in total), use column “FOI\_TEXT”

Word List: [‘ALCL’, ‘anaplastic large cell lymphoma’]

Fuzzy Match Rate: 90%

If one record contains at least one word in Word List, it would be considered as ALCL related record.

**Question 3. Investigate duplicated reports in MAUDE database.**

In the research, we found there are some duplicated report numbers in MAUDE database in foitext files. When we go through some of the duplicated records, we found that it’s mainly because the length limitation of MDR text.

For example, we found one report number whose text content is an academic paper. The report is split to 4 records with the same report number, but the text is different. In other word, the abstract and body of the paper is split to 4 pieces and stored in MAUDE database.

That’s the reason why we will get some duplicate records in Question 1 and Question 2. We’d like to whether we need to count the duplicate into our statistics.

**Question 4. Explain tables and columns used in Q1 and Q2. Present the variety of Brand Name and Model Number in BI records**

For this question, please see the following file:

6\_BI\_Records\_Foidev\_Table\_Column\_Statistics.xlsx

7\_BI\_Records\_Mdrfoi\_Table\_Column\_Statistics.xlsx

For each column statistics, you can find it by the name of sheet.