Guide to Using
FDA's Manufacturer and
User Facility Device
Experience Database -
(“MAUDE”) on Your Desktop.

Transforming Public Data
into Actionable Knowledge.
About This Ebook

This document is a compilation of our notes for processing the content available at the Food and Drug Administration’s (“FDA”) MAUDE website. This ebook is neither endorsed nor approved by the FDA. Visit http://nihpo.com/fda-maude.html for more details.

NIHPO licenses the entire FDA MAUDE dataset for use on your desktop, and for integration into your existing databases. You can process this data yourself (see detailed pointers below), or you can save time and money by licensing this data from us. Contact us: Data@NIHPO.com or +1 (561) 777-2577.

Free Sample

Contact us to receive a free sample of this dataset: Data@NIHPO.com or +1 (561) 777-2577

Available Data Sources

NIHPO has the following datasets available for license.

Clinical Trials:
* EudraCT - EU Clinical Trials Register
* US - ClinicalTrials.gov

FDA – Human:
* FDA Adverse Event Reporting System (“FAERS”)
* Drug Establishments Current Registration Site (“DECRS”)
* Manufacturer and User Facility Device Experience Database - (“MAUDE”)
* National Drug Code Directory (“NDC”)
* Structured Product Labeling (“SPL”) - Human
* Structured Product Labeling (“SPL”) - Images

FDA – Veterinary:
* Electronic Animal Drug Product Listing Directory
* Adverse Drug Experience (“ADE”) Reports
* Approved Animal Drug Products (“Green Book”)
* Structured Product Labeling (“SPL”) - Animal

Medicare National Provider Identifier Standard (“NPI”)

NLM:
* ChemID
* PubChem

About NIHPO

NIHPO’s platform transforms Open Government raw data from state, federal, and international agencies into on-demand, actionable knowledge. Please visit our website at http://nihpo.com/data for more information about us. And you can contact us at Data@NIHPO.com or at +1 (561) 777-2577.
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Source Data Files

The FDA's MAUDE website (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm) has a search interface that allows users to search for information on millions of adverse events reported about medical devices. The FDA MAUDE website looks like this:

But what if you would like to download all the data files from this site and store them locally on your computer? How would you organize the data? The rest of this ebook will answer that question.
Embedded Structure

The FDA MAUDE data files are available as 04 separate raw data files:

**FOIDEV**

The files are available by year, from 1996 until now.

These are 10 sample records:

1016329|2911779|N|B|1|03/21/2008|INTELECT|GZJ, STIMULATOR, NERVE, TRANSCUTANEOUS, FOR PAIN RELIEF, 882.5810|CHATTANOOGA GROUP||HIXSON|TN||US||2760|2760||0HP|N||GZJ|DA|N|||
1016328|2906404|N|B|1|03/21/2008|INTELECT 4CH STIM|GZJ, STIMULATOR, NERVE, TRANSCUTANEOUS, FOR PAIN RELIEF, 882.5810|CHATTANOOGA GROUP||HIXSON|TN||US||7560R|7560R||0HP|N||GZJ|DA|N|||
1016327|2908585|N|B|1|03/21/2008|D-3 HYDROCOLLATOR HEATING UNIT|890.5730 MOIST HEAT PACK|CHATTANOOGA GROUP||HIXSON|TN||US|||D-3|D-3||0HP|N||IMA|N|||
1016326|2906416|N|B|1|03/21/2008|LEGEND XT 4CH COMBO|GZJ, STIMULATOR, NERVE, TRANSCUTANEOUS, FOR PAIN RELIEF, 882.5810|CHATTANOOGA GROUP||HIXSON|TN||US||2788|2788||0HP|N||GZJ|DA|N|||
1008008|2884738|N|B|1|03/04/2008|IMPLANTIUM|ENDOSSEOUS DENTAL IMPLANT|DENTIUM|27-5 LEUI-DONG|YEONGTONG-GU, SUWON-SI|GYEONGGI-DO|||KS|443-270||MF FX4808||0HP|Y|02/19/2008|DZE|DA|Y|||
985553|2551068|N|B|1|10/19/2007|FREESTYLE FLASH|BLOOD GLUCOSE MONITORING SYSTEM|ABBOTT DIABETES CARE INC., USA|1360 SOUTH LOOP RD.||ALAMEDA|CA|94502||US|||NI|17001|NI|OLP|Y|08/01/2007|NBW|DA|Y|||
980584|2900077|Y|B|1|01/07/2008|SMOOTH MAMMARY PROSTHESIS|MENTOR||IRVING|TX|75038||US||3503251BC|5741530||0HP|N||FTR|R|||
961544|2900041|N|B|1|12/06/2007|KAPPA XLT|PATIENT MONITOR|DRAEGER MEDICAL SYSTEMS, INC.|16 ELECTRONICS AVE.||DANVERS|MA|01923||US||MS14618|MS14618E549U|NA|NA|0HP|N||MHX|DA|R|||
931457|2813426|N|B|1|10/23/2007|ABACUS TPN CALCULATING SOFTWARE|ABACUS SINGLE WORK STATION|BAXA CORP.|14445 GRASSLANDS DRIVE||ENGLEWOOD|CO|80112||US||8300-0048|8300-0048|NA|NA|0HP|Y|LNX|DA|Y|||
886507|2902605|N|V|1|07/26/2007|PFC KEEL TIB TRAY CEM SZ3|87JWH|DEPUY-CORK - DEPUY ORTHOPAEDICS||LOUGHBEG, RINGASKIDDY CO, CORK|||EI|NA|864181|220006|NA|0HP|N||JWH|DA|R|||

**FOITEXT**

The files are available by year, from 1996 until now.

These are 10 sample records:

2891886|16968741|D|1||A REPORT WAS RECEIVED THAT THE PATIENT UNDERWENT A POCKET REVISION PROCEDURE DUE TO POCKET PAIN. THE PATIENT EXPERIENCED POCKET SITE IRRITATION IN WHICH THE PHYSICIAN BELIEVED IT TO BE DUE TO SLOW AND IMPROPER WOUND HEALING FROM THE TIME IT WAS IMPLANTED.

2891887|16968741|D|1||IT WAS REPORTED THAT THE PATIENT WAS EXPERIENCING...
SYMPTOMS OF BLURRINESS AFTER IMPLANTATION OF THE INTRAOCULAR LENS (IOL) AND WAS NOT SATISFIED. IT WAS STATED THAT THE LENS WAS EXPLANTED. NO COMPLICATIONS WERE REPORTED. IT WAS STATED THAT THE LENS WAS DISCARDED IN THE FIELD AND THEREFORE WILL NOT BE RETURNED FOR EVALUATION. IT WAS STATED THAT THE PATIENT WAS DOING WELL.

2891887|16968770|N|1||(B)(4). PRIOR TO RELEASE TO MARKET THE INTRAOCULAR LENS MET ALL MANUFACTURING SPECIFICATIONS. ALL PERTINENT INFORMATION AVAILABLE TO ABBOTT MEDICAL OPTICS HAS BEEN SUBMITTED.

2891919|16968750|N|1||ADDITIONAL SUSPECT MEDICAL DEVICE COMPONENT INVOLVED IN THE EVENT: MODEL #: SC-8216-70, SERIAL #: (B)(4), DESCRIPTION: ARTISAN SURGICAL LEAD, 70CM. THE EXPLANTED DEVICES WERE NOT RETURNED TO BSN AS THEY WERE DISCARDED BY THE MEDICAL FACILITY.

2891919|16968749|D|1||A REPORT WAS RECEIVED THAT THE PATIENT UNDERWENT AN EXPLANT AND RE-IMPLANT PROCEDURE DUE TO PAIN AT THE LOWER EXTREMITY. THE WHOLE SYSTEM WAS REPLACED WITH NEW ONES. THE DEVICES WERE WORKING PROPERLY PRIOR TO EXPLANT. THE PATIENT WAS REPORTEDLY DOING WELL FOLLOWING THE PROCEDURE.

2891919|17232987|D|1||A REPORT WAS RECEIVED THAT THE PATIENT UNDERWENT AN EXPLANT AND RE-IMPLANT PROCEDURE DUE TO PAIN AT THE LOWER EXTREMITY. THE WHOLE SYSTEM WAS REPLACED WITH NEW ONES. THE DEVICES WERE WORKING PROPERLY PRIOR TO EXPLANT. THE PATIENT WAS REPORTEDLY DOING WELL FOLLOWING THE PROCEDURE.

2891919|17232990|N|1||ADDITIONAL INFORMATION WAS RECEIVED THAT THE PATIENT WAS EXPERIENCING PAIN WHEN THE STIMULATION WAS OFF. THE PAIN WAS NOT DEVICE RELATED. THE SYSTEM WAS REPLACED DUE TO PHYSICIAN'S PREFERENCE.

2891920|16968762|D|1||IT WAS REPORTED THAT THE PATIENT WAS EXPERIENCING SYMPTOMS OF BLURRINESS AFTER IMPLANTATION OF THE INTRAOCULAR LENS (IOL). IT WAS STATED THAT A YAG CAPSULOTOMY WAS PERFORMED TO REDUCE THE SYMPTOMS EXPERIENCED BY THE PATIENT. IT WAS REPORTED THAT THE YAG CAPSULOTOMY PROVED UNHELPFUL AND THE LENS WAS EXPLANTED. NO COMPLICATIONS WERE REPORTED. PATIENT WAS STATED TO BE DOING WELL.

2891920|16968765|N|1||(B)(4).PRIOR TO RELEASE TO MARKET THE INTRAOCULAR LENS MET ALL MANUFACTURING SPECIFICATIONS.(B)(4): PLACEHOLDER.

2891920|17244405|N|1||THE INTRAOCULAR LENS (IOL) WAS RETURNED TO THE MANUFACTURER. VISUAL INSPECTION SHOWED A LENS WHERE THE OPTIC WAS CUT IN HALF, NO OPTICAL DEVIATIONS ON THE OPTIC PARTS COULD BE FOUND. DUE TO THE CONDITION OF THE RETURNED SAMPLE, A DIOPTER MEASUREMENT COULD NOT BE PERFORMED.CONCLUSION: THE IOL PASSED ALL ACCEPTANCE CRITERIA FOR ALL TESTS PERFORMED AND WAS WITHIN ALL SPECIFICATIONS DURING THE MANUFACTURING PROCESS, THEREFORE NO PRODUCTION RELATED CAUSE IS EXPECTED.(B)(4): PLACEHOLDER.

**MDRFOI**

These records are available in a single, very large file (819MB) until 2012. Then regular updates. 
These are 10 sample records:

**Patient**

These records are available in a single, large file (97MB) until 2012. Then regular updates.

These are 10 sample records:

- 2891812 | 31-DEC-12 | 1,D;
- 2891824 | 09-JAN-13 | ;1,R;
- 2891826 | 31-DEC-12 | 1,R;
- 2891835 | 31-DEC-12 | PLATE, SCREWS;
- 2891848 | 31-DEC-12 | 1,R;
- 2891872 | 19-FEB-13 | PSCST30 SILVER CARTRIDGE;
- 2891875 | 31-DEC-12 | 1,R;
- 2891886 | 31-DEC-12 | 1,R;
- 2891887 | 31-DEC-12 | 1,R;
- 2891919 | 31-DEC-12 | 1,R;
- 2891920 | 31-DEC-12 | 1,R;
Transformed Structure

This chapter describes the database structure (ie. “schema”) NIHPO designed to store all the information present in every raw data file available from the FDA MAUDE website.

A note on nomenclature: each table's name starts with “ZZFDAMAUDE”. This parses as follows: “ZZ” refers to the federal level of the US government. (NIHPO also licenses state-level datasets). “FDA” refers to the source agency, in this case the FDA. “MAUDE” is the name of the individual dataset, in this case “MAUDE”

**ZZFDAMAUDEDEVICE**

This table includes records from the “foidev” files.

**ZZFDAMAUDEMDRFOI**

This table includes records from the “mdrfoi” file.

**ZZFDAMAUDEPATIENT**

This table includes records from the “patient” file.

**ZZFDAMAUDETEXT**

This table includes records from the “foitext” files.
Data Element Description

These are the individual fields inside each table.

ZZFDAMAUDEMDRFOI

zzfdamrfoid - "Added: ZZFDAMDRFOI ID."
mdrreportkey - "MDR Report Key"
eventkey - "Event Key"
reportnumber - "Report Number"
reportsourcecode - "Report Source Code"
manufacturerlinkflag - "Manufacturer Link Flag"
numberdevicesinevent - "Number Devices in Event"
numberpatientinevent - "Number Patient in Event"
datereceived - "Date Received"
adverseeventflag - "Adverse Event Flag"
productproblemflag - "Product Problem Flag"
datereport - "Date Report"
dateofevent - "Date of Event"
singleuseflagreprocessorflag - "Single Use Flag (Reprocessor Flag)"
reporteroccupationcode - "Reporter Occupation Code"
healthprofessional - "Health Professional"
initialreporttofda - "Initial Report to FDA"
distributorname - "Distributor Name"
distributoraddressline1 - "Distributor Address line 1"
distributoraddressline2 - "Distributor Address line 2"
distributorcity - "Distributor City"
distributorstatecode - "Distributor State Code"
distributorzipcode - "Distributor Zip Code"
distributorzipcodeext - "Distributor Zip Code Ext"
datefacilityaware - "Date Facility Aware"
typeofreport - "Type of Report"
reportdate - "Report Date"
reporttofda - "Report to FDA"
datereporttofda - "Date Report to FDA"
eventlocation - "Event Location"
reporttomanufacturer - "Report to Manufacturer"
datereporttomanufacturer - "Date Report to Manufacturer"
manufacturername - "Manufacturer Name"
manufactureraddressline1 - "Manufacturer Address line 1"
manufactureraddressline2 - "Manufacturer Address line 2"
manufacturercity - "Manufacturer City"
manufacturerstatecode - "Manufacturer State Code"
manufacturerzipcode - "Manufacturer Zip Code"
manufacturerzipcodeext - "Manufacturer Zip Code Ext"
manufacturerpostalcode - "Manufacturer Postal Code"
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.genericname - "Generic Name (D2)"
manufacturername - "Manufacturer Name (D3)"
manufactureraddress1 - "Manufacturer Address 1 (D3)"
manufactureraddress2 - "Manufacturer Address 2 (D3)"
manufacturercity - "Manufacturer City (D3)"
manufacturerstatecode - "Manufacturer State Code (D3)"
manufacturerzipcode - "Manufacturer Zip Code (D3)"
manufacturerzipcodeext - "Manufacturer Zip Code ext (D3)"
manufacturercountrycode - "Manufacturer Country Code (D3)"
manufacturerpostalcode - "Manufacturer Postal Code (D3)"
expirationdateofdevice - "Expiration Date of Device (D4)"
modelnumber - "Model Number (D4)"
lotnumber - "Lot Number (D4)"
catalognumber - "Catalog Number (D4)"
otheridnumber - "Other ID Number (D4)"
deviceoperator - "Device Operator (D5)"
deviceavailability - "Device Availability (D10). Choices: Y = Yes; N = No; R = Device was returned to manufacturer; * = No answer provided"
datereturnedtomanufacturer - "Date Returned to Manufacturer (D10)"
devicereportproductcode - "Device Report Product Code"
deviceage - "Device Age (F9)"
deviceevaluatedbymanufacturer - "Device Evaluated by Manufacturer (H3). Choices: Y = Yes; N = No; R = Device not returned to manufacturer; * = No answer provided"
baselinebrandname - "Baseline brand name"
baselinegenericname - "Baseline generic name"
baselinemodelno - "Baseline model no"
baselinecatalogno - "Baseline catalog no"
baselineotheridno - "Baseline other id no"
baselinedevicefamily - "Baseline device family"
baseshelflifecontainedinlabel - "Baseline shelf life contained in label. Choices: Y = Yes; N = No; A = Not applicable; * = No answer provided."
baseshelflifeinmonths - "Baseline shelf life in months"
baselinepmaflag - "Baseline PMA flag"
baselinepmano - "Baseline PMA no"
baseline510kflag - "Baseline 510(k) flag"
baseline510kno - "Baseline 510(k) no"
baselinepreamendment - "Baseline preamendment"
baselinetransitional - "Baseline transitional"
baseline510kexemptflag - "Baseline 510(k exempt flag"
basedatedfirstmarketed - "Baseline date) first marketed"
basedatedceasedmarketing - "Baseline date ceased marketing"
reportyear - "Added: year report was received."

**ZZFDMAUDEPATIENT**

zzfdamaudepatientid - "Added: ZZFDMAUDEPATIENT ID."
mdrreportkey - "MDR Report Key (from patient report table)"
patientsequencenumber - "Patient Sequence Number (from patient report table)"
datereceived - "Date Received (from mdr_document table)"
treatment - "Treatment -- multiple source type"
outcome - ="Outcome -- multiple source type. Choices: L - Life Threatening; H - Hospitalization; S - Disability; C - Congenital Anomaly; R - Required Intervention; O - Other; * - Invalid Data; U - Unknown; I - No Information; A - Not Applicable; D - Death."
reportyear - "Added: year report was received."

ZZFDAMAUDETEXT

zzfdamaudetextid - "Added: ZZFDAMAUDETEXT ID."
mdrreportkey - "MDR Report Key"
mdrtextkey - "MDR Text Key"
texttypecode - "Text Type Code (D=B5, E=H3, N=H10 from mdr_text table)"
patientsequencenumber - "Patient Sequence Number (from mdr_text table)"
datereport - "Date Report (from mdr_text table)"
mdrtext - "Text (B5, or H3 or H10 from mdr_text table)"
reportyear "Added: year report was received."