

DIOGENES[®]: Adverse Drug Events Database

FILE DESCRIPTION

DIOGENES[®]: Adverse Drug Events Database consists of two subfiles: Adverse Drug Reactions (ADR) and Adverse Event Reporting System (AERS). ADR records contain data regarding a single patient's experience with a drug or combination of drugs as reported to the U.S. Food and Drug Administration (FDA). Since 1969, the FDA has legally-mandated adverse drug reaction reports from pharmaceutical manufacturers and maintained them in their ADR system. The original reports varied greatly in detail, some providing only minimal details.

In November 1997, the ADR database was replaced by the Adverse Event Reporting System (AERS). AERS events are described on MedWatch form DGA-3500A and contain many more details than appeared on the earlier ADR records. Reports in the AERS file are evaluated by clinical reviewers in FDA's Center for Drug Evaluation. When information is unknown, it is omitted.

Vaccines are reported in a separate system and are not included in ADR data.

SUBJECT COVERAGE

The scope of DIOGENES[®]: Adverse Drug Events Database is FDA-related data regarding drugs as reported by drug manufacturers, individuals, health professionals, and medical studies. Records provide:

- FDA Report Number and FDA Receipt Date
- Manufacturer's Report Number
- Drug Name and Reaction Date
- Patient age and sex
- Reported reactions and Outcomes
- Concomitant drugs

Records also contain manufacturer name, dosage, administration route, and drug lot number, when this information is known.

SOURCES

Data included in ADR records is drawn from the ADR database, which began in 1969. From November 1997 onward, the information is taken from the AERS database, as described above.

TIPS

USE FILE 181

to monitor reported adverse drug reactions.

SEARCH /NA or NA=

to find suspect or concomitant drug names:

S INSULIN/NA

S NA=WARFARIN

SEARCH /CO or CO=

to find specific drug manufacturers or reporting manufacturers:

S BAYER/CO

USE /AER

to restrict to more recent AER data:

S BETASERON/AER

DIALOG FILE DATA

Inclusive Dates: ADRs - 1969 through October 1997
AERs - November 1997 to the present

Update Frequency: Quarterly

File Size:

More than 3,000,000 records as of January 2006

CONTACT

DIOGENES[®]: Adverse Drug Events Database is produced by the FOI Services, Inc. Questions concerning file content should be directed to:

FOI Services, Inc.

704 Quince Orchard Road

Suite 275

Gaithersburg, MD 20878

Phone: 301-975-9400

Fax: 301-975-0702

E-Mail: diogenes@foiservices.com

SAMPLE RECORD

DIALOG(R)File 181:DIOGENES(r) Adverse Drug Events
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0002965633

AA= FDA Report number: 4058668
PD=,PY= FDA Receipt Date: October 28, 2002

Report Title:

/TI,NA,NA=,NS,NS= AERS Drug Report. 1 Suspect Drug(s): BETASERON. Total 6 Drug(s) Cited.

/CO,CO=,SM,SM= Sending Manufacturer: BERLEX LABORATORIES

FS= ADR/AER: AER

RC= Report Code: Expedited (15-day: reported by manufacturer)

RS= Report Source: Consumer; Health Professional; Physician

Date on Report: October 23, 2002

Source/update date: FDA AERS list (20030821)

RN= Manufacture Report#: USA-2002-002832

FDA Image ID: 4058668-8

Initial/follow-up: Followup

Follow-up sequence#: 2

CN= Case number: 3837144

Electronic submission:No

RD=,RY= Reaction Date: January 7, 2002

RE= Reactions: GLIOBLASTOMA

OT= Outcomes: Death

Death Date: 20020716

Patient Information:

AG= Age: 53 Years

SX= Sex: Female

Weight: 46.7 KG

Drug Information:

/NA,NA= Primary Suspect: BETASERON; Manufacturer Reported: Unknown; Dosage
/TX Reported: 8 MIU, EVERY 2D, SUBCUTANEOUS; Reported Route: SUBCUTANEOUS;
N/A Dechallenge Result; N/A Rechallenge Result; Validated Trade Name
Drug Name Source; Unknown Lot Number; Unknown Expiration; Therapy Dates
(Start-End): 19991129-20020716

/NA,NA= Concomitant: CLONIDINE; Manufacturer Reported: Unknown; Dosage Reported:
/TX Unknown; Reported Route: Unknown; Unknown Dechallenge Result; Unknown
Rechallenge Result; Validated Trade Name Drug Name Source; Unknown Lot
Number; Unknown Expiration

/NA,NA= Concomitant: FUROSEMIDE; Manufacturer Reported: Unknown; Dosage Reported:
/TX Unknown; Reported Route: Unknown; Unknown Dechallenge Result; Unknown
Rechallenge Result; Validated Trade Name Drug Name Source; Unknown Lot
Number; Unknown Expiration

/NA,NA= Concomitant: MIACALCIN; Manufacturer Reported: Unknown; Dosage Reported:
/TX Unknown; Reported Route: Unknown; Unknown Dechallenge Result; Unknown
Rechallenge Result; Validated Trade Name Drug Name Source; Unknown Lot
Number; Unknown Expiration

/NA,NA= Concomitant: KLOR-CON; Manufacturer Reported: Unknown; Dosage Reported:
/TX Unknown; Reported Route: Unknown; Unknown Dechallenge Result; Unknown
Rechallenge Result; Validated Trade Name Drug Name Source; Unknown Lot
Number; Unknown Expiration

/NA,NA= Concomitant: CALCIUM (CALCIUM); Manufacturer Reported: Unknown; Dosage
/TX Reported: Unknown; Reported Route: Unknown; Unknown Dechallenge Result;
Unknown Rechallenge Result; Verbatim Drug Name Drug Name Source;
Unknown Lot Number; Unknown Expiration

SEARCH OPTIONS

BASIC INDEX

| SEARCH SUFFIX | DISPLAY CODE | FIELD NAME | INDEXING | SELECT EXAMPLES |
|---------------|--------------|---|----------|-------------------|
| — | — | All Basic Index Fields | Word | S SUSPECT |
| /CO | CO | Company Name ¹ | Word | S BERLEX/CO |
| /NA | DI | Drug Name ^{1,2} | Word | S BETASERON/NA |
| /NS | DI | Named Suspect Drug ¹ | Word | S BETASERON/NS |
| /SM | SM | Sending Manufacturer ^{1,3} | Word | S BERLEX/SM |
| /TI | TI | Title | Word | S BETASERON/TI |
| /TX | TX,NT | Text of Drug Information and Notes ⁴ | Word | S SUBCUTANEOUS/TX |

¹ Searchable in the Basic Index and in the Additional Indexes.

⁴ Notes are present only in ADR subfile records.

² Includes Named Suspect Drug (NS=).

³ Present only in AER subfile records.

ADDITIONAL INDEXES

| SEARCH PREFIX | DISPLAY CODE | FIELD NAME | INDEXING | SELECT EXAMPLES |
|---------------|--------------|---|----------|----------------------|
| AA= | AA | Supplier Accession Number/FDA Report Number | Phrase | S AA=4058668 |
| AG= | AG | Age | Phrase | S AG=030:040 |
| — | AZ | DIALOG Accession Number | | |
| CN= | CN | Case Number | Phrase | S CN=3837144 |
| CO= | CO | Company Name ¹ | Phrase | S CO=BERLEX LAB? |
| — | DD | Death Date | | |
| — | DI | Drug Information | | |
| — | DR | Date on Report | | |
| FI= | FI | Follow-up/Initial Report | Phrase | S FI=INITIAL |
| FS= | FS | Subfile/File Segment | Phrase | S FS=AER |
| LA= | LA | Language | Phrase | S LA=ENGLISH |
| NA= | DI | Drug Name ^{1,2} | Phrase | S NA=BETASERON? |
| NS= | DI | Named Suspect Drug ¹ | Phrase | S NS=BETASERON? |
| OT= | OT | Outcome | Phrase | S OT=(DEATH OR DIED) |
| PD= | PD | FDA Receipt Date | Phrase | S PD=20021028 |
| PY= | PY | FDA Receipt Year | Phrase | S PY=2002 |
| RC= | RC | Report Code | Phrase | S RC=EXPEDITED? |
| RD= | RD | Reaction Date | Phrase | S RD=20020107 |
| RE= | RE | Reaction | Phrase | S RE=GLIOBLASTOMA |
| RN= | RN | Manufacturer Report Number | Phrase | S RN=USA-2002-002832 |
| — | RP | Report Type | | |
| RS= | RS | Report Source | Phrase | S RS=CONSUMER |
| RY= | RY | Reaction Year | Phrase | S RY=2002 |
| SM= | SM | Sending Manufacturer ^{1,3} | Phrase | S SM=BERLEX? |
| — | SO | Source Information | | |
| SX= | SX | Sex | Phrase | S SX=FEMALE |
| UD= | — | Update | Phrase | S UD=9999 |
| — | WT | Weight | | |

SPECIAL FEATURES

For command descriptions, enter HELP LIMIT, HELP SORT, HELP RANK online.

| | | |
|--------------|---|--------------------------------------|
| LIMIT | /ADR -- ADR Subfile Record /AER -- AER Subfile Record /YYYY -- Publication Year | S S2/ADR S S2/AER S S3/2002 |
| SORT | AA, NA, PD, PY | SORT S6/ALL/PY PRINT S3/5/1-24/NA |
| RANK | All phrase- and numeric-indexed fields in the Additional Indexes can be ranked. | RANK CO S3 |

PREDEFINED FORMAT OPTIONS

| NO. | DIALOGWEB FORMAT | RECORD CONTENT |
|-----|---------------------|--|
| 1 | -- | DIALOG Accession Number |
| 2 | -- | Suspect Drug Name, Title, Dates, Report Code, Report Source, Manufacturer Report Number, FDA Request Number, Sending Manufacturer, Reaction Data and Outcomes, and Patient Information |
| 3 | Medium | Suspect Drug Name, Title, Dates, Report Code, Report Source, Manufacturer Report Number, FDA Request Number, and Sending Manufacturer |
| 4 | -- | Full Record with Tagged Fields |
| 5 | -- | Full Record with Drug Information Text (includes if known Concomittant Drugs, Manufacturer Reported, Dosage, Reported Route, and Therapy Dates) |
| 6 | Free | Suspect Drug Name, Title, and FDA Receipt Date |
| 7 | -- | Suspect Drug Name, Title, Dates, Report Code, Report Source, Manufacturer Report Number, FDA Request Number, Sending Manufacturer, Reaction Data and Outcomes, and Patient Information |
| 8 | Short | Title and Sending Manufacturer |
| 9 | Full | Full Record with Drug Information Text (includes if known Concomittant Drugs, Manufacturer Reported, Dosage, Reported Route, and Therapy Dates) |
| K | -- | KWIC (Key Word In Context) displays a window of text; may be used alone or with other formats |

OTHER OUTPUT OPTIONS

For an explanation, enter HELP TYPE, HELP UDF, HELP TAG online.

| | | |
|-----------------------------|---|--|
| USER DEFINED FORMATS | User-defined formats may be specified using the display codes indicated in the Search Options tables. | TYPE S3/NA,TI,RE/1-5 |
| TAG | TAG may be used for tagged fields. | TYPE S3/3/1-5 TAG |
| DIRECT RECORD ACCESS | DIALOG Accession Number | TYPE 120491/5 DISPLAY 119604/TI PRINT 117590/3 |

FOR ONLINE HELP:

See HELP FIELDS 181 for searchable fields; HELP FORMAT 181 for output formats; HELP LIMIT 181 for limits; HELP RATES 181 for cost information; HELP SORT 181 for sorts.