ARDSNET 01/03 Limited Access Dataset: Summary of Changes

This document explains all of the modifications and deletions that have been made to the ARDSNet01 (KARMA/ARMA) and ARDSNet03 (LARMA) datasets.

I. Base Data Set:

A. Data fields / tables used to enter data from the source documents, and data from the sample repository, were included.

B. Additional data fields were also included in both the '01' and '03' data sets. These fields were added to the original dataset, based upon the judgements of the clinical staff of the ARDSNet Coordinating Center regarding the collected data.
  1. ARDSNet01 'AER' table includes: system1, system2, failure, msof, death
  2. ARDSNet03 'AER' and 'DEATH' tables include: system1, system2, failure, msof
  3. The variables system1, system2, and failure were derived from the World Health Organization Adverse Event Thesaurus (July 1993).
  4. Variable definitions:
      a. system1 = body system class
      b. system2 = body system subclass
      c. failure = adverse event name within the body system subclass
      d. msof = multiple system organ failure (yes or no response)
      e. death = did patient die (yes or no response)

II. Changes:

A. Fields that had meaning only in reference to the electronic data entry software were removed:
  1. KARMA/ARMA fields 'scrn', 'copsts', and 'ckstamp' were removed from the tables:
      • AER, BABG, BRUSS, DEMO, GLASGOW, INCLUDE, MED, OSCHEST, PHYSIO, SCREEN, SPEC, TERM, VENT, VITAL, WEAN
  2. LARMA fields 'scrn', 'copsts', 'chxval', and 'ckstamp' were removed from the following tables:
      • ADI, ADT, AEM, AER, AFI, AMN, APT, AVI, AWI, BABG, BACTR, BRUSS, DDC, DDSL, DEATH, DEMO, ECG, GLASGOW, INCLUDE, MM, OSCHEST, PHYSIO, PNEUM, SCREEN, SEPTIC, SPEC, TERM, VENT, VITAL, VITALFD, WEAN

B. Fields that contained patient-identifying information were removed or masked, where appropriate, in accordance with the NHLBI policy for Distribution of Data (http://www.nhlbi.nih.gov/resources/deca/policy.htm).
  1. KARMA/ARMA fields for patient initials, data entry user name, site ID number, and date of data entry were removed from the following tables:
      • AER, BABG, BRUSS, DEMO, GLASGOW, INCLUDE, MED, OSCHEST, PHYSIO, SCREEN, SPEC, TERM, VENT, VITAL, WEAN

2. LARMA fields for patient initials, data entry user name, site ID number, and date of data entry were removed from the following tables:
- ADI, ADT, AEM, AER, AFI, AMN, APT, AVI, AWI, BABG, BACTR, BRUSS, DDC, DDSL, DEATH, DEMO, ECG, GLASGOW, INCLUDE, MM, OSCHEST, PHYSIO, PNEUM, SCREEN, SEPTIC, SPEC, TERM, VENT, VITAL, VITALFD, WEAN

3. KARMA/ARMA and LARMA 'SCREEN' tables: variable for hospital name was removed.

4. KARMA/ARMA 'KETO3a' table: barcode numbers were removed and replaced with a coded patient ID (see item 11 below).

5. LARMA 'CTI10' table: barcode numbers were removed and replaced with a coded patient ID (see item 11 below).

6. Data from patients who were screened and not enrolled, were found in, and removed from the following tables:
- K/ARMA AER: 1 instance
- K/ARMA SCREEN: 4508 instances
- LARMA INCLUDE: 5 instances
- LARMA TERM: 1 instance
- K/ARMA INCLUDE: 101 instances
- K/ARMA TERM: 8 instances
- LARMA SCREEN: 2046 instances

7. Free-text fields that contained dates and other identifying information were deleted from the following tables:
- K/ARMA and LARMA AER tables: 'other' and 'desc' variables removed
- K/ARMA and LARMA COMMENTS tables: whole table removed
- K/ARMA and LARMA EXCLUDE tables: whole table removed
- K/ARMA and LARMA SCREEN tables: 'comment' variable removed
- K/ARMA WEAN table: 'wea5txt' and 'wea2no' variables removed
- LARMA DDC table: 'othertxt' variable removed
- LARMA DEATH table: 'desc' and 'dcause' variables removed
- LARMA WEAN table: 'wea5txt' variable removed

8. References to illegal drug use (sensitive data) were removed from the KARMA/ARMA and LARMA 'SCREEN' forms.

9. Race-Ethnicity information (KARMA/ARMA and LARMA 'SCREEN' forms) was conflated into three categories: 'white', 'black', and 'other'.

10. Weights and heights were truncated to remove extremes:
- if height> 74 in (188 cm), then truncate to 74 in (188 cm)
- if height< 60 in (152 cm), then truncate to 60 in (152 cm)
- if weight> 355 lbs (161 kg), then truncate to 355 lbs (161 kg)
- if weight< 79 lbs (36 kg), then truncate to 79 lbs (36 kg)

11. Ages (KARMA/ARMA and LARMA 'SCREEN' forms) higher than 89 were truncated to '89'.

12. All dates were coded to be a number relative to each patient's study day 0. No KARMA/ARMA or LARMA table contains an absolute date field.
- Example: Suppose a patient was randomized on June 2, 2003; this is the patient's study day 0. Any date fields recorded for this patient may be represented with reference to this date. If this patient was discharged on June 15, 2003, the database contains a recoded value of '13' for 'date of discharge'.

13. Patient IDs were recoded to mask site of origin. A master list of patients was used to randomly assign new patient IDs (01-001 through 01-667 for KARMA/ARMA patients, and 03-001 through 03-235 for LARMA patients). The master lists were then used to encrypt the 'ptID' variable in all tables.
- PLEASE NOTE that, since it is impossible to determine the location of a patient, it is therefore also impossible to apply altitude corrections to P/F ratio values in the dataset. Recorded P/F ratios are the non-altitude corrected values. 27 % of KARMA/ARMA patients and 22% of LARMA patients were from sites at high altitudes.
- All tables were sorted by the new patient ID variable.

D. User-defined SAS formats were removed from the KARMA/ARMA and LARMA datasets.

E. One electronic system error was corrected: the electronic data entry system attempted to calculate kilograms from weight entered in pounds, but the output to the KARMA/ARMA 'VITAL' table was erroneous. The KARMA/ARMA 'VITAL' table had to be corrected for this error. Both kilograms and pounds are now correct.