

# MINI-SENTINEL DISTRIBUTED DATABASE SUMMARY REPORT

**YEAR FOUR** 

Version 1.1

**Prepared by Mini-Sentinel Data Core** 

August 2014

Mini-Sentinel is a pilot project sponsored by the <u>U.S. Food and Drug Administration (FDA)</u> to inform and facilitate development of a fully operational active surveillance system, the Sentinel System, for monitoring the safety of FDA-regulated medical products. Mini-Sentinel is one piece of the <u>Sentinel Initiative</u>, a multi-faceted effort by the FDA to develop a national electronic system that will complement existing methods of safety surveillance. Mini-Sentinel Collaborators include Data and Academic Partners that provide access to health care data and ongoing scientific, technical, methodological, and organizational expertise. The Mini-Sentinel Coordinating Center is funded by the FDA through the Department of Health and Human Services (HHS) Contract number HHSF2232009100061.



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# **OVERVIEW**

The *Mini-Sentinel Distributed Database Summary Report* presents a high-level summary of the information available in the Mini-Sentinel Distributed Database (MSDD). To generate the information in this report, the Mini-Sentinel Operations Center (MSOC) developed and distributed programs that Data Partners ran on their local implementation of the Mini-Sentinel Common Data Model (MSCDM). Results from the programs were returned to MSOC for review, aggregation and reporting. The *MSDD Summary Report* represents the data found in the MSDD at the time the programs were executed. The report is updated periodically, and is one of many tools used by MSOC, the Data Partners, and FDA to characterize the data available in the MSDD and assess data quality. The purpose of this report is to provide the FDA and Mini-Sentinel communities a summary of descriptive characteristics of the MSDD at a given point in time. Please refer to the Mini-Sentinel Common Data Model specifications for more information.

The data presented in this report are current as of August 22, 2013. This report includes data from 18 Mini-Sentinel Data Partners – Aetna, HealthCore, the HMO Research Network (6 sites), Humana, Kaiser Permanente (6 sites), Lovelace Clinic Foundation, OptumInsight, and Vanderbilt.

The *Mini-Sentinel Distributed Database Summary Report* summarizes each data table in the MSDD. A summary of each table and the data presented follows. Please note that the report reflects the MSDD "as-is" and does not account for different data extract windows across the Data Partners, including different start and end dates, and partial data for 2012 and 2013 for some Data Partners. The number of Data Partners by year is noted in the relevant tables.

The **Enrollment Table** contains records for all individuals who were health plan members during the period included in the data extract. It includes one record for each member enrollment period defined by a unique combination of drug and medical coverage flags. The table is used to identify enrollment periods. As of August 22, 2013, the Enrollment Table includes information from January 2000 through June 2013. These enrollment periods reflect over 150 million unique person identifiers and represent more than 356 million person-years of observation time. Seventy percent of the enrollment periods in the MSDD include both medical and drug coverage; 24% of periods include only medical coverage (Table 1, Figure 3). The drop in enrollment records in 2013 reflects the number of Data Partners contributing data and lack of complete information for 2013 (Figure 1). The enrollment table is often used to restrict assessment of exposures and outcomes to periods of enrollment.

The **Demographic Table** includes race, sex, ethnicity and age. The table has one record for every unique person in the MSDD. Some Mini-Sentinel Data Partners provide care to individuals who are not health plan members (e.g., in ambulatory clinics and hospitals), and information for these non-members is included in this table but not in the Enrollment Table. Therefore, everyone in the Enrollment Table should be in the Demographic Table, but not everyone in the Demographic table will be in the Enrollment Table. As of August 22, 62% of individuals are between the ages of 22 and 64 (Figure 4) and the sex distribution is approximately equal (Figure 5). Race and ethnicity are unknown or frequently missing at most Data Partner sites (Table 2, Figure 6).

The **Dispensing Table** represents outpatient pharmacy dispensings captured by the Data Partners. The table has one record per dispensing. The MSCDM requires that the Data Partners process source data to remove rollback (negative) transactions (e.g., restocking of prescription fills that were not picked up)



and process other adjustments before populating the table. Infused medications, vaccinations, and injections provided directly by medical providers are captured in the Procedure Table using the appropriate procedure codes. There were about 3.9 billion dispensings and over 88 million unique persons in the Dispensing Table. Only 2.8% of dispensings were for more than 99 days (Table 3) and the majority of dispensings are for between 21 and 33 days supplied (Figure 8). The drop in dispensing records in 2013 reflects the number of Data Partners contributing data and lack of complete information for 2013 (Figure 7).

Each record in the **Encounter Table** represents a unique health care visit in the ambulatory or inpatient setting (see "Encounter Type" in Glossary). The Encounter Table includes dates of service, provider identifiers, and the setting in which care was provided. There were approximately 4.0 billion encounters and over 120 million unique persons in the encounter file (Table 4, Figure 9). Diagnoses and procedures recorded during encounters are recorded in separate tables.

The **Death Table** records death dates. As of August 22, 2013, there were approximately 3.1 million unique patient identifiers included in the Death Table (Table 5). Seventy-six percent of the deaths recorded were determined using local source systems at Data Partner sites; most of the remaining records used state death files to determine death date (Figure 10). The increase in records in 2008 reflects the number of Data Partners contributing data; the drop in records in 2012 reflects variation in data availability (data lag) across Data Partners.

The **Cause of Death Table** records diagnosis codes reflecting the conditions that contributed to death. There were over 1.5 million unique patient identifiers in the Cause of Death Table (Figure 13). State death files were the source of the information in over three-fourth of records (Figure 13). The proportion of deaths captured by the Data Partners is unknown. As many Data Partners link to state death registries to update the death status of their members, and these updates are performed infrequently, a two-year data lag in cause of death data is not uncommon.

The death and cause of death tables have not yet been thoroughly reviewed or tested for use within Mini-Sentinel.

The **Laboratory Result Table** contains selected outpatient laboratory test results from twelve Data Partners. Laboratory test results incorporated into the MSCDM to date include: alkaline phosphatase (ALP), alanine aminotransferase (ALT), absolute neutrophil count (ANC), total bilirubin, creatine kinase total, creatine kinase MB fraction, creatine kinase MB to total creatine kinase index, creatinine, fibrin d-dimer, glucose, hemoglobin, glycosylated hemoglobin (HgbA1c), influenza viruses A, B, and A + B, International Normalized Ratio (INR), lipase, pregnancy test, platelet count, troponin I cardiac, and troponin T cardiac. There were nearly 24.7 million individuals with at least one of the listed laboratory results (Table 6). The number of results each year for each laboratory test is depicted in Figure 15. Table 7 lists laboratory result units by test type and Data Partner for quantitative tests. Variation in Data Partner source data (e.g., different result units) and in accuracy of data extraction and loading individual tests into the MSCDM (e.g., populating urine glucose into the blood glucose variable) has necessitated characterization and standardization of each laboratory test. Laboratory tests that have been standardized to date include: ALT, creatine kinase total, creatinine, glucose, HgbA1c, and INR. However, not all Data Partners had incorporated all standardization requests at the time the data for the tables and figures in this report were compiled.



The **Vital Signs Table** contains height, weight, blood pressure and smoking status data from nine Data Partners. Over the years 2006-2011, the number of individuals with at least one height measurement went from 2.5 to 4.2 million. Similar increases were found for weight and systolic and diastolic blood pressure measurements (Table 8).

# **GLOSSARY**

Age - defined as (Refresh Date – Date of Birth).

Amount Dispensed - number of units (e.g., pills, tablets, vials, mL, etc.) dispensed.

Confidence - all linkages to external data sources have some level of uncertainty, and many linkage algorithms include an assessment of the confidence of the match. Reported as Excellent, Fair or Poor:

- Death Records captures the confidence in the certainty that the member drawn from the source data represents the actual member
- Cause of Death (COD) Records confidence in the accuracy of the COD based on source, match, number of reporting sources, discrepancies, etc.

Days Supplied - number of days that the medication supports as reported on the dispensing record.

Data Partners – refers to Mini-Sentinel collaborating partners who have created the Mini-Sentinel Distributed Database using their administrative, claims, and electronic health record data. Each Data Partner was assigned a random ID that remains consistent throughout this report.

Encounter ID - encounter-level identifier used to link the Encounter, Diagnosis, and Procedure tables.

### Encounter Type

- Inpatient Hospital Stay Includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.
- Non-Acute Institutional Stay Includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis, and other non-hospital stays.
- Emergency Department Includes ED encounters that became inpatient stays (in which case inpatient stay would be a separate encounter). Excludes urgent care visits. ED encounters should be identified before hospital stays to insure that ED with subsequent admission won't be incorporated into the hospital event.
- Ambulatory Visit Includes visits at outpatient clinics, same day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.
- Other Ambulatory Visit Includes other non-overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone, and email consultations.

Enrollment Period - defined as Enrollment End Date — Enrollment Start Date. A member may have multiple enrollment periods. Changes in drug or medical coverage status will result in a new enrollment period.



Hispanic - identifies a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race (defined by Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity from the Office of Management and Budget (OMB), http://www.whitehouse.gov/omb/fedreg\_1997standards).

Patient ID (PatID) — a pseudoidentifier with a consistent crosswalk to the true identifier retained by the source Data Partner. For analytical data sets requiring patient-level data, only the pseudoidentifier is used to link across all information belonging to a patient.

Race - definitions for Race are based on the Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity from the Office of Management and Budget (OMB), http://www.whitehouse.gov/omb/fedreg\_1997standards.

- American Indian a person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.
- Asian a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
- Black/African American a person having origins in any of the black racial groups of Africa.
- Native Hawaiian or Other Pacific Islander a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- White a person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Refresh Date - the latest date in the Data Partner's enrollment, dispensing, or utilization tables.

Sex - has values of Male, Female, Ambiguous (transgender/hermaphrodite) or Unknown.

Source of Death and Cause of Death Records - source of the mortality information, which can come from state or national records, tumor registries or from locally defined sources.



# Mini-Sentinel Distributed Database At A Glance

As of August 22, 2013

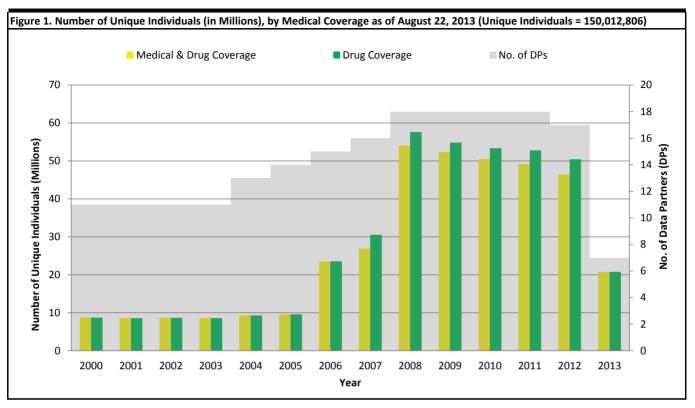
<u>The Mini-Sentinel Distributed Database is comprised of quality-checked data held by 18 partner organizations.</u>

- 150 million individuals\*
  - 356 million person-years of observation time
  - 49 million individuals currently enrolled, accumulating new data
  - ° 35 million individuals have over 3 years of data
- 3.9 billion dispensings
- Accumulating over 45 million dispensings per month
- 4.0 billion unique encounters, including 41 million acute inpatient stays
- Accumulating over 51 million encounters per month
- 24.7 million individuals with at least 1 laboratory result\*\*
  - \* The potential for double-counting exists if individuals change health plans.
  - \*\*Laboratory results include: alkaline phosphatase (ALP), alanine aminotransferase (ALT), absolute neutrophil count (ANC), total bilirubin, creatine kinase total (CK), creatine kinase MB (CK-MB), ratio CK-MB/CK, creatinine, fibrin d-dimer, glucose (fasting and randomized), hemoglobin, glycosylated hemoglobin (HbA1c), influenza virus (A, B, A+B, and not specified), international normalized ratio (INR), lipase, pregnancy test, platelet count, troponin I cardiac, and troponin T cardiac.

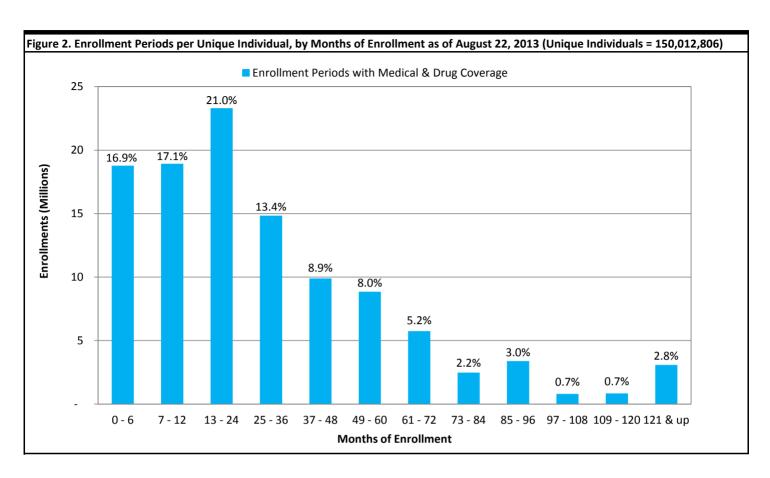


Table 1. Snapshot of the Mini-S	Sentinel Di	istributed	Database	Enrollme	nt Table a	s of Augus	st 22, 201	3 (Unique	Individua	ls =150,01	2,806)								
	DP1	DP2	DP3	DP4	DP5	DP6	DP7	DP8	DP9	DP10	DP11	DP12	DP13	DP14	DP15	DP16	DP17	DP18	Total
Number of enrollment periods																			
per unique individual	3.7	1.3	2.4	1.6	1.7	1.1	1.6	1.6	1.1	1.6	1.2	3.5	1.5	1.7	1.9	1.3	1.2	3.1	1.3
Records with <i>only</i> medical																			
coverage	10.0%	3.8%	3.1%	15.5%	36.1%	0.4%	0.0%	12.4%	40.0%	17.2%	0.3%	51.2%	3.5%	5.1%	11.5%	11.7%	42.9%	7.8%	24.2%
Records with <i>only</i> drug																			
coverage	0.0%	0.0%	0.0%	0.0%	0.0%	49.2%	0.0%	0.0%	2.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.4%	0.0%	0.0%	4.4%
Records with medical +																			
unknown drug coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	42.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.6%	11.1%	0.0%	0.0%	0.0%	1.0%	1.0%
Records with both medical																			
and drug coverage	90.0%	96.2%	96.9%	84.5%	63.9%	50.4%	58.0%	87.6%	58.0%	82.8%	99.7%	48.8%	95.8%	83.8%	88.5%	87.9%	57.1%	91.3%	70.4%
Length of enrollment:																			
Statistics (months):																			
Min	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
P1	1	1	1	1	2	1	1	1	1	1	1	2	1	1	1	1	1	1	1
P5	3	3	3	2	6	2	3	5	2	2	2	5	2	4	2	2	2	3	2
P25	11	12	12	12	24	9	12	21	9	12	10	19	11	20	12	10	8	12	10
Median	24	33	30	37	56	19	32	48	18	36	24	44	26	55	27	24	18	30	23
P75	54	78	69	97	108	36	74	84	36	88	60	79	59	118	58	48	34	70	46
P95	121	159	138	161	132	65	90	153	57	161	143	150	102	156	127	88	63	114	88
P99	144	159	150	161	144	65	96	156	57	161	159	150	102	156	146	88	63	114	156
Max	144	159	150	161	148	65	96	156	57	161	159	150	102	156	146	88	63	114	161
Distribution (months):																			
0 - 6	15.6%	13.8%	12.8%	15.2%	5.5%	17.0%	13.7%	7.3%	19.3%	14.7%	18.6%	7.5%	15.6%	9.2%	14.8%	16.7%	19.7%	14.1%	16.9%
7 - 12	16.4%	12.3%	13.4%	10.9%	9.0%	23.3%	13.4%	7.0%	19.9%	11.4%	14.5%	9.2%	14.7%	8.6%	14.0%	15.1%	20.6%	12.9%	17.1%
13 - 24	19.5%	15.7%	17.9%	13.9%	11.4%	21.9%	16.4%	15.2%	23.8%	14.2%	17.3%	14.8%	18.1%	12.0%	18.0%	20.0%	24.7%	17.6%	21.0%
25 - 36	12.3%	11.2%	12.0%	9.6%	10.6%	13.4%	11.7%	11.9%	14.2%	10.1%	11.7%	12.1%	11.6%	9.2%	12.6%	13.9%	14.2%	12.5%	13.4%
37 - 48	8.5%	8.7%	8.8%	7.3%	9.1%	8.8%	7.7%	9.0%	9.0%	7.9%	7.8%	10.0%	8.5%	7.6%	10.5%	10.0%	8.1%	8.4%	8.9%
49 - 60	6.8%	6.4%	6.7%	5.8%	7.3%	5.7%	6.5%	7.8%	13.9%	6.1%	5.5%	8.9%	7.4%	6.5%	7.0%	6.8%	5.0%	6.1%	8.0%
61 - 72	4.6%	5.0%	5.2%	4.7%	6.4%	10.0%	5.1%	11.9%	0.0%	5.1%	4.4%	8.4%	5.3%	5.7%	5.3%	5.6%	7.7%	4.8%	5.2%
73 - 84	4.3%	4.5%	3.9%	4.0%	6.5%	0.0%	19.4%	5.0%	0.0%	4.4%	3.5%	6.6%	4.8%	5.1%	3.7%	4.1%	0.0%	3.7%	2.2%
85 - 96	2.8%	3.9%	3.8%	3.5%	5.0%	0.0%	6.3%	4.1%	0.0%	3.9%	3.0%	5.7%	5.3%	4.6%	3.5%	7.9%	0.0%	3.9%	3.0%
97 - 108	2.6%	3.2%	3.0%	3.1%	5.3%	0.0%	0.0%	3.9%	0.0%	3.5%	2.6%	4.2%	8.7%	4.0%	2.4%	0.0%	0.0%	3.3%	0.7%
109 - 120	1.5%	2.8%	3.4%	2.9%	4.5%	0.0%	0.0%	3.9%	0.0%	3.0%	3.5%	2.5%	0.0%	3.7%	2.4%	0.0%	0.0%	12.8%	0.7%
121 & Up	5.1%	12.7%	9.0%	19.1%	19.3%	0.0%	0.0%	13.0%	0.0%	15.6%	7.7%	10.0%	0.0%	23.9%	5.9%	0.0%	0.0%	0.0%	2.8%









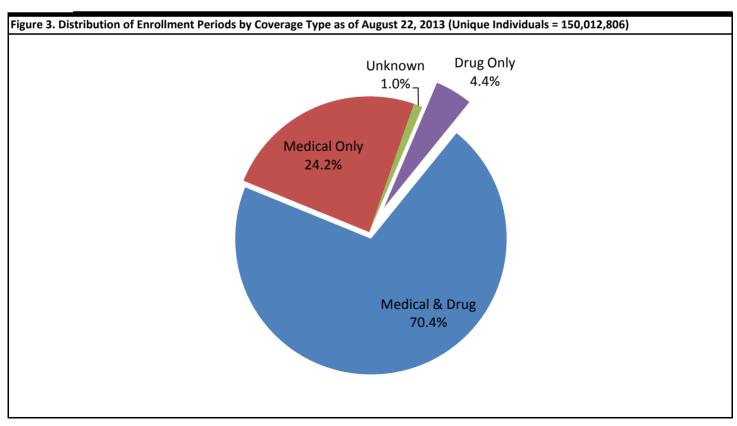
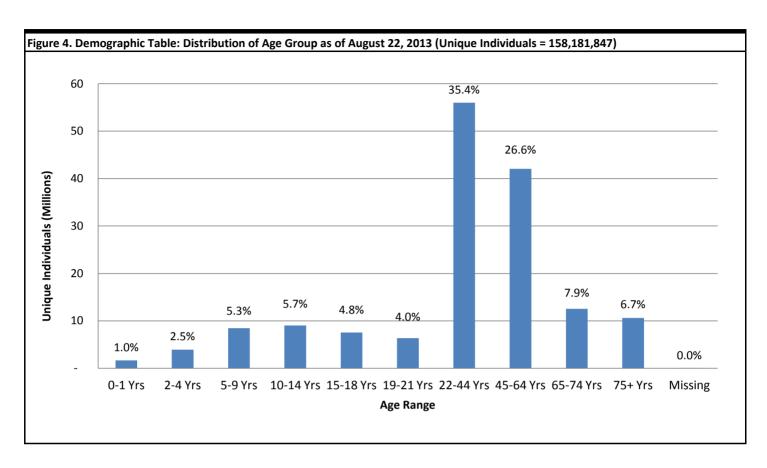
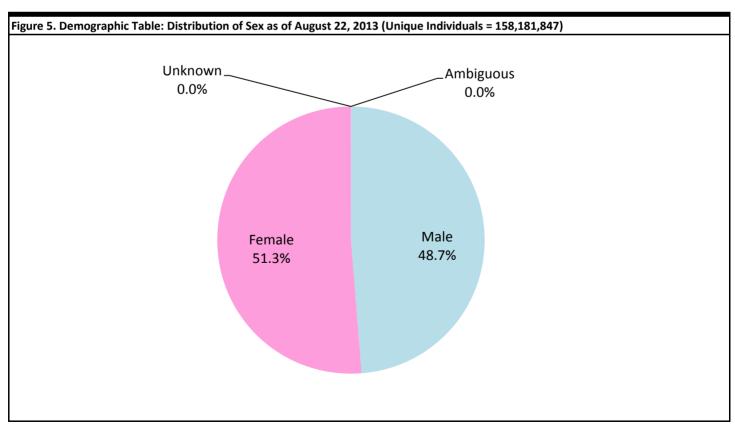




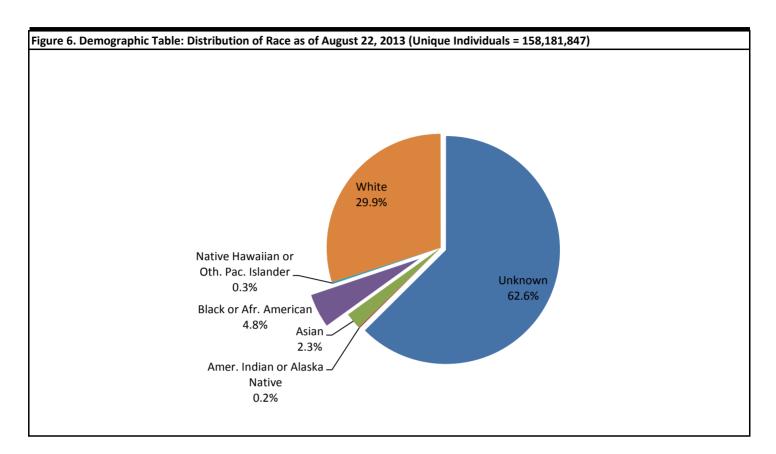
Table 2. Snapshot of the Mini-					•		•												
	DP1	DP2	DP3	DP4	DP5	DP6	DP7	DP8	DP9	DP10	DP11	DP12	DP13	DP14	DP15	DP16	DP17	DP18	Total
Race																			
Unknown American Indian /	89.8%	65.9%	92.8%	55.3%	11.5%	33.0%	71.3%	8.2%	43.6%	54.6%	73.9%	54.4%	100.0%	20.2%	82.8%	100.0%	74.0%	78.8%	62.6%
Alaska Native	0.0%	0.4%	0.0%	0.8%	0.3%	0.4%	0.2%	0.2%	0.1%	0.4%	0.2%	0.4%	0.0%	0.4%	0.1%	0.0%	0.2%	0.4%	0.2%
Asian	0.5%	1.4%	0.0%	15.5%	2.8%	1.3%	3.0%	1.4%	3.0%	2.4%	1.6%	0.6%	0.0%	13.7%	1.0%	0.0%	1.6%	1.8%	2.3%
African American Native Hawaiian / Other	0.8%	2.3%	0.0%	0.8%	27.9%	7.8%	13.5%	25.4%	6.6%	1.8%	12.8%	0.3%	0.0%	6.2%	2.1%	0.0%	2.8%	1.2%	4.8%
Pacific Islander	0.0%	0.1%	0.0%	12.5%	0.0%	1.8%	0.2%	0.0%	0.0%	0.3%	0.0%	0.1%	0.0%	0.5%	0.0%	0.0%	0.1%	0.3%	0.3%
White	8.9%	29.9%	7.1%	15.0%	57.4%	55.7%	11.7%	64.8%	46.6%	40.5%	11.5%	44.3%	0.0%	58.9%	14.0%	0.0%	21.3%	17.4%	29.9%
Sex																			
Male	48.4%	48.6%	48.7%	50.6%	47.2%	44.8%	48.0%	43.4%	49.5%	48.9%	47.8%	48.1%	45.4%	50.0%	49.0%	50.0%	48.8%	47.4%	48.7%
Female	51.6%	51.4%	51.3%	49.4%	52.8%	55.2%	52.0%	56.6%	50.5%	51.1%	52.2%	51.9%	54.6%	50.0%	50.8%	50.0%	51.2%	52.5%	51.3%
Ambiguous	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Unknown	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.2%	0.0%	0.0%	0.1%	0.0%
Hispanic																			
Yes	0.5%	6.5%	0.0%	3.5%	1.6%	2.0%	3.5%	5.2%	7.4%	3.3%	1.6%	1.0%	46.3%	21.1%	0.5%	0.0%	2.9%	1.0%	4.4%
No	10.2%	33.9%	0.0%	16.4%	9.6%	67.0%	11.1%	91.8%	56.4%	16.8%	0.0%	55.1%	53.7%	0.0%	0.0%	0.0%	0.6%	21.4%	24.9%
Unknown	89.3%	59.6%	100.0%	80.1%	88.9%	31.0%	85.3%	3.0%	36.2%	79.9%	98.4%	43.9%	0.0%	78.9%	99.5%	100.0%	96.5%	77.6%	70.7%
Age																			
Statistics																			
Mean	39.3	39.9	42.5	42.2	47.7	60.5	38.8	33.5	36.3	40.1	37.3	49.2	33.8	40.0	40.9	37.9	36.6	45.7	
STD	175.9	133.5	84.0	98.1	194.9	422.7	113.5	229.1	660.1	133.3	105.3	87.4	87.4	308.2	254.7	562.3	632.5	202.1	
Min	-1	0	-1	0	-1	0	0	0	0	0	0	0	0	-1	-7888	0	0	-1	
Max	131	124	126	126	112	112	113	198	212	128	113	206	113	127	171	113	118	213	
Distribution																			
0 - 1 yrs	0.7%	1.0%	0.5%	0.7%	0.6%	0.2%	0.7%	3.0%	1.4%	0.9%	1.3%	1.1%	1.9%	1.2%	1.0%	0.8%	1.1%	0.5%	1.0%
2 - 4 yrs	1.7%	2.0%	1.4%	1.6%	1.2%	0.7%	2.0%	5.3%	3.3%	1.8%	1.9%	2.2%	4.4%	2.3%	2.2%	2.1%	2.7%	1.1%	2.5%
5 - 9 yrs	4.5%	4.7%	4.1%	3.6%	2.5%	1.9%	5.1%	9.6%	6.3%	4.4%	4.7%	4.3%	10.3%	4.8%	4.5%	5.6%	5.8%	2.4%	5.3%
10 - 14 yrs	6.2%	6.1%	5.3%	4.7%	3.6%	2.0%	5.5%	9.7%	6.5%	6.0%	6.6%	5.2%	9.4%	5.7%	5.2%	6.0%	5.9%	3.4%	5.7%
15 - 18 yrs	5.2%	4.9%	4.9%	3.7%	3.8%	1.6%	4.8%	7.0%	5.3%	5.0%	5.4%	4.4%	6.7%	4.8%	4.6%	4.9%	5.1%	3.9%	4.8%
19 - 21 yrs	4.1%	3.8%	3.9%	3.2%	3.7%	1.3%	3.9%	5.4%	4.1%	3.9%	4.2%	3.5%	5.1%	3.9%	3.8%	4.1%	4.8%	3.5%	4.0%
22 - 44 yrs	36.1%	36.7%	33.3%	38.5%	31.1%	15.7%	38.6%	30.3%	37.1%	37.6%	39.6%	26.3%	29.8%	36.9%	35.6%	38.0%	39.1%	34.3%	35.4%
45 - 64 yrs	30.7%	27.4%	30.4%	27.9%	29.6%	19.7%	28.1%	15.4%	27.9%	26.2%	27.8%	22.4%	20.2%	25.9%	29.4%	28.2%	26.2%	31.9%	26.6%
65 - 74 yrs	6.9%	7.4%	7.5%	8.5%	8.6%	27.8%	7.2%	5.6%	4.8%	7.8%	5.3%	8.5%	6.1%	7.1%	6.4%	6.6%	5.6%	9.4%	7.9%
75 + yrs	3.9%	6.1%	8.6%	7.5%	15.3%	29.1%	4.1%	8.6%	3.3%	6.4%	3.1%	22.1%	6.0%	7.4%	7.2%	3.5%	3.7%	9.6%	6.7%







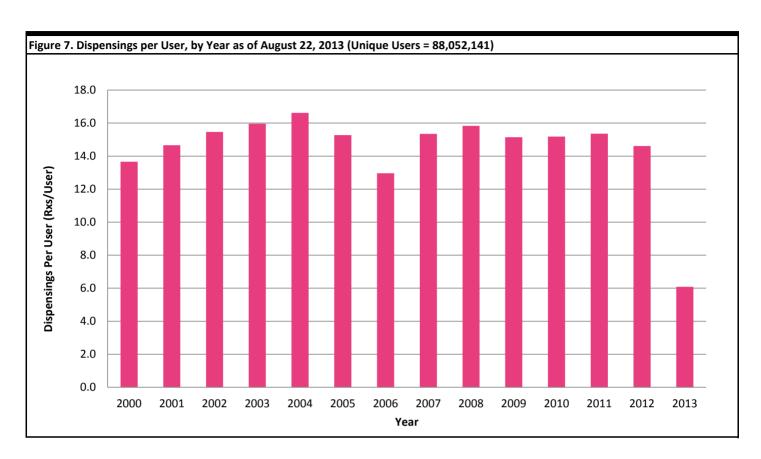






	DP1	DP2	DP3	DP4	DP5	DP6	DP7	DP8	DP9	DP10	DP11	DP12	DP13	DP14	DP15	DP16	DP17	DP18	Total
istribution of:																			
Days Supplied																			
MISSING	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.8%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
< 0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%	2.1%	0.0%	0.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.2%
> 0 - 33	91.9%	50.8%	80.8%	70.8%	71.9%	85.1%	56.8%	97.5%	90.3%	68.4%	82.7%	80.2%	91.8%	51.3%	80.6%	88.7%	87.7%	71.8%	83.9%
34 - 66	0.9%	35.8%	8.4%	4.7%	11.3%	1.7%	16.2%	0.1%	0.8%	4.1%	4.0%	4.4%	1.4%	10.9%	3.5%	2.5%	0.8%	4.7%	3.1%
67 - 99	7.2%	12.6%	7.8%	23.9%	11.2%	13.2%	25.9%	0.2%	8.8%	25.4%	13.0%	13.9%	6.8%	6.2%	15.6%	8.5%	11.5%	22.5%	10.1%
100 - 499	0.0%	0.8%	2.9%	0.6%	5.6%	0.0%	0.2%	0.0%	0.1%	1.6%	0.3%	1.6%	0.0%	31.5%	0.3%	0.2%	0.1%	1.0%	2.8%
>= 500	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%





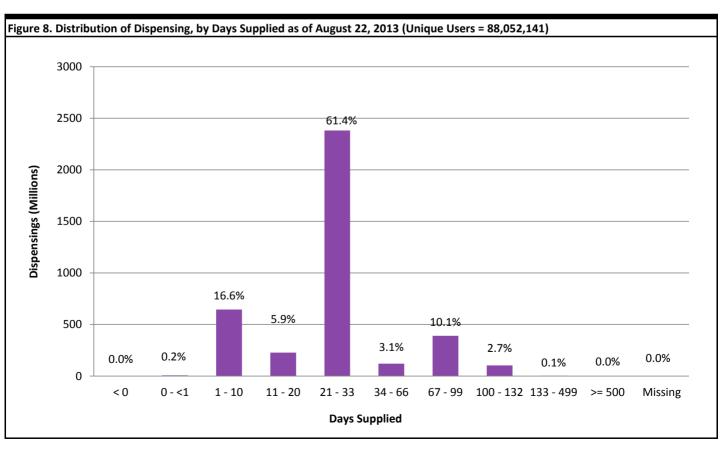
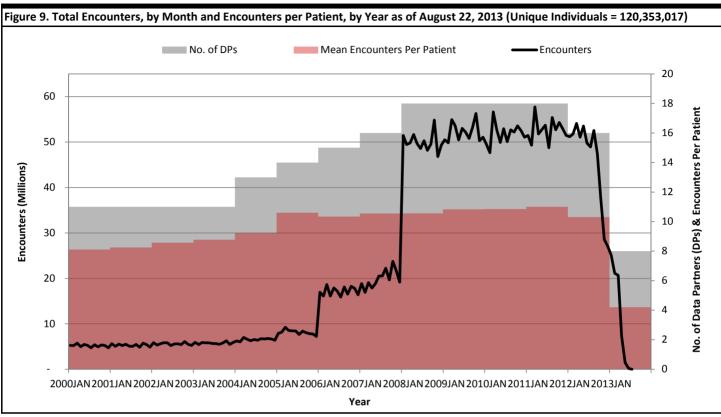




Table 4. Snapshot of the Mini-Sentin	nel Distri	buted Da	atabase I	Encounte	er Table	as of Au	gust 22, 2	2013 (Un	ique Ind	ividuals	= 120,35	3,017)							
							, ,	•				-,- ,							
	DP1	DP2	DP3	DP4	DP5	DP6	DP7	DP8	DP9	DP10	DP11	DP12	DP13	DP14	DP15	DP16	DP17	DP18	Total
Mean Number of Encounters per																			
Patient (All Years)	37.9	39.9	53.3	50.3	27.0	40.8	54.3	55.8	26.6	68.6	36.8	90.1	34.0	51.6	35.2	35.2	25.3	55.6	33.2
2000	8.75	5.76	11.10	8.87	7.66			8.19		11.47	6.52	10.10		7.50	7.58				8.11
2001	9.28	6.52	9.90	8.98	7.87			8.30		11.86	6.76	10.46		7.55	7.73				8.25
2002	9.71	7.11	10.69	9.19	7.90			8.71		13.05	7.05	10.65		7.70	7.95				8.57
2003	9.78	7.15	10.16	9.08	7.88			9.23		13.31	7.28	10.99		7.84	8.17				8.77
2004	10.00	6.81	11.41	13.78	7.84			9.48		13.50	8.22	11.23	5.44	7.88	8.42			12.31	9.22
2005	10.20	7.82	13.84	16.11	7.75		10.44	7.66		13.60	8.97	11.51	8.49	12.15	8.74			13.28	10.60
2006	10.63	8.01	11.56	12.97	8.02		11.74	8.50		13.82	8.69	13.09	8.92	10.92	8.93	10.27		13.74	10.34
2007	10.22	8.78	12.75	10.04	8.06	9.43	13.31	8.66		14.78	9.03	13.84	9.26	10.96	9.18	10.72		14.22	10.55
2008	10.50	9.33	14.01	10.57	8.17	14.67	13.73	8.94	10.78	15.30	9.13	14.22	9.43	10.65	9.29	10.96	9.16	14.48	10.55
2009	10.85	9.92	12.28	11.16	8.18	16.34	15.25	9.27	11.08	16.00	10.28	12.98	10.03	10.35	9.65	11.28	9.34	14.97	10.83
2010	10.80	10.37	15.53	11.29	8.17	17.37	15.39	9.05	10.96	15.76	13.57	12.88	9.66	10.09	9.53	11.27	9.32	14.77	10.85
2011	10.73	10.93	17.47	11.63	8.14	18.40	15.77	10.91	11.04	16.31	14.20	12.71	9.59	9.99	9.59	11.21	9.27	15.25	11.00
2012		11.22	8.51	11.90	4.81	16.67	16.95	12.34	8.97	16.60	14.71	7.79	9.63	10.08		10.84	9.39	15.52	10.31
2013		4.64		6.40						9.03	5.89		1.07			4.47	3.54	8.34	4.20
Encounter Type																			
Inpatient Hospital Stay	0.8%	1.0%	0.8%	0.8%	1.2%	1.1%	2.8%	3.9%	0.7%	0.6%	0.7%	1.3%	1.3%	1.0%	1.1%	0.9%	0.8%	0.6%	1.0%
Non-Acute Institutional Stay	0.2%	0.2%	0.8%	0.1%	0.0%	1.4%	0.3%	0.4%	0.1%	0.1%	0.0%	0.0%	0.6%	0.1%	0.1%	1.1%	0.1%	1.3%	0.4%
Emergency Department	2.6%	2.2%	1.1%	1.9%	10.9%	1.6%	1.3%	12.4%	2.3%	1.6%	1.6%	3.2%	4.1%	2.9%	2.0%	3.6%	2.7%	1.9%	3.2%
Ambulatory Visit	78.5%	54.8%	73.4%	65.7%	86.2%	74.5%	43.7%	83.2%	84.1%	43.3%	51.2%	69.2%	72.7%	63.3%	95.1%	77.6%	91.6%	53.0%	78.6%
Other Ambulatory Visit	17.9%	41.8%	23.9%	31.5%	1.6%	21.4%	51.9%	0.0%	12.8%	54.4%	46.5%	26.4%	21.3%	32.7%	1.8%	16.7%	4.8%	43.2%	16.7%



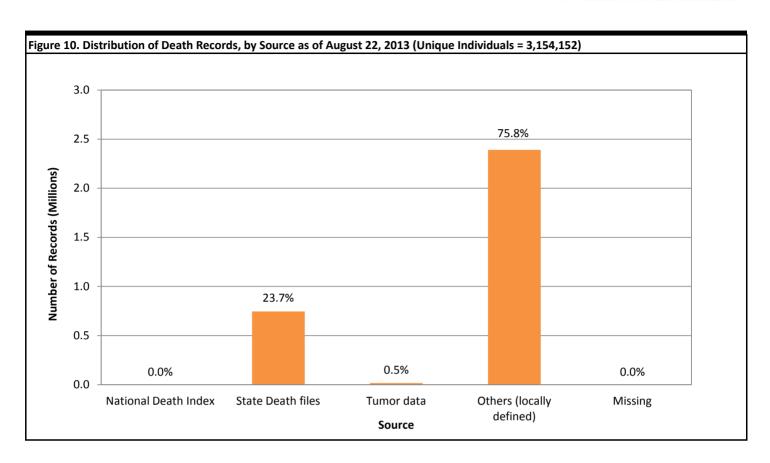


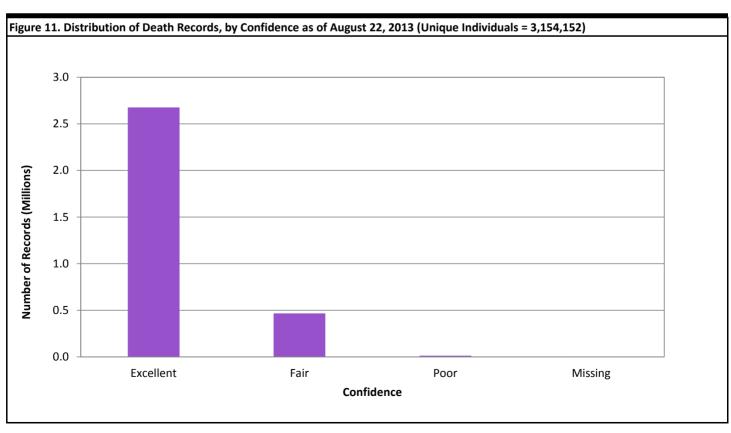
NOTE: Mean Encounters is among patients with at least one encounter of any type.



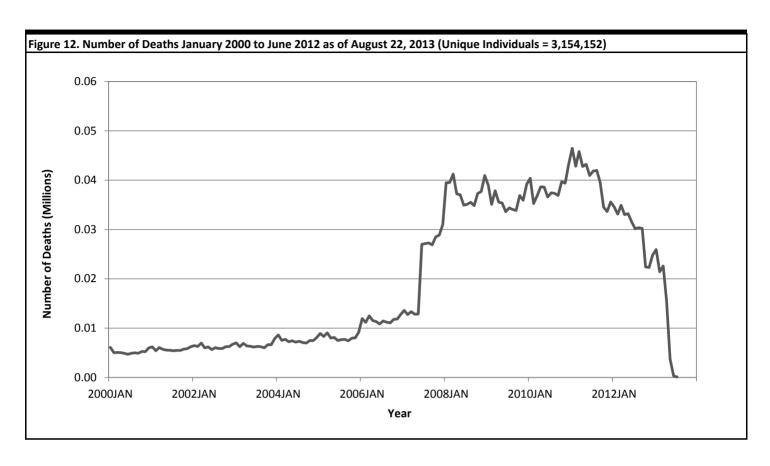
Table 5. Snapshot of the Mi	ni-Sentine	el Distrib	uted Datal	oase Death	Table a	as of Augu	st 22, 201	3 (Unique	Individual	s = 3,154,	152)								
	DP1	DP2	DP3	DP4	DP5	DP6	DP7	DP8	DP9	DP10	DP11	DP12	DP13	DP14	DP15	DP16	DP17	DP18	Total
Source																			
State Death Files	92.0%	37.4%	100.0%	0.0%		0.0%	0.0%	100.0%	0.0%	78.5%	46.5%	50.2%		35.4%	87.4%	0.0%		89.7%	23.7%
National Death Index	0.0%	0.0%	0.0%	0.0%		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		0.0%	0.0%	0.0%		0.0%	0.0%
Tumor data	0.4%	15.8%	0.0%	0.6%		0.0%	0.0%	0.0%	0.0%	8.8%	1.0%	0.0%		0.0%	0.0%	0.0%		3.5%	0.5%
Other, locally defined	7.5%	46.7%	0.0%	99.4%		100.0%	100.0%	0.0%	100.0%	12.6%	52.5%	49.8%		64.6%	12.6%	100.0%		6.9%	75.8%
Missing	0.0%	0.0%	0.0%	0.0%		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		0.0%	0.0%	0.0%		0.0%	0.0%
Invalid Code	0.0%	0.0%	0.0%	0.0%		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		0.0%	0.0%	0.0%		0.0%	0.0%
Confidence																			
Excellent	86.5%	91.9%	100.0%	100.0%		100.0%	98.7%	100.0%	100.0%	100.0%	60.1%	100.0%		98.2%	87.4%	8.4%		71.2%	84.8%
Fair	13.5%	7.1%	0.0%	0.0%		0.0%	0.0%	0.0%	0.0%	0.0%	32.7%	0.0%		1.7%	12.6%	91.6%		19.0%	14.8%
Poor	0.0%	0.9%	0.0%	0.0%		0.0%	1.3%	0.0%	0.0%	0.0%	7.2%	0.0%		0.1%	0.0%	0.0%		9.8%	0.4%
Missing	0.0%	0.0%	0.0%	0.0%		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		0.0%	0.0%	0.0%		0.0%	0.0%
Invalid Code	0.0%	0.0%	0.0%	0.0%		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		0.0%	0.0%	0.0%		0.0%	0.0%

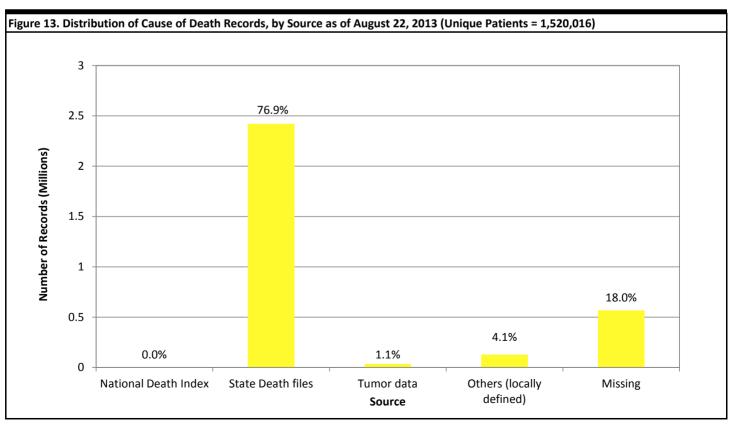




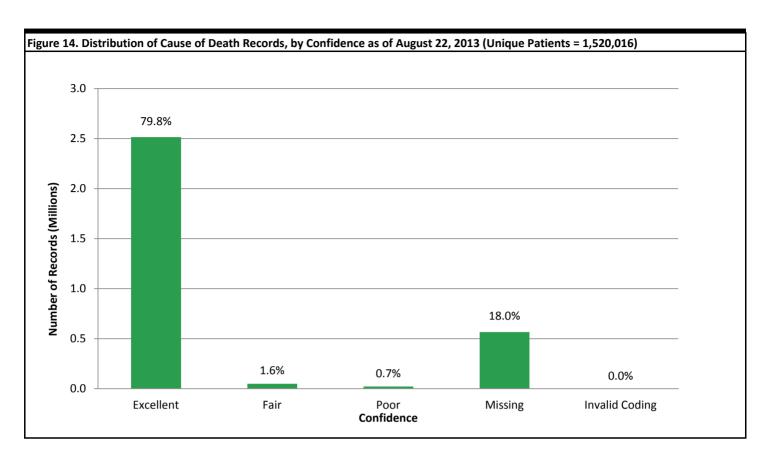














# Table 6. Snapshot of the Mini-Sentinel Distributed Database Laboratory Result Table as of August 22, 2013 Value Number of Unique Individuals: with any Lab result<sup>1</sup> 24,653,620 with any Lab result with Eligibility<sup>2</sup> 24,401,330 with any Lab result within the Enrollment Period<sup>3</sup> 24,179,583

1 Includes number of individuals who have any one of the following lab results regardless of enrollment status: alkaline phosphatase (ALP), alanine aminotransferase (ALT), absolute neutrophil count (ANC), total bilirubin, creatine kinase total (CK), creatine kinase MB (CK-MB), ratio CK-MB/CK, creatinine, fibrin d-dimer, glucose (fasting and randomized), hemoglobin, glycosylated hemoglobin (HbA1c), influenza virus (A, B, A+B, and not specified), international normalized ratio (INR), lipase, pregnancy test, platelet count, troponin I cardiac, and troponin T cardiac.

2 Includes number of individuals with a lab result with at least one enrollment period

3 Includes number of individuals with a lab result during an enrollment period



Table 7. Laboratory Result Units for	DP2	DP3	DP4	DP6	DP7	DP10	DP11	DP12	DP14	DP16	DP17	DP18	Tot
Alkaline phosphatase (ALP)													
IU/L	99.3%	0.1%	0.1%	25.4%	-	-	99.8%	1.7%	0.0%	-	11.9%	-	12.2
IU/ML	0.0%	-	-	0.0%	-	_	-		-	_		_	0.0
U/L	-	98.3%	99.9%	36.1%	100.0%	100.0%	0.2%	98.3%	100.0%	100.0%	86.7%	100.0%	80.4
OTHER	0.0%	-	-	0.9%	-	-	-	-	-	0.0%	1.4%	-	0.7
BLANK/MISSING	0.7%	1.6%	0.0%	37.6%	0.0%	_	0.0%	_	0.0%	-	-	_	6.6
Alanine aminotransferase (ALT)	*****												
IU/L	100.0%	0.0%	0.0%	25.2%	-	-	99.9%	1.5%	-	100.0%	11.9%	0.0%	31.1
U/L	-	99.2%	100.0%	36.6%	100.0%	100.0%	0.0%	98.5%	100.0%	-	85.1%	100.0%	62.6
OTHER	0.0%	-		0.9%		-	-	-	-	0.0%	3.0%	-	1.1
BLANK/MISSING	-	0.8%	0.0%	37.3%	0.0%	-	0.0%	-	-	-	-	-	5.2
Absolute neutrophil count (ANC) /UL		14.8%	_	0.0%	_		_		_	56.1%	_	_	18.0
K/UL	100.0%	35.2%	100.0%	5.9%	-	-	-	-	100.0%	43.9%	-	99.6%	50.3
OTHER	-	46.0%	-	53.2%	100.0%	100.0%		100.0%	-	0.0%		0.4%	22.
BLANK/MISSING	-	4.1%	-	40.8%	-	0.0%	-	-	-	-	-	-	9.0
Total bilirubin													
MG/DL	100.0%	98.3%	100.0%	62.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	97.0%	100.0%	92.
OTHER	-	-	-	0.0%	-	-	-	-	-	0.0%	3.0%	-	1.2
BLANK/MISSING	0.0%	1.7%	0.0%	38.0%	0.0%	-	-	-	0.0%	-	-	-	6.7
Creatine kinase total (CK)	0.0%	79.2%	100.0%	EQ 20/	100.09/	100.0%	2.5%	02.00/	100.09/	96.3%		100.09/	74.
U/L OTHER	100.0%	19.0%	100.0%	58.3% 4.7%	100.0%	100.0%	93.8%	93.8% 6.2%	100.0%	3.7%	100.0%	100.0%	22.
BLANK/MISSING	0.0%	1.8%	0.0%	36.9%	0.0%	_	3.8%	-	0.0%	3.770	-	_	3.4
CK_MB	0.070	1.570	0.070	30.370	0.070		3.370		0.070				٥.٠
NG/ML	96.9%	98.9%	100.0%	73.0%	90.3%	97.9%	84.7%	100.0%	100.0%	-	-	99.9%	96.
U/L	-	-	-	0.0%	-	-	-	-	-	-	~	-	0.0
OTHER	3.1%		-	2.0%	9.7%	2.1%	15.3%	-	-	100.0%	100.0%	0.1%	3.3
BLANK/MISSING	0.0%	1.1%	-	25.0%	-	-	-	-	-	-	-	-	0.0
Ratio CK-MB/CK				22 70/									4
% PERCENT	99.2%	100.0%	-	22.7% 0.1%	-	-	-	-	41.8%	-	-	-	41.
OTHER	JJ.470 -	-	-	35.1%	-	-	-	100.0%	41.8% 58.2%	-	-	100.0%	51.
BLANK/MISSING	0.8%	-	100.0%	42.0%	-	_	-	-		_	-	-	5.0
Creatinine													
MG/DL	100.0%	98.5%	100.0%	64.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	97.9%	100.0%	94.
OTHER	-	0.0%	-	0.0%	-	-	-	-	-	0.0%	2.1%	-	0.0
BLANK/MISSING	0.0%	1.5%	0.0%	35.7%	0.0%	-	-	-	0.0%	-	-	-	4.
Fibrin d-dimer													_
FEU	-	-	-	0.2%	-	-	-	0.1%	-	-	-	-	0.
MCG/ML MG/L	-	-	-	0.6% 1.6%	-	-	96.1%	1.8%	-	-	-	0.0%	0.
MG/ML	0.0%			1.6%	-		96.1%	1.8%	-	-	-	-	0.
NG/ML	99.2%	_	_	1.1%	_	98.7%	_	6.6%	100.0%	_	_	100.0%	75
NG/ML(FEU)	-	-	-		-	-	-	1.9%	-	-	-	-	0.
UG/ML(DDU)	-	-	-	-	-	-	-	89.5%	-	-	-	-	7.
OTHER	0.8%	-	100.0%	70.5%	-	1.3%	-	-	-	-	100.0%	-	10.
BLANK/MISSING	0.0%	-	-	25.9%	-	-	3.9%	-	0.0%	100.0%	-	-	5.3
Glucose, fasting													
MG/DL	100.0%	98.2%	100.0%	83.3%	100.0%	100.0%	99.9%	100.0%	100.0%	100.0%	99.8%	100.0%	99.
U/L OTHER	-	-	-	0.0%	-	-	0.0%	-	-	-	0.2%	-	0.0
BLANK/MISSING	0.0%	1.8%	0.0%	16.7%	0.0%		0.0%	-	-	-	0.2%	-	0.
Glucose, random	0.070	1.070	0.070	10.770	0.070		0.170						0.
MG/DL	100.0%	97.8%	100.0%	64.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	97.7%	100.0%	93
OTHER	-	0.0%	-	0.0%	-	-	0.0%	-	-	0.0%	2.3%	-	0.
BLANK/MISSING	0.0%	2.2%	0.0%	36.0%	0.0%	-	0.0%	-	0.0%	-	-	-	6.
Hemoglobin													
G/DL	100.0%	98.5%	0.5%	58.4%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	-	100.0%	68
GM/DL	-	-	99.5%	4.8%	-	-	- 0.00/	-	-	-	97.9%	-	27
MG/DL	- 0.00/	0.0%	-	0.0%	-	-	0.0%	-	-	0.06/	2 10/	-	0.
OTHER BLANK/MISSING	0.0%	0.0% 1.5%	0.0%	0.1% 36.6%	0.0%	-	0.0%			0.0%	2.1%	-	0. 3.
Glycosylated hemoglobin (HbA1c)	-	1.3%	0.0%	30.0%	0.0%	-	0.0%	-	-	-	-	-	3.
%	_	_	_	35.5%	-	_	-	_	-	_	97.5%	_	33
PERCENT	100.0%	86.9%	-	0.3%	100.0%	100.0%	100.0%	-	100.0%	100.0%	-	-	48
OTHER	-	12.9%	100.0%	28.6%	-	-	-	100.0%	-	-	2.5%	100.0%	12
BLANK/MISSING	-	0.2%	-	35.6%	0.0%	-	-	-	-	-	-	-	5.
International normalized ratio (INR)													
RATIO	-	0.0%	-	1.6%	-	-	-	-	100.0%	-	-	100.0%	44
THERAPEUTIC	5.0%	-	-	- 70/	-	-	-	-	-	-	-	-	0.
OTHER BLANK/MISSING	95.0%	100.0%	100.0%	0.7% 97.7%	100.0%	100.0%	100.0%	100.0%	-	100.0%	100.0%	-	0. 55
Lipase	95.0%	100.0%	100.0%	97.770	100.0%	100.0%	100.0%	100.0%	-	100.0%	100.0%	-	33
IU/L	-	_	_	4.8%	-	_	-	6.9%	1.9%	1.2%	6.0%	_	2.
MG/DL	-	-	-	-	-	-	0.0%	-	-	-	-	-	0.0
U/L	99.9%	97.1%	100.0%	57.2%	100.0%	100.0%	99.0%	93.1%	98.1%	96.3%	92.5%	100.0%	94.
OTHER	0.1%	-	-	1.8%	-	-	0.0%	-	-	2.6%	1.5%	-	0.
BLANK/MISSING	-	2.9%	0.0%	36.2%	-	-	0.9%	0.0%	-	-	-	-	2.
Platelet count													
K/UL	100.0%	80.3%	98.1%	7.7%	100.0%	-	-	-	100.0%	100.0%	100.00/	100.0%	57
OTHER DI ANK /MISSING	- 0.09/	18.5%	1.9%	54.9%	0.0%	100.0%	100.0%	100.0%	-	0.0%	100.0%	-	38
BLANK/MISSING Pregnancy	0.0%	1.2%	-	37.4%	0.0%	-	0.0%	-	-	-	-	-	3.
Pregnancy MIU/ML	65.9%	94.9%	100.0%	67.5%	79.9%	98.9%	85.8%	98.6%	99.9%	_	_	89.3%	51
OTHER	30.6%	0.5%	100.0%	10.9%	79.9% 20.1%	98.9% 1.1%	14.2%	1.4%	99.9%	-	100.0%	89.3% 10.7%	48
BLANK/MISSING	3.5%	4.6%	0.0%	21.6%	0.0%	1.176	0.0%	1.476	0.1%	-	-	-	1.
roponin I cardiac	3.370		0.070	21.070	0.070		0.070		0.170				1.
NG/ML	100.0%	94.8%	100.0%	93.9%	98.6%	100.0%	66.8%	96.4%	100.0%	100.0%		100.0%	98
OTHER	0.0%	-	-	0.1%	-	-	33.2%	3.6%	-	-	100.0%	-	1.
BLANK/MISSING	-	5.2%	0.0%	6.1%	1.4%	-	-	-	-	-	-	-	0.
Troponin T cardiac													
roponin T cardiac NG/ML OTHER	-	-	-	99.8%	100.0%	-	-	-	-	100.0%	- 100.0%	-	94 5.



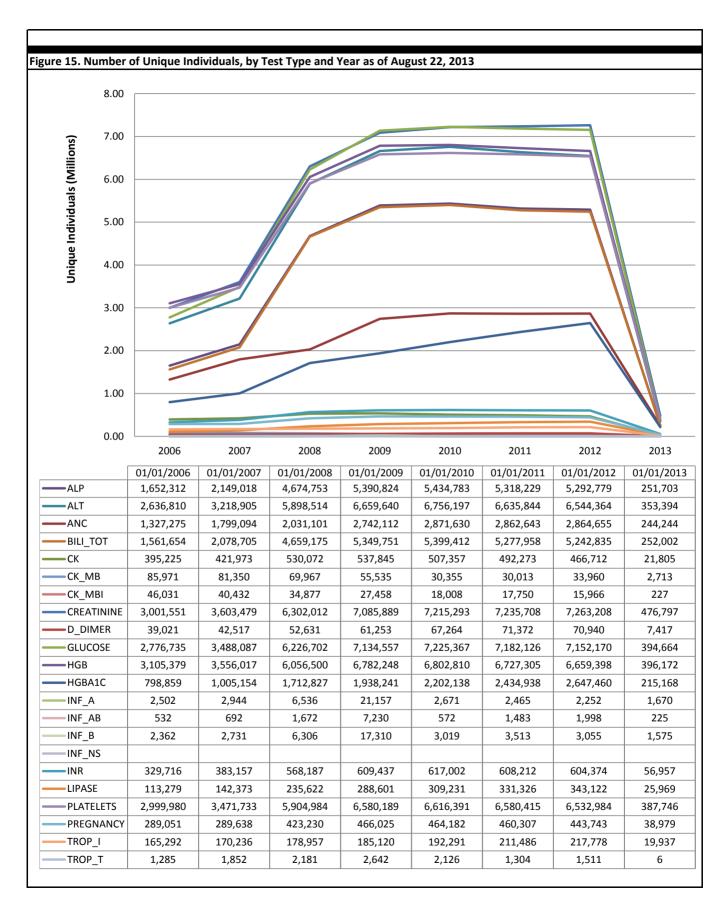




Table 8. Snapshot of the Mini-Sentinel Distributed Database Vitals Table as of August 22, 2013

# Number (%) of Individuals with at least one measurement by year

Year	Number of Measurements	Height - A	All	Height - Pedia	atrics*	Weight -	All	Weight - Ped	iatrics	Systolic Blood I	Pressure	Diastolic Blood	Pressure
2006	1	786,699	30.9%	179,409	47.3%	407,549	14.6%	130,071	22.5%	375,849	15.3%	375,852	15.3%
	2-3	1,003,904	39.4%	167,061	44.0%	1,110,564	39.8%	250,150	43.3%	924,174	37.6%	924,176	37.6%
	4+	755,045	29.7%	33,165	8.7%	1,275,602	45.7%	198,117	34.3%	1,155,708	47.1%	1,155,702	47.1%
	Total	2,545,648	100.0%	379,635	100.0%	2,793,715	100.0%	578,338	100.0%	2,455,731	100.0%	2,455,730	100.0%
2007	1	828,965	23.8%	192,053	37.7%	426,060	11.2%	132,834	17.6%	396,590	11.7%	396,588	11.7%
	2-3	1,343,715	38.5%	256,132	50.3%	1,395,766	36.8%	311,213	41.3%	1,183,762	35.0%	1,183,767	35.0%
	4+	1,316,037	37.7%	60,694	11.9%	1,970,836	52.0%	309,905	41.1%	1,801,224	53.3%	1,801,219	53.3%
	Total	3,488,717	100.0%	508,879	100.0%	3,792,662	100.0%	753,952	100.0%	3,381,576	100.0%	3,381,574	100.0%
2008	1	835,825	21.8%	193,781	33.2%	431,312	10.5%	130,250	16.1%	401,580	10.8%	401,580	10.8%
	2-3	1,427,826	37.2%	295,558	50.7%	1,406,075	34.2%	312,920	38.7%	1,203,987	32.4%	1,203,988	32.4%
	4+	1,572,487	41.0%	94,012	16.1%	2,275,104	55.3%	365,868	45.2%	2,106,242	56.7%	2,106,241	56.7%
	Total	3,836,138	100.0%	583,351	100.0%	4,112,491	100.0%	809,038	100.0%	3,711,809	100.0%	3,711,809	100.0%
2009	1	838,522	21.1%	187,511	29.1%	441,331	10.5%	125,299	15.2%	403,759	10.6%	403,758	10.6%
	2-3	1,488,291	37.4%	315,403	48.9%	1,411,652	33.6%	310,835	37.6%	1,223,802	32.1%	1,223,802	32.1%
	4+	1,652,482	41.5%	141,509	22.0%	2,345,886	55.9%	390,007	47.2%	2,182,513	57.3%	2,182,513	57.3%
	Total	3,979,295	100.0%	644,423	100.0%	4,198,869	100.0%	826,141	100.0%	3,810,074	100.0%	3,810,073	100.0%
2010	1	820,023	20.2%	173,939	25.1%	459,433	10.9%	126,812	15.6%	409,095	10.7%	409,094	10.7%
	2-3	1,540,057	38.0%	335,669	48.4%	1,430,793	34.1%	316,317	38.9%	1,247,114	32.5%	1,247,114	32.5%
	4+	1,697,293	41.8%	184,585	26.6%	2,308,065	55.0%	369,224	45.5%	2,178,810	56.8%	2,178,810	56.8%
	Total	4,057,373	100.0%	694,193	100.0%	4,198,291	100.0%	812,353	100.0%	3,835,019	100.0%	3,835,018	100.0%
2011	1	867,554	20.2%	171,628	23.1%	501,411	11.4%	127,536	15.2%	441,118	10.9%	441,124	10.9%
	2-3	1,648,140	38.4%	364,141	49.0%	1,506,819	34.3%	328,592	39.3%	1,333,376	32.9%	1,333,378	32.9%
	4+	1,773,567	41.3%	208,125	28.0%	2,389,128	54.3%	380,929	45.5%	2,272,684	56.2%	2,272,679	56.2%
	Total	4,289,261	100.0%	743,894	100.0%	4,397,358	100.0%	837,057	100.0%	4,047,178	100.0%	4,047,181	100.0%

<sup>\*</sup>The pediatric population is a subset of individuals aged <15 years of age