

Electronic pre-market safety reporting

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Disclaimer

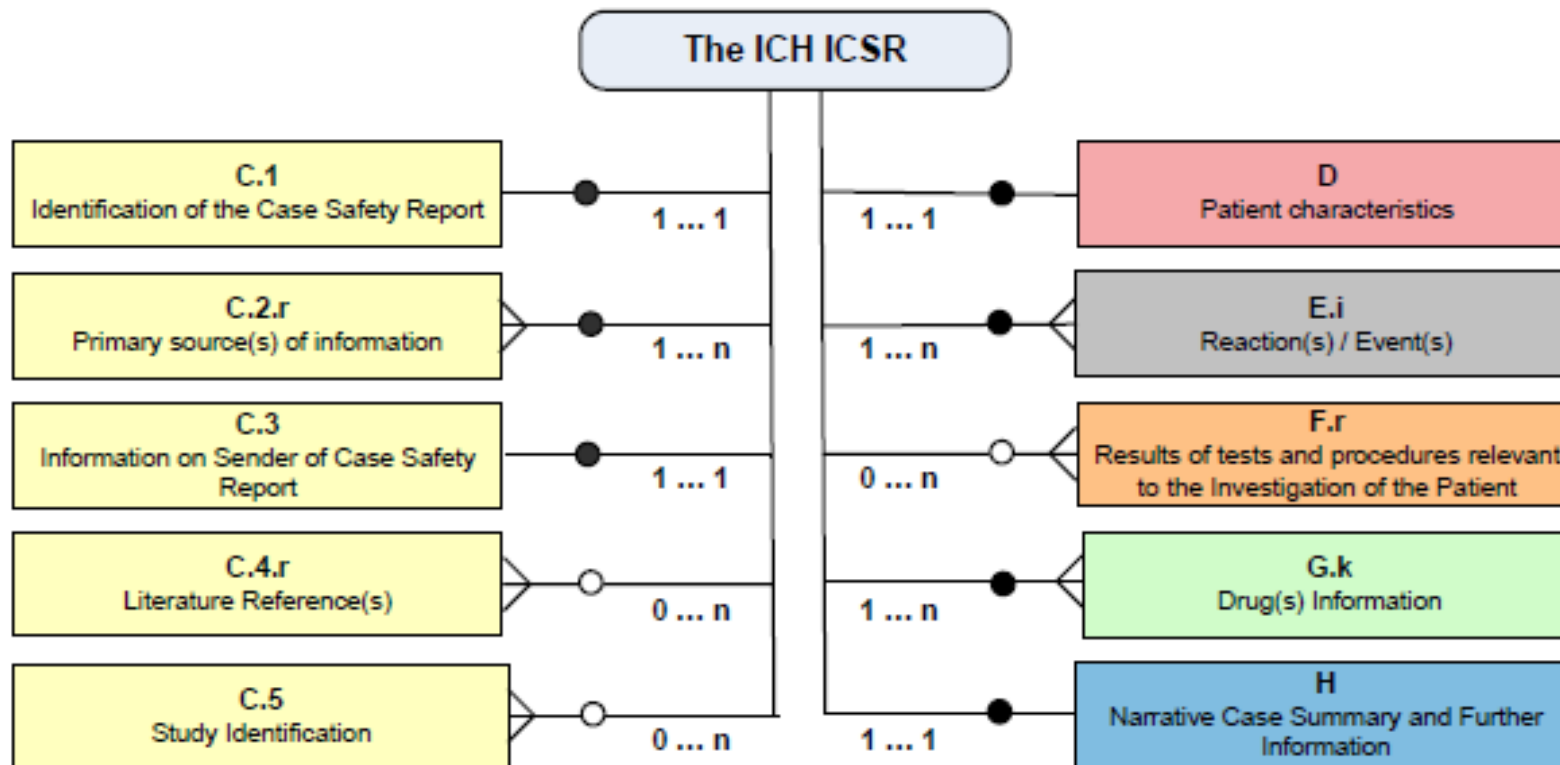
No one who knew anything about this project was available to present, so you are stuck with me.

Legal basis -- 21 CFR 312.32

- (c)(1) *IND safety reports*. The sponsor must notify FDA and all participating investigators ..., as soon as possible, but in no case later than 15 calendar days after the sponsor determines that the information In each IND safety report, the sponsor must identify all IND safety reports previously submitted to FDA concerning a similar suspected adverse reaction, and must analyze the significance of the suspected adverse reaction in light of previous, similar reports or any other relevant information.
- (i) *Serious and unexpected suspected adverse reaction*. The sponsor must report any suspected adverse reaction that is both serious and unexpected. The sponsor must report an adverse event as a suspected adverse reaction only if there is evidence to suggest a causal relationship between the drug and the adverse event, such as:
 - (A) A single occurrence of an event that is uncommon and known to be strongly associated with drug exposure (e.g., angioedema, hepatic injury, Stevens-Johnson Syndrome);
 - (B) One or more occurrences of an event that is not commonly associated with drug exposure, but is otherwise uncommon in the population exposed to the drug (e.g., tendon rupture);
 - (C) An aggregate analysis of specific events observed in a clinical trial (such as known consequences of the underlying disease or condition under investigation or other events that commonly occur in the study population independent of drug therapy) that indicates those events occur more frequently in the drug treatment group than in a concurrent or historical control group.
- ...
- (v) *Submission of IND safety reports*. The sponsor must submit each IND safety report in a narrative format or on FDA Form 3500A or in an electronic format that FDA can process, review, and archive.
- ...
- (2) *Unexpected fatal or life-threatening suspected adverse reaction reports*. The sponsor must also notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor's initial receipt of the information.

Guidance – ICH E2B Data elements for individual case reports (1/2)

- Complete XML messaging standard (HL7v3)



Guidance – ICH E2B Data elements for individual case reports (2/2)

- Terminology standards
 - Medical products/dosing
 - MedDRA
 - History
 - Indication
 - Adverse event
 - Tests
 - Diagnoses

ICH E2B data map to FDA Form 3500A...

Reset Form

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (10/15)

For use by user-facilities,
importers, distributors and manufacturers
for MANDATORY reporting

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Form Approved: OMB No. 0910-0291. Expires: 9/30/2018
See PRA statement on reverse.

Mfr Report #
UF/Importer Report #
FDA Use Only

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier	2. Age <input type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Days(s)	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight <input type="checkbox"/> lb <input type="checkbox"/> kg
or Date of Birth (e.g., 08 Feb 1925)			
In Confidence			
5.a. Ethnicity (Check single best answer) <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino	5.b. Race (Check all that apply) <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander		

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)

2. Outcome Attributed to Adverse Event (Check all that apply)

Death Include date (dd-mmm-yyyy): _____

Life-threatening Disability or Permanent Damage

Hospitalization – initial or prolonged Congenital Anomaly/Birth Defects

Other Serious (Important Medical Events)

Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (dd-mmm-yyyy) _____

4. Date of this Report (dd-mmm-yyyy) _____

5. Describe Event or Problem

3. Dose Frequency Route Used

#1			
#2			

4. Therapy Dates (If unknown, give duration) from/ to (or best estimate) (dd-mmm-yyyy)

#1 _____

#2 _____

5. Diagnosis for Use (Indication)

#1 _____

#2 _____

6. Is the Product Compounded?

#1 Yes No

#2 Yes No

7. Is the Product Over-the-Counter?

#1 Yes No

#2 Yes No

8. Expiration Date (dd-mmm-yyyy)

#1 _____ #2 _____

9. Event Abated After Use Stopped or Dose Reduced?

#1 Yes No Doesn't apply

#2 Yes No Doesn't apply

10. Event Reappeared After Reintroduction?

#1 Yes No Doesn't apply

#2 Yes No Doesn't apply

D. SUSPECT MEDICAL DEVICE

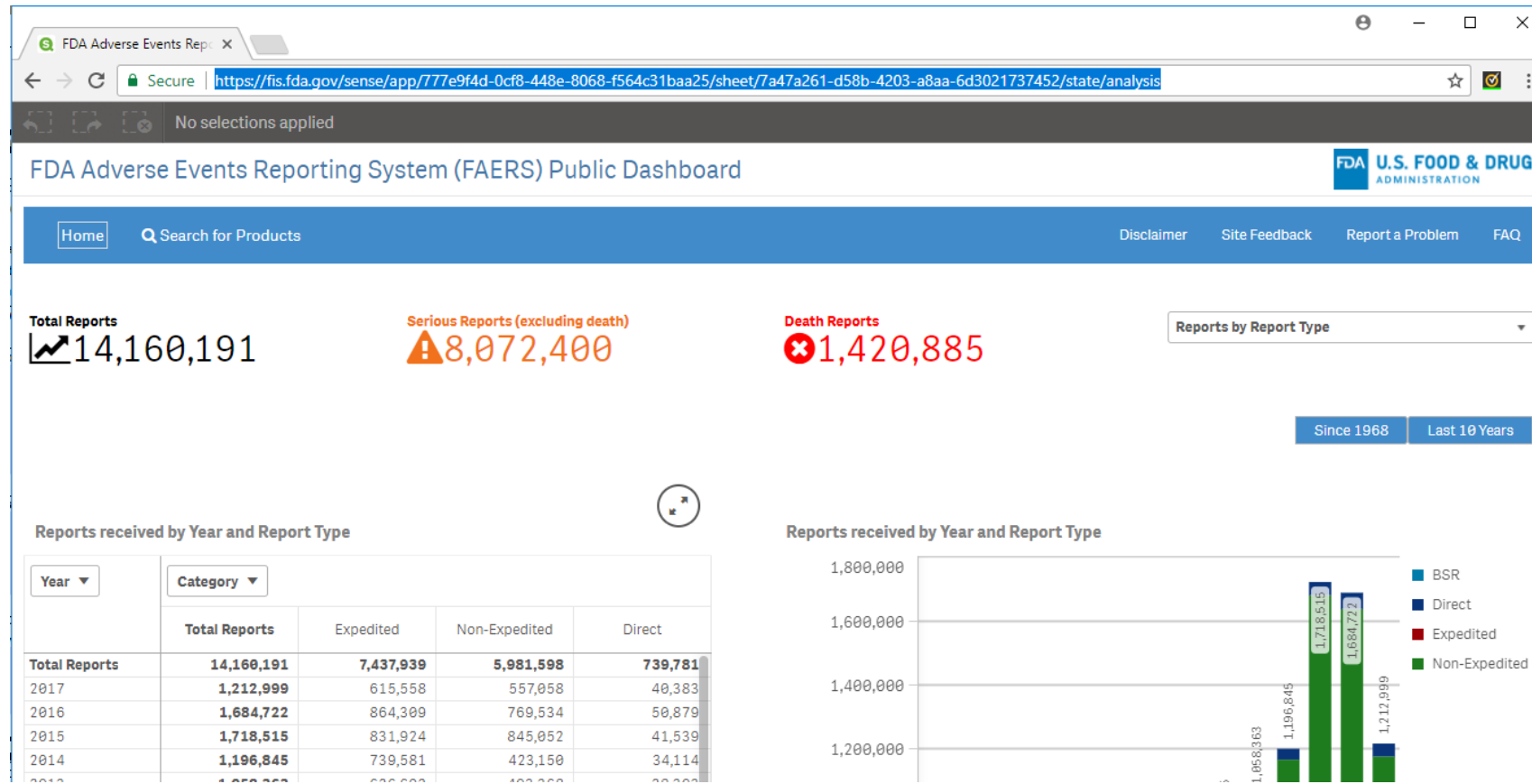
1. Brand Name

2. Common Device Name 2b. Procode

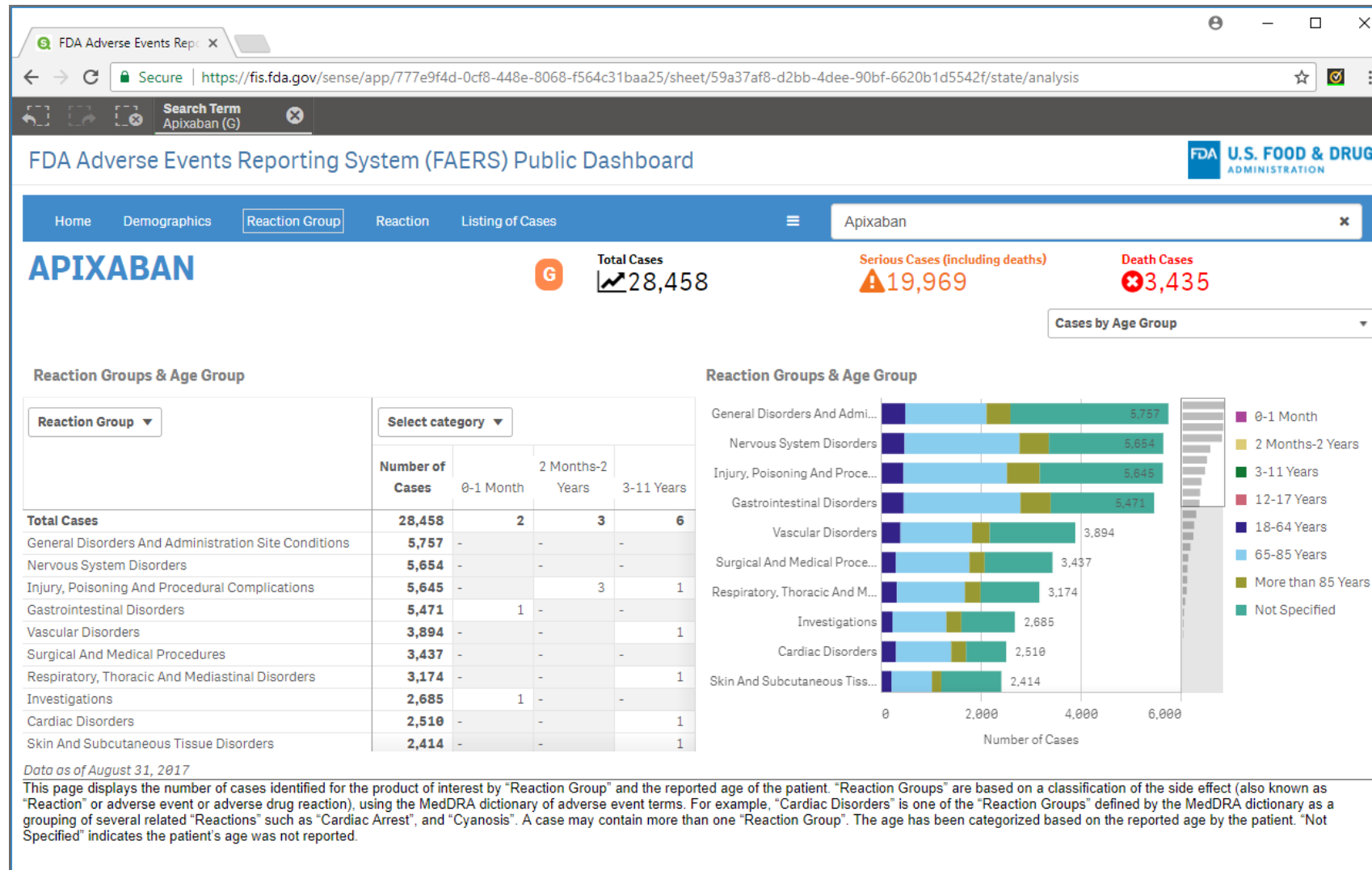
3. Manufacturer Name, City and State

JSE BLACK INK

...and can be transmitted through the ESG to FAERS



FAERS tools supports surveillance activities



Summary

- Project was joint effort of OHOP and OSE
- Piloted (2016) by Merck, AZ, Novartis, & Genentech
- Uses a different instance of FAERS from the post-marketing database
- Allows same set of reviewer tools to be used for pre- and post-marketing surveillance work
- Potentially could be set up to permit access by FDA and the investigators of a particular development program