

## Improving Drug Safety: We Can Do This Now

A Real-World Application of the Retrieve Form  
for Data Capture Profile in an Ambulatory Care  
Electronic Health Record Setting

HIMSS09 Interoperability Showcase Theater Presentation  
Michael A. Ibara, Pharm. D.  
Pfizer, Inc.

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16 YEARS

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The current ...FDA...system of regulating drug safety has serious limitations and is in need of changes. The major problems include...*massive underreporting of adverse events* to the FDA postmarketing surveillance system reduces the ability to quantify risk accurately...



The FDA and drug safety: a proposal for sweeping changes.  
Furberg CD, Levin AA, Gross PA, Shapiro RS, Strom BL.  
Arch Intern Med 2006 Oct 9; 166(18):1983-42

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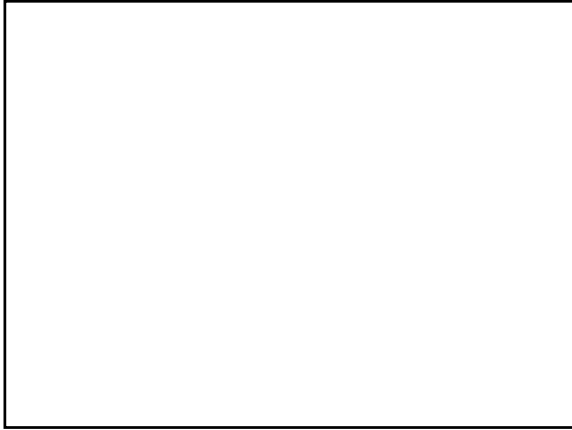
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When a drug goes to market, we know everything about its safety.

Wrong.

1-800-FDA-1088.

**FDA MEDWATCH**  
If it's serious, we need to know.



MEDWATCH		ADVICE ABOUT VOLUNTARY REPORTING	
<p>Department of Health and Human Services Food and Drug Administration - MedWatch 10903 New Hampshire Avenue Building 22, Mail Stop 4447 Silver Spring, MD 20993-0092</p>		<p><b>U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> Food and Drug Administration</p>	
<p>The public reporting burden for this collection of information has been estimated to average 36 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p>		<p><b>OMB statement:</b> "In agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."</p>	
<p>Department of Health and Human Services Food and Drug Administration - MedWatch 10903 New Hampshire Avenue Building 22, Mail Stop 4447 Silver Spring, MD 20993-0092</p>		<p><b>BUSINESS REPLY MAIL</b></p>	





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- Not part of normal routine
- Not available at point of recognition
- Duplicate data entry
- High nuisance factor

Reporting adverse events interrupts the routine of providing care and imposes a burden on providers – greatly decreasing the probability that events will be reported




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**Our old business model**

- ...36 minutes per response - **under a minute**
- ...time for reviewing instructions - **no instructions needed**
- ...searching existing data sources - **no searching required**
- ...gathering and maintaining the data needed - **transparent**
- ...completing and reviewing the information - **minimal interaction**

**We need business models that will take advantage of big data in healthcare data**

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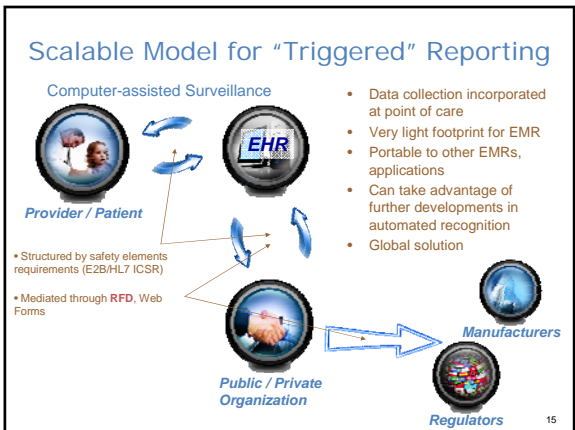
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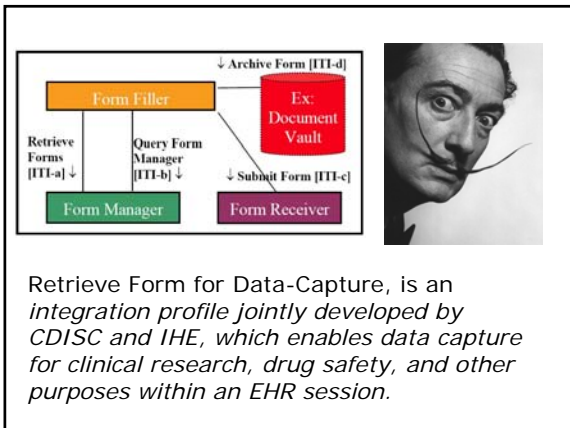
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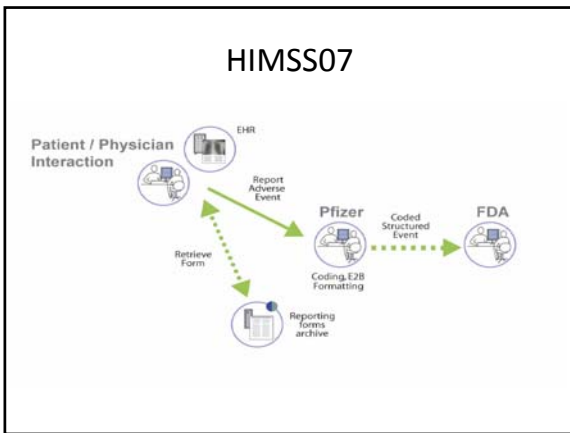
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**\*ASTER started Nov 2008**  
**30 Ambulatory care physicians**  
**Will complete June 2009**  
**> 150 Reports Sent to FDA**

David Westfall Bates, MD, M.Sc.  
 Chief of the Division of General Internal Medicine at the Brigham and Women's Hospital; Professor of Medicine at Harvard Medical School and Professor of Health Policy and Management at the Harvard School of Public Health (Co-Director of the Program in Clinical Effectiveness)

Jeffrey A. Linder, MD, MPH, FACP - PI of \*ASTER  
 Assistant Professor of Medicine, Harvard Medical School  
 Division of General Medicine and Primary Care, Brigham and Women's Hospital, Boston MA

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Friday, January 2, 2009 As of 12:00 PM GMT

**THE WALL STREET JOURNAL | HEALTH**

U.S. Edition | Today's Paper | Video | Columns | Blogs | Graphics | Journal Community

*Boston Hospitals to Use Electronic Records to Encourage Doctor Reporting*

Article | Comments (3)

Martin P. Solomon, another Brigham and Women's internist, said he had submitted only a half dozen reports in 32 years of seeing patients because the reports took so long to fill out and send. Since the study began Dec. 9, Dr. Solomon estimates he has filed at least a dozen.

Now when Dr. Solomon notes in a patient's computerized chart that he has dropped a drug because of a side effect, a window pops up on his computer asking for the severity of the reaction and a few additional details. Then he clicks a submit button.

The process takes Dr. Solomon 30 seconds at most. "It's a blink," he said.

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## The Postmarketing Reporting System

- Patients
- Providers
- Hospitals
- Regional Organizations
- Payers
- Point of Care Applications
- Data Collection and Storage Technologies
- Communications Technologies
- Pharmaceutical Companies
- FDA
- EMEA
- Other Regulators Worldwide

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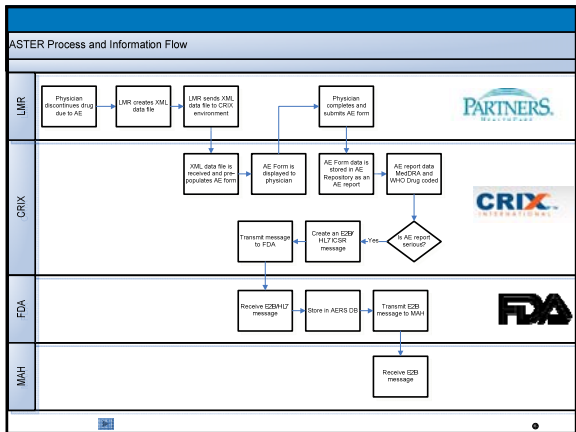
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## Output

- ASTER's output is formatted in ICH/E2B xml
- Output is also converted to MedWatch .pdf file
- E.g. [XML file](#)
- E.g. [MedWatch file](#)

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## RESULTS TO DATE

...Physician interaction – "a blink (60 secs)"  
...time for reviewing instructions - **no instructions needed**  
...searching existing data sources - **no searching required**  
...gathering and maintaining the data needed - **transparent**  
...completing and reviewing the information - **minimal interaction**

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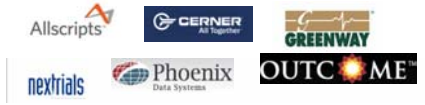
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Please see the showcase to see a demonstration of how RFD facilitates rapid and accurate adverse event reporting from EHRs



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