
Pharmacy-based Postmarketing Safety Surveillance Network

March 7, 2007

Sentinel Network To Promote Medical Product Safety; FDA Public Meeting

Benjamin Bluml, RPh, VP Research, American Pharmacists Association Foundation

Jonathan Seltzer, MD, MBA, MA, FACC, President Applied Clinical Intelligence

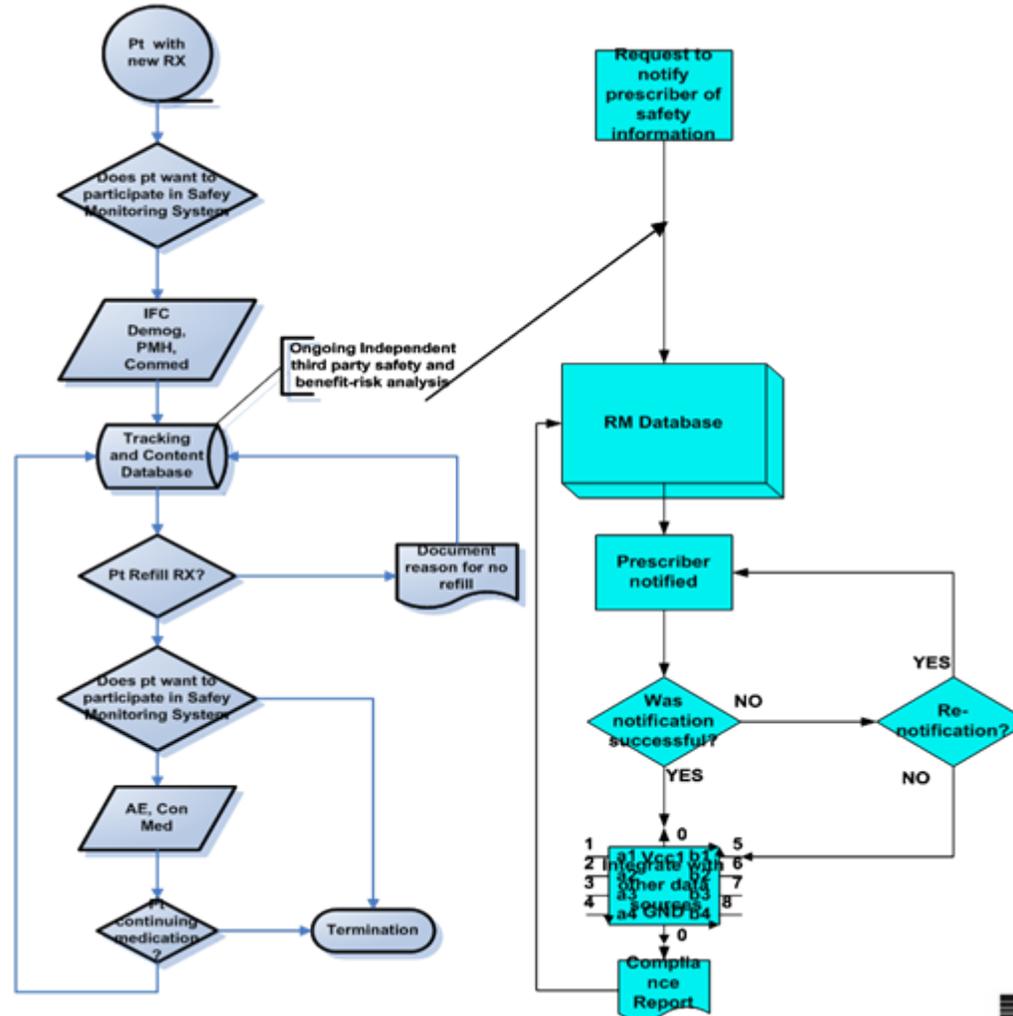
Pharmacy-based Postmarketing Safety Surveillance Network

- A clinical trial network dedicated to rapid provision and trusted communication of postmarketing rate-based drug safety information

Pharmacy-based Postmarketing Safety Surveillance Network

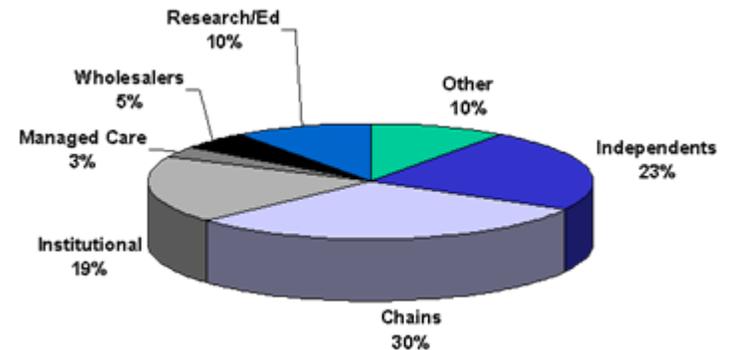
- A systems-based approach to improve proper medication use by providing
 - **Rapid acquisition of metric-based safety information**
 - 21CFR11 compliant, Standards based (CDISC data)
 - Targeted patient populations
 - **Transparency**
 - Contact with Pharmacist
 - Easily Understandable
 - **Continuous Improvement**
 - Real time third-party analysis with rapid adjudication
 - Flexible data collection allows for measurement of intervention
 - **Connectivity**
 - Physician Collaboration
 - Database Collaboration

Safety-Surveillance Research Process Model



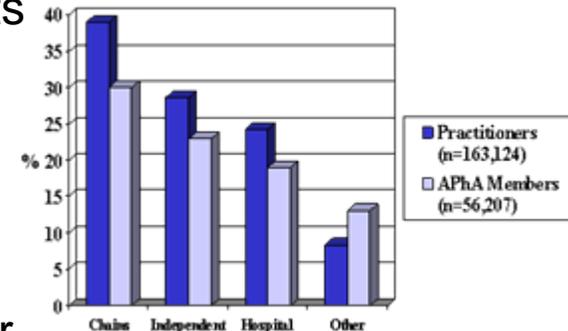
Pharmacy-based Postmarketing Safety Surveillance Network

- Features
 - Central IRB
 - Centralized Training through APhA Foundation
 - Site Selection through APhA
 - Pt Recruitment locally
 - Simple Standard Data Collection
 - Third Party Expert Analysis
 - Economically Viable
 - Real Time Reporting



Pharmacy-based Post marketing Safety Surveillance Network

- American Pharmacists Association (APhA)
 - Approximately 60,000 members
 - APhA Foundation Activities
 - National Demonstration Projects
 - Public Education
 - Quality Improvement
 - Research
- Applied Clinical Intelligence
 - CDISC Registered Service Provider
 - Activities
 - Data Monitoring Committees
 - GCP level Data Collection and Biometrics
 - Collaborative and Analytic technology solutions



Pharmacy-based Postmarketing Safety Surveillance Network

- ACI and APhA have been developing program for over 3 years
- Proven track record of high quality community pharmacist research and intervention
- Over 200 qualified research sites have participated
- Electronically linked network technologies









Collaboration and Communication

Home Documents and Lists Create Site Settings Help Up to ACI ClinicalSafety.net



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	Case Report Form	1/23/2007 8:16 PM	Mark Williams	
	Protocol	1/23/2007 8:16 PM	Mark Williams	
	Regulatory Documents	1/23/2007 8:17 PM	Mark Williams	
	Training Materials	1/23/2007 8:18 PM	Mark Williams	

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Title	Location	Begin	End
Good Clinical Practice Training		1/23/2007 12:00 AM	9/15/2008 12:00 AM
Pharmacy Investigator Training	On-line training	2/1/2007 12:00 AM	1/1/2008 1:00 AM

Links

- [APhA Foundation](#)
- [MedWatch Instructions](#)
- [Data Safety Monitoring Board](#)
- [Safety Analysis Site](#)

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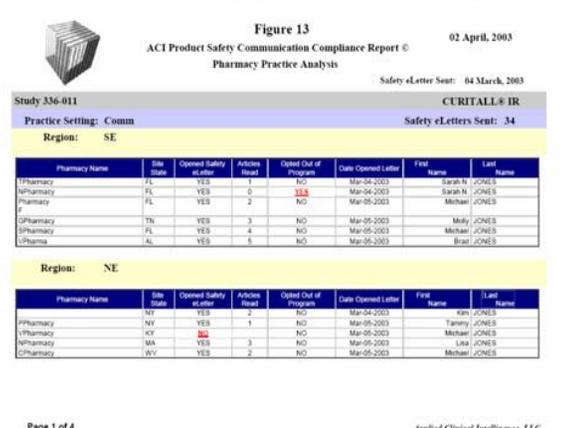
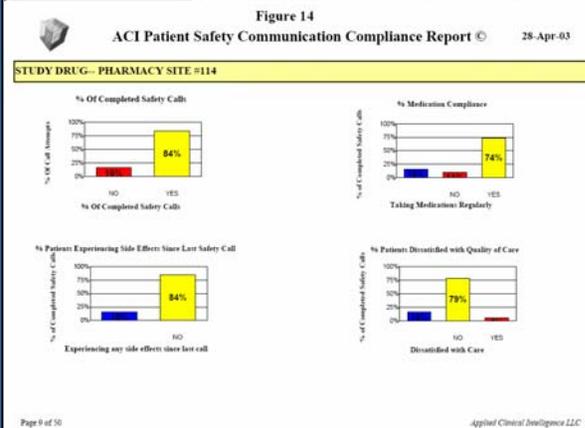
Last Name	First Name	Business Phone	E-mail Address
Bluml	Benjamin	(816) 969-7071	BBluml@AphAnet.org
Ellis	William	(202) 429-7565	wellis@aphanet.org
Seltzer	Jonathan	484-429-7200 ext 11	jseltzer@a-ci.com

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Tasks

Title	Assigned To
Please Fax All Data by February 15th	Mark Williams

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Safety View™_{by}



Project List Project Overview

Welcome back **Jon Seltzer** Logout

STUDY: POSIT-1 - Laboratory Data

Adverse Events
% Subjects with AEs

0 0 0 1
Subjects with Serious AEs

ECG Analysis
% Subjects with any ECG PCS

0 1 2 7
Subjects with Post Dose ECG Data

Laboratory Data
% Subjects with PCSAs

Subjects with Post Dose Lab Samples 0 0 9 0

Study Progress
% Enrolment

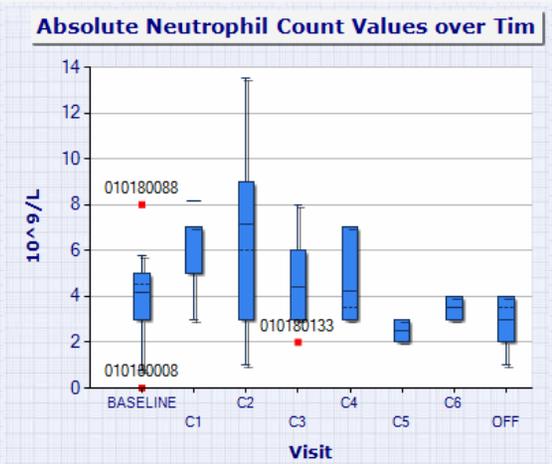
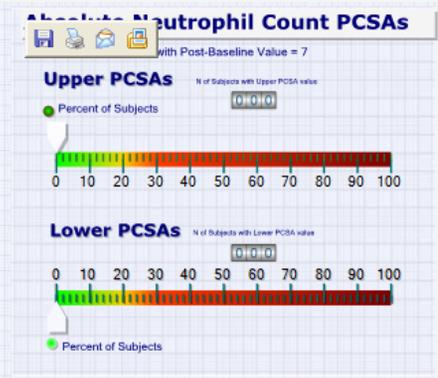
Centers 0 0 5
Subjects 0 0 5 4

Laboratory Data Laboratory Test

Site: All MOK4

Treatment Group: All Active Agent Control Agent

- Absolute Neutrophil
- Alanine Transam
- Albumin
- Alkaline Phosphat
- Aspartate Transam
- Basophils
- Bicarbonate
- Calcium
- Chloride
- Creatinine
- Creatinine Clearan
- Eosinophils
- Glucose
- Hematocrit
- Hemoglobin
- LDH
- Lymphocytes
- Monocytes
- Neutrophils



Questions



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