

SUMMARY AND DETAILS REPORTS WEB-BASED APPLICATION ENABLES COLLABORATIVE RESULTS CON  
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# PVPLAN

**PVPLAN is a part of United BioSource Corporation's safety and risk management product and services suite.**

To learn more visit [www.unitedbiosource.com](http://www.unitedbiosource.com).

## **PVPLAN Benefits:**

- » Document Safety Concerns and Associated actions throughout the product lifecycle, with an easy-to-use, web-based platform.
- » Develop and maintain a Pharmacovigilance Plan consistent with EMEA Risk Management Plan (EU-RMP) template.
- » Share information and manage pharmacovigilance actions among diverse and/or geographically distributed teams.
- » Easily track decisions, actions, follow-up and next steps, and maintain an ongoing audit trail.

## **United BioSource Corporation**

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Develop and Manage a Pharmacovigilance Plan

» Track and Manage Safety Concerns in Accordance with EMEA Guidance on Risk Management

From United Biosource Corporation

**Web-based Application** enables information sharing among graphically-dispersed teams across the product development lifecycle

**Comprehensive coverage for all Safety Concerns** (identified by clinical studies, literature review, routine pharmacovigilance, data mining, epidemiology study, etc.)

**Summary and detail reports** provide transparency into the pharmacovigilance process

**Option to integrate the results** of quantitative signal detection into the pharmacovigilance plan

**Flexible role-based functionality** supports pharmacovigilance workflow:

- >> Describe Safety Concerns
- >> Manage Actions and Milestones
- >> Document Ongoing Protocols and Studies
- >> Document Related Evidence

**Available as a hosted application or installed on client's intranet**

>> **COLLABORATIVE** RESULT  
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>> **Manage Actions and Milestones**

**PV Plan : Manage Safety Concern Action Details**  
**Project:** Pergolide  
**Safety Concern:** Cardiac Valve Disorders

Safety Concern Action Details		<a href="#">Edit</a>
<b>Action Name</b>	Epidemiology Study	
<b>Action Due Date</b>	12/1/2008	
<b>Actual Completion Date</b>		
<b>Status</b>	In Progress	
<b>Assigned</b>	S. Reisinger	
<b>Action Objective</b>	Study the incidence of this event in an exposed population using a large, observational database.	
<b>Date Last Modified:</b>	6/12/2008	<b>User:</b> Steph Reisinger
<b>Action Rationale</b>	Spontaneous data is hard to interpret. Need to study incidence of this event.	
<b>Date Last Modified:</b>	6/12/2008	<b>User:</b> Steph Reisinger
<b>Results</b>		
<b>Date Last Modified:</b>		<b>User:</b>
<b>Further Measures</b>		
<b>Date Last Modified:</b>		<b>User:</b>

**Action Milestones (New)**

Due Date	Milestone	Status	Assigned	Actual Completion Date
12/1/2008 12:00:00 AM	<a href="#">Study Report Available</a>	Not Started	K. David	
11/1/2008 12:00:00 AM	<a href="#">Perform Study</a>	Not Started	K. David	
8/30/2008 12:00:00 AM	<a href="#">Protocol Development</a>	Not Started	K. David	
8/1/2008 12:00:00 AM	<a href="#">Data Use Agreement</a>	In Progress	F. Rivera	