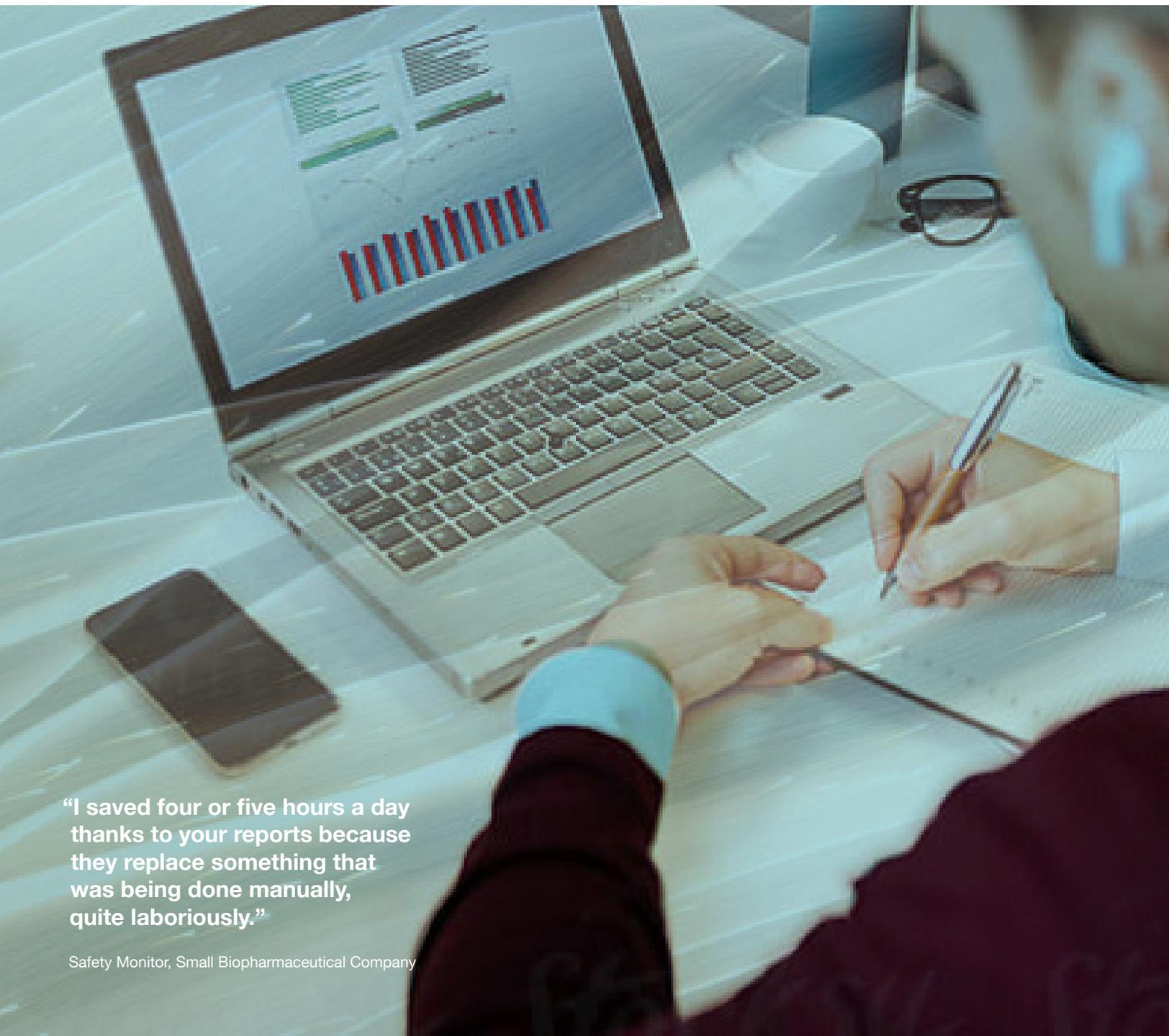

Safety System

An innovative, modular safety system that makes safety and risk management easy, compliant, and affordable for any life sciences company.



“I saved four or five hours a day thanks to your reports because they replace something that was being done manually, quite laboriously.”

Safety Monitor, Small Biopharmaceutical Company

Speed up the detection, analysis, and reporting of safety events for your study or program

Prevail's Safety Management System provides a validated safety database that automatically reconciles safety events with the clinical database.

With the Prevail Safety System you can:

- Track adverse events from any place in the world
- Reduce manual effort and risk with fields that auto-populate straight from the clinical database
- Analyze safety in context across multiple study visits
- View concomitant medications' impact on lab results or AEs without having to leave a single page

3 Reasons to Choose the Prevail Safety System

1. Reduce Case Intake and Processing Time By 50% Or More

Automated workflows populate fields directly from your clinical database and safety events, with the latest versions of MedWatch or CIOMs forms and Dear Investigator Letters ready to be sent out sooner and with a higher degree of accuracy.

2. Identify and analyze safety and risk signals sooner

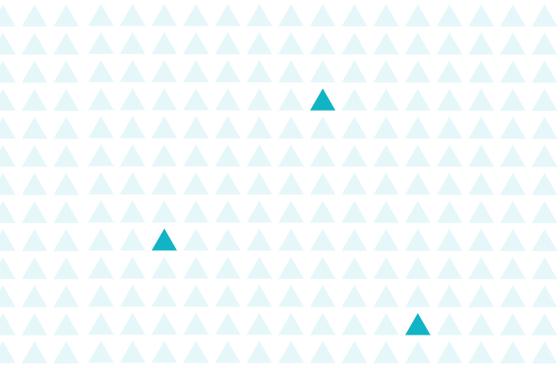
Prevail's unique Signal Detection & Risk Management module aggregates safety and efficacy datasets from your systems and third-party sources into one reporting engine – letting your team and key business stakeholders quickly and easily spot correlative trends that may impact mean outcome measures if not understood early enough.

3. Achieve global compliance with less effort and cost

The Prevail Safety System provides a single global database that can encompass a study or entire program, preventing expensive reconciliation of multiple databases. It also supports rapid case processing and aggregate / expedited reporting via E2B (R3), E2B(R2), and other leading standards. Pre-built connectors with clinical systems get you up and running quickly and at a lower cost than other safety systems.



Source and system-agnostic, Prevail's safety system easily aggregates and analyzes data from any system and source, including EDC, CTMS, labs, imaging, ECG, IRT, ePRO, accounting, and more.



Prevail Safety System: Key Features & Benefits

Improve Compliance While Reducing Risk

The Prevail Safety System offers everything you need to manage the intake, analysis, reporting, and reconciliation of adverse events and serious adverse events for your study or program, quickly and accurately in the cloud. In addition, Prevail offers unique signal detection and risk management functionality – available with the core Prevail Safety System or as a standalone module – to identify and assess patient and study risk earlier.

Enhance Patient Safety and Compliance

Maintaining a validated safety database across multiple phases or studies is crucial to identifying and proactively managing any safety issues that may arise. The Prevail Safety System includes a safety database built into the Prevail trial platform, or take advantage of Prevail’s pre-built connectors with all leading clinical trial systems. Prevail automatically reconciles safety events with the clinical database and allows for tracking of events from any place in the world.

Reduce Case Intake and Processing Time By 50% Or More

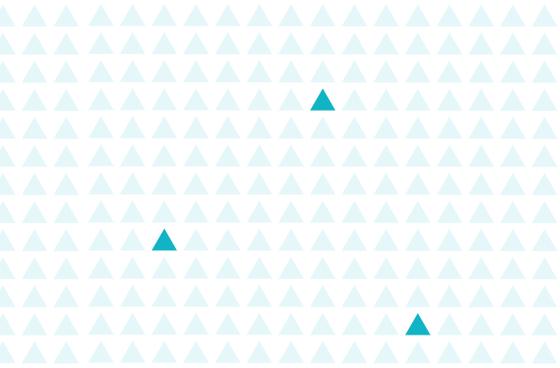
The Prevail Safety System includes automated workflows to save time and effort while reducing errors that can lead to compliance issues. Instead of having team members type in the appropriate forms whenever an event occurs, the system auto-populates fields straight from the clinical

database, thus reducing the chance of human error. The latest versions of MedWatch or CIOMs forms and Dear Investigator Letters are therefore ready to be sent out much sooner and with a higher degree of accuracy.

Prevail’s robust yet easy-to-use software also dramatically reduces the labor-intensive process of reconciling and correcting mismatches between two separate databases by auto-populating fields and providing built-in mismatch reports.

Prevail’s Safety System is a user-friendly, robust and powerful tool for tracking, managing and reporting Adverse Events and Serious Adverse Events.

Expedited	Case Number	Description	Patient ID	Report Date	Status	CRF	Follow Up	MedWatch	CIOMS
	SAP-ABC-XYZ-1234-10029-V	Fever	03	13 May 2023	View Details		Follow Up		
	SAP-ABC-XYZ-1234-10030-V	Cold	015890	11-Jan-2021	View Details		Follow Up		
	SAP-ABC-XYZ-1234-10031-V	Cold	015890	02-Feb-2021	View Details		Follow Up		
	SAP-ABC-XYZ-1234-10032-V	Brain Injury	000003	05-Jan-2021	View Details		Follow Up		
	SAP-ABC-XYZ-1234-10033-V		0874563	02-Nov-2020	View Details		Follow Up		
	SAP-ABC-XYZ-1234-10034-V	SAR event	0840435	09-Oct-2020	View Details		Follow Up		
	SAP-ABC-XYZ-1234-10035-V	Fever	000006	20-Sep-2020	View Details		Follow Up		



Identify Safety Signals and Risk Factors Earlier in Your Studies

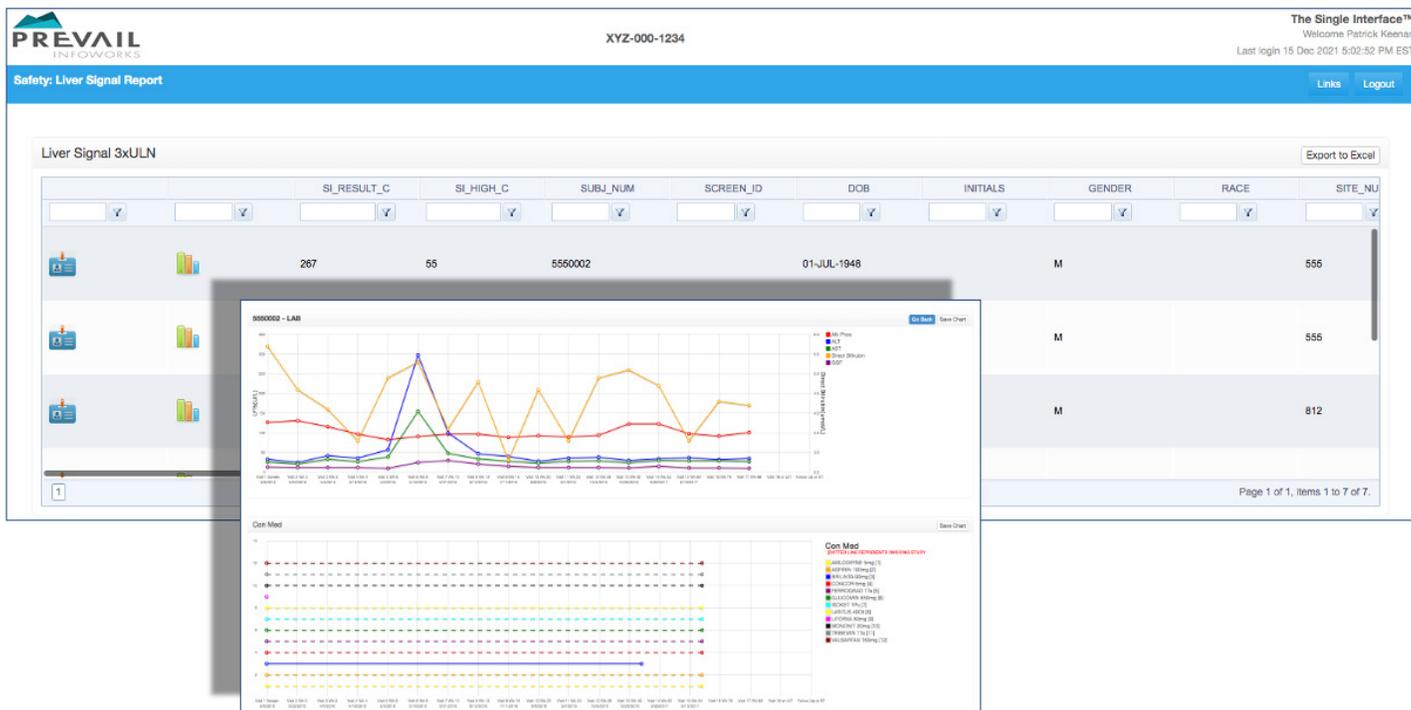
With the Prevail Safety System's integrated Signal Detection & Risk Management module, medical monitors and safety specialists can easily review detailed subject safety data through comprehensive reports and analytics. Upon receipt of a safety event, the module also enables instantaneous alerts to all required users without requiring human action.

Complex analytics provide context to safety events and enable fast interpretation of safety labs, ECGs, diagnostics, concomitant medications and other CRF data. Analyze S/AEs in context and track them across multiple study visits, review the impact of concomitant medications on lab results or AEs in a single unified view, and much more.

Users can instantly see across multiple studies to gain a broader understanding of safety issues and relationships with factors such as different dose levels, patient populations, geographies, concomitant medications, and more.

Fast Time-to-Value

Thanks to more than 100 pre-built connectors to commonly used vendor systems, you can start seeing the benefits of Prevail technology in as little as two weeks for simpler studies, and in six weeks or less for even the most complex protocols. Our innovative SaaS technology fully automates the data extraction process from any existing internal system, as well as external ones provided by CROs and other service providers - independent of whether a system supports APIs or SFTPs, and in any format.





RISE
ABOVE

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About Prevail InfoWorks

Prevail is a pioneering life sciences software company with a unique combination of clinical expertise and engineering prowess, delivered through a best-in-class, modular eClinical ecosystem with sophisticated analytics and visualizations and supported by Prevail domain experts.

Our innovative and patented technology quickly and easily integrates, normalizes, reconciles, and presents aggregated data, analysis, trends, and metrics encompassing all study-related data sources through a single interface - making clinical development faster and easier, while reducing trial risk. With Prevail, trial sponsors can obtain unmatched, real-time answers to virtually any clinical, operational, and financial question regarding a study or program.