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# Prevail InfoWorks Corporate Overview



RISE  
ABOVE

Prevail helps life sciences companies achieve better clinical trial outcomes through groundbreaking yet affordable smart technologies, domain intelligence, and expert services that illuminate and improve every aspect of your trial.

A photograph of a woman with blonde hair, wearing a light blue button-down shirt and a gold watch, smiling while looking at a laptop screen. She is holding a red pen in her right hand. Another person is partially visible on the left side of the frame.

**“Using Prevail, it’s a methodology for understanding your data better. We all see data but we rarely understand what it really means. We actually shortened our development cycle because of this.”**

Aurinia Pharmaceuticals

## The Industry's Only Unconditional Satisfaction Guarantee

All of Prevail's products and services are backed by an unconditional, 100% satisfaction guarantee included in every contract. Will your vendor do the same?

### HEAR WHAT OTHERS ARE SAYING

"The Single Interface is awesome - it's a gift that keeps on giving"

- Public Biotech CMO

"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

"Tremendously Impressive"

- Head of Biometrics

"The communication has been tremendous, a breath of fresh air to work with a company that even if you don't know the answer on the spot, you tell us you will work it out and get back to you"

- CMO, BioPharma Company

"Has everything we need and less expensive than the alternative"

- Public Biotech

"You have better signal-to-noise ratio. You get rid of the garbage. You have a better understanding of what the drug does in that indication. That actually helps the FDA and helps them understand what the risk to benefit ratio is [of the drug]"

- Public Biotech

"We made the right choice"

- Head of ClinDev, Med. Device Company

"Using Prevail, it's a no-brainer"

-VP, Clinical Affairs

## How We Help Our Customers Rise Above

### A Case History

Biotech was first to obtain FDA approval in a critical therapeutic area where dozens of other companies had failed. The company credits Prevail with:

#### Avoided Clinical Hold

### \$9 Million Savings\*

Company used Visual Patient Profile and other analytics to immediately convince FDA that SAEs not clinically related.

*\* FDA and Gartner*

#### Phase 2 = Pivotal

### \$50 Million Savings\*

Based on quality and tightness of the data, FDA accepted Phase 2 study as a pivotal and only required one phase 3 study for NDA submission.

*\* US Department of Health and Human Services: Company SEC filings*

### Successful NDA for Breakthrough Therapy

## FDA Approval Following Priority Review

Biotech: "Prevail played such a critical role in helping us successfully implement a challenging protocol and achieve our study endpoints. You and your team deserve a lot of credit for this approval. Thank you."

### New Drug Indication

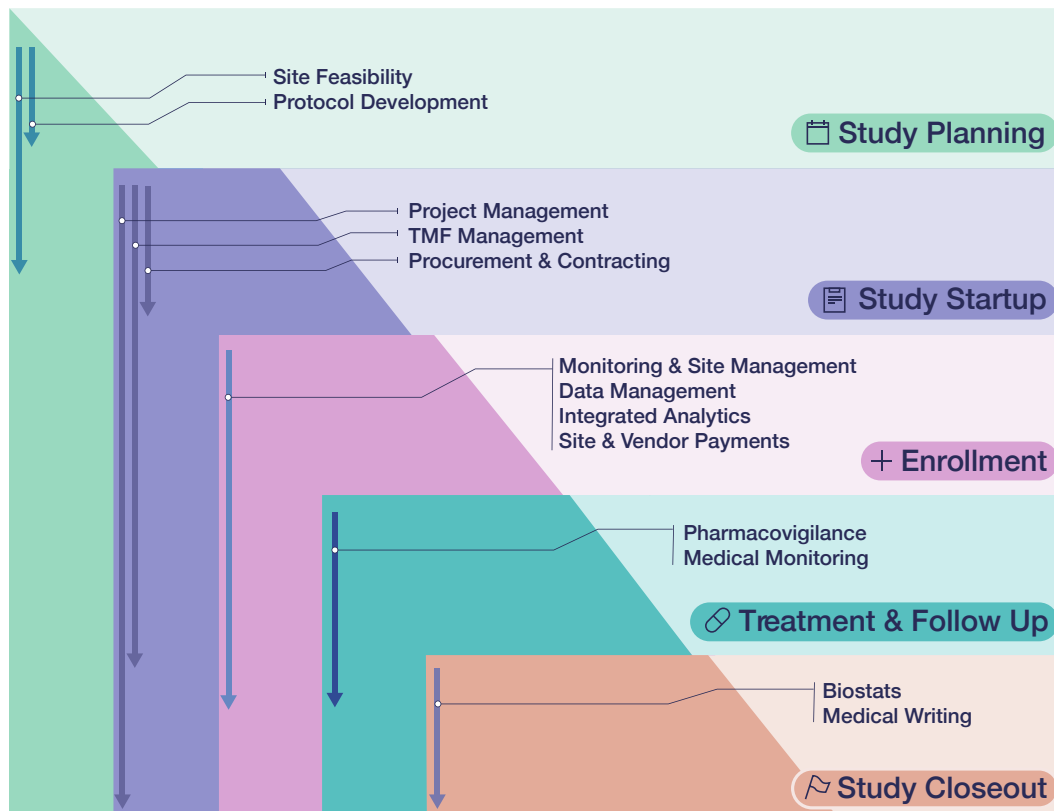
## \$\$\$\$\$\$\$\$\$

By eliminating noise and identifying a signal in the data, were able to substantiate a new indication for the drug **during the study**.

### Prevail InfoWorks At A Glance

- 17 U.S Patents (296 innovations)
- Integrate data from ANY system, in ANY format, at ANY time
- 15+ years, 400 clinical trials (Phase I - IV) across drug, medical device, and diagnostics
- Key support for 7 FDA investigational product approvals
- 6 continents / 1000s of users
- Highly experienced teams for Project Management, Monitoring, Quality Assurance, Regulatory, Data Management/Data Science, Software/DB Development, Integrations
- 21 CFR Part 11, GCP, ICH, GDPR compliant (passed multiple audits including FDA audit)
- SOC 3 Type II, ISO/IEC 27001:2013 compliant
- Robust business continuity & disaster recovery plans
- Software-as-a-Service (SaaS) uptime >99.9%

# Flexible, Expert eClinical Ecosystem Can Improve Outcomes for Specific Study, or Across a Program



## *Prevail Invests In Your Trial Success with Expert Support At Every Step*

With Prevail, your trial is fully supported from start to finish by cross-functional teams with 15+ years of proven customer success managing more than 400 Phase I-IV trials in drug, medical device, and diagnostics. We can augment your existing teams for a specific need such as data management and data science, or easily scale to meet additional requirements.

Since our clinical operations teams are expert users of our technologies, they can leverage these systems to minimize operational risk, identify safety trends sooner, and provide a cleaner and faster locked database - typically within 48 hours of receiving last patient data.

## *Optimize Studies While Preserving Your Investment In Systems, People, and Processes*

Most clinical organizations today seek to augment and optimize existing systems with best-of-breed solutions. As expert clinical software developers and highly experienced integrators, we take an agnostic approach and have successfully worked with every system presented to us.

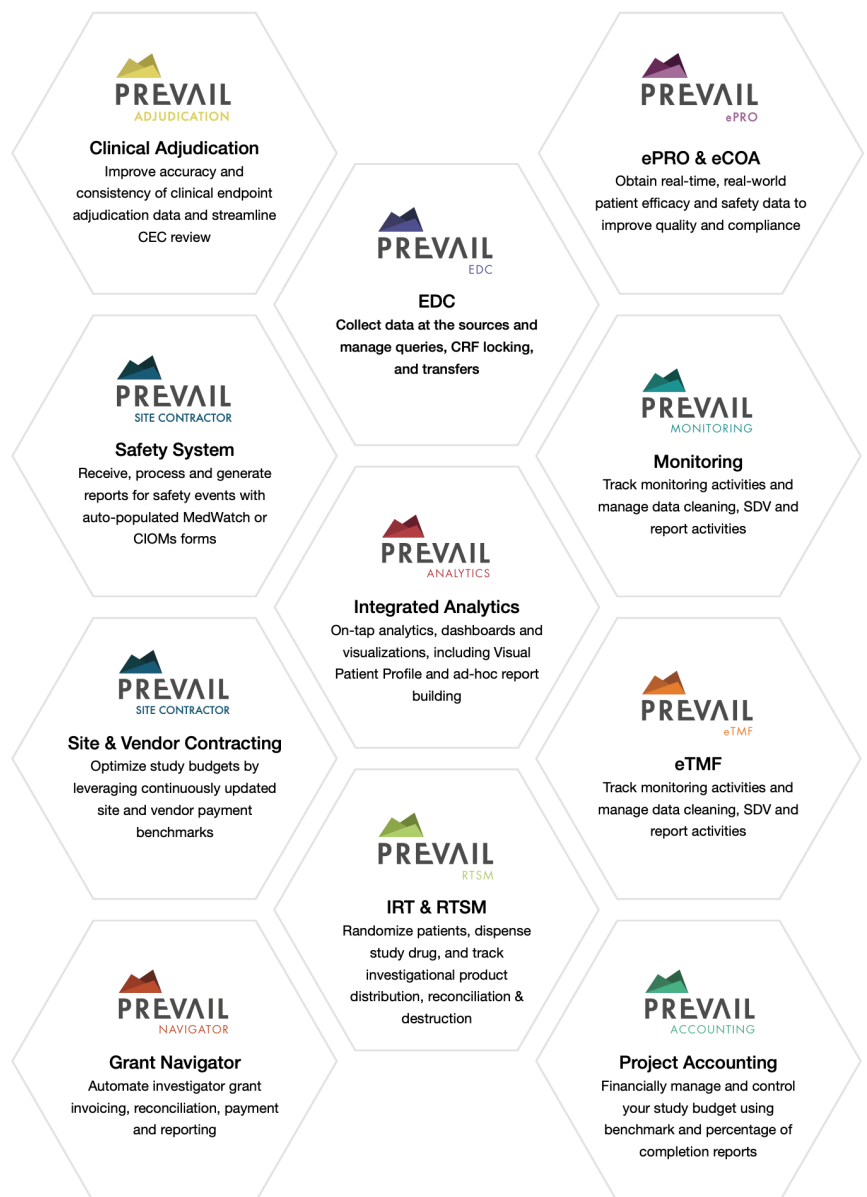
## You Benefit from Advanced Technology Completely Built and Backed by a Single Provider

Unlike many clinical systems, all Prevail technologies have been built from the ground up by Prevail's technology and domain experts.

The result? Efficient and affordable eClinical systems, purpose-built for life sciences:

- Analytics
- Clinical Adjudication
- Clinical Monitoring
- Clinical Trial Management
- EDC
- ePro
- eTMF
- Grant Payments
- Project Accounting
- RTSM
- Safety System
- Site Contracting

# Integrated Yet Modular eClinical Technologies Improve Data and Processes While Reducing Manual Effort



Prevail's innovative product ecosystem is designed for efficient integration, allowing you to quickly utilize any of our best-of-breed solutions without impacting your existing system infrastructure and standardized processes.



## Accelerating Value: Prevail Expertise at Work

Database locked in less than 1 hour after receiving last patient data in pivotal study of 227 patients at 45 sites that produced high quality data (p <0.001).

Suite of integrated clinical, logistics and financial oversight systems fully deployed in only 17 days in a large Phase III study, with the first patient enrolled on day 18.

Database locked on the same day as last patient visit in a 450 patient, 10 countries, 50 site Phase III study that generated over 20,000 records.

## *Easily Aggregate and Utilize Data from ALL Your Disparate Clinical and Operational Systems*

Underpinning Prevail's proven ability to help life sciences organizations improve operational efficiency and clinical outcomes is the Single Interface™ - the result of nearly 300 patented innovations. This unique technology combines advanced data synthesis and analytics in a single, affordable SaaS offering that is usually live within 4-6 weeks of project kickoff.



The Single Interface integrates or synthesizes all of your data in real or near real-time, within and across studies - without breaking the blind or spending alpha. How? Two key areas make Prevail's technology unique in the industry:

1. Unlike other systems that can only manage automated file transfers with systems that support an API (application programming interface) or SFTP (Secure File Transfer Protocol), Prevail has fully automated the data extraction and reconciliation processes.
2. Prevail technology is data and system agnostic and can integrate data from any system in any format, not just SAS.

### *The Result? Prevail's customers are able to:*

- Accelerate clinical timelines and reduce cost by quickly obtaining data-driven insights into hidden trends, correlations, and outliers in aggregated data and workflows.
- Improve trial outcomes with real-time, actionable intelligence into every aspect of a study.
- Get rapid time-to-value with Prevail technology often up and running in as little as two weeks for simpler studies, and in six weeks or less for even the most complex protocols.

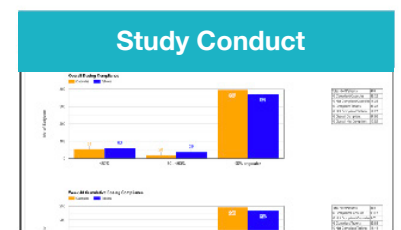
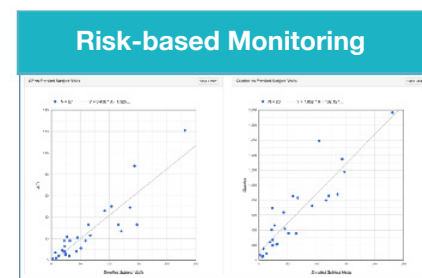
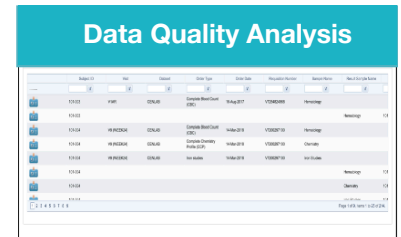
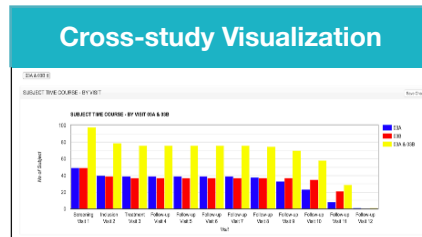
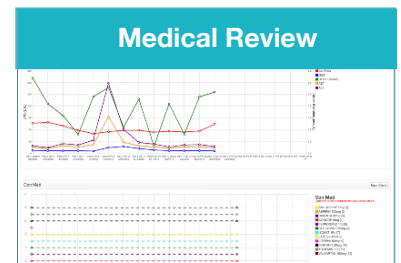
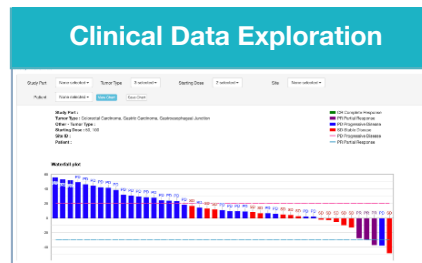
## Improve Your Trial's Chances of Success: Contact Prevail Today

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*Prevail Unified Analytics and Visualizations Put the Power of Early Observations In the Hands of Your Researchers for Immediate Action*



Offered as a standalone solution and included in every Prevail software module, our advanced analytics provide early observations of aggregated clinical and operational data across studies and programs. You can quickly and easily assess data quality and efficacy signals during live studies, regardless of protocol, data, and system complexity – all without breaking the blind.

- Real-time analytics, visualizations and predictive and diagnostic algorithms
- Tabular and visual trends of endpoints and exploratory objectives across all patients
- Ability to combine safety and efficacy datasets from different sources into one view
- Live correlation of current study data with prior studies, concurrent studies, or publication data
- Intra-study visual correlations and regression analyses of relational measurements within a study



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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.