

**HCLTech** | Supercharging  
Progress™

Enhancing **drug  
safety** with global  
pharmacovigilance  
and epidemiology



Drug safety is a critical aspect of healthcare and pharmacovigilance plays a vital role in achieving this objective. Through systematic monitoring, analysis and reporting of adverse drug reactions, pharmacovigilance helps identify and mitigate risks associated with pharmaceutical products. This proactive approach to drug safety allows regulatory authorities and healthcare providers to make informed decisions, implement necessary precautions and ensure public safety.

At HCLTech, our focus is on enhancing drug safety through a comprehensive suite of client-based services. These services span clinical development, post-marketing activities and regulatory compliance, designed to cater to the critically unique needs of our clients. With decades of industry experience combined with emerging expertise, HCLTech is uniquely positioned to deliver exceptional quality services. We leverage the skills of our seasoned industry experts and operational excellence on a global and local level. Furthermore, as the industry constantly evolves, we are committed to staying ahead of the curve by integrating the latest technologies into our solutions, driving the next generation in global pharmacovigilance and epidemiology (GPV & E).



**25+ years** of experience in PV oversight for clinical trials and post-marketed products



**25+ years of partnership experience** in product safety



**Technology expertise**



ICSR (individual case safety report) cases **annually** (with 80% in complex indications)



**50+ databases** implemented



**100%** internal/external/health authority audit compliance



**75,000 literature** review abstracts managed yearly



**150+ audits, 2 FDA audits** with no 483s, complete HIPAA/21 CFR part 11, EU privacy compliance and more

## Our pharmacovigilance capabilities

### GPV & E partnership

- A complete suite of business unit services, including:
  - Individual case processing
  - Aggregate reporting
  - Reporting and signal detection
  - Surveillance
  - Epidemiology
  - Automation systems
  - QPPV (qualified person for pharmacovigilance)
  - Local safety representations, and more
- PV overall strategy implementation
- PV business processing
- Overall benefits and risk analysis
- Application implementation, support and expansion
- PV emerging technologies
- Transformation roadmap and implementation partnership
- Global health authorities' representation and advocacy

### System implementation and integrations

- Safety database hosting
- Safety database platform implementation and system integrations
- Safety database upgrades
- MedDRA & WHO DD (drug dictionary) support
- Data migration and validation
- Application maintenance
- DR (disaster recovery) activities
- Dedicated PV service desk
- Production support

### Technology capabilities

- Global Oracle partner
- Argus cloud hosting
- Oracle certified specialist for Argus implementation
- Experience in system integrations, analytics, SAS and BI
- Service desk support

### GPV & E technology and automation

At HCLTech, we leverage cutting-edge technology and automation to streamline GPV & E processes and enhance efficiency.

- AI-enabled case intake platform
- Oracle Safety One for automated case intake
- AlertAE for identifying, extracting and classifying adverse events, product quality complaints and medical inquiries
- Streamlined workflows with automated empowered QC features
- Auto-narrative generation
- Signal detection
- Gen AI-enabled assisted authoring for aggregate reports
- GenAI empowered literature review and submissions
- Aggregate automated surveillance operations using multicomponent systems of AI/ML, including the use of LLM

HCLTech is dedicated to enhancing drug safety through our comprehensive suite of client-based services in pharmacovigilance. With decades of experience and a strong focus on emerging technologies, we are well-equipped to support clinical development, post-marketing activities and regulatory compliance.

# HCLTech | Supercharging Progress™

HCLTech is a global technology company, home to more than 227,000 people across 60 countries, delivering industry-leading capabilities centered around digital, engineering, cloud and AI, powered by a broad portfolio of technology services and products. We work with clients across all major verticals, providing industry solutions for Financial Services, Manufacturing, Life Sciences and Healthcare, Technology and Services, Telecom and Media, Retail and CPG, and Public Services. Consolidated revenues as of 12 months ending March 2024 totaled \$13.3 billion. To learn how we can supercharge progress for you, visit [hcltech.com](https://hcltech.com).

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