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 the overall well-being of patients.

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 specific 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)

54+ databases implemented.

100% audit compliance

75,000 literature review abstracts managed yearly

150+ audits, 2 FDA audits with no 483s, complete HIPAA, 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

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
- Auto-narrative generation
- Signal detection
- GenAI enabled assisted authoring for aggregate reports

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HCLTech is a global technology company, home to more than 221,000 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 September 2023 totaled $12.9 billion. To learn how we can supercharge progress for you, visit hcltech.com.