DRUG SAFETY & PHARMACOVIGILANCE

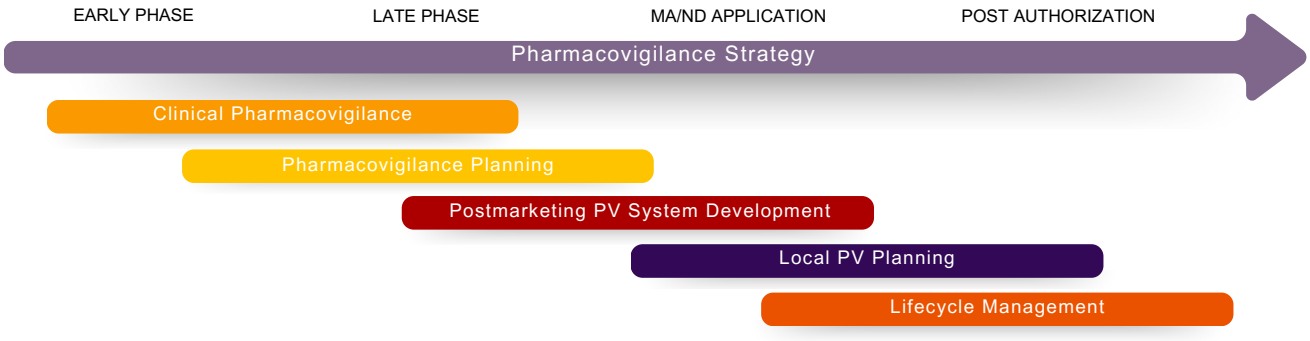
Providing transformative efficiency-driven pharmacovigilance solutions through a flexible partnership model

Through a combination of technology and deep-rooted expertise, Allucent offers transformative, efficiency-driven pharmacovigilance (PV) solutions to our partners across clinical, expanded access, and the entire post-marketing lifecycle.

By leveraging expertise in PV, medical, regulatory, clinical, and quality to provide comprehensive and innovative patient safety solutions from clinical to commercialization, Allucent forges long-lasting relationships as our customer's full-service PV provider. We deliver operational excellence through comprehensive safety surveillance and risk management solutions, global QPPV services, and technical PV consulting, including global PV audit strategy development and execution.

Allucent's safety systems include the latest innovations in technology, combining efficiency, global compliance, and complete oversight and access to your safety data. Our systems experts can seamlessly consolidate your safety data allowing you to immediately benefit from industry-leading technology.

Allucent's Pharmacovigilance -Team devote their full attention to small and mid-sized biotechs, working side-by-side with you across clinical, peri-approval, and post-approval.



Clinical safety, expanded access, and post-marketing PV services

Clinical Pharmacovigilance

Allucent provides flexible, global solutions that streamline clinical safety operations at the study or portfolio level in a pharmacovigilance partnership model. Leveraging the latest technology advancements in combination with deep expertise enhances pharmacovigilance efficiency, providing high quality, complete safety oversight.

- Safety planning and strategy development
- Global safety database set-up and management
- Legacy data migration
- Case management
- Regulatory reporting and intelligence
- Aggregate safety reports
- Safety monitoring and risk management planning
- Safety committee coordination
- Audits and inspections
- Pharmacovigilance consulting services

Post-Marketing Pharmacovigilance

Post-marketing pharmacovigilance is a critical component of the drug development lifecycle, ensuring their safe and effective use in the real world. Allucent's global post-marketing pharmacovigilance solutions integrate expertise in pharmacovigilance, medicine, regulatory affairs, clinical operations, and quality assurance, leveraging technology-driven efficiencies to minimize manual effort and reduce costs.

- PV planning and strategy development
- PV system and global safety database set-up and management
- Adverse event management and expedited reporting
- Regulatory intelligence
- Aggregate safety reports and benefit-risk profile
- Safety surveillance and risk management evaluation
- Qualified Person Responsible for Pharmacovigilance (QPPV) and Pharmacovigilance System Master File (PSMF)
- Local contact person for pharmacovigilance (LCPPV)
- Global and local literature screening
- GVP audits and inspection readiness
- SDEA/PVA management
- PV Consultancy Services

About Allucent

Allucent is a global provider of comprehensive drug development and commercialization solutions, including pharmacovigilance, regulatory consulting, clinical operations, biometrics, and clinical pharmacology, across a variety of therapeutic areas. With more than 30 years of experience in over 75 countries, we assist our small and mid-sized biotech clients in successfully navigating the complexities of delivering novel treatments to patients.

Allucent®
Helping bring new therapies to light
2000 Centregreen Way, Suite 300, Cary, North Carolina 27513 | +1 919-361-2286 | Allucent.com