



MARKET ACCESS & PHASE IV SOLUTIONS

# Transforming Patient Safety to the Next Level

# Integrated Patient Safety

## Optimized efficiencies, scalability and product value

In light of the ever-increasing complexity of regulatory requirements for product safety, surveillance and signal detection, the continuous monitoring of the benefit-risk relationship continues to dominate the imperatives of life science organizations. A truly integrated approach to pharmacovigilance (PV) and risk management can help organizations optimize their practices to meet the market dynamics and facilitate the success of a product in the market.

The Labcorp operating model provides efficiencies and scalability to sponsors, while enabling them to maintain the value of their products. An integrated solution to safety that includes adverse event reporting, proactive signal detection and global regulatory and safety writing expertise that is driven by optimized processes and innovative technologies is an absolute necessity.

## Transforming Patient Safety to the Next Level

The Labcorp integrated drug safety solution incorporates a comprehensive set of pharmacovigilance (PV) services across all aspects of the product lifecycle through our state-of-the-art technology platform and streamlined processes. As a result, we are able to facilitate evidence-based proactive drug safety decision-making by leveraging our scientific experts who are skilled at aggregating safety information from all sources, including individual cases and published safety data. Our holistic approach to risk management provides your organization with up-to-date safety profiles of your clinical and post-market products to assist in addressing emerging safety issues and regulatory requirements in a proactive, comprehensive, efficient and timely manner.

This integrated approach of employing drug safety and therapeutic area expertise across all areas of your PV operations enables us to maintain high-quality safety data and ensure scalability and predictability. Employing optimized and efficient processes, industry best practices, robust metrics and state-of-the-art technology helps us to strengthen this approach. Our LEAN process and automated operations provide clients with a 360-degree view of their operations through well-defined metrics, seamless information flow, effective monitoring and resource utilization.

## People, Process and Technology

The Labcorp automated enterprise platform, process management systems and proprietary workflow engine enable you to customize processes and metrics to your specifications. Our platform lets you track the process; monitor metrics and extract meaningful reports, all in real time, either on your phone, tablet or laptop. Our knowledge management system not only helps us capture, share and use our expert's knowledge across the organization and with our clients, but also implement optimal processes and tools that leverage collected data for better decision making, at all stages.

Clients who have partnered with us, whether for end-to-end safety solutions or for niche PV services, have benefited from our synergistic combination of procedural expertise, domain knowledge, innovative streamlined processes and robust technology.

Our service teams have supported small, medium and large clients across a broad spectrum of activities, ranging from setting up full-function safety systems and processes to adopting a single, well-defined, mature process. Our extensive client base and growth in projects with global clients across all major therapeutic areas is evidence of the value.

The Labcorp integrated drug safety solution offers support for your current needs but also provides rapid and flexible adaptation to your evolving requirements. We facilitate swift and effective decisions regarding all aspects of drug safety.

## The Labcorp Integrated Patient Safety Solution



Medical Information & Intake Management



Safety Database Management



Case Management



Aggregate Reporting Management



Surveillance & Signal Management

Technology and innovation

Thought leadership and transformation

Quality management system

Project Management Office (PMO)

# Patient Safety

## Optimized efficiencies, scalability and product value

### Consulting and QPPV Services

- PV strategy and roadmap
- PV process re-engineering and optimization
- Audit and inspection support
- QPPV, Deputy QPPV and Local Responsible Person for PV (LPVRP) support
- Regulatory communications
- Dossier compilation and submission (PSMF, RMP, etc.)

### Medical Contact Center

- Adverse events
- Product complaints
- Medical information
- 24x7 coverage, multi-lingual support

### Clinical Safety Management

- SAE, SUSAR processing, electronic submission
- AE reconciliation
- Set-up Safety Assessment Committee (SAC)

### Post-Market Safety Management

- Case processing including intake/triage, medical review
- Medical literature monitoring search set-up, review and processing
- Submission to regulatory agencies (gateway and web traders)
- SDEA (Safety Data Exchange Agreement) support and management

### Aggregate Safety Reporting

- Periodic safety reports (development and post-approval)
- Integrated summaries of safety
- Clinical and nonclinical overviews
- Ad-hoc safety issue analyses

### Surveillance and Signal Management

- Ongoing medical review and analysis of cases
- Meta-analysis of published safety data
- Qualitative and statistical signal detection, validation and management

### Risk Management and Communication

- Risk management plans (RMPs), risk evaluation and mitigation strategies (REMS), medication guides, patient education materials, Dear Doctor letters
- Post-approval safety studies, patient registries
- Product labels (safety updates)

### Technology and Automation

- Technology support for medical call center
- Safety database implementation, support, maintenance
- Safety automation tools

Learn more at [www.drugdevelopment.labcorp.com/patient-safety](http://www.drugdevelopment.labcorp.com/patient-safety)