Leveraging Technology
Advancing Outcomes

Ultragenic

CORPORATE PROFILE

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Setting The Stage

BACKGROUND / VISION

The PV function was established against the backdrop of damning evidence that medicines caused side-effects. These side effects could not be identified during the clinical trial process and presented massive health risks. The express intent of the PV function was to manage such health risks by deploying resources towards discovering side-effects quickly & effectively and acting upon corrective steps efficiently.

Over time, the PV function has been heavily influenced by the need for the Pharmaceutical Industry to fulfill regulatory requirements, with the unintended consequence of losing track of the prime objective of individual safety. The paperwork is overwhelming, resulting in PV professionals spending disproportionate amount of time on functions, which at best, support the real objective of patient safety. We have fallen into the classic trap of focusing too much on data collection and reporting, and too little on analytics and inference.

This can be attributed to several factors - PV is a relatively young industry, over-reach of regulators, circumspect attitude of pharma companies, lack of adequate technology tools and slow adoption of best-in-class process optimization techniques from other industries. However, with the onset of digitized healthcare data, the industry stands at the cusp of a new age. With the emergence of technology and process solutions, there is a unique opportunity for us to challenge traditional methods of operation and deliver meaningful and relevant results.

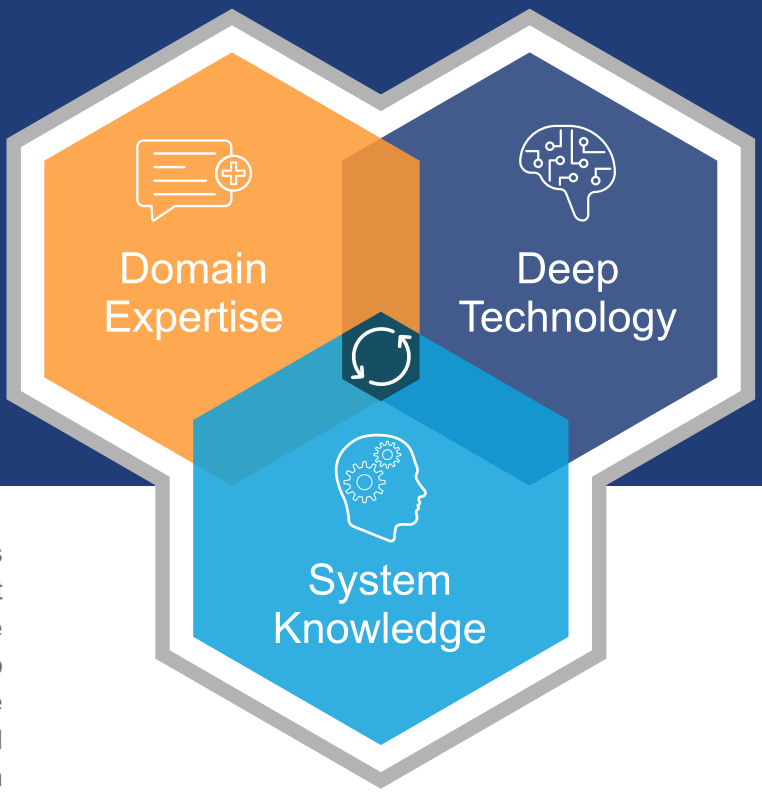
> “It is the knowledge that there exists huge potential to address these long-standing challenges plaguing the PV industry and transforming it into a truly patient outcome driven function, which has led us to establish Ultragenic – an organization focused on leveraging new methods and technologies and applying them to the PV industry.”

Aggregate › Synergize › Innovate

WHO WE ARE

Ultragenic brings together Life sciences domain expertise, Third party system knowledge and Deep technology to develop well-defined solutions, which address challenges across Medical Affairs, Regulatory and Safety functions.

> “It is our firm belief that the most effective means of addressing the long standing challenges of the life sciences industry is to develop solutions in an organization model that combines these disciplines tightly together.”



We are committed to bringing focus to things that really matter for advancing patient outcomes. Our solutions free-up responsible personnel within Pharma companies to execute their stated responsibilities while staying true to the laws of the land, and ultimately achieving balance between compliance and managing business risks.

Our solutions are agile, flexible and scalable, developed using advanced technologies that enable us to serve large and small organizations, both in developed and emerging markets.

Our Team

Our team has over two decades of experience in engineering and deploying best-in-class life sciences solutions.

Amit Jain is a Founder of the Company. In his previous stint, Amit was Partner at Foresight Group International – a leading player in the PV Technology Consulting space.

The core team is a mix of deep technical, business and regulatory expertise, with rich industry experience spanning a global customer base. Their track record in scaling operations globally in line with business demands makes Ultragenic an ideal partner in achieving your business objectives.

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Leveraging Technology,
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OUR OFFERINGS

1. SOLUTIONS

A. Safety Suite Implementation

When it comes to handling critical Safety Suite Implementation projects, you can trust our established frameworks and team of domain & technology experts with proven experience.

Substantial investment of time, money and effort are required for any upgrade or implementation project, irrespective of its size. Ultragenic team assists its clients maximize their return on investment by adding efficiency on all three counts. We have proven project plans and sequencing to minimize rework loops and reduce project duration. Our third party system knowledge, including Argus, Aris, and Perceive, helps us leverage pre-built artifacts to reduce cost and time to market. And our well-crafted methodology developed over 100+ implementations ensures error-free results.

Our system implementation & upgrade methodology includes:

- Project Management
- Requirements Analysis
- Solution design
- Safety System setup (installation/upgrade)
- Configuration
- Computer System Validation
- Deployment and HyperCare

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B. Safety System Data Migration

Leverage Ultragenic's proprietary tools and frameworks to ensure quality of data migrations and expedited project execution. We specialize in migrating from any source Safety System to Argus

A well-managed data migration can save organizations costly compliance repercussions – financial and legal, especially those in the pharma industry given their business dynamics. Ultragenic team is well placed to handle your data migration needs, having managed migrations from a few hundred cases to a few million, across various business scenarios – from organizations shifting to a new system to acquiring new products, moving service providers to being part of an M&A.

Our safety system data migration solutions cater to:

- Small to large volume data migrations
- Migrations from single or multiple source systems to single or multiple target systems
- E2B based migrations
- Combination of E2B and database migrations
- Data clean up assignments
- Specialized migration solution for CROs, given their ongoing migration needs

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C. PV Analytics Solutions

Leverage our solutions developed on contemporary technologies, incorporating varied learnings over the last decade, to address evolving reporting and risk management needs.

PV ANALYTICS AND REPORTING SOLUTIONS

Our comprehensive self-service Reporting and Analytics solution is built on a data lake populated through latest data streaming technology supported by our PV Analytics Works (PAW) offering. It is designed to meet your real-time, operational and regulatory needs.

Our intuitive and self-service data analytics solution includes:

- Regulatory Reports: configurable periodic and aggregate reports such as PBRER and DSUR
- MIS and Compliance Dashboard: Dynamic and responsive dashboards for insightful data visualization through charts and graphs, with smartphone and tablet support
- Operational Dashboard: Near real time operational dashboards for productivity management
- Ad-hoc Reporting: User friendly ad-hoc reporting interface for faster Daily Data analysis and Information sharing reports
- Japanese Data: Support for Japanese data fields with Japanese user interface
- Frequently used standard queries and report templates with easy configuration

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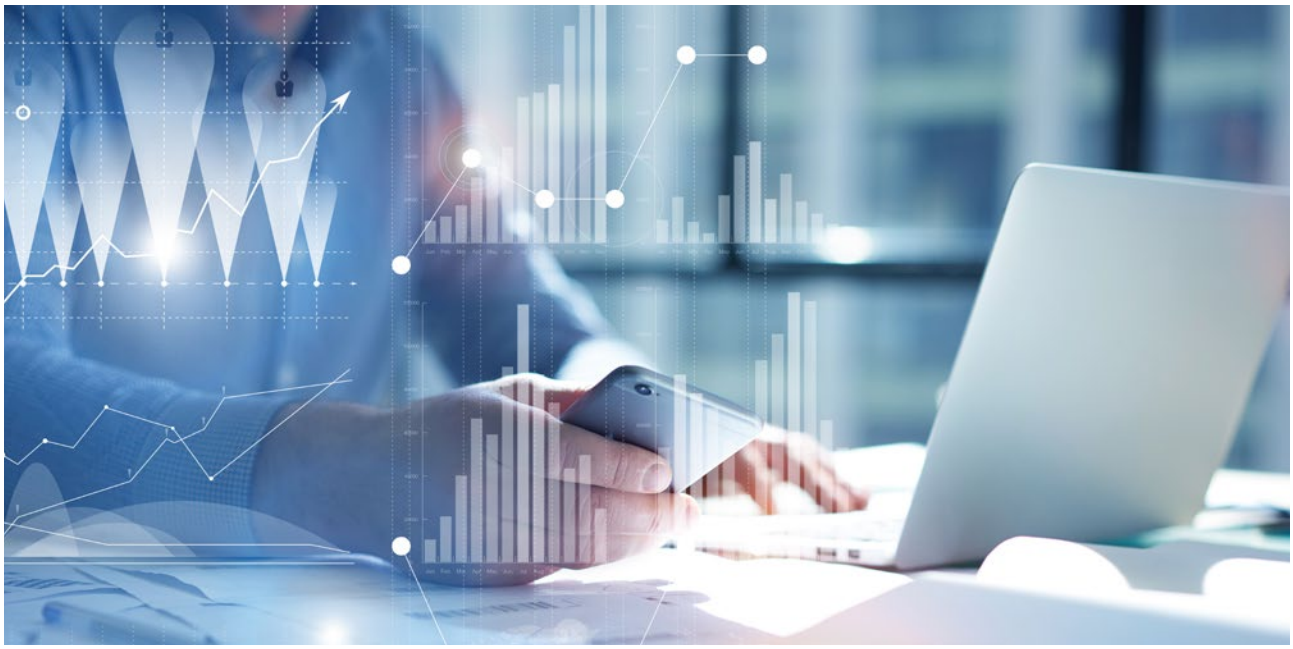

D. Signaling Solutions

Signaling is an ML and AI based data mining solution, designed to detect safety signals, identify patterns and predict trends using several data sources. It also tracks and manages the identified signals.

Our Signaling Solution includes:

SIGNAL DETECTION

- Qualitative Analysis: ICSR case reviews using a user-friendly interface
- Quantitative Analysis: Industry standard statistical algorithm-based data analysis for faster trend detection across multiple data sources

SIGNAL TRACKING AND MANAGEMENT

- Intuitive and user-friendly interface with multiple configurable workflow states for effective planning, prioritization, tracking, evidence capturing, notification and auditing of observed safety issues
- Single platform for multiple teams to collaborate, review, validate, assess and refute/confirm the signal

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E. Adverse Event Intake System

Adopt our advance application developed to automate case intake and processing using the latest in NLP and deep learning technology.

Case Intake represents a significant portion of the cost of processing an adverse event. Adopt our advanced and automated case intake to eliminate errors, increase efficiency, save time and lower implementation costs. Our intake solution is built on a cloud-based platform to extract, track and analyze data from structured or unstructured sources using OCR, Computer vision and Text mining. It then interprets this data for consumption by any system and in any structured format.

Why clients choose our Intake solution:

INCREASES EFFICIENCY BY:

- Employing deterministic algorithms.
- Extracting data from any language, with support for translation to English
- Using simplified validation
- Automating reconciliation with target system
- Offering unlimited scalability and improved performance

ADDRESSES COMPLIANCE BY:

- Eliminating manual data entry processes
- Improving data extraction accuracy of over 95%

ENHANCES SECURITY BY:

- Masking privacy data at source to meet global data protection standards
- Being a true cloud application architecture

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F. Delivery Assurance

Navigate through rapidly emerging technology & service partner options, project approaches and program management with our expert and trusted advisory services.

Defining the problem accurately is a crucial first step in finding an effective solution. The next steps of identifying the right approach, best suited technologies and reliable partners to deliver these solutions are equally important. Over two decades of engineering and deployment experience makes us your ideal partners to simplify this challenging ask by helping you converge on the optimal mix and manage the overall program.

Our Delivery Assurance solutions include:

- Defining the project scope of the project to be undertaken
- Identifying the right implementation approach
    - Deciding the upgrade version, on premise or cloud hosting
    - Defining data integration/migration approaches
- Creating the Request for Proposal
- Evaluating proposals
- Selecting vendor and technology
- Program Management
- Computer System Validation

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G. Business Transition

Harmonize changes to your business by leveraging our expertise in designing & implementing integrated processes and associated change management activities

Pharma industry experiences frequent Mergers & Acquisitions and changes to marketing authorization holder based on business dynamics. PV departments also adopt new software systems periodically. This leads to internal changes in the PV departments that need to be managed. Ultragenic Business transition & change management services help optimize your processes and enable change management.

Our Business Transition and Change Management Services include:

- Organization Design and Structure
- Change Management during M&A, Divestments or Restructuring
- Process design or optimization and translation to system workflow
- Training PV services and software personnel
- Authoring Data Entry Manual, SOPs, Work Instructions
- Licensing agreements
- Augmenting missing roles in the PV function

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2. QUALITY AND COMPLIANCE

A. Audit and Inspection Readiness

Our subject-matter experts prepare you for regulatory audits and inspections through our specialized readiness solution.

Findings in regulatory Audits and Inspections can lead to punitive and costly implications for organizations. Our team of regulatory experts assist PV organizations be prepared by conducting preparatory exercises, reviews and dry runs.

Our Audit and Inspection readiness solutions include:

MOCK REGULATORY AGENCY INSPECTIONS AND SYSTEM AUDITS:

- Prepare a document staging area (War Room)
- Prepare staff for inspection with interview training and role play
- Conduct a Gap Analysis of all systems and departments
- Identify deficiencies and areas of concern
- Recommend and prioritize remediation and CAPA

INSPECTION READINESS

- Identify potential areas and organize documents relevant to the regulatory authority
- Review SOPs to check compliance with regulations – advise updates/ CAPAs
- Review processes to check compliance with SOPs – advise updates/ CAPAs
- Prepare compliance reports, summaries and tables
- Review ongoing and closed CAPAs
- Review Pharmacovigilance System Master File
- Prepare Presentations for inspections

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B. Regulatory Guidance and System Support

Keeping you compliant with the dynamic global regulatory environment from a business and technology perspective.

Ultragenic's team of business experts keep themselves updated with the latest in global regulatory landscape. They work closely with our technology and safety system teams to develop business and technical guidance & solutions. This ensures complete and timely compliance of PV departments.

Our current Regulatory Guidance and System Support includes:

EU MDR MIR Form (Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (MDD/IMDD/IVDD). Ultragenic Offers:

- Creation of additional data entry fields and the definition of conventions
- Generation and submission of new MIR (v.7.2) Form
- Compatibility with IMDRF AER codes
- Notification of Economic Operators (EOs)
- Periodic Reporting

FDA PMSR compliance deadlines. The FDA has set two new PMSR enforcement dates, tied to the system combination product applicants use to submit individual case safety reports, or ICSRs. Ultragenic Offers:

- Interpretation of the regulation vis a vis your safety system configuration
- Custom profile solution for the Post Marketing Safety Reporting (PMSR) of combination products
- Rapid 3-4 week deployment with minimal business disruption

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C. Quality Assurance As A Service (QaaS)

Our Quality Assurance is offered as a Service to help clients optimize their processes and meet their regulatory and compliance needs.

A leaner set of processes are easy to understand, adopt and execute. Ultragenic QMS can be adopted by Small and Medium sized organizations with minimal need for modifications. It helps simplify your overall compliance framework for GxP systems.

Our QaaS includes:

- Standard QMS (set of Processes & Policies)
- Quality Management Operational Services
- Pre-qualified Standard Automation Framework
- Standard Validation Kits and Automation Scripts
- Audit Framework and Support
- CAPA support services

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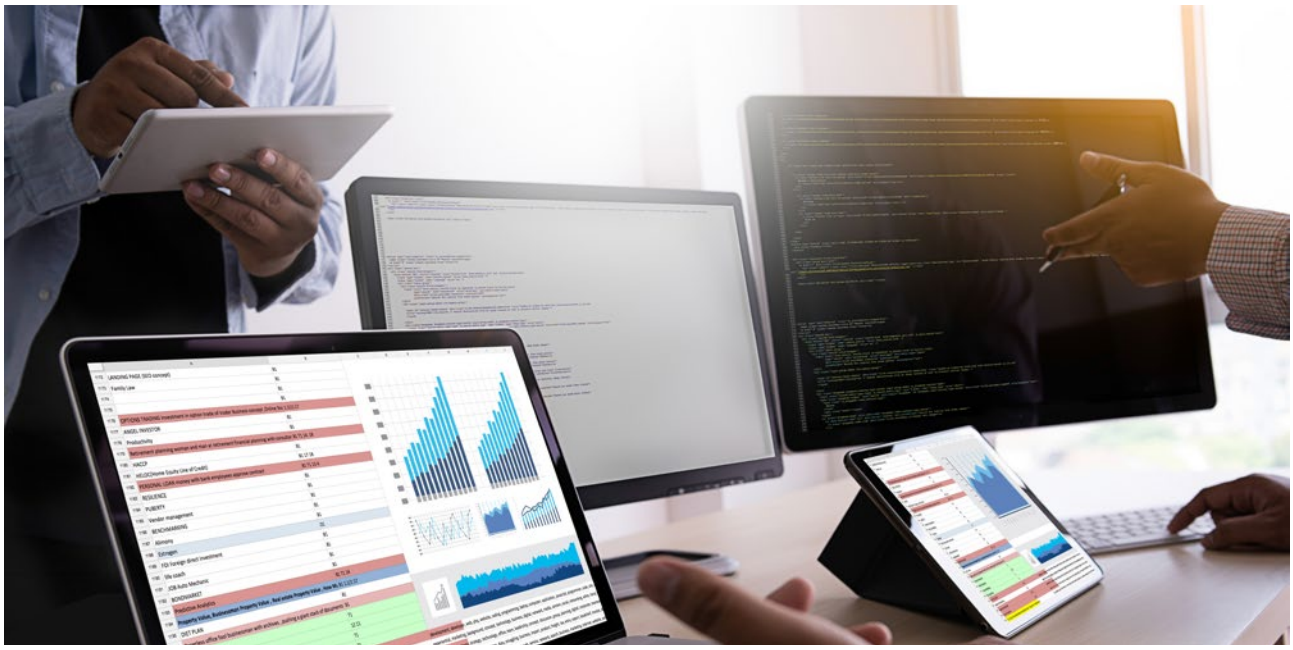

3. PV TECH SERVICES

A. PV Analytics Works (PAW)

Our dedicated team of PV reporting experts cater to your ongoing reporting needs using Agile methodology within the Managed Services framework.

The reporting needs of a PV organization evolve continuously given the business and internal dynamics. While reporting systems are set up during the initial implementation, there is a need to cater to ongoing business demands of ad-hoc and canned reports. Ultragenic offers dedicated capacity of PV reporting experts, trained in your business and tech environment, enabling quick response to your reporting needs. The solution is Safety System agnostic.

Our PV reporting services include:

- Custom report development and enhancement
    - Operational
    - Regulatory
    - Compliance management
    - Signaling
- Aggregate / Periodic reports configuration and development
- Ad-hoc query services

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B. Hosting and Managed Services

Let the management of your safety applications be handled by our experts in a secure and reliable cloud hosted environment.

HOSTING SERVICES

Continuous maintenance and upgrade of infrastructure to meet the requirements of safety applications costs time, money and effort. All of it could be avoided by hosting your safety database on our cloud. You are assured a world class hosting facility that is fully compliant with all requisite geography-specific certifications.

MANAGED SERVICES

Once a system goes live, comprehensive understanding of the PV space is critical to support ongoing operations. Business and technology demands continue to evolve with changes in external and internal environments. Our managed services team includes business and tech experts, tied together in an established ITIL process framework, with extensive experience across a varied customer base.

Our managed services include:

- Application Managed Services
- Operations Support
- Change Control Management
- Infrastructure Managed Services

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C. PV Automated Platform

With a tech-enabled platform employing automation technologies, we offer a ready to deploy, pre-validated Argus Safety Platform focused on productivity and ease of use.

Oftentimes, drug safety system acquisition & implementation becomes an arduous process for organizations as they source and coordinate their technology demands, infrastructure needs and implementation services through different solution providers. The Ultragenic PV Platform offers a seamless integration of Technology, Infrastructure and Services, freeing up clients' time to spend on critical business outcomes. Our safety platform is built with Argus Safety at the core, enabled with automation tools.

HOSTED PLATFORM INCLUDES:

- Argus Safety hosted on AWS
- Pre-Validated Argus Safety application
- Client Db specific, multi-tenant and single-tenant set-ups
- QMS
- Country specific certifications
- Disaster recovery and RTO/RPO
- Alignment to data privacy and protection requirements

TECH ENABLEMENT INCLUDES:

- Custom E2B Profiles
- Auto Seriousness
- Auto Population
- Auto Narratives
- Auto Labelling
- Automated Processing Bots using (RPA)
- Interface with RIMS
- Case Prioritization
- Duplicate Search

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4. DRUG SAFETY SERVICES

A. Drug Safety Services

In collaboration with our strategic partner, Continuum India, we deliver the entire range of pharmacovigilance services seamlessly.

Continuum is a contract research organization offering drug safety and pharmacovigilance services ranging from Single Case management to Aggregate Report preparation to the pharmaceutical industry worldwide. The focus is on excellence: through accuracy, on-time delivery and efficiency, achieving the highest quality output for our customers.

Continuum's team consists of among the best physicians and life science experts in the outsourcing industry. At its core is a cumulative pharmacovigilance experience of decades. This experience is hard to match and over the years many clients (including 6 of the top 10 Pharma companies) have benefited from it.

The range of PV services, offered by Continuum to global pharmaceutical and biopharmaceutical companies in a wide range of therapeutic areas, include:

- Aggregate Reports
- Single Cases
- Safety Physicians
- Signal Management & Safety Surveillance
- Literature
- Affiliate Services
- Medical Information Call Centre

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Collaborative Partnerships

CO CREATE

> “Our experience in engineering and deploying best-in-class life sciences systems has convinced us that meaningful solutions can only be developed through collaborative partnerships between the industry and technology experts.”

Replacing Safety databases can result in business disruption and financial investments. However, PV departments need the benefits of recent technological advances that aren’t available on their legacy systems.

We engage with your business team(s) to identify gaps in the presently deployed safety systems, advise necessary changes to the processes and work closely to develop cloud-based generally available SaaS technology solutions, which are deployed after requisite testing and client specific validation. By layering newer technologies and systems over your legacy safety system we achieve the desired transition in a disruption-free manner and at a lower cost.

We can partner with you to co-develop these solutions.

Our spheres of prioritized interests include:

- Adverse Event Intake – Form, Text, Voice, Literature
- PV Analytics – Self-service, Dashboards and Reporting
- Signaling – Capture, Assessment, Management and Reporting
- Case Workflow Automation – Assessments, Intelligent routing

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