Persistent

WHITEPAPER

Elevating CROs into Full-Stack Sponsor Partners

How CROs that address operational challenges for drug safety programs through platform-driven REMS, CTCCS and Medical Information unlock $10 billion in new value

Executive Summary

With the number of drugs under active development having doubled in the last decade, driven by global clinical trials and herding (or when multiple firms research similar drugs), the time to launch has significantly compressed.

In such an environment, regulatory authorities, payers and patients demand higher scrutiny on drug safety, requiring sponsors to enforce risk monitoring and patient safety programs across the clinical trial lifecycle. This expands the scope for contract research organizations (CROs), to whom sponsors turn to manage risk evaluation from pre-clinical toxicology to post-marketing surveillance.

Regulatory Process for Investigational Drugs

Sources: US Food and Drug Administration.

Drug Discovery and Design

Identifying, designing and testing potential therapeutic compounds to develop novel treatments.

Regulatory Review

Based on preclinical data, regulatory bodies (e.g., U.S. Food and Drug Administration, European Medicines Agency) sign-off that the treatment is safe for testing in people. Sponsor firms also submit detailed outlines for planned clinical studies to ensure patient safety and data accuracy.

Phase II: Does the treatment work?

Study Participants: Up to several hundred people with disease / condition.

Length of Study: Several months to 2 years.

Purpose: Evaluate efficacy and establish side effects. Approximately 33% of drugs move to next phase.

Regulatory Review

If the treatment shows that it is more effective or safer than the current treatment, regulatory bodies evaluate it for commercial approval.

In the US, sponsors must submit a New Drug Application (NDA) or a Biologics License Application (BLA) to the FDA.

During the evaluation process, the FDA might seek inputs from Advisory Committee (AdComm) to make an informed decision if approval of the drug is warranted, but the ultimate authority for approval rests with the FDA.

Preclinical Studies

Evaluate efficacy and safety of the investigational treatment by testing the therapy in isolated cells in a laboratory (in-vitro) or by administering to animals (in-vivo).

Phase I: Is the treatment safe?

Study Participants: 20 to 100 healthy volunteers or people with disease / condition.

Length of Study: Several months.

Purpose: Evaluate safety and determine dosage. Approximately 70% of drugs move to next phase.

Phase III: Is it better than what's already available?

Study Participants: 300 to 3,000 volunteers with disease / condition.

Length of Study: 1-4 years

Purpose: Efficacy and monitoring of adverse effects and tolerability compared to standard of care. Approximately 25-30% of drugs move to next phase.

Phase IV: Is the therapy performing as expected?

Study Participants: Thousands.

Purpose: Evaluates long-term efficacy and safety of the drug.

This momentum pushes CROs into a new curve, with the market projected to grow from $55.84 billion in 2024 to close to $106 billion by 2033, at a CAGR of 7.42%. CROs need to develop pharmacovigilance expertise and ecosystem coordination to position themselves as strategic partners for sponsors, driving safety initiatives, such as Risk Evaluation and Mitigation Strategies (REMS), clinical services, such as Clinical Trial Contact Center Solutions (CTCCS) or CTCCS-type frameworks and global Medical Information (MI) operations.

However, amid an exponential increase in data sources and communication channels, CROs need a new approach. The new requirements call for robust systems that collect, process and report Adverse Events (AEs). Regulations mandate these systems to be validated, highly reliable and capable of rapid scaling to manage global safety data. The need for faster global reporting is driving the transition to cloud-based systems.

As CROs make this pivot to a cloud-native platform, they need to partner with strategic technology providers to orchestrate technical and domain capabilities across the clinical trial ecosystem. Together, they can unlock $10 billion in new value.

This whitepaper explains how a platform-based approach can help CROs standardize processes across sponsors and regions to reduce errors and deviations in compliance-critical activities and build integrated views of evidence to enable proactive safety and medical strategies, stronger real-world evidence, better payer negotiations and more effective drug lifecycle management.

Strategic CRO Imperative

As regulators seek structured safety studies and ongoing benefit-risk evaluation, the sponsor workload is increasing. Regulations mandate risk management strategies and the use of real-world data (RWD) and real-world evidence (RWE) across the clinical trial lifecycle.

Consequently, sponsors are increasingly outsourcing operations to CROs, expecting them to:

- Run multilingual, multi-channel Medical Information services
- Manage long-term observational studies, registries and pragmatic trials
- Design and operate end-to-end REMS programs
- Provide integrated analytics across safety, medical and RWE domains

> **The expanding scope presents both an opportunity and risk. The CROs that industrialize pharmacovigilance capabilities will strengthen their strategic and market relevance. Those who do not risk rising costs, compliance exposure and margin erosion.**

Expansion Opportunities for End-to-End CRO Capabilities

	Description	Services	Estimated value opportunity ($billions)
Core Services	**Foundational clinical trial management services**	○ Project management ○ Feasibility, study startup / patient recruitment ○ Monitoring (site, medical) ○ Data management ○ Biostatistics	~25 ○ Safety / Pharmacovigilance ○ Regulatory (clinical development) ○ Medical writing ○ Quality assurance (good clinical practice)
Near Adjacencies	**Value-added capabilities for end-to-end clinical development vendor through some adjacency expansion**	○ Laboratory (central, bioA) ○ Imaging ○ Pharmacometrics ○ Clinical supplies, logistics and distribution (including comparator sourcing, EAP)	15+ ○ Clinical tech services (such as eCOA / ePRO, CTMS, wearables) ○ Quality (GLP, GMP) ○ Regulatory (CMC) ○ RWE / RWD (including registries)
Medium Adjacencies	**Synergistic growth in pharma service adjacencies**	○ Translational research / precision medicine ○ Patent support services / hub ○ Medical affairs ○ Analytical development, GMP testing, TICC	15+ ○ Other commercialization services (such as medical communications) ○ Formulation development ○ Drug product clinical manufacturing
Further Adjacencies	**Long-term strategic pharma service expansion areas**	○ Discovery (such as AI drug discovery, biologics, biospecimens) ○ Preclinical (such as novel models and toxicity)	20+ ○ CDMO (such as biologics drug substance and product manufacturing)

Sources: Industry Standard Research; MarketView Research; GlobalData; BCC; Market participant interviews; BCG analysis.

Note: bioA = bioanalytical; eCOA = electronic clinical outcome assessment; ePRO = electronic patient-reported outcome; CTMS = clinical trial management system; EAP = expanded access program; GLP = good laboratory practice; GMP = good manufacturing practices; CMC = chemistry, manufacturing and controls; RWE / RWD = real-world evidence / data; TICC = testing, inspection and certification; CDMO = contract development and manufacturing organization.

Workflow Consolidation: Evolving Post-Market Scope for CROs

CROs, with their specialized domain offerings and partner coordination mechanisms, are uniquely positioned to orchestrate complex post-market operations, including structured risk mitigation, targeted patient engagement and data-driven activities.

REMS: Structured Risk Mitigation at Scale

REMS programs are formal mechanisms mandated by the US Food and Drug Administration (FDA) to ensure that the benefits of certain drugs outweigh the risks.

REMS Stakeholder Journey

Data Collection

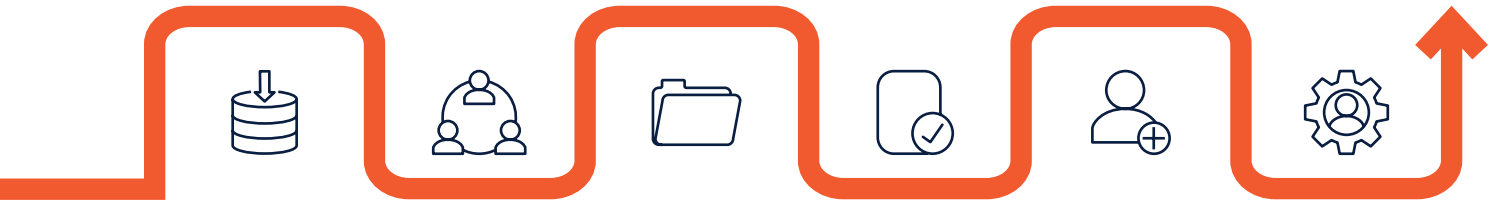
- Website
- Email
- Fax

Document Processing

- Document processing as attachments to case

Account Creation

- Portal account creation before or after enrollment
- Access management
- Manual or automatic approval process for account creation



Case Management and Stakeholder Engagement

- Case assignment based on source and case type
- Task management

Program Specific Validations

- Automatic or semi-automatic validation checks on entity information, training completion, affiliation, attestation
- Missing information follow-up

Enrollment and Account Maintenance

- Enrollment status maintenance business rules
- Reenrollment and reverification
- Enrollment status checks

For CROs, REMS operations include:

- Developing risk mitigation strategies and documentation
- Deploying education programs for healthcare providers (HCPs), pharmacists and patients
- Managing certification, enrolment and monitoring requirements
- Providing ongoing support for data collection, reporting and audits

This requires close coordination between multiple stakeholders, such as sponsors, specialty pharmacies, prescribers, health systems, regulators and patients, across channels and geographies. The volume and frequency of interactions create data management challenges due to an inherently complex, constantly changing operational footprint.

Medical Information: Data-Rich Touchpoint Across Lifecycle

Sponsors and regulators seek a comprehensive understanding of treatment impact beyond traditional trial settings. Consequently, clinical trials are slowly moving beyond controlled environments to include real-world evidence sourced from electronic health records, insurance claims, laboratory results, medical devices and patient-reported outcomes.

Med Info Services Stakeholder Journey

Data Collection

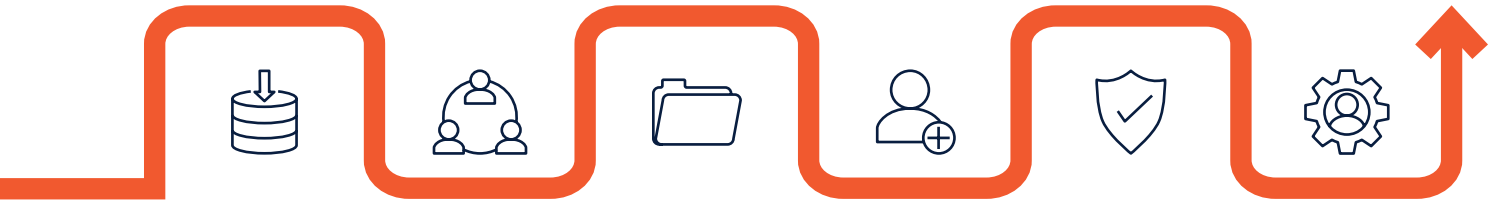
- Phone
- Email
- Fax

Document Processing

- Document processing as attachments to case

Capture, Provide Information and Safety Management

- Ability to capture unsolicited queries, respond accurately via materials from validated sources
- Capture, report AE, PQC



Case Management and Stakeholder Engagement

- Case assignment based on source and case status
- Task management

Account Creation

- Access management
- Manual process for account creation

Quality Review and Account Maintenance

- Program specific business rules
- User, stakeholder maintenance
- Data, case, safety, process management quality review and maintenance

Sponsors need to invest significantly in long-term extension studies and post-authorization safety investigations, as well as in establishing product and disease registries for ongoing monitoring. To remain a strategic partner, CROs must manage data ecosystems that span:

- Traditional clinical trial data structures
- Observational and registry data, often collected in heterogeneous formats
- Linkages to external RWD sources
- Integration with safety and medical information systems

This translates into a need for robust data governance, standards and technology platforms that can support continuous, lifecycle-oriented evidence generation and drug-reception monitoring.

CTCCS-Type Post-Market Frameworks

CTCCS has evolved from a responsive clinical trial call center function to a critical, insight-rich component of the drug lifecycle that:

- Handles unsolicited inquiries from HCPs, patients and caregivers across phone, email, chat, portals and social media
- Delivers consistent, compliant and medically accurate guidance, aligned with approved labels and scientific data
- Captures structured and unstructured data that can inform safety surveillance, medical strategy and even commercial insights

CTCCS Stakeholder Journey

Data Collection

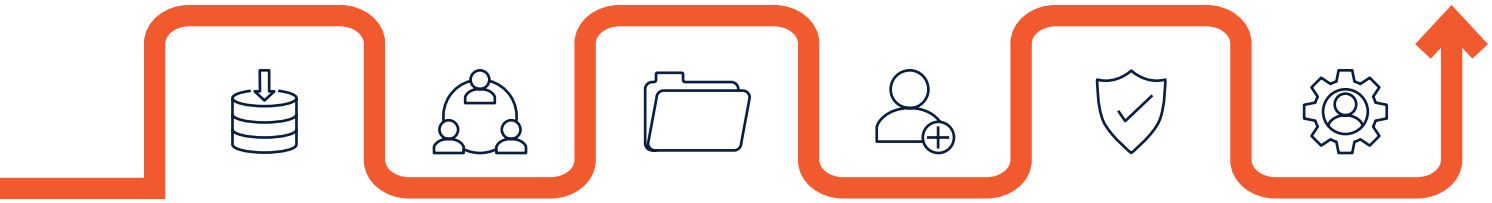
- Email
- Fax

Document Processing

- Document processing as attachments to case

Clinical Trial and Safety Management

- Support, remind, support patients through various clinical trial stages
- Capture patient outcome via surveys
- Capture, report AE



Case Management and Stakeholder Engagement

- Case assignment based on source and case status
- Task management

Account Creation and Enrollment

- Access management
- Manual process for account creation
- Stakeholder enrollment

Clinical Trial and Account Maintenance

- CT maintenance business rules
- CT status checks

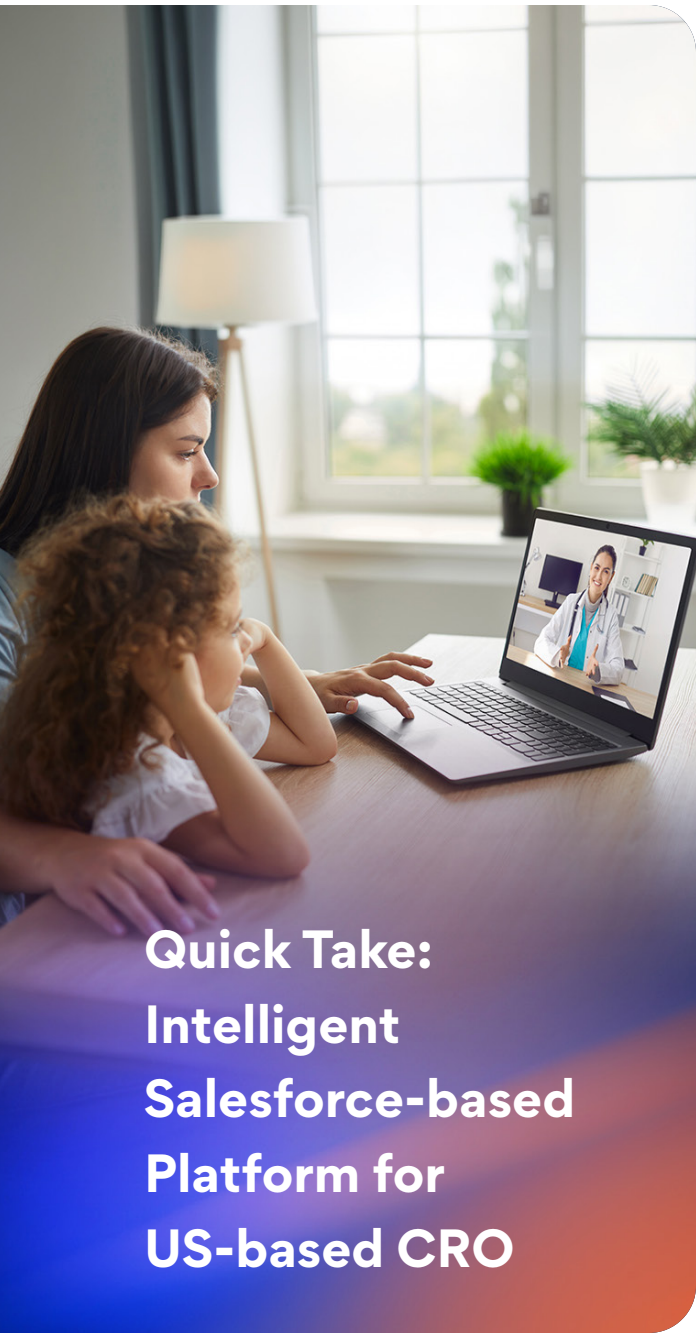
CROs need additional capabilities, such as 24/7, multi-lingual coverage, high content governance and version control as well as seamless integration with pharmacovigilance and quality systems, particularly for adverse events and drug quality complaint routing.

Cost to Business: Four Operational and Process Imperatives

To drive these functions, CROs should address the following operational gaps:

1. **Fragmented Landscape:** CROs maintain bespoke systems aligned to each sponsor or program, creating a fragmented mesh of separate instances or platforms. These platforms deploy distinct tools for critical study functions, including REMS operations, analytics and case management, further siloed by region-specific requirements.

   This significantly hinders control and process standardization, contributing to a lack of cohesion that impedes cross-program analytics and oversight, including the ability to generate aggregated risk views. The inability to efficiently reuse configurations, templates and content leads to unnecessary duplication of effort and resources, ultimately impacting operational effectiveness.



Quick Take: Intelligent Salesforce-based Platform for US-based CRO

Client Success

Read more

A major US-based CRO turned to Persistent to enhance data management, streamline regulatory compliance and meet evolving sponsor expectations.

Persistent's life sciences experts implemented the Salesforce Health Cloud as a single source of truth for patient, HCP and sponsor data, enabling secure, real-time information exchange across post-market surveillance functions.

> **The platform helps standardize data structures, processing and insight generation, with compartmentalized environments for different clients, ensuring role-based access and control.**

The platform, with a unified data backbone, unlocked AI and predictive analytics to automate eligibility checks, documentation and reporting, with in-built guardrails for adherence to FDA drug safety requirements and GxP, 21 CFR Part 11 and GDPR standards. The automated workflows streamline data structure, bringing transparency, auditability and scale to meet sponsor requirements.

With the Salesforce Health Cloud, the CRO has a scalable, validated and compliant operational structure, supporting proactive medical communication, efficient post-market surveillance and measurable business value for sponsors in a highly regulated landscape.

2. **Reliance on Manual, Spreadsheet-Driven Workflows:** Critical CRO activities continue to rely heavily on manual processes, such as eligibility checks and document reconciliation, ad hoc data transfers typically conducted via Excel and email and the preparation of individual reports and presentations.

   This opens the door to data entry errors and inconsistencies, leading to delayed reporting and difficulty meeting regulatory timelines, further escalating costs and eroding sponsor trust. Scaling with increased headcount without addressing underlying inefficiencies would continue to hinder growth.

Quick Take: AI-powered Data Engine Improves Forecasting by 40%

Client Success

Read more

A global CRO struggled with operational inefficiencies due to disparate, inconsistent and siloed data across inoperable systems. Teams spent considerable time manually consolidating records, leading to limited visibility into resource availability and delayed responses to business opportunities. These issues threatened regulatory compliance, strategic planning and collaboration with sponsors, ultimately risking business growth and expansion.

To address these challenges, Persistent implemented an AI-powered Master Data Management (MDM) Hub. This harmonized over 2.2 million reference data points, significantly reduced data duplication and inaccuracies and automated patient profiling and matching.

AI-driven validation and quality checks accelerated new data integration by 60% and improved forecasting by 40%. The centralized repository and automated governance ensured compliance and streamlined operations, making previously unattainable KPIs, such as timely resource forecasting and rapid business expansion, achievable.

3. **Regulatory Dynamism and Rising Sponsor Expectations:** Regular guidance updates on post-market surveillance activities, data methodologies and the use of digital channels introduce new compliance requirements. At the same time, sponsors increasingly expect CROs to implement near-real-time monitoring and analytics, deliver global standardization while maintaining local regulatory compliance and provide technology-enabled solutions that extend beyond mere staff augmentation. These heightened expectations signal the need to adopt advanced, integrated approaches to meet both operational and compliance demands.

4. **Cost, Margin and Talent Constraints:** Post-market engagements frequently extend over several years, during which volumes and requirements change. High levels of manual work and the need for custom solutions can significantly reduce margins, only compounded by an increasingly competitive market for specialist talent such as data engineers, medical information experts and REMS operations professionals.

   At the same time, sponsors are trialling outcome-based or risk-sharing commercial models, which puts even greater emphasis on efficiency and the ability to demonstrate value. Without a well-defined strategy, CROs are likely to struggle to maintain sustainable financial performance throughout the post-market lifecycle.

Client Success

Read more

Persistent collaborated with one of the world's leading CROs to bring scalability, data standardization and operational efficiency.

We developed a scalable genomic big-data platform and a comprehensive data lake, facilitating seamless data ingestion from multiple sources. Based on modern cloud data stacks to enhance governance and security, the solution automated collection-to-reporting workflows.

This led to a 70% increase in throughput and compressed variant interpretation from weeks to days. Most notably, Persistent's platform enabled the client to reduce the cost per sample to less than one US dollar.

Technology Uplift: Framing the North Star

To plug these gaps, CROs need an integrated technology and data stack grounded in regulatory and operational realities to evolve into end-to-end R&D partners. The selection strategy should focus on:

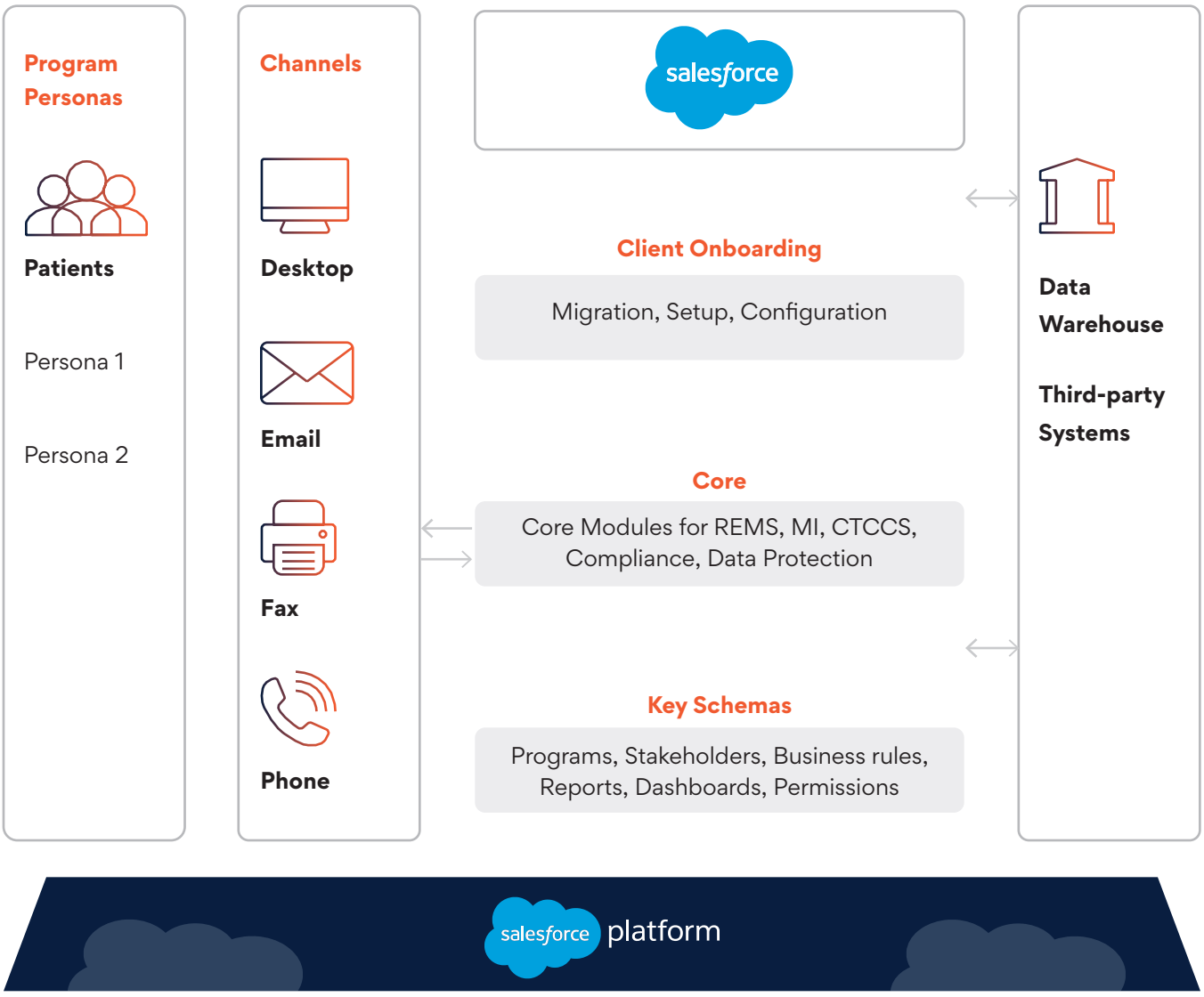
Life Sciences Expertise with Engineering Excellence

While cloud platforms can unlock integration architecture, data engineering, automation or AI / Machine Learning capabilities, they need to be bolted on with business logic around pharmacovigilance, medical affairs, RWE and regulatory compliance. This requires engineering expertise rooted in life science workflows for safety, medical information, CRM and analytics to ensure not just technically sound implementation, but also fully compliant operations attuned to sponsor expectations, responsive to the operational realities at the frontline.

From Project-Specific Builds to Reusable Platforms

Pivoting away from custom solutions for each sponsor or product, the right technology should enable configurable, multi-tenant platforms that support multiple post-market programs simultaneously. This requires establishing a shared services backbone for REMS, Medical Information and CCTCS-like coordination frameworks, designed to be parameterized rather than reconstructed for new scenarios. Standard data models and integration patterns can facilitate cross-program analytics and oversight, unlocking additional efficiencies.

Multi Tenant, Scalable and Extensible Solution



Operational, Compliance and Strategic Outcomes

Modernizing post-market operations delivers a multi-dimensional impact:

Compliance and Inspection Readiness

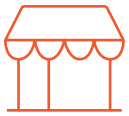
- Complete, accurate and traceable records for REMS, MI and post-market data
- Faster and more consistent responses to regulatory information requests and inspections

Quality and Consistency

- Standardized processes, templates and content across sponsors and geographies
- Lower error rates and fewer deviations in critical compliance workflows

Insight Generation and Strategic Value

- Integrated views of post-market evidence, enabling more proactive safety and medical strategies
- Enhanced ability to support sponsors in RWE generation, payer negotiations and lifecycle management



Market Differentiation

- Positioning as a technology-enabled, strategic partner for sponsors rather than a purely transactional vendor
- Ability to articulate clear value propositions around speed, quality and insight-generation in post-market services

Operational Efficiency and Scalability

- Reduced manual effort through automation and integrated workflows
- Ability to accommodate volume surges (e.g., new indications, label changes, safety events) without linear increases in personnel
- Robust multi-tenancy enables secure, compliant management of multiple sponsors on a shared infrastructure
- Efficient scaling and flexible configuration for diverse client needs

Partner to Win

In a market where the true measure of success extends beyond regulatory approval to sustained, real-world drug performance, CROs that invest in technology-enabled pharmacovigilance capabilities will be best positioned to create value for sponsors and, ultimately, for patients.

Persistent, a digital engineering and enterprise modernization leader, offers deep life sciences expertise to CROs looking to make the pivot. We bring a rich ecosystem of partnerships with leading cloud and vertical platform providers, such as Salesforce, along with a suite of in-house accelerators and domain experts who simplify last-mile implementations aligned with business context.

We have helped leading CROs consolidate and modernize fragmented systems, automate and standardize high-volume, high-risk processes and establish robust governance and compliance structures to drive REMS, CTCCS and MI capabilities. Our solutions enable clients to deliver differentiated, insight-driven post-market services that position them as trusted R&D partners.

Our work in the industry has been recognized by leading analysts, such as ISG, in its Provider Lens™ Salesforce Ecosystem Partners 2024 report, highlighting our expertise in Salesforce Health Cloud and Life Sciences Cloud across process consulting, design, configuration, data clean-up, migration and go-live support.

Re(AI)magining™ the World

Learn how Persistent can help operationalize post-market clinical trial activities and position your CRO as a trusted sponsor partner.

Contact Us

About Persistent

Persistent Systems (BSE: 533179 and NSE: PERSISTENT) is a global services and solutions company delivering AI-led, platform-driven Digital Engineering and Enterprise Modernization to businesses across industries. With over 27,500 employees located in 18 countries, the Company is committed to innovation and client success. Persistent offers a comprehensive suite of services, including software engineering, product development, data and analytics, CX transformation, cloud computing, and intelligent automation. The Company is part of the MSCI India Index and is included in key indices of the National Stock Exchange of India, including the Nifty Midcap 50, Nifty IT, and Nifty MidCap Liquid 15, as well as several on the BSE such as the S&P BSE 100 and S&P BSE SENSEX Next 50. Persistent is also a constituent of the Dow Jones Sustainability World Index. The Company has achieved carbon neutrality, reinforcing its commitment to sustainability and responsible business practices. Persistent has also been named one of America's Greatest Workplaces for Inclusion & Diversity 2025 by Newsweek and Plant A Insights Group. As a participant of the United Nations Global Compact, the Company is committed to aligning strategies and operations with universal principles on human rights, labor, environment, and anti-corruption, as well as take actions that advance societal goals. With 468% growth in brand value since 2020, Persistent is the fastest-growing IT services brand in 'Brand Finance India 100' 2025 Report.

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