White Paper

Turn Insight into Action with Connected Intelligence

Leveraging compliance expertise, data, and automation to drive better outcomes

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Introduction

Life sciences companies that position themselves to be early adopters of human data science will be ahead of the curve

Well-managed compliance data collection and reporting processes can mitigate compliance risk, but there's an even more compelling reason to invest in policies and protocols to optimize these business functions: Tools that support the relational analysis of disparate data, position compliance departments at the leading edge of a new landscape of ideas and innovations in data utilization.

The best compliance management systems can yield enterprise-wide benefits. You can unlock actionable insights to inform future business decisions — creating a positive feedback loop for meeting and improving performance benchmarks. These intelligent solutions don't just facilitate compliance, they encourage adoption, giving companies the tools needed to adapt and improve business processes.

"Life science companies dedicate 80% of resources to making sense of data, while realizing only 20% of its value is in the form of useful generated insights. All too often, these investments take place in disconnected silos. Additionally, 77% of enterprises struggle with the business adoption of the insights, limiting their ability to act, measure and adjust. IQVIA Connected Intelligence™ is how global healthcare domain expertise, transformative technology, unparalleled data, and advanced analytics come together to transform insight into action."

77%

OF ENTERPRISES STRUGGLE WITH BUSINESS ADOPTION OF INSIGHTS

HARNESSING THE POWER OF COMPLIANCE DATA: GO BEYOND TRANSPARENCY ANALYTICS TO ACHIEVE GREATER INSIGHT

At the nexus of information and analysis is human data science — a discipline that blends the consultative focus of IQVIA's benchmark-establishing expertise with next-generation analytics that leverage machine learning to create holistic compliance risk perspective.

Here's how to launch that transition.

1. **Tap new data streams:** Think beyond CMS and internal audit results. Advances in data collection and reconciliation make it possible for a life sciences company to monitor compliance across a wide range of inputs in almost real-time. This allows more proactive risk management—from HCP office visits to call logs, from grant and donation management to medical information requests, from fee for service documentation to compliance training records.

   - Augment the effectiveness of internal controls by using automation and Artificial Intelligence/ Machine Learning (AI/ML) to facilitate reconciliation and integration between various data sources.
   - Establish compliance benchmarking with KPI metrics and both short- and long-term goals for identifying and mitigating risk.
   - Augment the effectiveness of internal controls by using automation and AI and ML to facilitate reconciliation and integration between various data sources.
   - Catalog and inventory available data assets across silos, including HR, sales and LMS, including any gaps that impede visibility into potential behavior risks.
   - Design a dashboard that reflects the alignment of these objectives with enterprise-wide business functions.
   - Evaluate your reporting policies to achieve operational consistency in monitoring methodology.

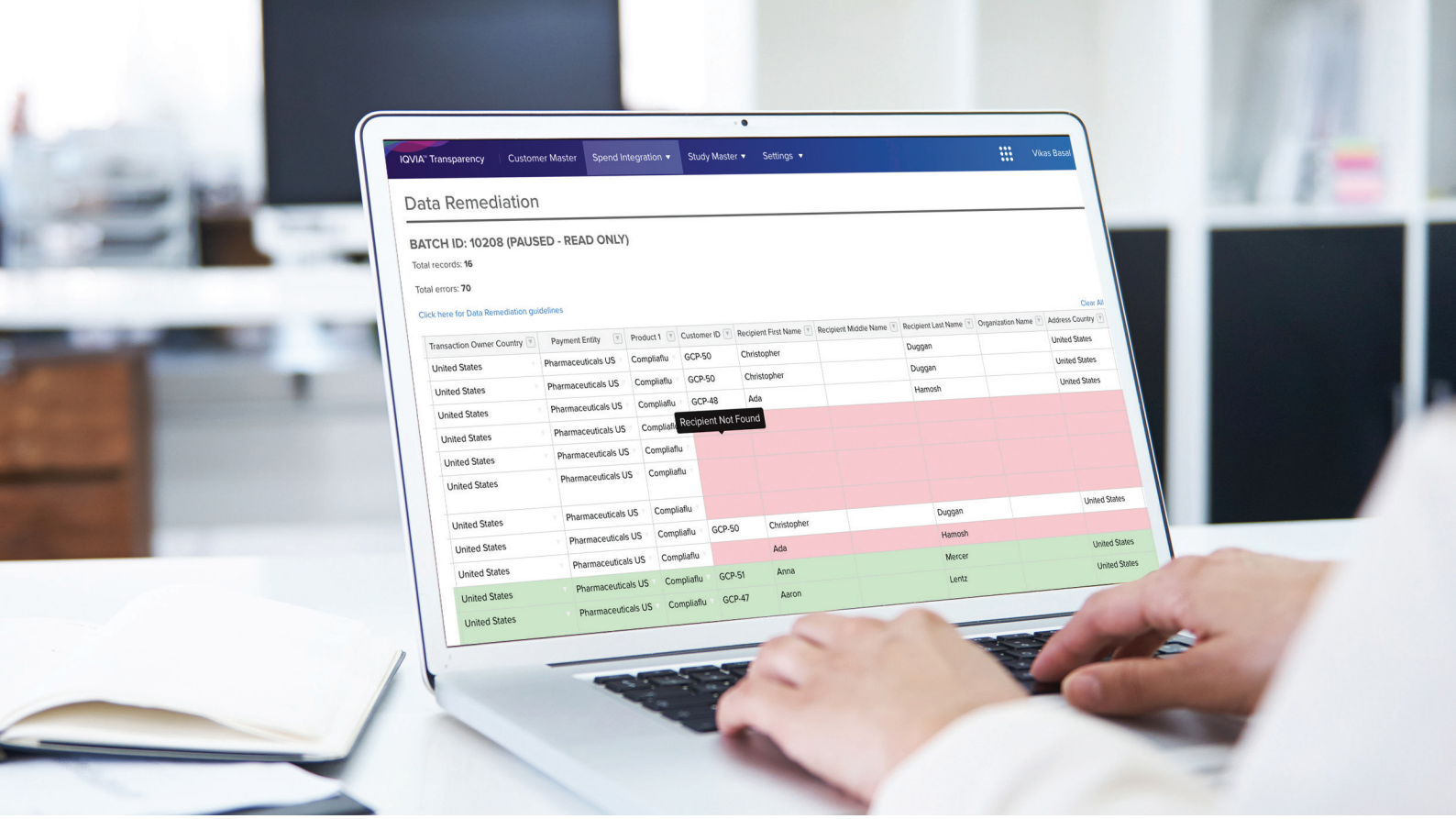
2. **Create a process management strategy:** Companies must make sure to accurately capture and report a proliferating cross-section of data points. A solution that embeds risk evaluation in review processes along with traditional live and transactional monitoring gives compliance professionals a comprehensive overview of key risk indicators on an ongoing basis.

   To achieve more responsive and nimble compliance management, establish a workflow and develop a platform comprising the following key elements:

   - Ongoing risk-based reviews — with real-time reconciliation, transactional and spending checks built into the technology.
   - Documentation of key findings — inclusive of continuous follow-up, systemic mitigation and seamless transition to a multi-step corrective protocol.
   - Reporting to high-level stakeholders — equip your compliance committee with the necessary communication tools to provide accessible and relevant updates to senior leadership.

3. **Remain dynamic:** Throughout the development process, compliance monitoring needs to be a flexible process for information to be leveraged to its full potential. Data is no longer static, so management needs to seek out agile, world-class technology to effectively capture the value that can be harnessed with AI-assisted analytics.

Compliance solutions must be integrated and consistently updated with accurate HCP/O information. IQVIA OneKey aggregates all compliance engagements at HCP/O level for accurate reporting — respecting different regulatory data formats including the provision of Unique Country Identifiers.



IQVIA Transparency Reporting Spend Remediation Intelligence enables the ability to learn from previous corrections, auto-applying changes to speed up processes.

AN OVERVIEW OF THE CURRENT MARKET TRENDS AROUND COMPLIANT HCP ENGAGEMENT: TRANSPARENCY BEGETS INNOVATION

Compliance requirements have driven much of the innovation at the forefront of today's market trends, as expanding transparency requirements demand more extensive documentation of interactions with HCPs, HCOs and patients.

A silver lining to increasing regulatory scrutiny is that data collection and reporting requirements yield a trove of data that companies can leverage for increased visibility into HCP interactions and the spending patterns associated with those touchpoints.

Artificial intelligence and machine learning translate this visibility into actionable insights professionals can use to improve business practices — not only within the realm of Commercial Compliance, but across the spectrum of Marketing, Field Sales, Legal, HR and R&D.

Target spending initiatives, in order to augment visibility into prescriber behavior in near-real time. With the help of sophisticated AI, you can spot patterns immediately, without waiting for an annual review to figure out what's working and what could be improved.

In such a dynamic industry, being able to pivot rapidly is a tremendous competitive advantage. For instance: See which activities are yielding the most high-quality engagement, and determine if your current resource allocation matrix is optimized or needs to be changed.

WHAT TECHNOLOGY CAN — AND CAN'T — DO FOR COMPLIANCE ANALYSIS: HOW TO MAXIMIZE THE VALUE OF YOUR INVESTMENT

Embedding compliance into the DNA of a technological solution gives managers real-time transparency into upstream and downstream sales and marketing activities, promotional programming and all kinds of HCP touchpoints. Ongoing operational monitoring adds value in two distinct ways: It relieves compliance departments of the burden of rectifying errors or patterns of problematic behavior after the fact, and the automated monitoring built into the system frees up human capital bandwidth so executives can devote more time to strategic pursuits.

The great promise of this technology is its ability to facilitate connectivity between platforms for CRM, expense management, promotional speaker contracting and content programming, logistics and other discrete business functions.

Once reporting methodology is standardized and seamless data collection is achieved, engagement management technology can generate insights that can be deployed to improve services and logistics processes — the catalyst for a virtuous cycle. The demand for more sophisticated data yields visibility into engagement outcomes, that can augment the value of the company's investment in transparency-promoting technology.

Managing compliance risk has never been about a single workflow or static set of best practices — and that axiom is now more than ever an enterprise-wide imperative for companies. The more diverse and holistic the data flowing into the system becomes, the better and more consistently compliance adherence can be accomplished.

CRAFTING THE IDEAL END-TO-END PROCESS: DISCOVER HOW (AND WHY) YOU SHOULD CREATE A NEW COMPLIANCE PARADIGM

Data isn't just a byproduct of compliance management. It is a resource that can and should be leveraged for competitive gains. Modernizing compliance programs means taking all of the relevant data and bringing it under a single technological roof.

HCP engagement risk is still a top risk for life sciences. Aside from the compliance benefits, centralized and standardized HCP engagement and spending data forms the building blocks of a cohesive predictive action plan. Drug, device and biologics manufacturers need a compliance technology platform backed by consultative excellence, so they can obtain guidance and insight in advance of development and deployment.

Improving the quality of data at the point of collection helps companies achieve optimized downstream reporting — but that's not the only benefit. In addition to facilitating end-to-end compliance, companies benefit when AI-assisted analytics alert the compliance department to future potential red flags, to enable the strategic deployment of limited resources to emerging risk areas.

In order for compliance programs to succeed, the technology used must be seamless, aligning with business processes to ensure adoption. A lack of adoption leads to a lack of data—diminishing system value. Usability of platforms must be a key consideration prior to implementation.

Technology has enhanced the agility of compliance and engagement protocols by leaps and bounds, but even good technology can't fix inadequate or outdated process management. Even though technology is considered the foundation — if the ground beneath isn't level, that foundation isn't going to be solid. As such, it is critical to assess, remediate and harmonize workflows prior to defining requirements and deploying technology.

Empower your compliance team to optimize their performance by adopting a risk-based approach to monitoring engagement as follows:

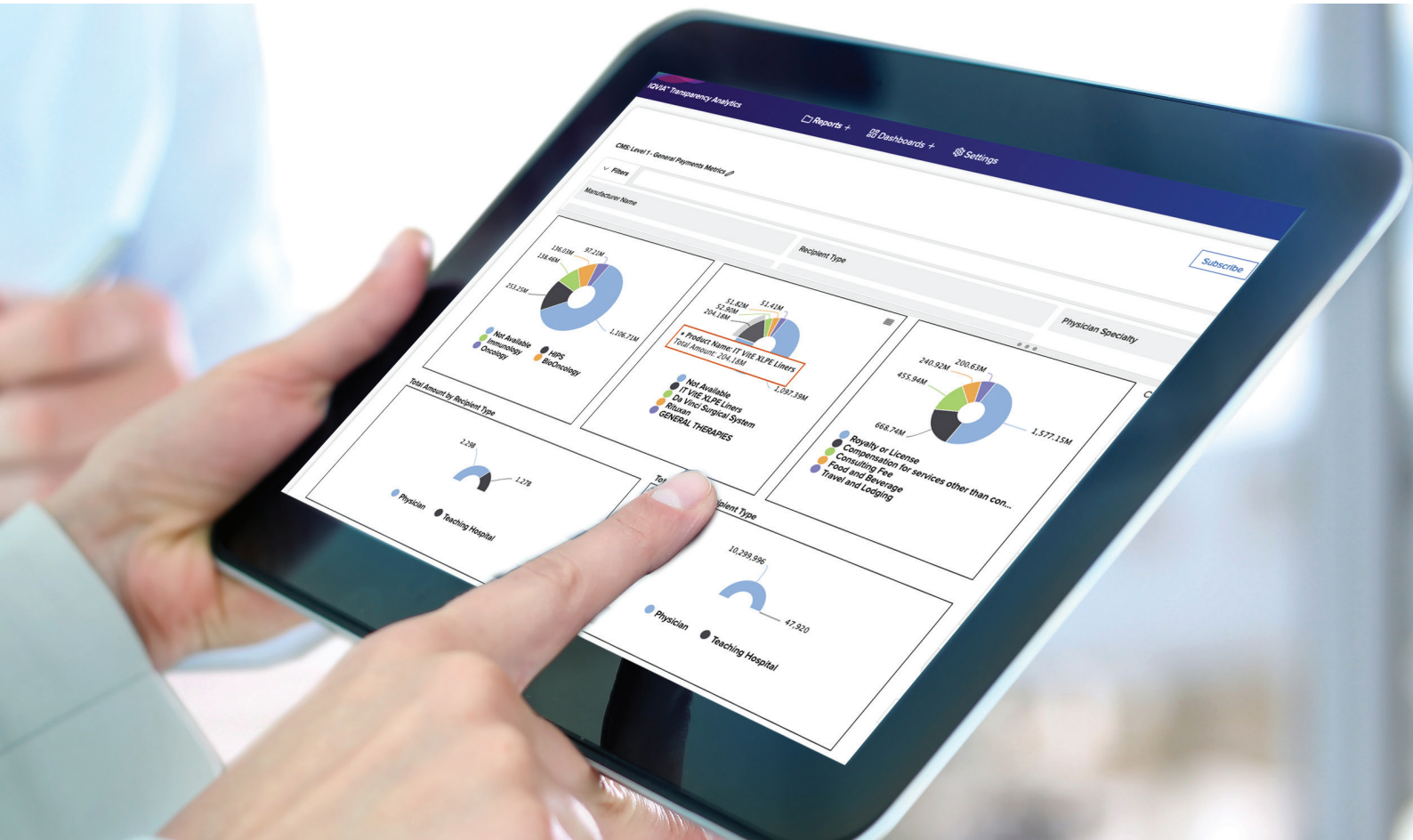
1. **Standardize data collection and reporting:** This process is a key step towards reducing the risk of ToV errors, and reconciling the number and type of HCP interactions—across therapeutic practice areas and all along the spectrum of promotional activities.

2. **Improve the end-user experience:** Improve relationships with your HCP audience and your KOLs by delivering a simple, user-friendly experience. A nimble, responsive interface increases user adoption. HCPs will have a better and more seamless experience, and companies will better synchronize both their touchpoint management and their compliance oversight. This allows organizers of promotional speaker series, grant programs, field reps and other stakeholders to all operate autonomously while simultaneously implementing compliance.

3. **Create internal efficiencies:** The industry needs connected data — not just to avoid regulatory violations, but in order to streamline and optimize business operations. By improving the data capture process, an initial engagement yields higher-quality data that facilitates more accurate downstream reporting. This, in turn, delivers cohesive, high-quality risk mitigation and real-time compliance monitoring.

4. **Mitigate risk**: Even "modern" compliance infrastructure is often a patchwork of disparate tools and systems — which is an open-ended conduit for risk. The more fragmented the operational structure, the more likely it is that HCP engagements will fall through the cracks or not be appropriately categorized; or that ToV will be incompletely or incorrectly calculated, or that HCPs will have to wade through multiple platforms — even when performing activities for the same company.

IQVIA Transparency Reporting allows commercial and compliance teams to leverage CMS data for strategy development and competitive insight through interactive dashboards and reports.



5. **Achieve master data management:** Piecemeal efforts at compliance management can have tangible detrimental effects on the business bottom line and inflate opportunity costs that can erode morale and management support. A system that is fluent in the "language" of both traditional and non-traditional data can be the catalyst for more nimble, responsive operational protocols.

6. **Transition from process to project:** An integrated, four-pronged strategic framework creates strength without unnecessary redundancy to ensure that every activity is filtered through an accurately deployed system of checks and balances for targeted risk oversight:

   - Create a "30,000-foot" view with an integrated monitoring dashboard that presents cohesive insight across therapeutic areas, field teams' HCP touchpoints and activities pertaining to patient assistance. To keep information both high-level and accessible, insights extracted and extrapolated from the data should be rendered in graphic format to make key activity risk indicators immediately actionable.

   - Implement live in-person monitoring to facilitate real-time oversight of a risk-targeted sample of business activity that can be overseen by an internal or external monitor.

   - Use desktop monitoring and transaction review checks for alignment of policies and protocols pertaining to HCP engagement rules, aggregate and individual spending limits and ToV documentation and reconciliation.

   - Expand the use and applications of data to proactively identify non-compliance trends and focus areas for monitoring. The use of data-enhanced risk identification enables access to highly granular information from nontraditional sources.

The ultimate outcome: Integration of silo-inclusive monitoring results facilitated by IQVIA's intelligent infrastructure. Improve return on investment when you deploy AI-enhanced technology to increase the agility and responsiveness of your commercial compliance.

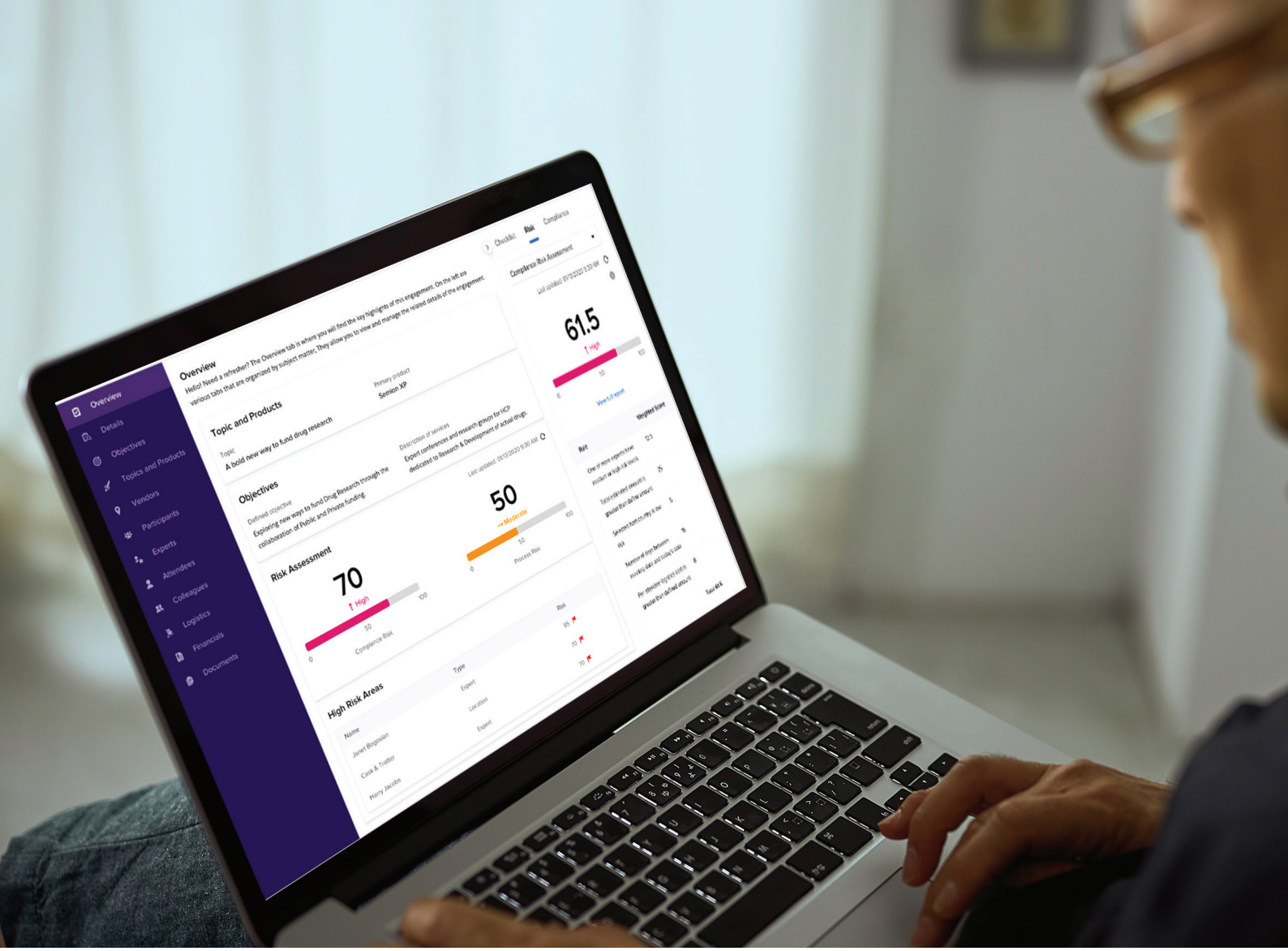
WHAT CAN GLOBAL HARMONIZATION DO FOR YOU? DON'T JUST THINK ACROSS SILOS — THINK ACROSS BORDERS

The trajectory is clear: Globalization is a key theme in today's economy. The multinational efforts of pharmaceutical companies in developing therapies and vaccines for COVID-19 are just the leading edge of the changes manifesting in the industry today.

In any discussion of the next frontier of compliance, globalization is a central topic. The industry's futurists know that the next phase for compliance isn't just cross-silo, but cross-border. Life sciences companies have to be prepared to compete on a global stage and adopt holistic compliance management to serve an expanding marketplace.

While implementing local or regional solutions might seem to address the issue in the near term, a centralized solution means a nimbler operation: It offers more political flexibility and promotes a more seamless data pipeline. Centralized management also is more agile in the face of regulatory transition, able to adapt without delay if a governing body changes its enforcement parameters with little notice.

As more countries and regions adopt Sunshine Law-style oversight, manufacturers have to keep abreast of a continually shifting legal landscape. Harmonization to a single platform adds value by improving cost-effectiveness and efficiency.



Built into IQVIA HCP/O Engagement Management, Automated Risk Scoring and Compliance Companion educates the end user of the boundaries of compliance, leveraging automated controls. This embedded monitoring frees up bandwidth, both mitigating risk and enabling more time for strategic pursuits.

LOOKING BEYOND 2021: WHAT ARE MY RISKS TODAY — AND WHAT WILL THEY BE IN THE FUTURE?

It is clear that the industry is at an inflection point: With technologies that are integrated and can communicate seamlessly, pivoting and staying on top of industry changes is easily achievable. Yesterday's risks are not today's risks, and today's risks are not tomorrow's.

1. **Transparency requirements grow more rigorous:** In the years ahead, enforcement will become even more of a critical priority, as the Department of Justice and other regulatory agencies — including, notably, state prosecutors — increase scrutiny on many long-standing industry practices like promotional speaker programs. The DOJ and states have been intensifying their scrutiny of CMS Open Payments data and companies' Sunshine Act data reporting in pursuit of compliance errors that can lead to penalties for violating the False Claims Act and the Anti-Kickback Statute.

The next phase for compliance is cross-border. Companies must compete on a global stage and adopt holistic compliance management to serve an expanding marketplace.

2. **A shift to virtual opens up new potential pitfalls in real-time risk mitigation:** Companies need to remain vigilant, even as much of the HCP engagement that has taken place over the previous year has moved to the virtual realm as a result of COVID-19. Nearly all aspects of an in-person or remote speaker program are in regulators' crosshairs, from site selection to meal-planning in accordance with FMV guidelines, to reconciliation and data capture around payments or other ToV made to participants.
3. **Evolving patient care pathways create new challenges in HCP engagement:** The need for connected data is only expected to become more pressing in the future—it reduces risk for manufacturer interactions with HCPs and promotes more favorable patient outcomes. The COVID-19 pandemic has altered traditional sales models, perhaps permanently. By improving the quality of data collection at each initial engagement touchpoint, companies can vastly improve downstream reporting — an outcome that obviously has strong positive ramifications for compliance management, but also holds the promise of a nimbler response when conditions on the ground change rapidly.

While no one can see into the future, the evolution of AI and ML technology is so rapid and its deployment so increasingly widespread that it has served as a catalyst for rethinking long-held operational routines and protocols. Use cases involving predictive technology encompass a proliferating array of business functions, and are increasingly relied upon to successfully achieve outcome-based goals.

From the beginning, IQVIA has been leading the evolution of commercial compliance: Its consultative approach and best-in-class technology offered the first solutions predicated on an end-to-end philosophy of HCP engagement data management. Today, it remains at the forefront as benchmarks for upstream and downstream data accuracy rise, and the prospect of using compliance data management to achieve enterprise-wide performance enhancement becomes reality. Through IQVIA Connected Intelligence™, companies can now access previously unseen insights from compliance data, informing smarter and more strategic commercial decisions.

About the authors

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Bill has 25+ years of experience in the areas of sales, operations, compliance, and leadership, including 20 years with IQVIA (through various acquisitions and mergers) and 7 years with Knoll Pharmaceuticals.

Currently Bill leads the US compliance and quality business unit with a goal on expanding compliance and quality offerings across IQVIA's vast customer base with a focus on customer satisfaction, technology innovation, service excellence, and employee growth. Prior to the Quintiles – IMS Merger and IMS Health's acquisition of Cegedim, Bill was the Senior Vice President of Business Development for Cegedim's U.S. business unit. Bill held several other leadership positions at Cegedim including Vice President of Global Compliance Solutions, and Vice President of US Compliance Solutions and OneKey divisions. Prior to Cegedim, Bill was co-owner of BuzzeoPDMA, a leading compliance solutions provider, which Cegedim acquired in 2005. Bill has a Bachelor of Science degree from Virginia Tech and a Master of Science from Syracuse University.

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With more than 20 years' experience in life sciences, Jill joined IQVIA in 2017, and currently leads Customer Enablement and Strategy at IQVIA Commercial Compliance. Her experience spans several functional areas including business development, sales strategy, revenue growth management, analytics and global insights. Prior to joining IQVIA, Jill held industry positions with Novartis, Kellogg, Pfizer, and Johnson & Johnson. In her current role, Jill drives thought leadership, subject matter expertise and global sales strategy, collaborating across global and regional teams, supporting content creation and solution design.

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Michael Utell is the General Manager of IQVIA's Commercial Compliance practice and its portfolio of technology products, global engagement services, and strategic consulting. With over a decade of experience in the compliance space, Michael brings expertise in regulatory policy, strategy, and software to IQVIA Technologies. Michael was previously a Partner at Polaris Solutions, and joined IQVIA in 2017 following their acquisition. At Polaris, he led the firm's technology practice where he oversaw the deployment of global compliance solutions. Michael has led engagements at over one hundred and fifty companies across a variety of disciplines including HCP management, aggregate spend technology, service delivery, master data management, and application integration. He holds a Bachelor of Science in Information Management & Technology from Syracuse University and completed his Master of Business Administration from Duke University's Fuqua School of Business.

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Justin is an accomplished compliance leader with over 12 years of diverse industry and consultancy experience developing, implementing and leading strategic compliance programs. Justin joined IQVIA from Arthrex, Inc. where he was the Regional Compliance Officer for North America and EMEA regions. Prior to Arthrex, Justin was the Regional Compliance Officer for the Americas at BioMerieux, Inc. Justin also spent several years with PwC assisting a diverse set of clients in the area of healthcare corporate compliance. Leading up to PwC he held several roles of increasing responsibility with AstraZeneca in global compliance commercial audit and internal audit. Justin holds a Graduate Certificate in Healthcare Compliance from George Washington University, a Juris Doctorate from Widener University School of Law, and a Bachelor of Science in Accounting from Saint Joseph's University.

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