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Listen. Advise. Implement.

Planning and Managing Audits- A service Provider Perspective

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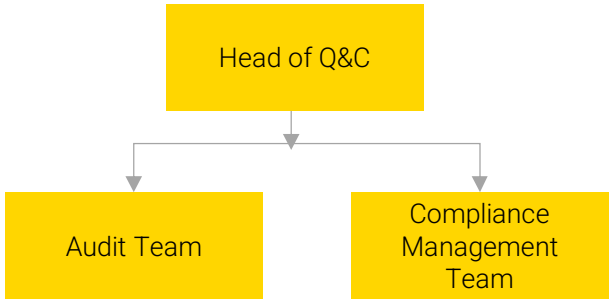
What's Changed in the last 5 years?

A number of changes have been noted in the last few years which introduces complexity to the 'PV Ecosystem'

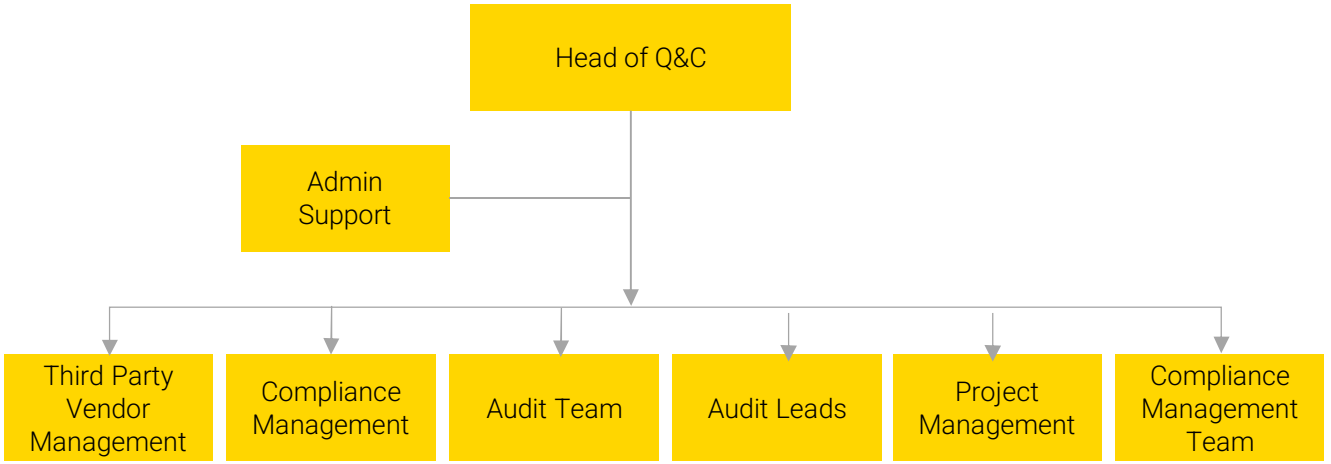
- Number of Clinica Trial Approvals
  - An increase in number of Commercial organizations investing in R&D without the strengthened understanding of GCP
- AI enabled and integrated Tools
  - Lots of them!
- Emerging Markets with developing PV Systems
  - How do we introduce a system of collection, evaluation and analysis when the Local PV role is less matured
- Acquisitions and Mergers
  - Lots of them!
- Pace of Approval

How have the Q&C teams evolved within a service provider

Q&C team 2020



Q&C team 2026



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Novo Nordisk- Post Marketing Adverse Drug Experience

- Internal criteria allowed **cancelling adverse event reports** when reporters believed events were unrelated to therapy, conflicting with FDA requirements to submit serious, unexpected events irrespective of suspected causality.
- Case intake processes, including call-center contractors, **inappropriately invalidated reports for "missing" identifiers** despite source documentation, resulting in at least one semaglutide-associated death not being reported.
- **Medical review workflows failed to triage and assess serious cases** promptly; a semaglutide suicidal ideation report received December 2024 was not reviewed until FDA inspection.
- **Follow-up procedures improperly required reporter consent**, delaying or preventing investigation and submission of serious cases, including at least one death, and raising concerns beyond sampled products.
- Remediation includes revising SOPs, **shifting intake to in-house HCPs**, **strengthening vendor oversight**, and retrospectively reviewing closed pharmacovigilance deviations back to June 2017.

Focus of Significant Change within the Service Provider

- Automation that have been introduced as a Service Provider
- Subcontracting as a Service Provider
- Delivering services in Emerging Markets
- Managing Transitions and Integrations eg 2 PV systems

Managing Automation within the Service Provider- AI inspection Readiness is a Baseline

- Two Forms of Automation have been introduced with Four more initiatives planned for 2026
  - Automated Intake
  - Literature Management

- The joint release of guiding principles by the FDA and EMA in 2026- made things very clear:
  - AI governance must be explainable , traceable and inspection ready
  - How can we prove that every model decision, automation role and LLM generated narrative can withstand regulatory scrutiny

- We as a service provider, must prove to you as our clients, that we can reconstruct every AI decision with complete traceability
  - We must prove that we control the AI within our PV ecosystems

- How do we prove that our AI system performs within defined parameters-
  - What are the performance metrics we use
  - When and how is human intervention required/ introduced

- Can we demonstrate continuous compliance throughout the AI lifecycle- from initial validation right through to ongoing monitoring to eventual retirement – we must follow GxP and good machine learning practice in PV principles

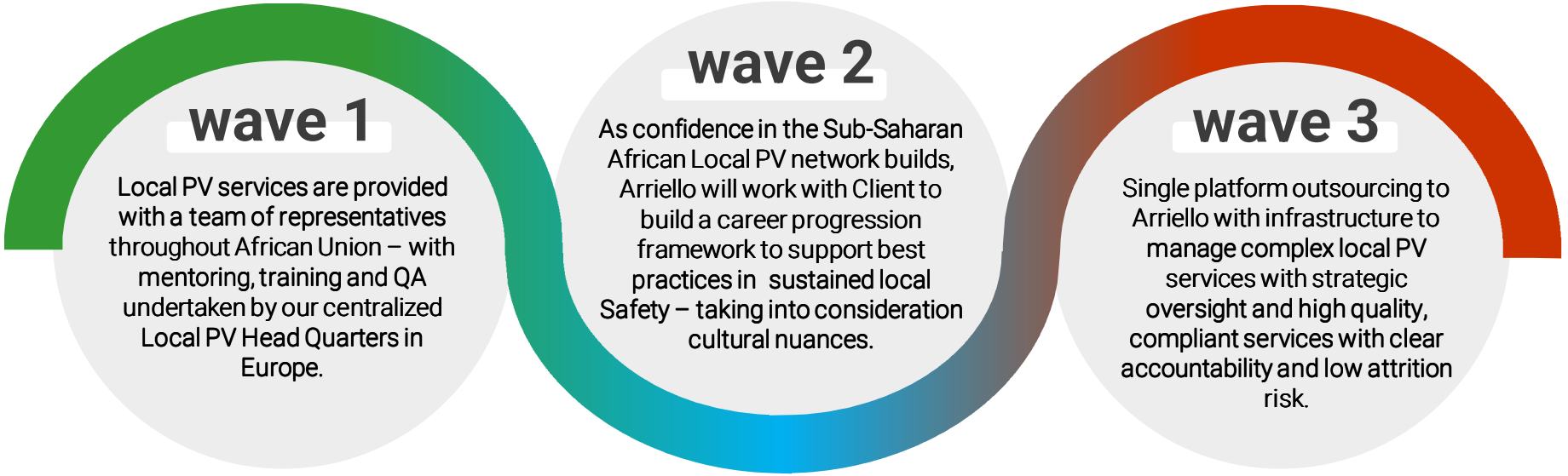
Clear Accountability with a RACI framework

Who is responsible for the AI decisions

- The first step in building defensible AI workflows is defining who owns what. Following best practices for AI governance in drug safety and pharmacovigilance, **primary accountability must sit with the PV process owner — not within IT or data science functions**.
- However, inspection-ready governance cannot operate under a single stakeholder. It requires a federated operating model where accountability, risk oversight, data stewardship, and technical execution are clearly separated but collaboratively governed.
- A robust governance structure includes:
- **Process Owner (Accountable):** The PV team member responsible for the business process using the AI, focused on outcomes rather than technical implementation
- **Data Owner (Responsible for quality):** Accountable for classification, protection, use, and quality of input data
- **Product Owner (Technical liaison):** Bridges the gap between technical AI implementation and business requirements
- **Risk Management Lead:** Coordinates risk identification, assessment, and mitigation strategies
- **Oversight Board:** Provides governance across technical, business, and risk domains

Arriello's Roadmap For Emerging Markets

Roadmap towards sustainable Patient Safety in the African Region:



Over a three-year period, Arriello will strengthen your Local PV output in a compliant manner, become a leader in the Pharmacovigilance space within Sub-Sahara Africa. Iteratively, year-on-year reduction in QA and oversight will yield a fit-for-future model and team for XXXXXX.

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Simplification of the Complexity

- Governance Calls with Service Provider should include :
  - An update from Service Provider on the output of our Automation Governance
  - Pertinent Updates on Sourcing strategy
  - Trends and Continuous Improvement Initiatives eg reducing the number of CAPAs
- Trust
  - Management of our Third- Party Vendors and audit categorization
  - Changes in Vendors and Resources- could be underlying issues
  - Empower the Service Provider to be responsible and accountable for the delegated activities
- Collaborate
  - Mistakes will happen
  - Emerging Markets are establishing themselves very quickly, but we need to build standards and KPIs that are suitable based on the maturity levels of the Pharmacovigilance system
  - Training Programs for the betterment of patient safety overall
- Plan
  - Be transparent about the strategy- divest or acquire
  - Think with the end in mind and force PV to be around the table when planning for acquisition
  - Due diligence ahead of Acquisitions

What does Business Transformation Mean to you?

- RFP Received in 2025 show:
  - Business Transformation is iterative , and some clients are failing first time with wanting to achieve too much in short space of time
  - If an RFP is being generated, does that suggest you as an organization are ready to accept change and further evolution
  - Have you planned for Geo-Expansion internally
- Have you reviewed processes first and determined they are fit-for purpose- eliminating unnecessary corporate nuances