

Is precision medicine truly precise in the absence of an AI foundation?

Governing informed consent and biosample data in precision medicine requires an audit trail.

Precision medicine is built on a promise to patients that the biological samples and genetic data they contribute will only be used as consented, will be governed carefully and will be protected from unauthorized secondary use. Regulators, ethics committees, and increasingly litigious patient advocates expect pharmaceutical companies to prove that promise, with evidence, not just assurances.

Yet for most precision medicine programs, the governance infrastructure behind Informed Consent Forms is manual, fragmented and dangerously dependent on individual expertise. Requests arrive by email. Reviews happen in spreadsheets. Decisions are communicated by email and stored as PDFs. When a regulator asks for the audit trail, or a biosample is requested for a secondary use, the evidence needed to confirm compliance is often reconstructed by hand, from sources that were never designed to support it, and with very limited decision-making confidence. The introduction of AI and agentic AI is set to further complicate compliance, with greater risk of exploiting the use of data with weak controls in place.

Where precision medicine organizations face the greatest governance risk.

- **No centralized Informed Consent Form (ICF) register:** ICFs, review decisions, country and site variations and biosample use permissions exist across email threads, Excel trackers and PDF archives, with no single governed inventory
- **Decisions depend on key individuals:** Decision rights and SME responsibilities are unclear, and institutional knowledge is concentrated in a small number of people. When SMEs are unavailable, reviews stall or bypass controls entirely
- **No comprehensive audit trail or governed ICF register:** The full journey from request initiation through triage, ICF review, SME escalation, decision and final approval is not systematically captured. Decisions are fragmented across email and Excel with no searchable, version-controlled record
- **Biosample reuse is ungoverned:** There is often no formal mechanism to track biosample-data reuse decisions. Classification by analysis type, country, permission status and mandatory versus optional collection is inconsistent, creating regulatory exposure and risk of unauthorized secondary use
- **ICF language drifts across countries and sites:** Protocol, master and country-site ICF language can diverge from approved templates without detection. Regulatory drift accumulates silently until an inspection surfaces it
- **Service Level Agreement (SLA) controls are absent:** 24- to 48-hour review windows can close without response. Follow-up and escalation are manual, creating operational risk and management blind spots. Accountability is absent. SLA breaches, escalation bypasses and overdue reviews are often invisible to management
- **ICF review is a compliance and reputational risk:** Unauthorized secondary usage of biosample data carries risk of litigation and loss of public trust, particularly where vulnerable patient populations are involved

You can't confirm consent compliance if the decision record depends on someone's inbox. You can't govern biosample reuse if classification has never been standardized.

Collibra Life Sciences solution

- **Centralized ICF register in Collibra:** Collibra creates a single governed register of ICF reviews, decisions, study and country context, permission status and biosample use classifications, as well as promoting a single source of truth for all review activity, accessible, searchable and audit-ready
- **Structured ICF intake and workflow:** Collibra replaces freeform email requests with a structured intake process capturing required fields, routing logic, SLA tracking, escalation paths and status visibility, eliminating missed information and manual coordination while making workload and accountability transparent to management
- **End-to-end audit trail and lineage:** Collibra captures the complete ICF journey from request initiation through triage, review, Subject Matter Expertise (SME) escalation, decision and final approval, retaining the evidence needed to reconstruct any decision for inspection or regulatory response without manual reconstruction
- **Consent decision classification:** Collibra standardizes classification of biosample and data consent by analysis type, country, permission status and mandatory versus optional collection, turning repeat reviews into searchable precedent lookups and supporting defensible reuse decisions across borders
- **SLA, escalation, and accountability dashboard:** Collibra tracks review SLAs, outstanding actions, overdue responses, escalation paths and bypass events with visible ownership, preventing reviews from silently lapsing, giving management real-time visibility into governance performance
- **Centralized biosample terminology and business glossary:** Collibra defines and governs the terminology, ownership and governance boundaries between physical biosamples and data generated from them, eliminating ambiguity in routing and classification that creates downstream compliance gaps
- **AI-assisted ICF template comparison with Deasy Labs:** Deasy Labs extracts structured attributes from finalized ICF PDFs, compares country and site ICF language against approved templates, and flags deviations and regulatory drift for SME validation
- **Governed ICF knowledge hub:** Collibra centralizes FAQs, approved guidance, prior decision history and review examples with a defined ownership model, making expert knowledge scalable, reducing repeated questions and eliminating key-person dependency

Key outcomes

Findable, traceable, defensible ICF governance at scale.

Collibra transforms precision medicine ICF governance from a manual, email-driven, key-person-dependent process into a governed, auditable and scalable operation. Every consent decision is recorded. Every biosample reuse classification is standardized. Every review is traceable from request to final ICF. That is not just inspection readiness; it is the dependable governance foundation that trustworthy precision medicine requires.

Collibra + Deasy Labs

Unlock the governance value locked inside finalized ICF PDFs. Bring machine learning and natural language processing to your unstructured data to extract structured attributes from consent documents at scale, enabling automated template comparison, deviation flagging and classification. Deasy Labs turns previously static documents into governed, searchable, reusable data assets for more reliable and complete decision making.



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