

One Workflow to Rule Them All

Uniting Anonymization and Confidential Information



Nirpal Virdee
Real Life Sciences,
a Medispense Company



Lee Berry
CSL Behring

Meet The Presenters



Nirpal Virdee
VP, Regulatory Science

New Jersey



Lee Berry
*Associate Director,
Data Transparency Lead*

King of Prussia, PA



The Reality We Were Facing

Today: CI and anonymization were operating in parallel – not together

Our current ways of working are under increasing pressure.

Ownership of Confidential Information (CI) decisions was distributed across teams. Anonymization was structured, but CI handling remained largely manual. As submission volume increased, the lack of unified workflow began to create friction, rework and inconsistency.

What we've experienced:

- “Anonymization was structured; CI review wasn't”
- “The same CI discussions kept resurfacing with every submission”
- “We lacked a single, documented source of truth”
- “Manual decision tracking created audit gaps”
- “As volume increased, so did inconsistency”

Tomorrow: The shift in thinking

Transparency could no longer be treated as a document-by-document exercise. We needed to move from isolated review to a controlled, governed workflow

CI and anonymization had to operate within a unified framework designed to:

- Create a single source of truth for CI decisions
- Apply consistent categorization and decision logic across submissions
- Reduce re-litigation of previously determined positions
- Surface potential CI systemically within documents
- Capture decisions in a way that is auditable and defensible

Confidential Information Does Not Live in One Function



The Complexity Wasn't the Problem

Complexity wasn't the problem.

The lack of structure across it was.

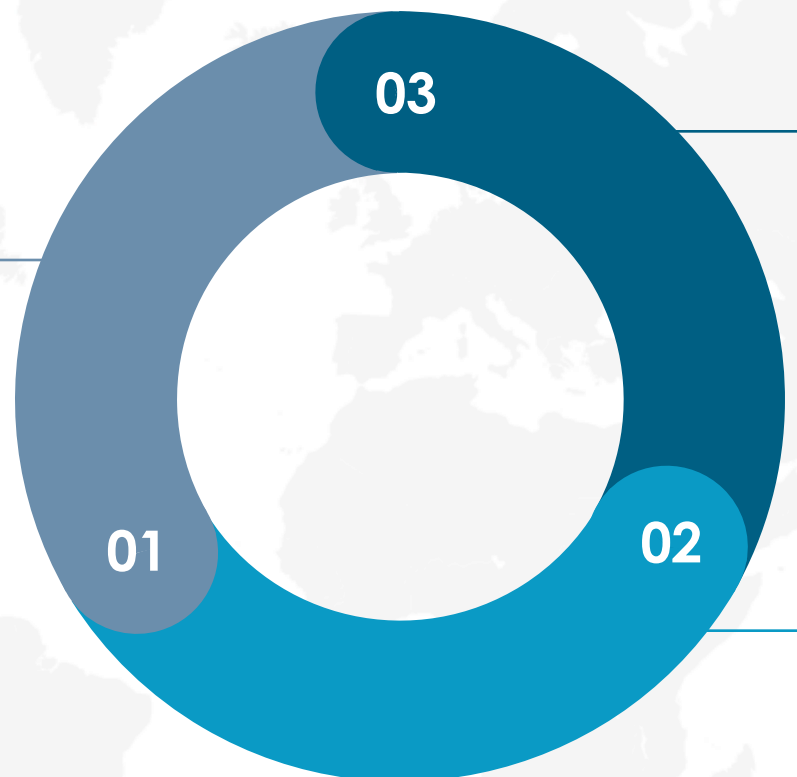


A Unified Framework Across Functions

Business & Scientific Input

- Medical Writing, Clinical, CMC and Operations contribute content
- Scientific integrity and data utility must be preserved
- Business context shapes sensitivity and competitive exposure

**Multiple stakeholders.
One decision framework.
Defensible outcomes.**



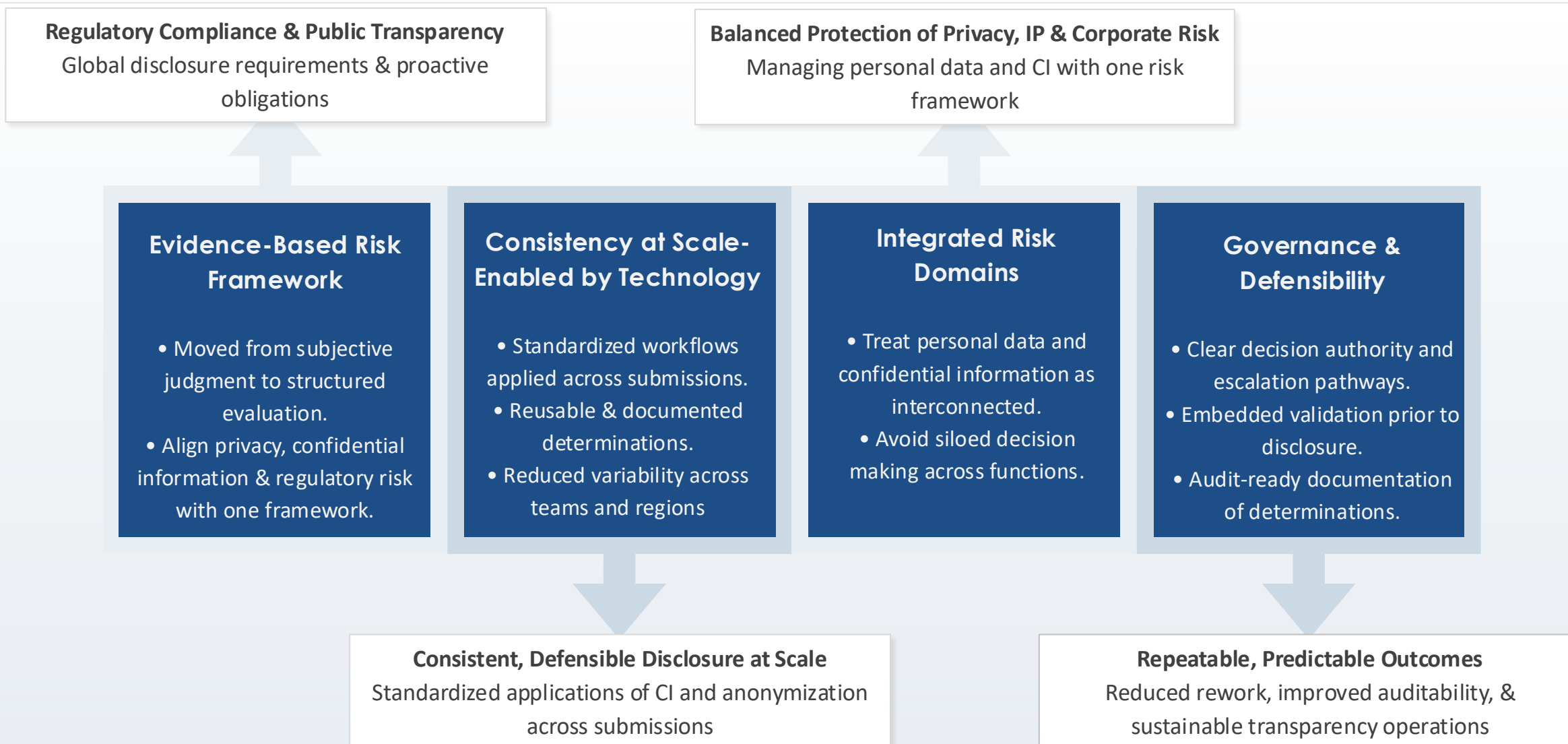
Controlled Disclosure & Defensibility

- Consistent application across documents and regions
- Embedded validation before publication
- Clear audit trail of determinations
- Transparency balanced with IP and regulatory protection

Governed CI Determination

- Structured intake and standardized review pathway
- Defined decision authority and escalation model
- Categorized & documented CI determinations
- Reusable logic applied consistently across submission

Principles of a Unified Disclosure Framework



What Structure Looks Like in Practice



Bringing Risk Domains into One Decision Model

Personal Data Risk

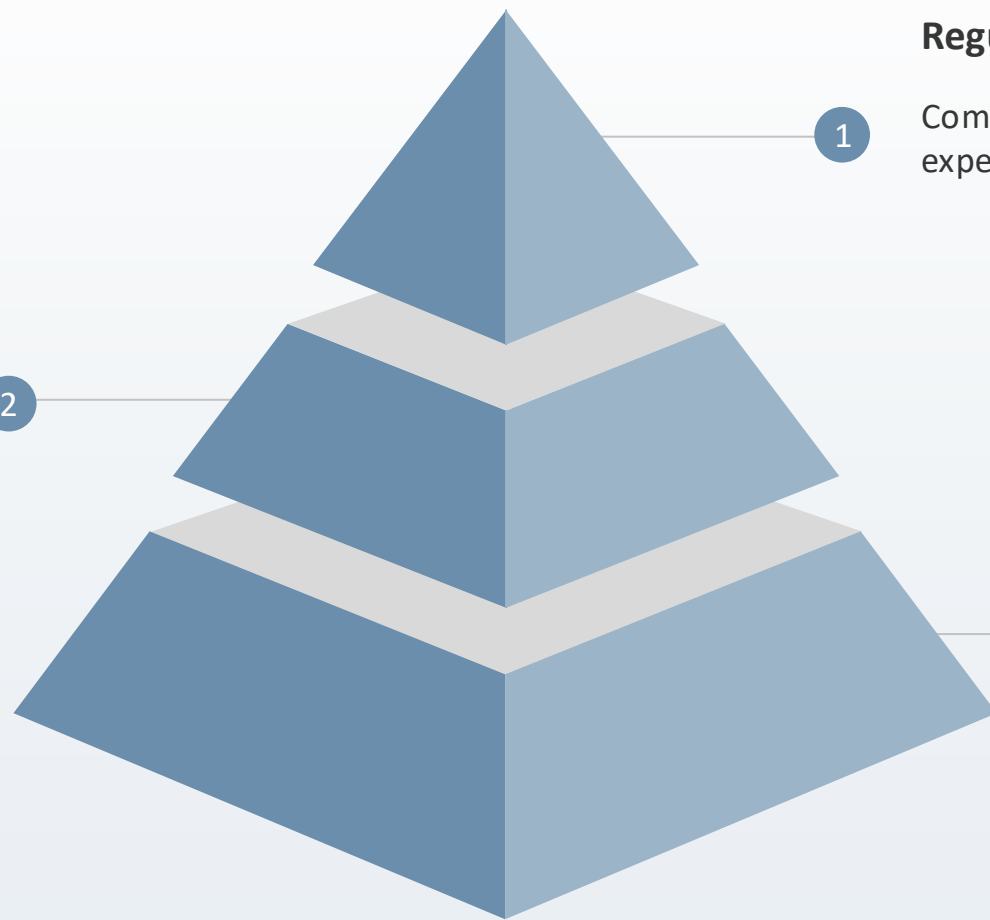
Privacy protection, re-identification thresholds, participant safeguards.

Regulatory & Public Disclosure Risk

Compliance obligations, transparency expectations, inspection defensibility.

Confidential & IP Risk

Commercial sensitivity, competitive exposure, proprietary information.



From Parallel Review to Controlled Execution

Governance first. Technology enabled. Control throughout.

A Structured, Governed Disclosure Workflow



1

Consistency across teams

2

Operational efficiency

3

**Defensibility with
submission-ready disclosure**

What Sustainable Disclosure Requires

Controlled, Defensible Transparency

Structured governance reduces variability and strengthens confidence in disclosure decisions

Sustainable transparency is not achieved through isolated redaction. It requires alignment of governance, integrated risk evaluation and disciplined execution.

Governance & Decision Discipline

- Clear authority and escalation
- Standardized categorization
- Documented rationale
- Defined thresholds

Operational Impact

- Consistency across teams
- Reduced repeatable debate
- Increased confidence at disclosure
- Strong inspection readiness

Lessons Learned

When structured governance & technology operate together



- ✓ IP accountability must be defined
- ✓ Clear authority prevents inconsistent protection
- ✓ CI decisions require the same rigor as patient data



- ✓ Consistency enables reuse
- ✓ Structured pathways create repeatable decisions
- ✓ Technology reinforces uniform application



- ✓ Rigor builds defensibility
- ✓ Documented rationale strengthens confidence
- ✓ CI is evaluated with regulated data discipline

Governance Alone Does Not Scale

What this means for sustainable transparency



Governance defines intent



Technology enables consistent execution



Sustainable transparency requires governance and technology operating as one controlled system

Thank You!



Nirpal Virdee
VP, Regulatory Science



Lee Berry
*Associate Director,
Data Transparency Lead*

