EPISTA

WHITEPAPER

Cloud-based Regulatory Spaces: What you need to know

A practical briefing on cloud-based regulatory spaces, the global dossier model, and what regulatory leaders need to do to prepare

THE BIG PICTURE

The way drugs reach patients globally is about to change

The way regulatory submissions are created, reviewed, and approved is changing. For decades, the industry has operated on a model of sequential, document-based submissions reviewed one product, one health authority at a time. The process works, but it is slow, duplicative, and increasingly misaligned with the expectations of a data-driven, globally connected world.

Cloud Based Regulatory Spaces (CBRS) represent the next step in that evolution and provide secure, governed cloud environments where sponsors, health authorities, partners, and affiliates can collaborate around structured regulatory data in real time, without duplicating effort or compromising compliance.

This primer explains what CBRS is, why regulatory operations leaders should be paying attention now, where the real opportunities lie, and what it takes to get there.

12-15 years

Time to approval

Current drug development cycle

2-7+ years

Market lag (today)

from US approval to global availability

~ 6 months

CBRS Target lag time

Compress time to new markets

*"The question for regulatory operations leaders is no longer whether Cloud-based Regulatory Spaces (CBRS) is coming. The question is **how far behind you will be when it arrives**."*

Brooke Casselberry
VP, Advisory & Delivery

WHAT IS A CBRS?

A secure, structured layer connecting sponsors and regulators

Cloud-based regulatory spaces are not a new submission format or a replacement for existing systems. They are governed cloud environments designed specifically for sharing regulatory data, documents, and structured content between sponsors and health authorities. Think of it as purpose-built infrastructure for regulatory collaboration, rather than general cloud storage adapted for compliance use.

Trusted by Design

Regulatory collaboration depends on knowing exactly who accessed what, and when. Cloud-based regulatory spaces use audited governance controls, role-based permissions, and chain-of-provenance tracking so every participant can trust the integrity of what they are reviewing. Access is federated, and sharing is governed by consensus, not assumption.

Designed for Regulated Environments

Not all cloud infrastructure is built for regulated submissions. These environments are designed from the ground up to meet standards like FedRAMP, GDPR, and ICH, with strong access controls and data immutability baked in. The goal is a platform that regulators can rely on, not a consumer tool retrofitted for compliance.

Cloud-based and Always Accessible

Unlike on-premise systems that require bilateral setup and heavy IT coordination, cloud-based regulatory spaces are accessible to all authorized participants through a shared, always-current environment. Sponsors and agencies interact with the same data in real time, reducing version confusion, submission delays, and the friction that comes with siloed infrastructure.

Structured for AI Readiness

Structured, governed data is the foundation for any meaningful use of AI in regulatory workflows. Because cloud-based regulatory spaces enforce consistent data formats and access controls, they create the conditions needed for automation, intelligent review assistance, and predictive analytics, without compromising compliance or audit integrity.

A GLOBAL DOSSIER

Author once. Submit everywhere

At the heart of CBRS is a shift in how sponsors structure regulatory content. The Global Dossier is a reusable core of scientific, quality, and clinical information that is authored once and adapted with minimal effort for each regional market.

eCTD is now mandated or actively adopted across more than 70 countries. The Common Technical Document (CTD) structure developed by ICH — Modules 1 through 5 covering administrative, summary, quality, nonclinical, and clinical data — provides the submission framework that the Global Dossier model builds upon.

Region	Status
United States (FDA)	Mandatory; v4.0 voluntary from 2024
European Union (EMA)	Mandatory; v4.0 transition planned
Japan (PMDA)	Mandatory; v4.0 target 2026
Canada, Australia	Mandatory / widely accepted
China (NMPA), Brazil	Adopted / mandate expanding

Standards enabling this shift

- **eCTD v4.0** — Structured, machine-readable submission content. Under voluntary acceptance at FDA since 2024; PMDA targeting mandate by 2026.
- **ICH M11** — Digital Protocol for structured clinical trial information
- **ISO IDMP** — Identification of Medicinal Products for product lifecycle data
- **FDA PQ/CMC** — Structured quality and chemistry, manufacturing, and controls data
- **ICH SPQS** — Structured Product Quality Submissions

REGULATOR COLLABORATION

Health authorities are already working towards this

Several active programs demonstrate that multi-jurisdictional regulatory collaboration is not theoretical.

It is already happening, and the infrastructure being built to support these programs will become the foundation for broader CBRS adoption.

ACTIVE PROGRAMS

Project Orbis

Concurrent oncology submission and review across partner agencies, reducing time to approval for life-saving therapies

Participants

FDA, TGA, Health Canada, MHRA, Swissmedic, ANVISA, HSA, IMoH

ACCESS Consortium

Joint review and work-sharing for new active substances and product variations to avoid duplicated regulatory effort.

Participants

TGA, Health Canada, Swissmedic, HSA, UK MHRA

WHO Good Reliance Practices

Global framework enabling national agencies to rely on trusted regulators' prior work, accelerating access in lower-resource markets.

Participants

WHO, global national regulatory agencies

WHAT CHANGES FOR SPONSORS?

It’s not just a technology decision

Moving to CBRS requires sponsors to address infrastructure, data, processes, and governance simultaneously. Organizations that treat this as a technology project alone will struggle. Those that address it as a data and organizational transformation will be positioned to benefit most.

Data & Standards Readiness

- IDMP implementation for product identification data
- Structured submission content aligned to PQ/CMC and M11
- eCTD v4.0 migration planning underway
- Data governance frameworks to maintain quality at scale

System & Infrastructure

- Cloud platform selection (Veeva Vault RIM and DNAnexus TRS are the leading integrated options)
- Integration with clinical operations, quality, and safety systems
- FedRAMP and GDPR-compliant architecture for HA data exchange

Use Cases Now Available

- Sponsor-to-HA collaboration during product review
- Sponsor-to-CRO and partner co-development workspaces
- HQ-to-affiliate labeling change coordination Reliance and work-sharing program participation
- Post-approval change management across markets

Process & Governance

- Separation of core dossier content from regional wrappers
- Data ownership and stewardship structures across functions
- Change management for teams moving from document-first to data-first workflows

HOW TO GET STARTED

A Strategy & Roadmap Framework for Cloud-based Regulatory Spaces

There is no single CBRS go-live date. Organizations should begin now with a clear-eyed assessment of where their data and systems stand today and build a practical roadmap toward the future state. We cover this within a 4-week strategic engagement

Our 4 week strategic engagement

WAVE 1

Current State & Readiness Assessment

We start by understanding where you are today, mapping your systems, data flows, and submission lifecycle to establish a clear baseline.

- Kickoff, alignment, and platform inventory
- Data flow and submission lifecycle mapping
- Cloud readiness and maturity scoring
- Risk, constraint, and dependency identification
- Partner, CRO, and affiliate landscape review

WAVE 2

Business Priorities & Use Case Definition

With your current state understood, we work with your team to define what matters most and where cloud adoption creates the greatest value.

- Business priorities and use case workshop
- Quick win vs foundational use case assessment
- Value, complexity, and risk scoring
- Target state vision and principles
- Platform role definition across collaboration, data, and core systems

WAVE 3

Roadmap & Implementation Plan

We translate priorities into a structured, actionable roadmap with the governance model needed to execute it.

- Roadmap and governance working session
- Operating model and ownership definition
- Business case development
- KPI and success metric definition
- Stakeholder alignment and change readiness

WAVE 4

Technical Architecture & Strategy Design

The final phase turns your roadmap into a deployable strategy with the architecture, resourcing, and organizational change plan to support it.

- Use case strategy and technical architecture
- Cost and resource planning
- Organizational change management (OCM)
- Business case finalization
- Implementation readiness and next steps

Why Epista Life Science?

Epista partners with pharmaceutical and biotech sponsors to bridge the gap between regulatory strategy and system execution. Our teams bring hands-on experience across Veeva Vault RIM implementations, IDMP and PQ/CMC data standards, clinical data remediation, and regulatory operations transformation.

We do not position CBRS as a future concept. We help organizations determine where they are today, what needs to change, and how to get there without disrupting the regulatory work that is already in flight.

EPISTA

Connect with our team today

Brooke Casselberry
VP Advisory & Delivery
bro@epista.com

Stephanie Silver
Account Partner
stef@epista.com

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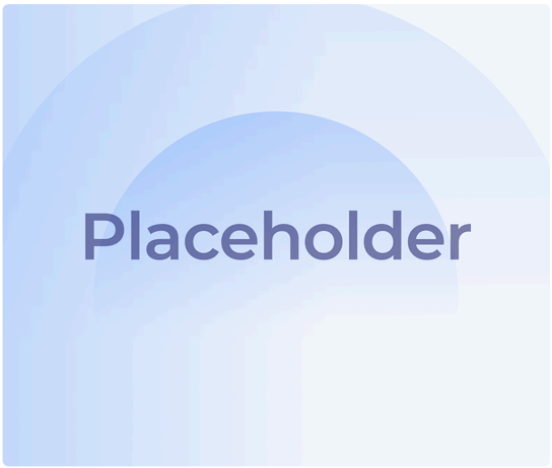

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