IQRA CLINICAL AI

AI-ASSISTED COMPLIANCE REVIEW PLATFORM

PRODUCT BROCHURE — 2026

IQRA Clinical AI

AI-Assisted Compliance Review Platform

Upload. Review. Comply. Inspect with Confidence.

A full regulatory compliance review — Rule-Based Review and AI-Assisted Review — in minutes, not weeks, for BA/BE studies. Built for CROs and sponsors.

by IQRA Clinical AI Systems

Now onboarding Founding CRO Partners

GAMP 5 Category 4 | 21 CFR Part 11 | ICH E6(R3) | NDCT Rules 2019 | DPDP & GDPR-aware

IQRA CLINICAL AI SYSTEMS
Hyderabad, India

admin@iqraclinicalai.com
iqraclinicalai.com

▪ WHY IQRA CLINICAL AI

From weeks to minutes

Clinical document compliance review, automated — without changing how your team already works.

THE PROBLEM

Manual review doesn't scale

Manual regulatory compliance review of clinical trial documents — Protocol, ICD, CRF — takes Regulatory Affairs teams days to weeks per study. A single missed requirement, a document reference, a sampling detail, a regulatory citation, can delay or derail a submission. Tracking the differing requirements of nine or more regulatory authorities by hand simply doesn't scale as a CRO's study volume grows.

THE SOLUTION

An AI-Assisted Compliance Review Engine

IQRA Clinical AI reviews uploaded documents against a purpose-built compliance engine (209 rules under the hood) covering all 10 TMF phases, cross-checked against major global regulatory authorities — CDSCO, USFDA, EMA, and others (see page 3). Every review runs Rule-Based Review checks — instant and always-on — with optional AI-Assisted Review for deeper analysis of ambiguous or borderline findings. The output is a structured findings report and an Inspection Readiness score (required-document completeness for the study's current phase, 0–100%), generated in minutes rather than weeks.

DOCUMENT INTELLIGENCE

Reviews large study dossiers without manual splitting

Study dossiers regularly run past 2,000 pages — large enough that manual review usually means splitting the document up first. IQRA Clinical AI processes them whole, using pdfplumber-based extraction combined with chunked OCR at 50 pages per batch, so document size is never the limiting factor in how fast a review can start.

▪ PLATFORM CAPABILITIES

What the platform reviews

Six areas of review, run continuously, built around how a BA/BE study actually moves through phases.

§01 **Study Milestone Tracker**

Follows a study through a progressive review workflow, phase by phase, so status is always current — not reconstructed the week before an audit.

§02 **Regulatory Mapping**

Supports major global regulatory requirements — CDSCO, USFDA, EMA, and other leading authorities relevant to your submission markets (full list on this page).

§03 **Multi-Tenant CRO Isolation & RBAC**

Complete data separation between CRO tenants, with Super Admin, Admin, Manager, Auditor, and Viewer roles controlling exactly who sees what (detailed on page 5).

§04 **SAE/AE Reporting & Subject Enrolment**

Tracks serious and adverse event reporting alongside subject enrolment, so safety signals stay visible against overall study progress.

§05 **Large-Document Processing**

Reviews large study dossiers whole, without manual splitting — 2,000+ pages, processed via pdfplumber extraction plus chunked OCR at 50 pages per batch.

§06 **21 CFR Part 11 Audit Trail**

Every review and sign-off is logged to Part 11 standards, keeping the study inspection-ready at 95%+ audit coverage across all phases.

AUTHORITY	REGION
CDSCO	India
USFDA	United States
EMA	European Union
ANVISA	Brazil
Health Canada	Canada
ICH	International harmonization guidelines
WHO	Global / prequalification
PMDA	Japan
TGA	Australia

EXAMPLE — CROSS-DOCUMENT FINDING

Ethics Committee (IEC) approval dated after first subject dosing.

The IEC/REB approval letter is dated **after** the first dosing date recorded in the study log — dosing began before ethics approval was in place. IQRA Clinical AI flags this automatically as a **CRITICAL GCP violation**, cross-referencing the two source documents rather than relying on either one being checked in isolation.

▪ WHO IT'S FOR

Built for every seat on a BA/BE study

One platform, role-based access — everyone sees exactly what their role is accountable for.

CROs

Run multiple studies, cleanly isolated. Multi-tenant CRO isolation keeps every sponsor's study data completely separate, while your team reviews across all of them from one platform — from a small CRO's first pilot study to an established CRO managing many studies at once.

Sponsors

Oversight without waiting on reports. See milestone progress, SAE/AE status, and audit coverage update continuously, rather than on the CRO's periodic reporting schedule.

Auditors & QA

Inspection readiness, always on. A 21 CFR Part 11 audit trail and a live readiness view mean there's no pre-inspection scramble to assemble evidence.

▪ HOW IT WORKS

Upload to report, in one pass

01
Upload
Your Protocol, ICD, CRF, or SOP documents.

02
Review
Rule-Based Review + AI-Assisted Review run automatically.

03
Report
Get a structured findings report + compliance score.

04
Export
As PDF, track fixes, re-run anytime.

▪ WHY IQRA CLINICAL AI

From weeks of manual checking to minutes of confidence

TRADITIONAL REVIEW	IQRA CLINICAL AI
Weeks per study	Minutes per study
Fully manual	Rule-Based + AI-Assisted Review
Human error risk	Consistent, logged review
No central tracking	Central dashboard

▪ SECURITY & GOVERNANCE

Built for regulated environments, from day one

Handled the way clinical data should be.

Multi-tenant data isolation
Your data never touches another CRO's tenant.

No PHI stored
Subject data uses initials/IDs only; documents are processed in memory.

21 CFR Part 11-compliant audit trail
Tamper-evident logging on every review and sign-off, with bcrypt-hashed authentication and session-based tokens.

Full GxP validation package available
VMP · URS · IQ · OQ · PQ · Risk Assessment — available under NDA. 98.3% automated test pass rate (IQ 100%, OQ 100%, PQ 92.3%) — zero failures across 59 tests; the sole remaining item is a by-design manual QA Manager sign-off step.

DPDP (India) / GDPR-aware data handling
Built around India's Digital Personal Data Protection Act, with GDPR-aware handling for global sponsors.

▪ ROLE-BASED ACCESS CONTROL

Role	Typical use
Super Admin	Full platform & tenant configuration
Admin	Tenant-level administration and user management
Manager	Study oversight, sign-offs, CAPA follow-up
Auditor	Read + audit-trail access for inspection prep
Viewer	Read-only visibility into study status

▪ BUSINESS VALUE

What changes for your team

01 Reduce manual review effort

02 Improve inspection readiness

03 Standardize compliance review

04 Reduce review turnaround time

05 Support quality teams centrally

06 Centralize study tracking

▪ ROADMAP & PLANS

Current release, and what's next

Current Release

- ✔ BA/BE Studies — Pilot
- ✔ BA/BE Studies — Pivotal

Roadmap

- ○ Clinical Trials — Phase I
- ○ Clinical Trials — Phase II
- ○ Clinical Trials — Phase III
- ○ Clinical Trials — Phase IV

▪ PRICING

We're onboarding founding CRO partners — plans are tailored on a call, not fixed in a brochure.

PLAN	STATUS
Demo	Free
Trial	7 Days
Starter	Contact Sales
Enterprise	Coming Soon

See it on your own documents

Start a 7-day free trial, or book a walkthrough with our team.

Scan to visit iqraclinicalai.com

admin@iqraclinicalai.com
iqraclinicalai.com
app.iqraclinicalai.com