



TECHNICAL & COMPLIANCE BRIEF

OASIS

OBSERVATIONAL ASSESSMENT STUDY FOR IBD IN SAUDI ARABIA

Platform specifications · compliance posture · comparison with mature international IBD registries

Hosted by the Saudi Gastroenterology Association · OASIS Platform · Riyadh

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SECTION 01 - PLATFORM SPECIFICATIONS

OASIS at a technical glance

OASIS is built on the Saudi Gastroenterology Association platform — a Next.js / TypeScript application backed by a relational database, with role-based authentication, an audit log, a federated query layer, and a bilingual EN/AR user interface.

Domain	Specification
Architecture	Next.js 14 (App Router) · TypeScript · React Server Components · Edge-deployed on Vercel
Data layer	PostgreSQL via Prisma ORM · row-level access control · automatic backups every 6 hours · 30-day point-in-time recovery
Authentication	NextAuth (Auth.js v5) · email + password with bcrypt hashing · optional Google SSO · role-based access (Director, Site PI, Data Manager, Statistician, Observer)
Authorisation	Server-side role check on every protected route · per-centre data partitioning · investigator can only see own centre patients
Common Data Model	OMOP-extended for IBD-specific elements · 10 case-report forms · 100+ named variables · bilingual labels and value sets
Audit log	Immutable append-only log of every record creation, update, view, and export, with timestamp, user ID, IP, and diff
Federated query	Approved scientific queries dispatched to each centre · executed locally · aggregate or de-identified analytic data returned to DCC
Storage encryption	AES-256 at rest · TLS 1.3 in transit · separate encryption key per tenant
Backups	Daily encrypted backup to a second region · annual disaster-recovery rehearsal
Localisation	English + Modern Standard Arabic · RTL layout · Hijri / Gregorian dual-date display where appropriate
Bilingual content	Every clinical label, value set, patient-facing summary, and PDF export ships in both EN and AR
Mobile	Progressive Web App · responsive design · works offline for read-only views
Print / export	PDF CRF export · CSV / Excel data dump (DCC only) · DICOM linkage planned for endoscopy images
Hosting	Vercel edge network · CloudFront CDN · servers in Frankfurt (closest GDPR-compliant region for Gulf latency) — option to move to Riyadh/Bahrain MOH-approved region on request

SECTION 02 - COMPLIANCE POSTURE

How OASIS meets Saudi and international standards

OASIS is designed from the ground up to meet Saudi Personal Data Protection Law (PDPL), the MOH National Centre for Health Data governance framework, SCFHS audit requirements, and internationally recognised standards for clinical research data (GDPR-equivalent, ISO 27001 principles, ICH-GCP).

Regulation / standard	How OASIS meets it
Saudi Personal Data Protection Law (PDPL)	Federated architecture — patient-level data never leaves the originating centre. Lawful basis: scientific research with PI-level institutional consent. Data minimisation by design (only registry-defined CDEs collected).
MOH National Centre for Health Data	Registry registered with MOH NCHD. Annual data-quality report submitted. Aligns with the National Health Data Strategy.
SCFHS audit standards	Audit log captures every data action with timestamped user attribution. Source-document validation visits supported by per-record link back to CRF.
ICH-GCP (clinical research)	Investigators trained on GCP at onboarding. Centre IRB approval required before any centre activates queries. Adverse-event reporting workflow built into the platform.
ISO 27001 principles	Access control, change management, incident response, data lifecycle, and risk assessment processes documented. Annual security review.
Patient consent	Two-tier model: (1) registry consent at the contributing centre (broad consent for IBD registry use) and (2) study-specific re-consent where required by IRB.
Right to erasure (PDPL Article)	Patient withdrawal honoured within 30 days. Past contributions to published datasets retained for scientific reproducibility per published policy.
Re-identification protection	k-anonymity ($k \geq 5$) applied to any analytic dataset shared outside the originating centre. Pseudonymisation key held by the centre, not by the DCC.
Pharmaceutical sponsorship	Industry funding declared on every output. Industry cannot direct scientific questions or veto publication. Separate Industry Liaison Committee.
Publication ethics (ICMJE)	All authors meet the four ICMJE criteria. Group-line collaborators receive traceable PubMed credit. Conflict-of-interest declared at submission.

SECTION 03 - COMPARISON WITH MATURE INTERNATIONAL REGISTRIES

Where OASIS sits among the world's leading IBD registries

OASIS is benchmarked against ENEIDA (Spain — the largest national IBD registry in Europe), IG-IBD (Italy), GETAID (France — the oldest collaborative IBD network), and SIBDCS (Switzerland — the deepest prospective cohort). The two tables below summarise scope (Part A) and governance / architecture (Part B), in the same format used by the OASIS Scientific Committee.

PART A - SCOPE AND DATA

	OASIS	ENEIDA	GETAID	IG-IBD	SIBDCS
Country	Saudi Arabia	Spain	France	Italy	Switzerland
Launched	2026	2003	1983	2007	2006
Patients (published)	Onboarding	~80,000	~50,000	~25,000	~5,500
Data model	OMOP-extended	Custom CDM	Custom	Custom	Custom
Variables	100+	600+	300+	250+	400+
Bilingual labels	EN - AR	ES - EN	FR - EN	IT - EN	DE - FR - IT - EN

PART B - GOVERNANCE AND ARCHITECTURE

	OASIS	ENEIDA	GETAID	IG-IBD	SIBDCS
Architecture	Federated	Centralised	Federated	Federated	Centralised
Patient consent	Per-centre IRB	Broad national	Per-centre	Per-centre	Specific cohort
Governance	SGA-hosted board	Spanish gov + GETECCU	GETAID society	IG-IBD society	SIBDCS network
Industry partnerships	Yes (Liaison Cmte)	Yes	Yes	Yes	Yes
Public dashboard	Yes (live)	Yes	Partial	Yes	Yes
Federated query layer	Yes	No	Yes	Partial	No
Patient advisory panel	Yes (3 members)	Yes	Yes	Partial	Yes

WHAT OASIS BORROWS — AND WHAT IT DOES DIFFERENTLY

Borrowed from ENEIDA. The depth of the clinical data dictionary, including pregnancy and CRC surveillance modules.

Borrowed from GETAID. The federated architecture and the publication / authorship policy — both proven over four decades.

Borrowed from IG-IBD. The committee structure and the proposal-to-publication pipeline.

Borrowed from SIBDCS. The patient-reported outcome integration and the patient advisory panel model.

Unique to OASIS. Bilingual EN/AR by default, alignment with PDPL and SCFHS audit, integration with the SGA platform (IBD Fellowship, SCOPE quality registry, Essential Guide to IBD).

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