SAUDI GASTROENTEROLOGY ASSOCIATION | الجمعية السعودية للجهاز الهضمي

CASE REPORT FORM BOOKLET

# OASIS

OBSERVATIONAL ASSESSMENT STUDY FOR IBD IN SAUDI ARABIA

The complete case-report-form booklet — ten forms, 100+ variables — for site-level data collection

Hosted by the Saudi Gastroenterology Association · OASIS Platform · Riyadh

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SECTION 00 · INSTRUCTIONS

# How to use this booklet

This booklet is the paper companion to the electronic case-report-form library in the OASIS investigator portal at www.saudigastro.com/oasis. It exists for three purposes:

**Reference for centre data managers.** Every variable in the OASIS Common Data Model with its label, value set, and IBD context.

**Backup paper data collection.** Used in clinics where direct electronic entry is not yet routine — paper forms are scanned and entered into the OASIS portal by the data manager within 7 days.

**Audit-ready documentation.** Source-document validation visits and SCFHS audits should be able to trace any registry variable back to a CRF page in this booklet.

### PATIENT HEADER (COMPLETE ON EVERY FORM)

| | |
|---|---|
| **Registry ID** | _____ |
| **Centre code** | _____ |
| **Date of entry** | _____ / _____ / _____ |
| **Investigator** | _____ |

FORM 01

# Demographic Data

**Arabic: ■■■■■■■■■ ■■■■■■■■■■■■■**

**Date of birth**
■■■■■ ■■■■■■■■
____ / ____ / _____ (DD / MM / YYYY)

**Sex**
■■■■■■

☐ Male ☐ Female

**Nationality**
■■■■■■■■

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**Region of residence**
■■■■■■ ■■■■■■■■

■ Central
■ Western
■ Eastern
■ Northern
■ Southern

**Hospital / Site**
■■■■■■■■■ / ■■■■■■■

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**Date of registry entry**
■■■■■■ ■■■■■■■ ■■ ■■■■■■
____ / ____ / _____ (DD / MM / YYYY)

**Date of last visit**
■■■■■■ ■■■■ ■■■■■■
____ / ____ / _____ (DD / MM / YYYY)

**Vital status**
■■■■■■■ ■■■■■■■■

☐ Alive ☐ Deceased ☐ Unknown

**Reason for end of follow-up (if applicable)**
■■■■ ■■■■■■■ ■■■■■■■■■

■ Lost to follow-up
■ Patient withdrew
■ Transferred care
■ Deceased
■ Other (specify)

**Consanguinity**
■■■■ ■■■■■■■■ ■■■■ ■■■■■■■■■

☐ First-degree ☐ Second-degree ☐ No ☐ Unknown

FORM 02

# Clinical Characteristics

**Arabic: ■■■■■■■■ ■■■■■■■■■**

### Date of diagnosis
■■■■■■ ■■■■■■■■

____ / ____ / _____ (DD / MM / YYYY)

### Type of IBD
■■■■ ■■■■■■

☐ Crohn's disease ☐ Ulcerative colitis ☐ IBD-Unclassified

### Montreal classification — Age at diagnosis
■■■■■■ ■■■■■■■■■ — ■■■■■■ ■■■■ ■■■■■■■■

☐ A1 (≤16) ☐ A2 (17–40) ☐ A3 (>40)

### Crohn's — Disease location
■■■■■ ■■■■ ■■■■■

■ L1 — Ileal
■ L2 — Colonic
■ L3 — Ileocolonic
■ L4 — Upper GI modifier
■ Not applicable

### Crohn's — Disease behaviour
■■■■■ ■■■■ ■■■■■

■ B1 — Non-stricturing, non-penetrating
■ B2 — Stricturing
■ B3 — Penetrating
■ p — Perianal modifier
■ Not applicable

### UC — Disease extent
■■■■■■■ ■■■■■■■ ■■■■■■■■ ■■■■■■■■

■ E1 — Proctitis
■ E2 — Left-sided
■ E3 — Extensive (pancolitis)
■ Not applicable

### Perianal disease
■■■■■■ ■■■■ ■■■■■■

☐ Present ☐ Absent ☐ Unknown

### Extra-intestinal manifestations (tick all)
■■■■■■■■ ■■■■■ ■■■■■■■■

■ Peripheral arthritis
■ Axial arthropathy / spondylitis
■ Erythema nodosum
■ Pyoderma gangrenosum

- ■ Uveitis / Episcleritis
- ■ Primary sclerosing cholangitis
- ■ Aphthous stomatitis
- ■ None / Unknown

**Complications (tick all)**

- ■ Strictures
- ■ Fistulae
- ■ Abscess
- ■ Toxic megacolon
- ■ Anaemia (Hb < 10)
- ■ Failure to thrive
- ■ None / Unknown

FORM 03

# Medical Treatment

**Arabic: ■■■■■■ ■■■■■**

**Aminosalicylates (5-ASA) — current or past use**
■■■■■■■■■■■■■■■

☐ Yes ☐ No ☐ Unknown

**5-ASA — start date**
____ / ____ / _____ (DD / MM / YYYY)

**Corticosteroids — current or past use**
■■■■■■■■■■■■■■■■■■■

☐ Yes ☐ No ☐ Unknown

**Corticosteroids — type**
■ Prednisone (oral)
■ Methylprednisolone (IV)
■ Budesonide MMX
■ Topical

**Steroid response**

☐ Responsive ☐ Dependent ☐ Refractory

**Enteral nutrition (EEN / partial)**
■■■■■■■■ ■■■■■■■■

☐ Yes ☐ No ☐ Unknown

**Endoscopic treatment (balloon, stricturoplasty)**
■■■■■■■ ■■■■■■■■■

☐ Yes ☐ No ☐ Unknown

**Apheresis**
■■■■■■■■

☐ Yes ☐ No ☐ Unknown

FORM 04

# Immunomodulatory Treatments

**Arabic: ■■■■■■■■ ■■■■■■■■**

**Drug type**

■■■ ■■■■■■

■ Azathioprine
■ 6-Mercaptopurine
■ Methotrexate
■ Calcineurin inhibitor
■ Other

**Start date**

____ / ____ / _____ (DD / MM / YYYY)

**End date (if discontinued)**

____ / ____ / _____ (DD / MM / YYYY)

**Indication**

■ Maintenance
■ Steroid-sparing
■ Combination with biologic
■ Other

**Efficacy**

☐ Effective ☐ Partial ☐ Failed ☐ Unknown

**Adverse effects (tick all)**

■ Cytopenias
■ Hepatotoxicity
■ Pancreatitis
■ Infection
■ Skin / mucocutaneous
■ None

**Reason for suspension**

■ Loss of efficacy
■ Adverse event
■ Pregnancy planning
■ Patient decision
■ Other

FORM 05

# Biologic & Advanced Therapies

**Arabic: ■■■■■■■■■ ■■■■■■■■■■■ ■■■■■■■■■■**

**Drug class**

■■■ ■■■■■■■

■ Anti-TNF (infliximab)
■ Anti-TNF (adalimumab)
■ Anti-integrin (vedolizumab)
■ Anti-IL12/23 (ustekinumab)
■ Anti-IL23 (risankizumab, mirikizumab)
■ JAK inhibitor (upadacitinib, tofacitinib)
■ S1P modulator (ozanimod, etrasimod)

**Start date**

____ / ____ / _____ (DD / MM / YYYY)

**End date**

____ / ____ / _____ (DD / MM / YYYY)

**Indication**

■ Induction
■ Maintenance
■ Bridge to surgery
■ Other

**Short-term efficacy (week 12 response)**

☐ Responder ☐ Partial ☐ Non-responder

**Long-term efficacy (week 52 remission)**

☐ In remission ☐ Partial ☐ Lost response

**Loss of response — present?**

☐ Yes ☐ No ☐ Unknown

**Loss of response — date**

____ / ____ / _____ (DD / MM / YYYY)

**Dose escalation**

☐ Yes ☐ No ☐ Unknown

**Adverse effects (tick all)**

■ Infusion / injection reaction
■ Infection (serious)
■ Tuberculosis / latent TB activation
■ Demyelinating event
■ Malignancy
■ Antibody formation
■ Other

**Reason for drug suspension**

FORM 06

# Surgical Treatments

**Arabic: ■■■■■■■■ ■■■■■■■■**

**Date of surgery**

____ / ____ / _____ (DD / MM / YYYY)

**Type of surgery**

■ Ileocolic resection
■ Segmental colonic resection
■ Subtotal colectomy
■ Proctocolectomy with IPAA
■ Strictureplasty
■ Fistula surgery (seton, advancement flap, LIFT)
■ Drainage of abscess
■ Other

**Indication**

■ Refractory disease
■ Stricture
■ Fistula
■ Abscess
■ Dysplasia / cancer
■ Toxic megacolon
■ Failure of medical therapy

**Complications**

■ Anastomotic leak
■ Wound infection
■ Bleeding
■ Pouchitis
■ Bowel obstruction
■ Re-operation
■ None

**Pouchitis (if pouch)**

☐ Acute ☐ Chronic ☐ Refractory ☐ None

**Definitive stoma**

☐ Yes ☐ No ☐ Unknown

FORM 07

# Risk Factors & Comorbidities

**Arabic: ■■■■■■ ■■■■■■ ■■■■■■■■■■ ■■■■■■■■■■**

**Family history of IBD (first-degree)**
■■■■■■■■ ■■■■■■■■

☐ Yes ☐ No ☐ Unknown

**Smoking status**
■■■■ ■■■■■■■■

☐ Never ☐ Current ☐ Ex

**Appendectomy**
■■■■■■■■ ■■■■■■■■

☐ Yes ☐ No ☐ Unknown

**Immune-mediated comorbidities (tick all)**

- ■ Coeliac disease
- ■ Psoriasis
- ■ Spondyloarthropathy
- ■ Type 1 diabetes
- ■ Thyroid (autoimmune)
- ■ Other

**Colorectal neoplasms (current or history)**

☐ Yes ☐ No ☐ Unknown

**BMI**

____ ____ kg/m²

**Nutritional status**

☐ Adequate ☐ Mild ☐ Moderate ☐ Severe

**TB screening result**

☐ Negative ☐ Latent ☐ Active ☐ Unknown

**Vaccinations up to date**

☐ Yes ☐ No ☐ Unknown

FORM 08

# Pregnancy & Fertility

**Arabic: ■■■■■ ■■■■■■■■**

**Sterility assessment performed**
■■■■■ ■■■■■

☐ Yes ☐ No ☐ Unknown

**Pregnancies (total)**
____ ____ n

**Miscarriages**
____ ____ n

**IBD activity during pregnancy**
☐ Remission ☐ Mild ☐ Moderate ☐ Severe

**Treatment continued during pregnancy (tick all)**
■■■■■■ ■■■■■ ■■■■■

■ 5-ASA
■ Thiopurine
■ Anti-TNF (continued)
■ Anti-TNF (stopped 3rd trimester)
■ Steroid
■ No therapy
■ Other

**Foetal malformations**
☐ Yes ☐ No ☐ Unknown

**Childbirth**
☐ Term vaginal ☐ Term C-section ☐ Preterm vaginal ☐ Preterm C-section ☐ Stillbirth

**Birth weight (g)**
____ ____ g

FORM 09

# Follow-up & Monitoring

**Arabic: ■■■■■■■■ ■■■■■■■■■■**

**Visit date**
____ / ____ / _____ (DD / MM / YYYY)

**Clinical activity index**
☐ Mayo ☐ Walmsley ☐ CDAI ☐ Harvey-Bradshaw ☐ PCDAI ☐ PUCAI

**Clinical activity score**
____ ____

**Endoscopic activity index**
☐ CDEIS ☐ Rutgeerts ☐ Mayo endo ☐ Baron ☐ UCEIS ☐ Not done

**Endoscopic score**
____ ____

**CRP**
____ ____ mg/L

**Haemoglobin**
____ ____ g/dL

**Albumin**
____ ____ g/L

**Faecal calprotectin**
____ ____ µg/g

**Weight**
____ ____ kg

**Height**
____ ____ cm

**BMI**
____ ____ kg/m²

**Hospitalisation since last visit**
☐ Yes ☐ No ☐ Unknown

**Reason for hospitalisation (if yes)**

FORM 10

# CRC Screening

**Arabic: ■■■ ■■■■■ ■■■■■■■■ ■■■■■■■■■■**

**Family history of colorectal cancer**
■■■■■■■■ ■■■■■■■■ ■■■■■■■■

☐ Yes ☐ No ☐ Unknown

**In CRC screening programme**

☐ Yes ☐ No ☐ Unknown

**Date of most recent surveillance colonoscopy**

____ / ____ / _____ (DD / MM / YYYY)

**Result of most recent surveillance**

☐ No dysplasia ☐ Indefinite for dysplasia ☐ Low-grade dysplasia ☐ High-grade dysplasia ☐ CRC

**CRC diagnosis outside screening**

☐ Yes ☐ No ☐ Unknown

**Dysplasia surveillance plan**

CRF · SIGN-OFF

# Investigator certification

I certify that the data recorded in this case-report form has been collected accurately from source documents, that all entries have been made in accordance with the OASIS Common Data Model, and that the patient has been informed of registry participation per the centre IRB.

Investigator name: _____

Signature: _____

Date: ____ / ____ / _____

*Submit completed paper CRFs to the centre data manager within 7 days of the patient encounter. The data manager enters all forms into the OASIS investigator portal at www.saudigastro.com/oasis/login.*