

Data Delivery Agreement (DDA) - Crohn's Disease Management

Document Information

- **Domain:** Crohn's Disease Management
- **Stakeholders:** Gastroenterologists, IBD Specialists, Nutritionists, Surgeons, Research Teams
- **Data Owner:** Director of IBD Center
- **Effective Date:** 2024-01-15
- **Review Cycle:** Monthly

Business Context

The Crohn's Disease Management domain supports comprehensive care for patients with Crohn's disease, a chronic inflammatory bowel condition. This DDA defines data requirements for disease monitoring, treatment optimization, surgical planning, and quality of life assessment.

Data Entities

Patient

- **Description:** Crohn's disease patient information
- **Key Attributes:**
 - Patient ID (Primary Key)
 - First Name, Last Name
 - Date of Birth
 - Gender
 - Diagnosis Date
 - Disease Location (Ileum, Colon, Both)
 - Disease Behavior (Inflammatory, Stricturing, Penetrating)
 - Family History of IBD
 - Smoking Status
- **Business Rules:**
 - Patient ID must be unique
 - Diagnosis date cannot be future
 - Disease location must be valid

Disease Activity Assessment

- **Description:** Clinical disease activity measurements
- **Key Attributes:**
 - Assessment ID (Primary Key)
 - Patient ID (Foreign Key)
 - Assessment Date
 - CDAI Score (Crohn's Disease Activity Index)
 - Harvey-Bradshaw Index
 - CRP Level
 - ESR Level
 - Fecal Calprotectin
 - Physician Global Assessment
- **Business Rules:**
 - Must reference valid Patient ID
 - Assessment date cannot be future
 - CDAI score must be 0-600

Endoscopy Report

- **Description:** Colonoscopy and endoscopy findings
- **Key Attributes:**
 - Report ID (Primary Key)
 - Patient ID (Foreign Key)
 - Procedure Date
 - Procedure Type (Colonoscopy, Upper Endoscopy, Capsule Endoscopy)
 - Endoscopist
 - Disease Location
 - Ulceration Score
 - Stricture Presence
 - Fistula Presence
 - Biopsy Results
- **Business Rules:**
 - Must reference valid Patient ID
 - Procedure date cannot be future
 - Ulceration score must be 0-3

Medication Therapy

- **Description:** Medications used in Crohn's treatment
- **Key Attributes:**
 - Therapy ID (Primary Key)

- Patient ID (Foreign Key)
 - Medication Name
 - Drug Class (5-ASA, Corticosteroids, Immunomodulators, Biologics)
 - Start Date
 - End Date
 - Dosage
 - Frequency
 - Response Assessment
 - Side Effects
- **Business Rules:**
 - Must reference valid Patient ID
 - End date must be after start date
 - Dosage must be positive

Nutritional Assessment

- **Description:** Nutritional status and dietary interventions
- **Key Attributes:**
 - Assessment ID (Primary Key)
 - Patient ID (Foreign Key)
 - Assessment Date
 - BMI
 - Weight Change
 - Albumin Level
 - Vitamin D Level
 - Iron Studies
 - Dietary Restrictions
 - Nutritional Supplements
- **Business Rules:**
 - Must reference valid Patient ID
 - Assessment date cannot be future
 - BMI must be positive

Surgical Intervention

- **Description:** Surgical procedures and outcomes
- **Key Attributes:**
 - Surgery ID (Primary Key)
 - Patient ID (Foreign Key)
 - Surgery Date
 - Procedure Type (Resection, Strictureplasty, Fistula Repair)
 - Surgeon
 - Indication
 - Complications
 - Post-op Recovery Time
 - Recurrence at Anastomosis
- **Business Rules:**
 - Must reference valid Patient ID
 - Surgery date cannot be future
 - Recovery time must be positive

Quality of Life Assessment

- **Description:** Patient-reported quality of life measures
- **Key Attributes:**
 - Assessment ID (Primary Key)
 - Patient ID (Foreign Key)
 - Assessment Date
 - IBD-Q Score
 - SF-36 Score
 - Work Productivity
 - Social Functioning
 - Emotional Well-being
 - Fatigue Level
- **Business Rules:**
 - Must reference valid Patient ID
 - Assessment date cannot be future
 - Scores must be within valid ranges

Relationships

Patient Relationships

- **Patient → Disease Activity Assessment (1:N)**
 - A patient can have multiple disease activity assessments
 - Each assessment belongs to exactly one patient
- **Patient → Endoscopy Report (1:N)**
 - A patient can have multiple endoscopy reports
 - Each report belongs to exactly one patient

- **Patient → Medication Therapy (1:N)**
 - A patient can have multiple medication therapies
 - Each therapy belongs to exactly one patient
- **Patient → Nutritional Assessment (1:N)**
 - A patient can have multiple nutritional assessments
 - Each assessment belongs to exactly one patient
- **Patient → Surgical Intervention (1:N)**
 - A patient can have multiple surgical interventions
 - Each surgery belongs to exactly one patient
- **Patient → Quality of Life Assessment (1:N)**
 - A patient can have multiple quality of life assessments
 - Each assessment belongs to exactly one patient

Treatment Relationships

- **Medication Therapy → Disease Activity Assessment (M:N)**
 - Medication therapies can be evaluated against disease activity
 - Disease activity can be influenced by multiple therapies
- **Surgical Intervention → Disease Activity Assessment (M:N)**
 - Surgical interventions can be evaluated against disease activity
 - Disease activity can be affected by surgical procedures

Cross-Domain Relationships

- **Endoscopy Report → Surgical Intervention (M:N)**
 - Endoscopy findings can indicate need for surgery
 - Surgical outcomes can be monitored by endoscopy

Data Quality Requirements

Completeness

- Patient ID must be present in all related records
- Assessment dates must be provided
- Required clinical scores must be recorded

Accuracy

- Laboratory values must be within physiological ranges
- Clinical scores must be calculated correctly
- Dates must be in ISO format (YYYY-MM-DD)

Timeliness

- Disease activity assessments must be updated monthly
- Endoscopy reports must be available within 48 hours
- Medication response must be assessed within 2 weeks

Access Patterns

Common Queries

1. Disease activity trends over time
2. Medication efficacy by patient characteristics
3. Surgical outcomes and complications
4. Quality of life correlation with disease activity

Performance Requirements

- Patient history retrieval: < 2 seconds
- Disease activity trend analysis: < 5 seconds
- Treatment response assessment: < 3 seconds

Data Governance

Privacy

- HIPAA compliance for all patient data
- PHI encryption at rest and in transit
- Patient consent required for research use

Security

- Role-based access control (RBAC)
- Audit logging for all clinical data access
- Two-factor authentication for medical staff

Compliance

- HIPAA compliance
- FDA reporting for adverse events
- Clinical trial data standards

Success Metrics

- 98% data completeness across all entities
- < 0.5% data quality issues in production
- 99.9% system availability
- < 3 second average query response time