FAERS Submission Application - User Guide

Version: 4.0 **Applies to:** Phase 5 (Enhanced Data Management & Medical Terminology)
Last Updated: January 2026

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1. Introduction

1.1 Purpose

The FAERS Submission Application is a desktop tool designed to help pharmaceutical and biotech companies create, manage, and export Individual Case Safety Reports (ICSRs) for submission to the FDA's Adverse Event Reporting System (FAERS).

1.2 Who Should Use This Application

- **Safety Officers** responsible for adverse event reporting
- **Pharmacovigilance Specialists** managing drug safety data
- **Regulatory Affairs Professionals** preparing FDA submissions
- **Clinical Safety Associates** documenting adverse events
- **Medical Reviewers** reviewing and approving cases
- **QC Reviewers** performing quality control
- **Administrators** managing users and system configuration

1.3 What This Application Does

- Creates structured ICSR cases following FDA E2B(R3) requirements
- Captures all required adverse event information
- Validates data before submission
- Generates compliant E2B(R3) XML files for FDA submission
- Stores cases locally for ongoing management
- **Supports multi-user authentication and access control**
- **Tracks audit history for 21 CFR Part 11 compliance**

1.4 Regulatory Context

The FDA requires pharmaceutical companies to report adverse events electronically using the E2B(R3) standard. Key reporting timelines include:

Report Type	Timeline
Expedited Reports (serious, unexpected)	15 calendar days
Non-Expedited Reports	Periodic (quarterly/annually)

2. Getting Started

2.1 System Requirements

Component	Requirement
Operating System	Windows 10+, macOS 11+, or Ubuntu 20.04+
Display	Minimum 1280 x 720 resolution
Storage	500 MB available space
Memory	4 GB RAM minimum

2.2 Installation

1. Download the installer for your operating system
2. Run the installer and follow the on-screen prompts
3. Launch the application from your Start Menu (Windows), Applications folder (macOS), or application menu (Linux)

2.3 First Launch

When you first launch the application:

1. The database will be automatically initialized
2. A default administrator account is created (see Section 3.2)
3. You'll see the login screen
4. Log in with your credentials to access the application

2.4 Data Storage Location

Your data is stored locally in:

Platform	Location
Windows	`%APPDATA%\FAERSApp\faers.db`

Platform	Location
macOS	`~/Library/Application Support/FAERSApp/faers.db`
Linux	`~/.config/FAERSApp/faers.db`

3. Logging In

3.1 Login Screen

When you start the application, you'll see the login screen:

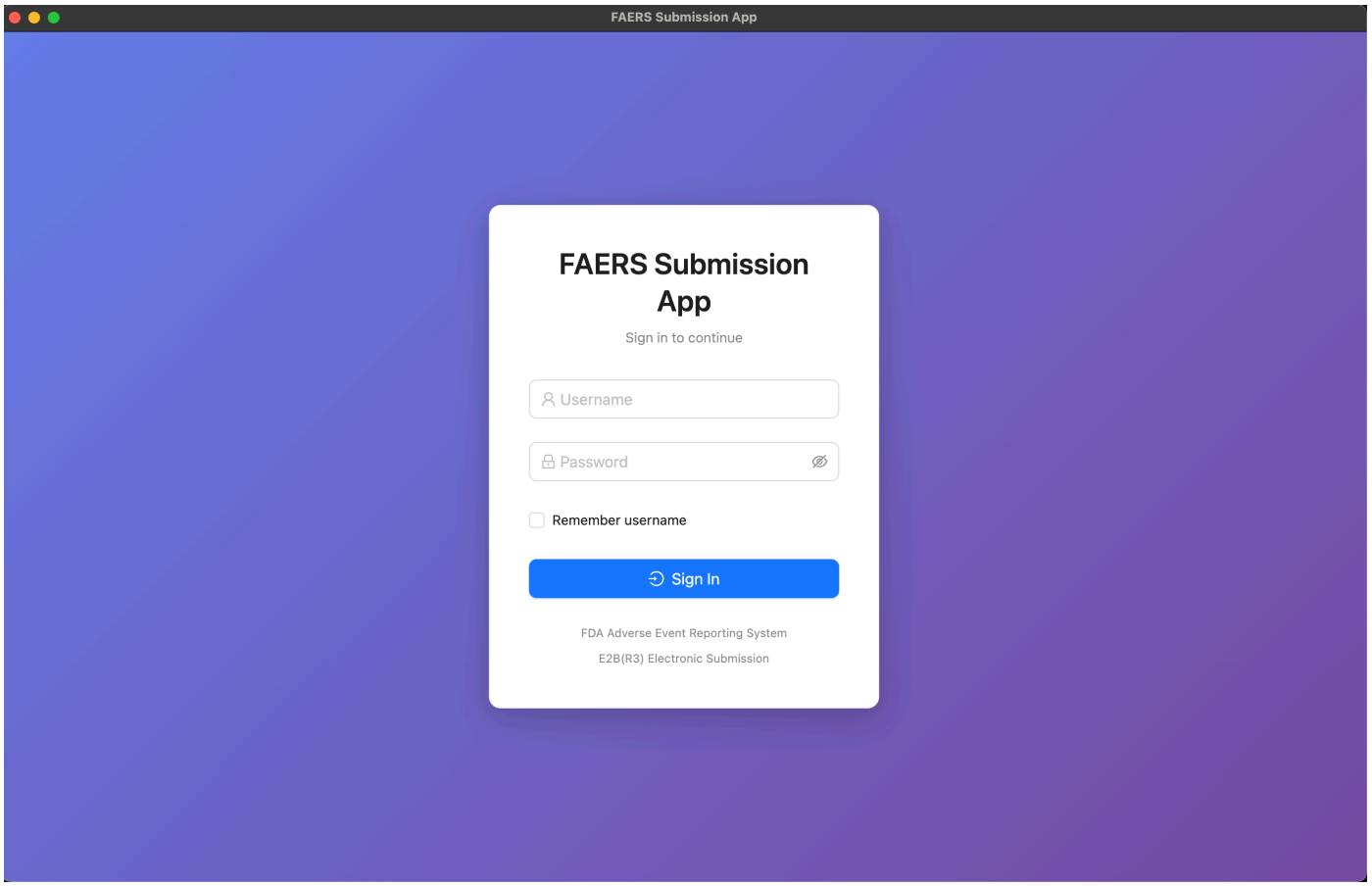

Figure 3.1: Login Screen

The login screen includes:

- Username field
- Password field (masked)
- "Remember username" checkbox
- Sign In button

3.2 Default Administrator Account

On first launch, a default administrator account is created:

Field	Value
Username	`admin`
Password	`Admin@123456`

Important: Change this password immediately after first login!

3.3 Logging In

1. Enter your username
2. Enter your password
3. Optionally check "Remember username" to save your username for next time
4. Click **Sign In**

3.4 Failed Login Attempts

For security, accounts are locked after 5 failed login attempts:

- You'll see a message indicating how many attempts remain
- After 5 failures, the account is locked for 30 minutes
- Contact your administrator if you need immediate access

3.5 First-Time Password Change

If your password was set by an administrator or has expired, you'll be required to change it before accessing the application:

1. Enter your current password
2. Enter a new password meeting the policy requirements
3. Confirm your new password
4. Click **Change Password**

3.6 Password Requirements

Passwords must meet the following requirements:

- At least 12 characters long
- Contains at least one uppercase letter (A-Z)
- Contains at least one lowercase letter (a-z)
- Contains at least one number (0-9)
- Contains at least one special character (!@#$%^&*)
- Cannot reuse the last 5 passwords

3.7 Session Timeout

For security, your session will expire after 30 minutes of inactivity:

- A warning dialog appears 5 minutes before timeout
- Click **Continue Session** to extend your session
- If you don't respond, you'll be automatically logged out
- Your unsaved work is preserved - log back in to continue

3.8 Logging Out

To log out:

1. Click your username in the toolbar (top right)
2. Select **Logout** from the dropdown menu

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4. Application Overview

4.1 Main Window Layout

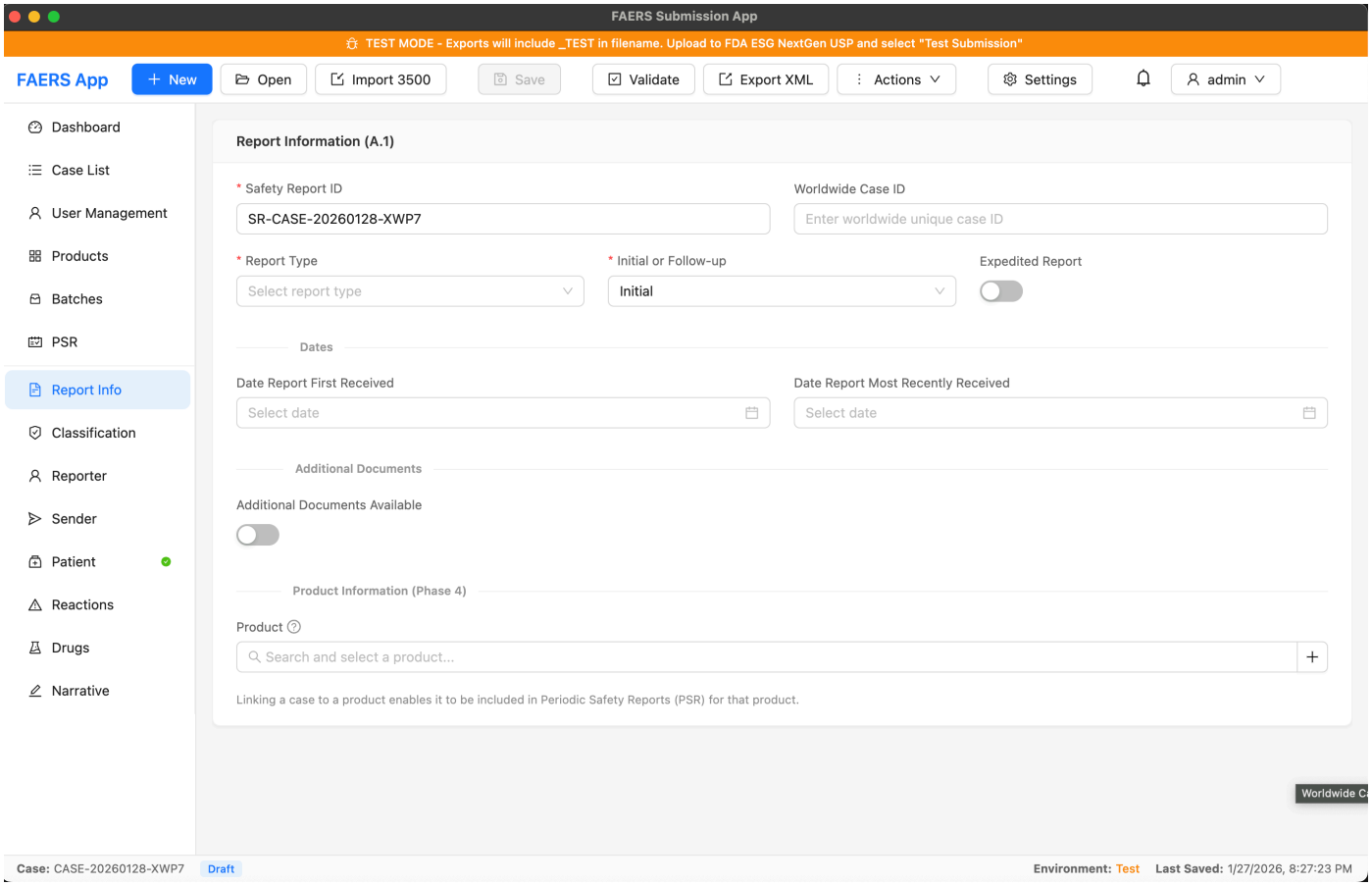

Figure 5.1: Creating a New Case from Toolbar

Method 1: Toolbar

1. Click the **New** button in the toolbar
2. A new case is created with a unique ID (format: `CASE-YYYYMMDD-XXXX`)
3. The case opens in the Report section

Method 2: Menu

1. Go to **File > New Case** or press `Ctrl+N` (Windows/Linux) or `Cmd+N` (macOS)

Method 3: Case List

1. Navigate to the Case List
2. Click the **New Case** button

5.2 Opening an Existing Case

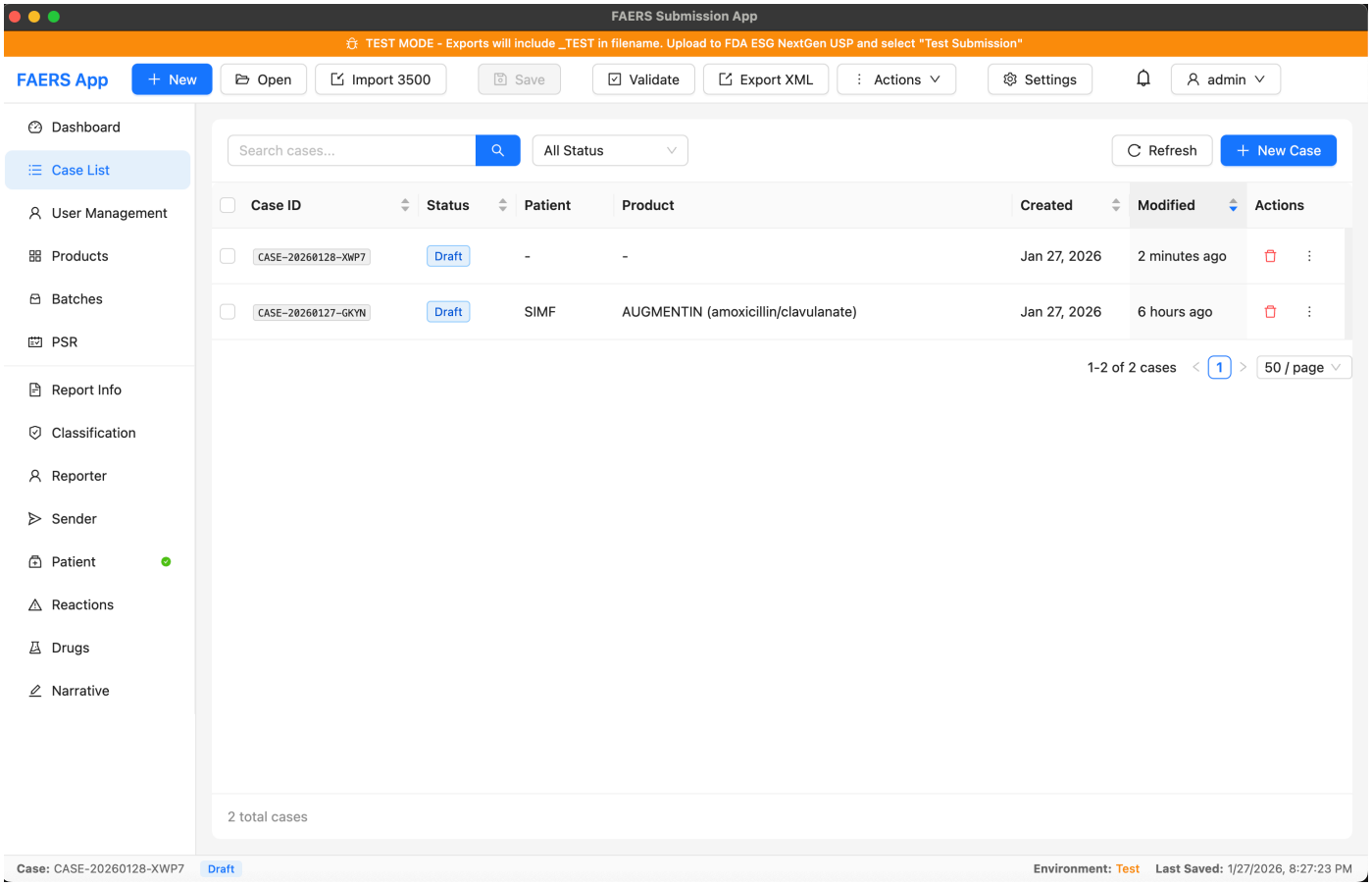

Figure 5.2: Case List View

1. Navigate to the **Case List** (click "Open" in toolbar or select "Case List" in sidebar)
2. Find your case using:
   - **Search box**: Search by Case ID or patient initials
   - **Status filter**: Filter by Draft, Ready, or Exported
   - **Column sorting**: Click column headers to sort
3. **Double-click** the case to open it, or right-click and select "Open"

5.3 Saving a Case

Cases can be saved at any time, even with incomplete data:

- Click **Save** in the toolbar
- Press `Ctrl+S` (Windows/Linux) or `Cmd+S` (macOS)
- The status bar shows "Last Saved" timestamp when successful

Auto-Save: The application automatically saves your work every 5 minutes.

Unsaved Changes: A yellow dot (●) in the status bar indicates unsaved changes.

5.4 Case Workflow Status

Cases progress through a defined workflow with these statuses:

Status	Description
Draft	Case is being created/edited by Data Entry.
Data Entry Complete	Data entry finished, ready for medical review.
In Medical Review	Assigned to Medical Reviewer for clinical assessment.
Medical Review Complete	Medical review finished, ready for QC.
In QC Review	Assigned to QC Reviewer for quality check.
QC Complete	QC review finished, ready for final approval.
Approved	Case approved for submission to FDA.
Submitted	Case has been submitted to FDA via ESG NextGen USP.
Acknowledged	FDA has acknowledged receipt of the submission.
Rejected	Returned by reviewer (requires correction and resubmission).

Note: See Section 6: Workflow Management for details on workflow transitions.

5.5 Duplicating a Case

Use duplication to create follow-up reports or similar cases:

1. In the Case List, right-click the case you want to copy
2. Select **Duplicate**
3. A new case is created with:
    - New unique Case ID
    - All data copied from the original
    - Report Type set to "Follow-up"
    - Link to the original case

5.6 Deleting a Case

Only **Draft** cases can be deleted:

1. In the Case List, right-click the case
2. Select **Delete**
3. Confirm the deletion in the dialog

Note: Deleted cases are soft-deleted and can be recovered by an administrator.

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6. Workflow Management

The application implements a structured workflow to ensure cases are properly reviewed and approved before submission to the FDA.

6.1 Workflow Overview

Cases progress through a series of review stages:

```
Draft → Data Entry Complete → In Medical Review → Medical Review Complete
      → In QC Review → QC Complete → Approved → Submitted → Acknowledged
                    ↓                          ↓
              (Rejected – returns to Draft)
```

6.2 Workflow States

State	Who Can Transition	Next Actions
Draft	Data Entry	Submit for Review
Data Entry Complete	Manager	Assign to Medical Reviewer
In Medical Review	Medical Reviewer	Approve or Reject
Medical Review Complete	Manager	Assign to QC Reviewer
In QC Review	QC Reviewer	Approve or Reject
QC Complete	Manager	Final Approval
Approved	Submitter	Submit to FDA

State	Who Can Transition	Next Actions
Submitted	Submitter	Record Acknowledgment
Acknowledged	-	Case complete
Rejected	Data Entry	Fix issues, resubmit

6.3 Workflow Actions

Available actions depend on your role and the case status:

Data Entry Users:

- **Submit for Review** - Send completed case for medical review

Medical Reviewers:

- **Approve** - Approve the case (requires electronic signature)
- **Reject** - Return the case with comments for correction

QC Reviewers:

- **Approve** - Approve the case (requires electronic signature)
- **Reject** - Return the case with comments for correction

Managers:

- **Assign Case** - Assign a case to a reviewer
- **Reassign Case** - Transfer assignment to another user

Submitters:

- **Submit to FDA** - Submit approved case (requires electronic signature)
- **Record Acknowledgment** - Record FDA acknowledgment

6.4 Performing Workflow Actions

1. Open the case you want to act on
2. Look for the **Workflow Actions** bar at the top of the case form
3. Available actions are displayed based on your permissions and the case status

4. Click the action button (e.g., "Approve", "Reject", "Submit for Review")
5. Complete any required dialogs:
    - **Approval**: Requires entering your password for electronic signature
    - **Rejection**: Requires entering a reason for rejection
    - **Submit for Review**: Optionally add comments

6.5 Case Assignment

Managers can assign cases to specific users for review:

Assigning a Case:

1. Open the case or select it from the Case List
2. Click **Assign** in the Workflow Actions bar
3. Select the user from the dropdown
4. Optionally set:
    - **Priority**: Normal, High, or Urgent
    - **Due Date**: When the review should be completed
    - **Notes**: Instructions for the assignee
5. Click **Assign**

Reassigning a Case:

1. Click **Reassign** in the Workflow Actions bar
2. Select the new assignee
3. Enter a reason for reassignment
4. Click **Reassign**

6.6 My Cases View

The "My Cases" view shows cases assigned to you:

- Cases are sorted by due date (most urgent first)
- Overdue cases are highlighted in red
- Click any case to open it
- Filter by status or priority

Workload Summary:

- View your current case count by status
- See upcoming due dates
- Track overdue cases

6.7 Due Dates

Due dates are calculated based on report type:

Report Type	Due Date
Expedited	15 calendar days from receipt
Non-Expedited	90 calendar days from receipt

Due Date Alerts:

- Cases approaching due date are flagged
- Overdue cases appear in red
- Notifications are sent at 7, 3, and 1 day before due date

6.8 Electronic Signatures

Certain workflow actions require electronic signatures for 21 CFR Part 11 compliance:

- **Medical Review Approval**
- **QC Review Approval**
- **Final Case Approval**
- **FDA Submission**

Signing a Record:

1. Perform the action (e.g., click "Approve")
2. The signature dialog appears
3. Review the signature meaning (e.g., "I have reviewed this case and certify it is accurate")
4. Enter your password to authenticate
5. Click **Sign**

Electronic signatures are recorded in the audit trail with:

- User identity
- Timestamp
- Action performed
- Signature meaning

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7. Comments and Notes

7.1 Comments

Comments are used for workflow communication and are visible to all users who can view the case.

Comment Types:

Type	Description
General	General discussion about the case
Query	Question requiring response
Response	Answer to a query
Rejection	Reason for rejection (auto-created)
Workflow	System-generated workflow comments

Adding a Comment:

1. Open the case and navigate to the **Comments** section
2. Select the comment type from the dropdown
3. Enter your comment text
4. Click **Add Comment**

Viewing Comments:

- Comments are displayed chronologically
- Each comment shows the author, type, and timestamp
- Comments cannot be edited or deleted after creation (audit requirement)

7.2 Notes

Notes are personal or team observations that may not need to be part of the official case record.

Note Visibility:

Visibility	Who Can See
Personal	Only you can see the note
Team	All users with access to the case can see

Adding a Note:

1. Open the case and navigate to the **Notes** section
2. Select visibility (Personal or Team)
3. Enter your note text
4. Click **Add Note**

Resolving Notes:

- Notes can be marked as "resolved" when addressed
- Click the checkmark icon next to a note to resolve it
- Resolved notes are shown with strikethrough text

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8. Data Entry Guide

8.1 Report Information Section

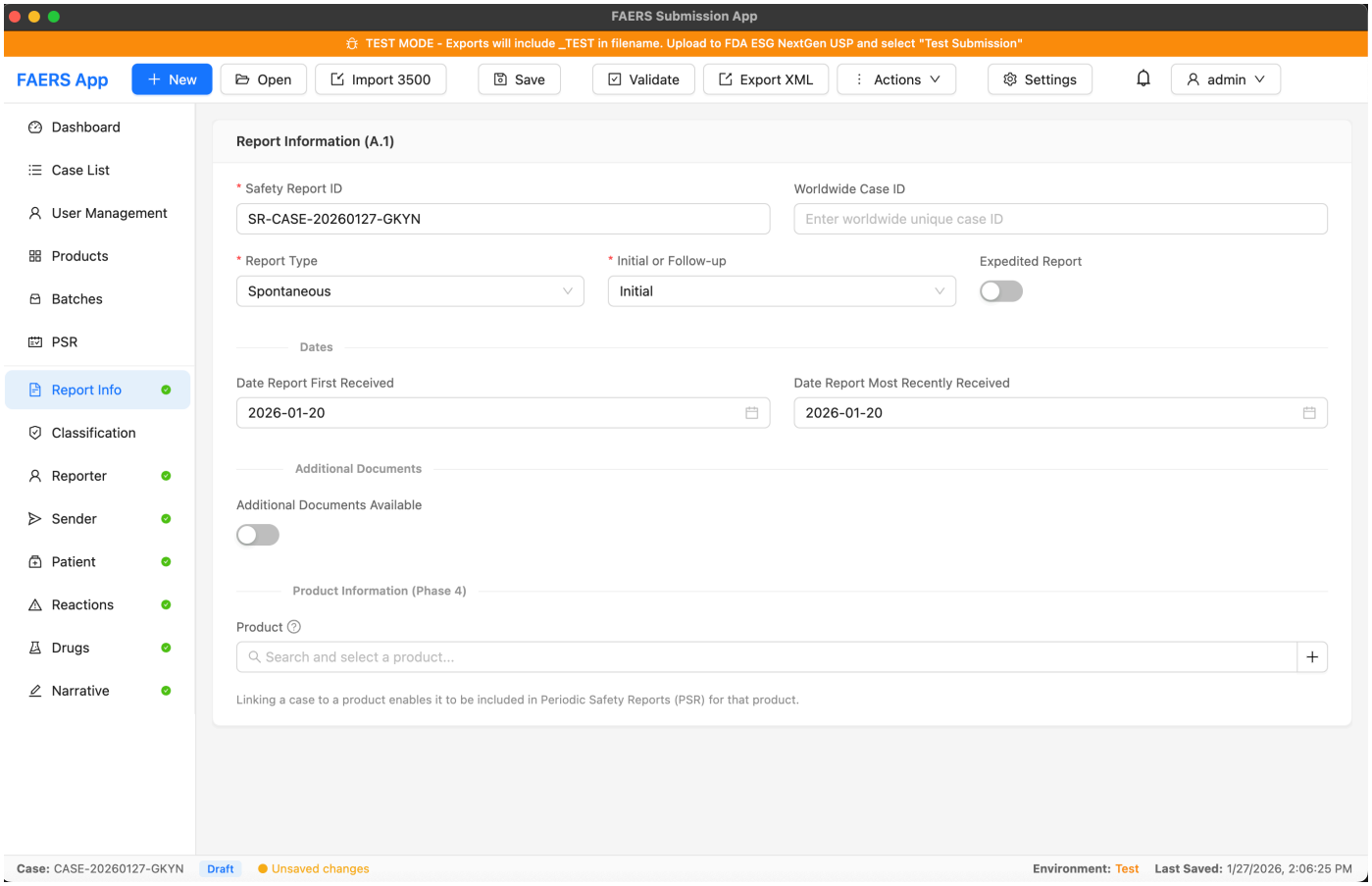

Figure 8.1: Report Information Section

This section captures administrative information about the report.

Field	Description	Required
Safety Report ID	Unique identifier (auto-generated)	Yes
Report Type	Spontaneous, Study, Other, Not Available	Yes
Initial/Follow-up	Whether this is an initial or follow-up report	Yes
Receipt Date	Date you first received the information	Yes
Most Recent Info Date	Date of most recent information	Yes
Expedited Report	Check if this meets expedited reporting criteria	No
Additional Documents	Check if supporting documents are available	No

Tips:

- For spontaneous reports from healthcare providers, select "Spontaneous report"
- For adverse events from clinical trials, select "Report from study"

8.2 Reporter (Primary Source) Section

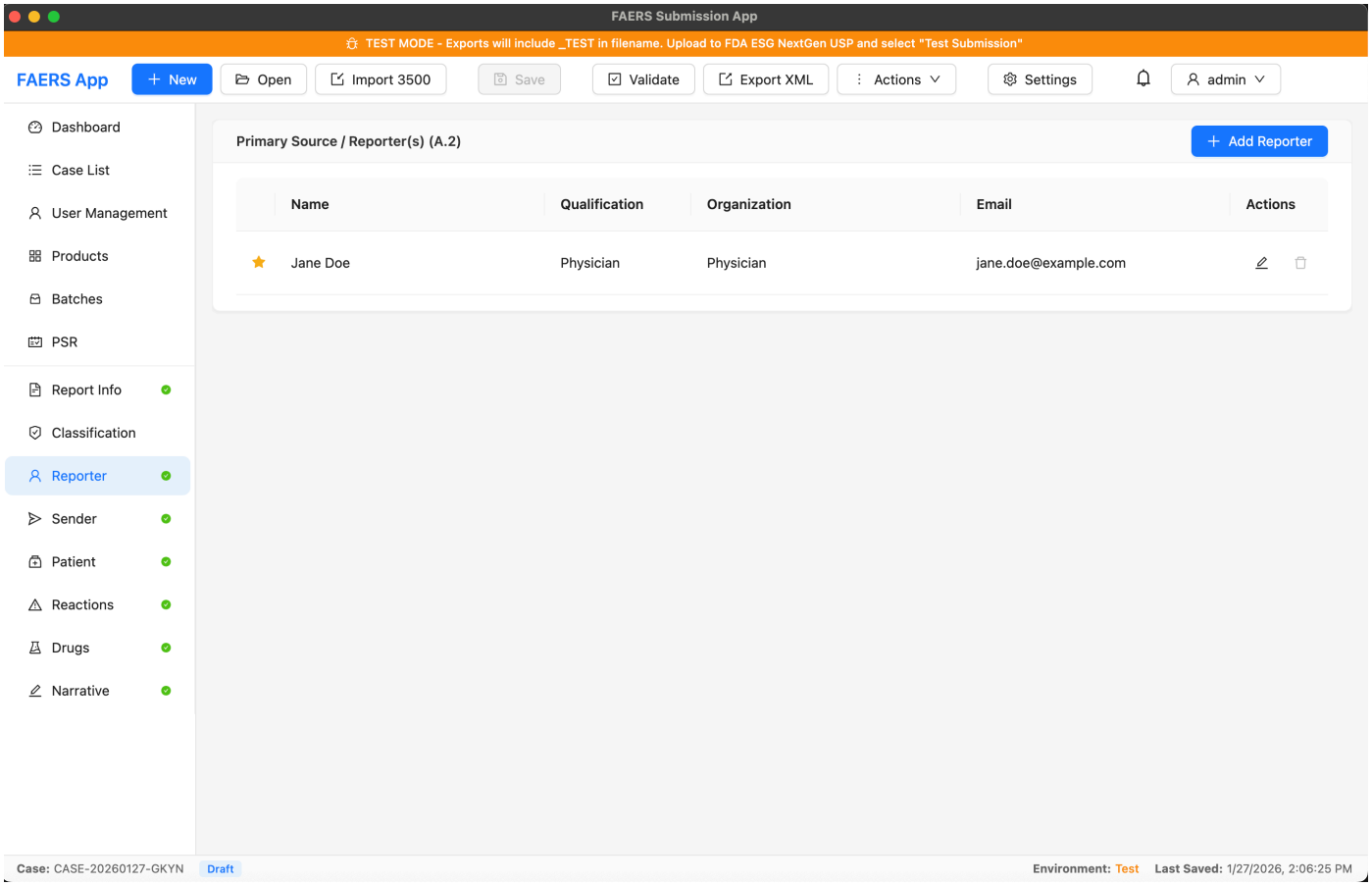

Figure 8.2: Reporter (Primary Source) Section

Information about who reported the adverse event.

Field	Description	Required
Qualification	Physician, Pharmacist, Other HCP, Lawyer, Consumer	Yes
Given Name	Reporter's first name	No
Family Name	Reporter's last name	No
Organization	Hospital, clinic, or company name	No
Country	Reporter's country (dropdown)	No
Email	Contact email (validated format)	No
Phone	Contact phone number	No

Tips:

- At minimum, capture the reporter's qualification
- For follow-up, having contact information is valuable
- You can add multiple reporters if the report came from several sources

8.3 Sender Information Section

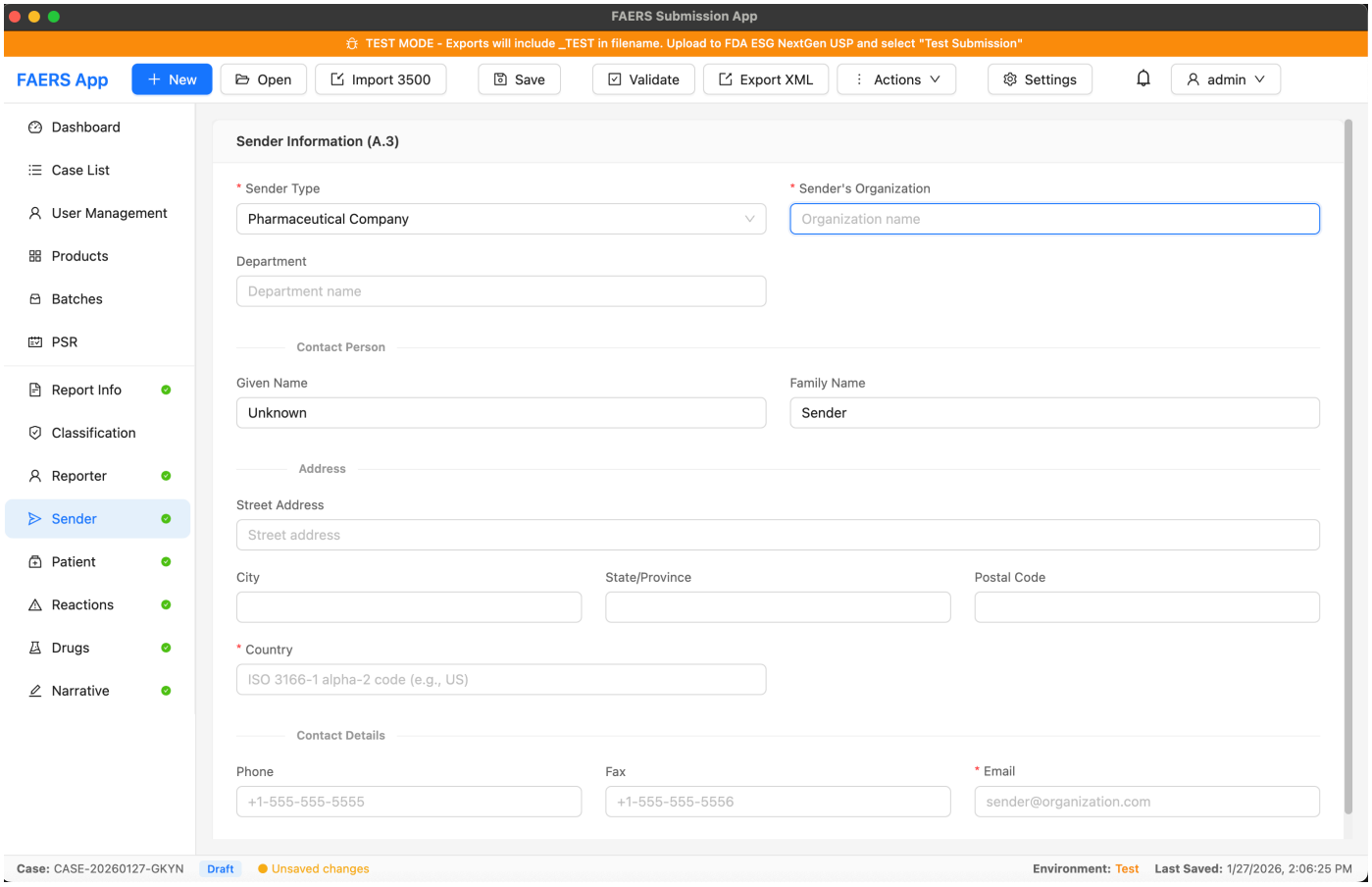

Figure 8.3: Sender Information Section

Your organization's information (the company submitting to FDA).

Field	Description	Required
Sender Type	Pharmaceutical company, Regulatory authority, etc.	Yes
Organization	Your company name	Yes
Given Name	Sender contact's first name	Yes
Family Name	Sender contact's last name	Yes
Address, City, Country	Your organization's address	No
Email	Contact email for FDA queries	No

Tips:

- This information is typically the same for all your cases
- Configure default sender information in Settings

8.4 Patient Information Section

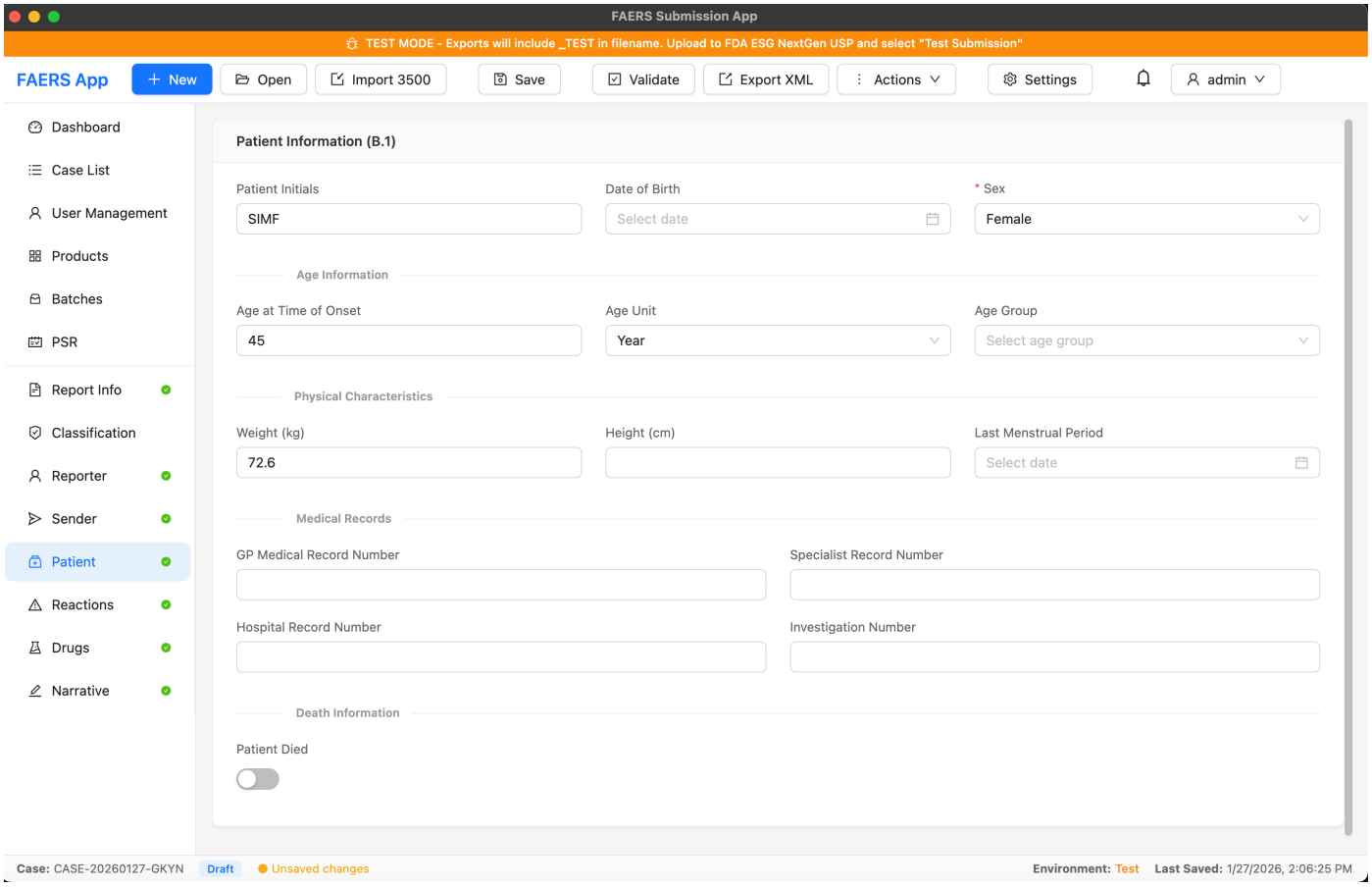

Figure 8.4: Patient Information Section

Demographics and medical history of the patient who experienced the adverse event.

Basic Information

Field	Description	Required
Patient Initials	Anonymized identifier (e.g., "JD")	Conditional
Sex	Male, Female, Unknown	Yes
Age at Onset	Age when reaction occurred	Conditional*
Birth Date	Patient's date of birth	Conditional*
Weight	Body weight in kg	No
Height	Height in cm	No

*Either Age or Birth Date must be provided.

Age Entry Options

You can enter patient age in several ways:

- **Exact birth date**: If known
- **Age with unit**: e.g., "45 Years" or "6 Months"
- **Age group**: Neonate, Infant, Child, Adolescent, Adult, Elderly

Medical History

Click **Add** to record relevant medical conditions:

Field	Description
Condition	Disease or condition name
Start Date	When condition began
Continuing	Is condition still present?
End Date	When condition resolved (if applicable)
Family History	Is this a family history item?

Death Information

If the patient died:

1. Check the **Patient Died** checkbox
2. Enter the **Date of Death**
3. Add **Reported Cause(s) of Death**
4. Indicate if **Autopsy** was performed
5. Add **Autopsy Findings** if applicable

8.5 Reactions Section

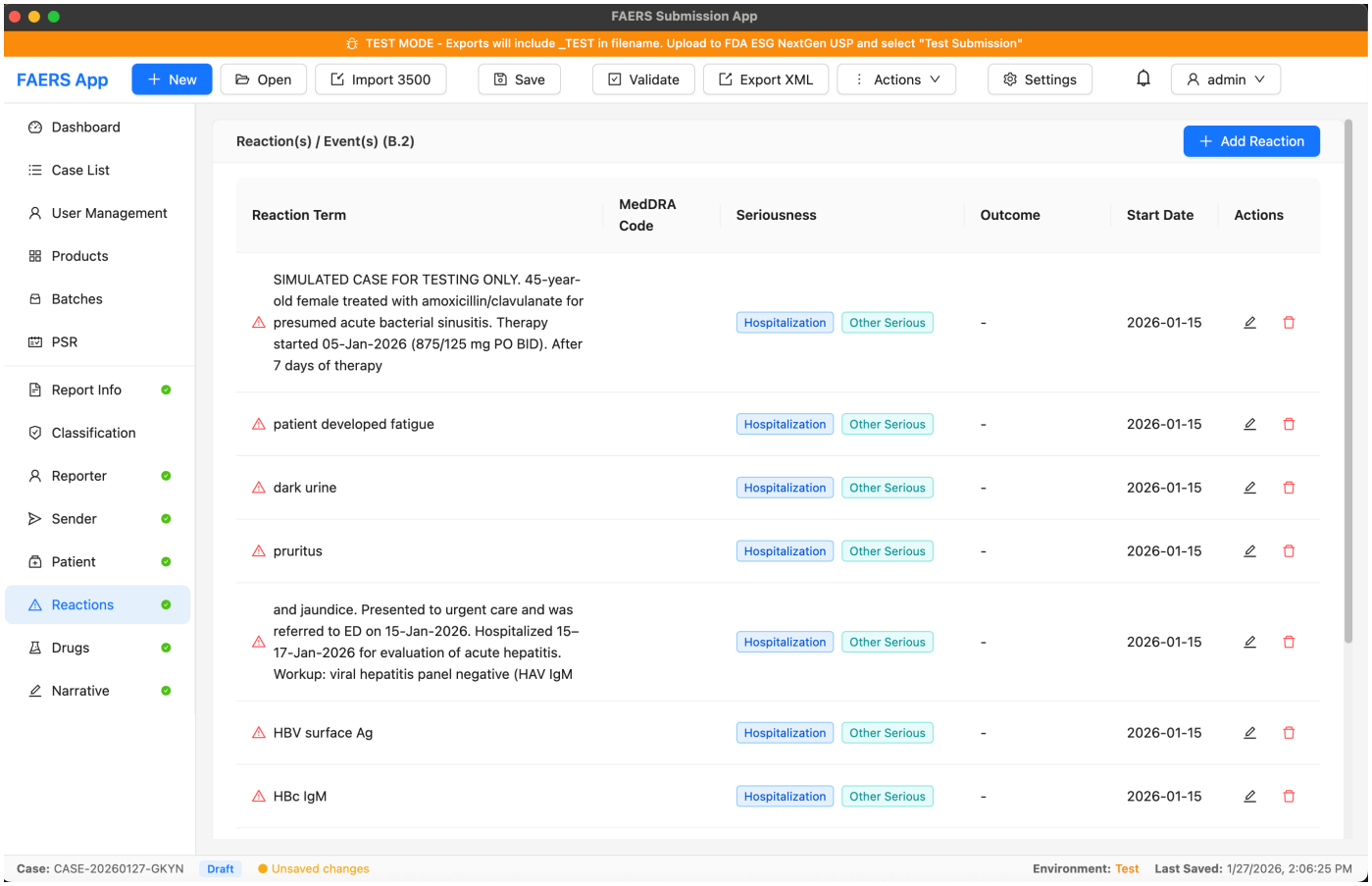

Figure 8.5: Reactions Section

Document each adverse event/reaction the patient experienced.

Adding a Reaction:

1. Click **Add Reaction**
2. Enter the reaction details

Field	Description	Required
Reaction Term	Adverse event description (MedDRA term preferred)	Yes
Start Date	When reaction began	No
End Date	When reaction resolved	No
Duration	How long the reaction lasted	No
Outcome	Recovered, Recovering, Not Recovered, Fatal, Unknown	No

Seriousness Criteria

For each reaction, indicate if it meets any seriousness criteria:

Criterion	Description
Results in Death	The reaction caused or contributed to death
Life-Threatening	Patient was at risk of death at the time
Hospitalization	Required or prolonged hospitalization
Disability	Resulted in significant incapacity
Congenital Anomaly	Caused birth defect in offspring
Other Medically Important	Other significant medical event

At least one seriousness criterion must be selected for each reaction.

8.6 Drugs Section

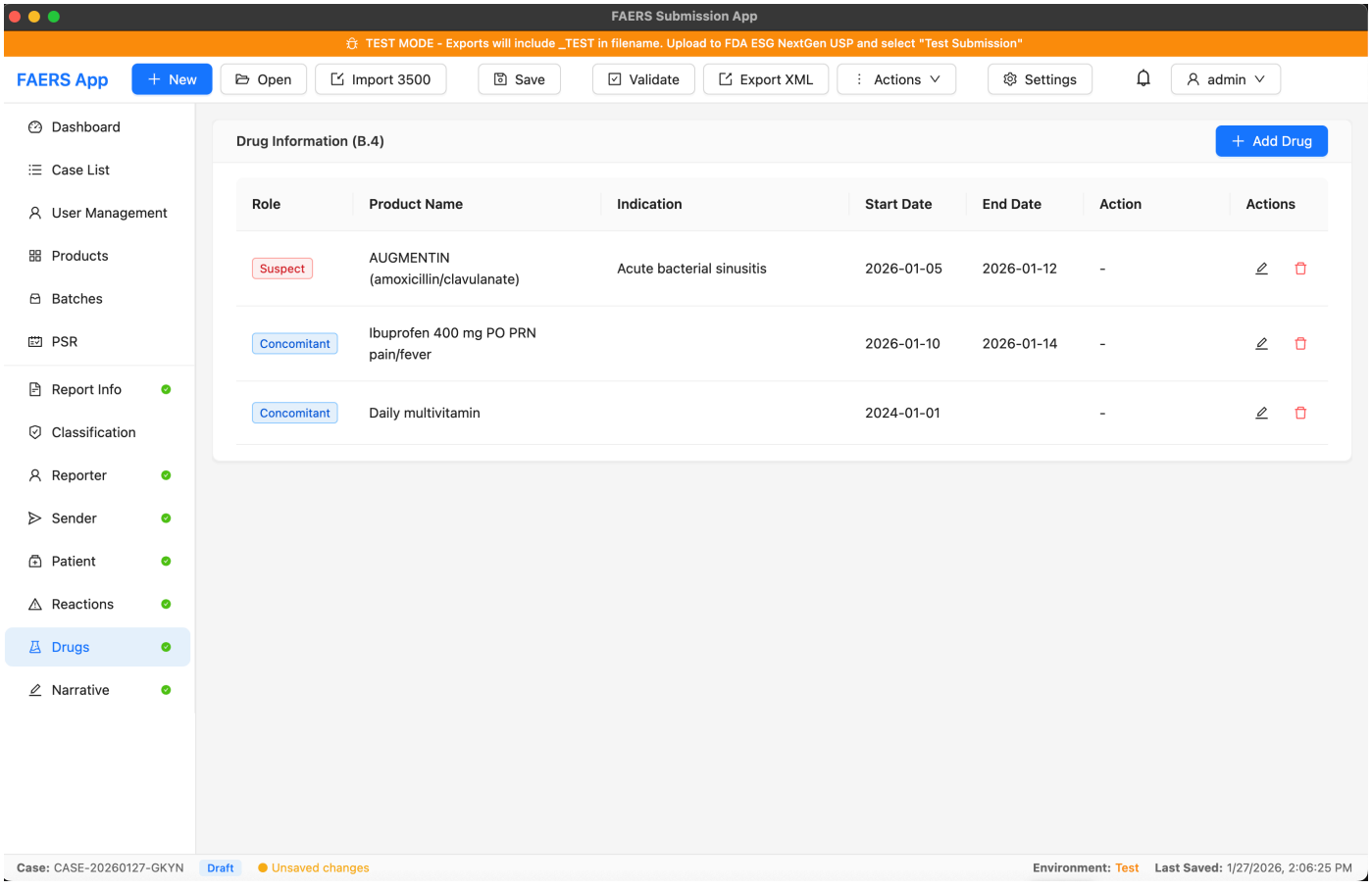

Figure 8.6: Drugs Section

Document all relevant medications.

Adding a Drug:

1. Click **Add Drug**

2. Select the drug characterization
3. Enter drug details

Drug Characterization

Type	Description
Suspect	Medication suspected of causing the reaction
Concomitant	Other medications being taken
Interacting	Medications that may have interacted

At least one Suspect drug is required.

Drug Information

Field	Description	Required
Product Name	Brand or generic name	Yes
Indication	Why the patient was taking this drug	No
Dosage	Amount and frequency	No
Route	How administered (oral, IV, etc.)	No
Start Date	When patient started taking	No
End Date	When patient stopped taking	No
Action Taken	Withdrawn, dose reduced, unchanged, etc.	No

Dechallenge/Rechallenge

Important for causality assessment:

Field	Options
Dechallenge	Did reaction abate when drug was stopped? Yes/No/Unknown/N/A
Rechallenge	Did reaction recur when drug was restarted? Yes/No/Unknown/N/A

8.7 Narrative Section

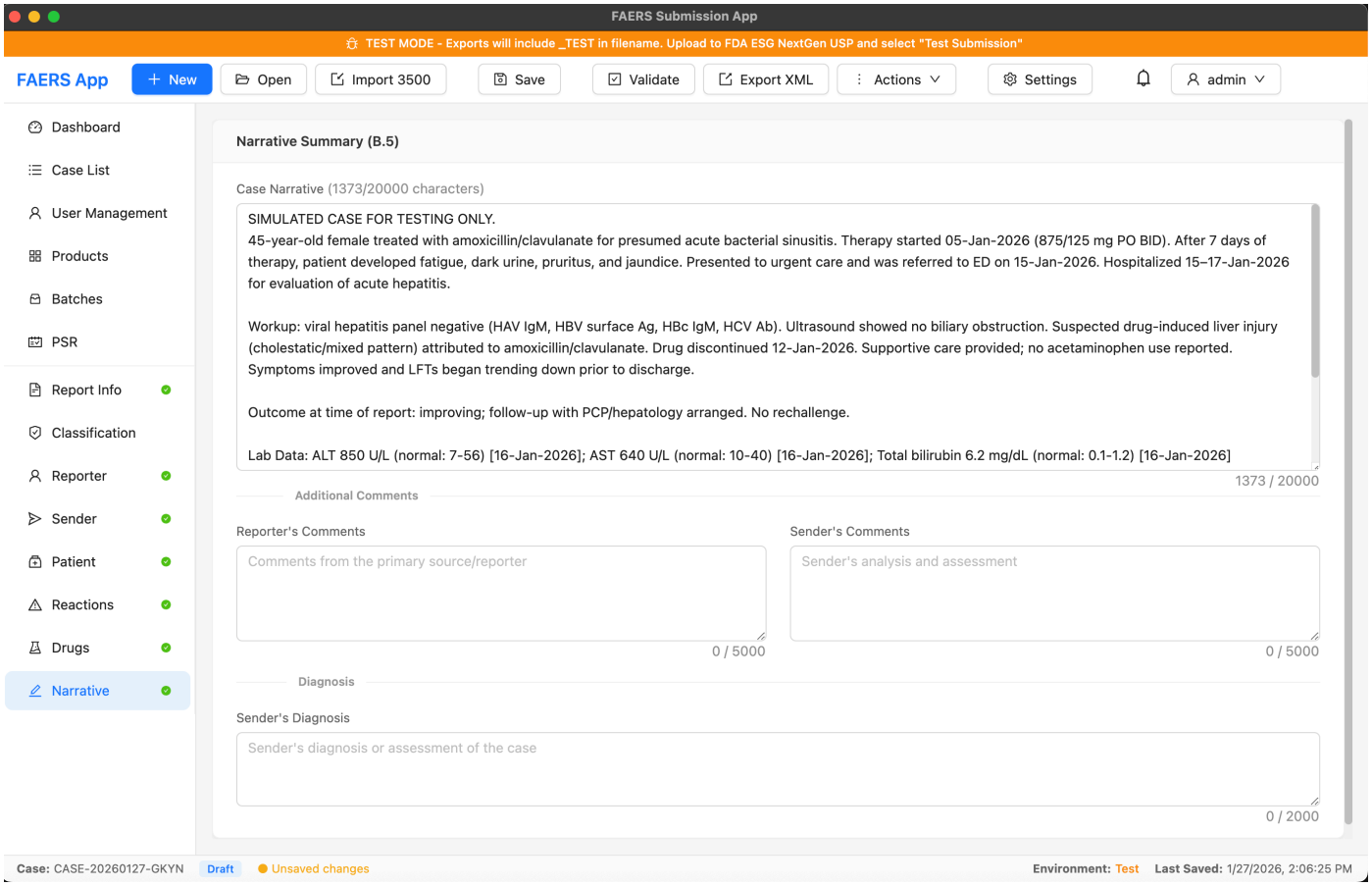

Figure 8.7: Narrative Section

The free-text summary of the case.

Field	Description	Required
Case Narrative	Complete description of the case	Yes
Reporter's Comments	Additional comments from the reporter	No
Sender's Comments	Your organization's assessment	No
Sender's Diagnosis	Your medical assessment	No

Writing an Effective Narrative

A good narrative should include:

1. **Patient description**: Age, sex, relevant medical history
2. **Drug exposure**: What medications, dosages, duration
3. **Event description**: What happened, when, severity
4. **Treatment**: What was done to treat the reaction
5. **Outcome**: How the patient recovered or current status
6. **Reporter's assessment**: Their opinion on causality

Example:

> A 65-year-old male with a history of hypertension and diabetes was started on Drug X 100mg daily for atrial fibrillation. Approximately 2 weeks after starting treatment, the patient developed a generalized skin rash with pruritus. Drug X was discontinued, and the rash resolved within 5 days without additional treatment. The patient has recovered without sequelae. The reporting physician considers the reaction probably related to Drug X.

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9. Validation

9.1 Running Validation

Before exporting XML, validate your case:

1. Click **Validate** in the toolbar, or press `Ctrl+Shift+V`
2. The validation panel appears showing results

9.2 Validation Results

Results are categorized as:

Level	Icon	Description
Error	Red	Must be fixed before export
Warning	Yellow	Should be reviewed
Info	Blue	Suggestions for improvement

9.3 Common Validation Errors

Error	Solution
"Receipt date is required"	Enter the date you first received the report
"At least one reaction is required"	Add at least one adverse reaction

Error	Solution
"At least one suspect drug is required"	Add at least one drug with "Suspect" characterization
"Seriousness criteria required"	Select at least one seriousness checkbox for each reaction
"Case narrative is required"	Enter a narrative summary
"Patient sex is required"	Select Male, Female, or Unknown

9.4 Navigating to Errors

Click on any validation message to navigate directly to the field that needs attention.

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10. Exporting XML

10.1 Generating XML

Once your case passes validation:

1. Click **Export XML** in the toolbar, or press `Ctrl+E`
2. If there are validation errors, you'll be prompted to fix them first
3. Choose a save location for the XML file
4. The file is saved with FDA-compliant naming format

10.2 XML File Contents

The generated XML follows the ICH E2B(R3) standard and includes:

- Message header with sender/receiver information
- Safety report identification
- Patient information
- Reaction details with MedDRA coding
- Drug information
- Narrative summary

10.3 After Export

- The case status changes to "Exported"
- The export timestamp is recorded
- The case can be submitted to FDA

10.4 Submitting to FDA

To submit your XML via FDA ESG NextGen USP:

1. Log in to the FDA Electronic Submission Gateway
2. Select "USP" (Universal Safety Portal)
3. Choose "Test Submission" for testing or "Production" for real submissions
4. Upload your XML file
5. Record the SRP Confirmation Number in the application
6. Monitor for acknowledgment

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11. Notifications

The application provides a notification system to keep you informed about case assignments, workflow changes, and due date reminders.

11.1 Notification Center

Access the Notification Center by clicking the bell icon in the toolbar. A badge shows the count of unread notifications.

11.2 Notification Types

Type	Description
Case Assigned	A case has been assigned to you
Case Reassigned	A case has been reassigned to another user
Workflow Changed	Case status has changed

Type	Description
Review Requested	Your review is requested on a case
Case Approved	A case you submitted has been approved
Case Rejected	A case you submitted has been rejected
Due Date Warning	A case is approaching its due date
Overdue Alert	A case has passed its due date
Comment Added	Someone commented on your case

11.3 Managing Notifications

Viewing Notifications:

1. Click the bell icon in the toolbar
2. A dropdown shows recent notifications
3. Click a notification to navigate to the related case

Marking as Read:

- Click a notification to automatically mark it as read
- Click "Mark All Read" to clear all unread notifications

Notification Preferences: Administrators can configure notification settings in system preferences.

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12. Audit Trail

The application maintains a comprehensive audit trail for 21 CFR Part 11 compliance.

12.1 What is Logged

All significant actions are recorded:

Action Type	Examples
User Authentication	Login, logout, failed login attempts
Case Operations	Create, update, delete, duplicate
Field Changes	Individual field modifications with old/new values
Workflow Transitions	Status changes, approvals, rejections
Electronic Signatures	Signature events with meaning
Exports	XML generation, audit log exports
User Management	User creation, role changes, password resets

12.2 Viewing the Audit Log

Administrators and Managers can access the audit log:

1. Navigate to **Audit Log** in the left sidebar
2. Use filters to narrow results:
    - **Date Range**: Start and end dates
    - **User**: Filter by specific user
    - **Action Type**: Filter by action category
    - **Entity Type**: Filter by case, user, or system
    - **Case ID**: Filter by specific case

12.3 Audit Log Columns

Column	Description
Timestamp	Date and time of action (UTC)
User	User who performed the action
Action	Type of action performed
Entity	Type and ID of affected entity
Field	Field name (for field changes)
Old Value	Previous value (for changes)

Column	Description
New Value	New value (for changes)
Details	Additional context

12.4 Case Audit History

To view the audit trail for a specific case:

1. Open the case
2. Click the **History** tab or button
3. View all changes made to the case chronologically

12.5 Exporting Audit Logs

To export the audit log for compliance reporting:

1. Navigate to the Audit Log
2. Apply any desired filters
3. Click **Export**
4. Choose format:
    - **CSV**: Spreadsheet-compatible format
    - **JSON**: Machine-readable format
5. Choose save location
6. The export action is itself logged

12.6 Audit Trail Integrity

The audit log is append-only:

- Entries cannot be modified or deleted
- Timestamps are recorded in UTC
- User identity is captured at time of action
- Database integrity is protected

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13. User Management (Administrators)

Administrators can manage users and their access through the User Management section.

13.1 Accessing User Management

1. Navigate to **User Management** in the left sidebar
2. Only users with Administrator role can access this section

13.2 Viewing Users

The user list shows:

- Username
- Full name
- Email
- Role
- Status (Active/Inactive)
- Last login date

Use the search box and filters to find specific users.

13.3 Creating a New User

1. Click **New User**
2. Enter required information:
    - **Username**: Unique login identifier
    - **Email**: User's email address
    - **First Name / Last Name**: User's full name
    - **Role**: Select appropriate role
3. Click **Create**
4. A temporary password is generated and displayed
5. Share the temporary password with the user securely
6. The user must change their password on first login

13.4 Editing a User

1. Click the user in the list
2. Click **Edit**
3. Modify user information:
    - First Name / Last Name
    - Email
    - Role
4. Click **Save**

Note: Usernames cannot be changed after creation.

13.5 Deactivating a User

To remove a user's access without deleting their account:

1. Select the user
2. Click **Deactivate**
3. Confirm the action

Deactivated users:

- Cannot log in
- Retain their audit history
- Can be reactivated later

13.6 Reactivating a User

1. Show inactive users using the status filter
2. Select the deactivated user
3. Click **Reactivate**

13.7 Resetting a User's Password

If a user forgets their password:

1. Select the user

2. Click **Reset Password**
3. A new temporary password is generated
4. Share the temporary password securely
5. The user must change their password on next login

13.8 User Roles

Role	Permissions
Administrator	Full system access, user management, audit access
Manager	View all cases, assign work, run reports, view audit log
Data Entry	Create/edit own cases, submit for review
Medical Reviewer	Review assigned cases, approve/reject
QC Reviewer	QC review assigned cases, approve/reject
Submitter	Submit approved cases to FDA
Read Only	View all cases (no editing)

14. Data Management

14.1 Backing Up Your Data

Regular backups protect against data loss:

1. Go to **File > Backup Database**
2. A backup file is created in: `Documents/FAERSApp/Backups/`
3. Filename format: `faers-backup-{timestamp}.db`

Recommendation: Back up before major updates or weekly.

14.2 Restoring from Backup

To restore from a backup:

1. Go to **File > Restore from Backup**
2. Select the backup file
3. Confirm the restoration

Warning: Restoring replaces all current data with the backup.

14.3 Automatic Backups

The application creates automatic backups:

- When closing the application (configurable)
- The last 10 backups are retained

---

15. User Account Management

15.1 Changing Your Password

To change your password:

1. Click your username in the toolbar
2. Select **Change Password**
3. Enter your current password
4. Enter your new password (must meet policy requirements)
5. Confirm your new password
6. Click **Change Password**

15.2 Password Policy

All passwords must meet these requirements:

Requirement	Description
Minimum Length	12 characters
Uppercase	At least one uppercase letter (A-Z)
Lowercase	At least one lowercase letter (a-z)

Requirement	Description
Number	At least one digit (0-9)
Special Character	At least one special character (!@#$%^&*)
History	Cannot reuse last 5 passwords
Expiration	Passwords expire after 90 days

15.3 Account Lockout

For security, accounts are automatically locked after 5 failed login attempts:

- Lockout duration: 30 minutes
- Contact your administrator for immediate unlock

15.4 Session Security

- Sessions automatically expire after 30 minutes of inactivity
- A warning dialog appears 5 minutes before expiration
- Click **Continue Session** to extend your session
- Only one session per user is allowed (logging in elsewhere logs you out)

15.5 User Roles

The application supports different user roles with specific permissions:

Role	Description
Administrator	Full access to all features including user management
Manager	Can view all cases, assign work, run reports
Data Entry	Can create and edit own cases, submit for review
Medical Reviewer	Can review and approve/reject cases
QC Reviewer	Can perform quality control review
Submitter	Can submit approved cases to FDA
Read Only	Can view all cases but cannot make changes

Contact your administrator to request role changes.

---

16. Report Type Classification

Phase 4 introduces automatic classification of reports as Expedited or Non-Expedited based on FDA reporting requirements.

16.1 Understanding Report Types

Report Type	Criteria	Reporting Timeline
Expedited	Serious AND Unexpected	15 calendar days
Non-Expedited	Non-Serious OR (Serious AND Expected)	Periodic (PSR)

16.2 Seriousness Criteria

A case is considered **Serious** if any of these criteria are met:

Criterion	Description
Results in Death	The reaction caused or contributed to death
Life-Threatening	Patient was at risk of death at the time of the event
Hospitalization	Required or prolonged inpatient hospitalization
Disability	Resulted in persistent or significant incapacity
Congenital Anomaly	Caused a birth defect in offspring
Other Medically Important	Other significant medical event requiring intervention

16.3 Expectedness

A reaction is considered **Expected** if it is listed in the approved product labeling. **Unexpected** reactions are those not listed in the labeling or that are more severe than described.

16.4 Classification Workflow

1. Open a case and navigate to the **Report Classification** section
2. Select the seriousness criteria that apply
3. Indicate the expectedness of each reaction
4. The system will suggest the appropriate report type
5. You can override the suggestion with justification if needed

16.5 Report Classification Section

The Report Classification Section displays:

- Seriousness checkboxes for each criterion
- Expectedness selection (Expected/Unexpected/Unknown)
- Auto-calculated classification (Expedited or Non-Expedited)
- Override option with required justification field

---

17. Product Management

Products are managed centrally to support PSR (Periodic Safety Report) scheduling and case aggregation.

17.1 Accessing Product Management

1. Navigate to **Products** in the left sidebar
2. Only users with Administrator or Manager role can create/edit products

17.2 Product Information

Each product record contains:

Field	Description	Required
Product Name	Brand or trade name	Yes

Field	Description	Required
Active Ingredient	Generic name of active substance	No
Application Type	NDA, BLA, or ANDA	No
Application Number	FDA application number	No
US Approval Date	Date of FDA approval	No
Marketing Status	Approved, Withdrawn, or Pending	Yes
Company Name	Marketing authorization holder	No

17.3 Creating a Product

1. Click **New Product** in the Products view
2. Enter the product information
3. Click **Save**

17.4 Configuring PSR Schedules

Products can have one or more PSR schedules configured:

1. Open a product
2. Navigate to the **PSR Schedule** tab
3. Click **Add Schedule**
4. Configure:
    - **Format**: PADER, PSUR, or PBRER
    - **Frequency**: Quarterly, Semi-Annual, Annual, or Biennial
    - **Start Date**: When the first period begins (defaults to approval date)
    - **DLP Offset**: Days before period end for Data Lock Point
    - **Due Offset**: Days after period end for submission due date
5. Click **Save**

17.5 Linking Cases to Products

Cases are linked to products through the **Product** field in the case form:

1. Open a case

2. In the Report section, select the product from the dropdown
3. This enables the case to be included in PSRs for that product

---

18. Follow-Up and Nullification Reports

Phase 4 supports creating follow-up reports and nullifying previously submitted cases.

18.1 Follow-Up Reports

Follow-up reports provide additional information about previously submitted cases.

Creating a Follow-Up:

1. Open the original submitted case
2. Click **Create Follow-Up** in the Actions menu
3. Select the follow-up type:
    - **Additional Information** - New info received about the case
    - **Outcome Update** - Patient outcome has changed
    - **Correction** - Correcting errors in original submission
    - **FDA Response** - Responding to FDA query
    - **Upgrade to Serious** - Case now meets seriousness criteria
    - **Downgrade** - Removing seriousness designation
4. Enter the date information was received
5. Click **Create**

A new case is created with:

- All original data copied
- Link to parent case (parent_case_id)
- Incremented version number
- Follow-up type recorded
- Due date calculated (15 days for expedited follow-ups)

18.2 Version Timeline

View the complete history of a case and its follow-ups:

1. Open any case in a version chain
2. Click **Version History** in the Actions menu
3. The timeline shows:
    - All versions of the case
    - Status of each version
    - Follow-up type and info date
    - Submission status

18.3 Nullification Reports

Nullification reports void previously submitted cases that should not have been submitted.

When to Nullify:

Reason	Description
Duplicate	Same case was submitted multiple times
Error	Case was submitted in error
Not an AE	Event is not actually an adverse event
Wrong Product	Case involves a different product
Consent Withdrawn	Patient withdrew consent for reporting

Creating a Nullification:

1. Open the submitted case to nullify
2. Click **Nullify** in the Actions menu
3. Select the nullification reason
4. If duplicate, enter the reference to the correct case
5. Click **Confirm Nullification**

The nullification report:

- Creates a new case version marked as nullified
- Contains the nullification reason
- Must be submitted to FDA to void the original

---

19. Batch Submission

Batch submission allows multiple cases to be bundled into a single E2B(R3) XML file for submission.

19.1 Batch Types

Type	Description	Use Case
Expedited	Individual serious, unexpected cases	15-day reports
Non-Expedited	Non-expedited cases for periodic reporting	General submissions
PSR	Cases included in a Periodic Safety Report	Bundled with PSR

19.2 Creating a Batch

1. Navigate to **Batches** in the sidebar
2. Click **New Batch**
3. Follow the wizard steps:

Step 1: Select Batch Type

- Choose Expedited, Non-Expedited, or PSR
- For PSR batches, select the PSR to associate

Step 2: Select Cases

- Filter cases by status, date range, product
- Select cases to include using checkboxes
- Only approved cases can be added to batches

Step 3: Validate

- All selected cases are validated
- Review any validation errors
- Cases with errors must be fixed or removed

Step 4: Create Batch

- Review the batch summary
- Click **Create Batch**
- Batch is created with status "Created"

19.3 Batch Status Workflow

Status	Description	Next Actions
Created	Batch created, ready for validation	Validate
Validated	All cases pass validation	Export XML
Exported	XML file generated	Submit to FDA
Submitted	Sent to FDA ESG	Wait for ACK
Acknowledged	FDA acknowledged receipt	Close
Failed	Submission failed	Review, resubmit

19.4 Exporting Batch XML

1. Open the batch
2. Click **Export XML**
3. Choose save location
4. The XML contains all cases in E2B(R3) format

Batch XML Structure:

- Single root element with batch header
- Multiple `<subject>` elements (one per case)
- Common sender/receiver information

19.5 Batch List View

The Batch List displays:

- Batch number
- Type (Expedited/Non-Expedited/PSR)
- Case count

- Status
- Created date
- Submitted date

Filter batches by:

- Status
- Type
- Date range
- Search by batch number

---

20. Periodic Safety Reports (PSR)

Periodic Safety Reports aggregate non-expedited cases for a defined reporting period.

20.1 PSR Formats

Format	Full Name	Use Case
PADER	Post-Approval Adverse Drug Experience Report	US NDA/BLA products
PSUR	Periodic Safety Update Report	International harmonized format
PBRER	Periodic Benefit-Risk Evaluation Report	EU-style comprehensive report

20.2 PSR Dashboard

Access the PSR Dashboard from the sidebar to view:

Summary Statistics:

- Overdue PSRs (highlighted in red)
- Due This Week
- In Progress (Draft/Under Review)
- Pending Cases (awaiting PSR assignment)

Upcoming Deadlines:

- Table of upcoming PSRs sorted by due date
- Color-coded due dates:
  - Red: Overdue
  - Yellow: Due within 7 days
  - Blue: Due within 30 days
  - Green: More than 30 days

Status Overview:

- Visual breakdown of PSRs by status
- Progress bars showing distribution

Recent Activity:

- Timeline of recent PSR actions
- Shows creation, transitions, submissions

20.3 PSR Status Workflow

Status	Description	Next Actions
Scheduled	Upcoming, not yet started	Start (move to Draft)
Draft	In preparation	Submit for Review
Under Review	Being reviewed	Approve or Return to Draft
Approved	Ready for submission	Submit to FDA
Submitted	Sent to FDA	Record Acknowledgment
Acknowledged	FDA confirmed receipt	Close
Closed	Period complete	None

20.4 Creating a PSR

Using the Wizard:

1. Click **Create PSR** in the PSR Dashboard

2. Follow the wizard steps:

Step 1: Select Product

- Choose the product from dropdown
- Select the PSR schedule to use
- View the next period dates (auto-calculated)

Step 2: Review Cases

- See eligible cases for the period
- Cases are automatically aggregated based on:
  - Product match
  - Receipt date within period
  - Non-expedited classification
  - Approved status
- Review case count

Step 3: Confirm

- Review PSR summary
- Verify dates and case count
- Click **Create PSR**

Step 4: Complete

- PSR is created with status "Draft"
- PSR number assigned (format: PSR-PRODUCT-YYYY-NNN)
- Navigate to PSR detail to manage cases

20.5 Managing PSR Cases

Included Cases Tab:

- View all cases currently in the PSR
- Remove cases with exclusion reason

Excluded Cases Tab:

- View cases removed from the PSR
- Each shows exclusion reason

- Can re-include if needed

Add Cases Tab:

- Load eligible cases not yet in PSR
- Select cases to add
- Bulk add functionality

20.6 PSR Case Eligibility

Cases are eligible for a PSR if:

- Linked to the same product
- Receipt date falls within the PSR period
- Classification is Non-Expedited
- Workflow status is Approved or higher
- Not already included in another PSR

20.7 PSR Period Calculation

Periods are calculated based on schedule configuration:

Frequency	Period Length
Quarterly	3 months
Semi-Annual	6 months
Annual	12 months
Biennial	24 months

Key Dates:

- **Period Start**: Day after previous period end (or schedule start date)
- **Period End**: Start + frequency duration
- **Data Lock Point**: Period End - DLP Offset days
- **Due Date**: Period End + Due Offset days

20.8 PSR List View

View all PSRs with:

- PSR Number
- Product
- Format (PADER/PSUR/PBRER)
- Period (start - end)
- Due Date
- Status
- Case Count

Filters:

- Status
- Format
- Due date range
- Product
- Search by PSR number

20.9 Submitting a PSR

1. Ensure all cases are finalized
2. Transition PSR to "Approved"
3. Click **Generate Batch** to create submission batch
4. Export the batch XML
5. Submit via FDA ESG
6. Record acknowledgment when received
7. Close the PSR

---

21. MedDRA Coding

21.1 Overview

MedDRA (Medical Dictionary for Regulatory Activities) is the international medical terminology standard used for coding adverse events. The application supports MedDRA's 5-level hierarchy:

Level	Description	Example
SOC	System Organ Class	Nervous system disorders
HLGT	High Level Group Term	Headaches
HLT	High Level Term	Headaches NEC
PT	Preferred Term	Headache
LLT	Lowest Level Term	Head pain, Cephalalgia

21.2 Importing MedDRA Dictionary


Settings Dictionaries Tab *Figure 21.1: Settings Dialog - Dictionaries Tab*

Administrators can import MedDRA dictionary files:

1. Navigate to **Settings > Dictionaries > MedDRA**
2. Click **Import Version**
3. Select the MedDRA distribution folder containing `.asc` files
4. Wait for import to complete (typically 5-10 minutes)
5. Set the imported version as active


MedDRA Import Wizard *Figure 21.2: MedDRA Dictionary Import Wizard*

21.3 Auto-Coding Reactions

When entering reaction text in the Reactions section:

1. Begin typing the reaction description
2. After 3 characters, suggestions appear automatically
3. Suggestions show: LLT name → PT name → SOC
4. Click a suggestion to select it
5. All MedDRA levels are automatically populated


MedDRA Auto-complete *Figure 21.3: MedDRA Auto-complete Suggestions*

Fuzzy Matching: The system handles common typos (e.g., "hedache" will find "headache")

21.4 Using the MedDRA Browser

To browse the full hierarchy:

1. Click the **Browse** button next to the reaction field
2. Expand the tree: SOC → HLGT → HLT → PT → LLT
3. Use the search box to filter terms
4. Select a term and click **Apply**


MedDRA Browser *Figure 21.4: MedDRA Hierarchy Browser*

Tips:

- Current LLTs are shown by default; check "Include non-current" for all terms
- Primary SOC paths are marked with a star
- Multi-axial terms show all SOC paths

---

22. WHO Drug Coding

22.1 Overview

WHO Drug Dictionary (WHODrug) is the international reference for medication coding. It provides:

- Trade name to generic name mapping
- ATC (Anatomical Therapeutic Chemical) classification
- Ingredient information
- Manufacturer details

22.2 Importing WHO Drug Dictionary

Administrators can import WHO Drug files:

1. Navigate to **Settings > Dictionaries > WHO Drug**
2. Click **Import Version**
3. Select the WHO Drug distribution files
4. Wait for import to complete

5. Set the imported version as active

Figure 22.1: WHO Drug Dictionary Import

22.3 Auto-Coding Drugs

When entering drug names in the Drugs section:

1. Begin typing the drug name
2. After 3 characters, suggestions appear
3. Suggestions show: Trade Name → Ingredient → ATC Code
4. Select a suggestion to auto-populate fields

Figure 22.2: WHO Drug Auto-complete Suggestions

22.4 Using the ATC Browser

To browse by therapeutic classification:

1. Click the **Browse ATC** button
2. Navigate the hierarchy: Anatomical group → Therapeutic → Pharmacological → Chemical
3. View drugs at any level
4. Select a drug to apply to the case

Figure 22.3: ATC Classification Browser

---

23. Advanced Search

23.1 Global Search

Use the search bar at the top of the Case List to search across all case fields:

- Case ID
- Patient information
- Narrative text
- Product names

- Reaction terms
- Reporter information

Search Syntax:

- `headache` - Simple search
- `"severe headache"` - Exact phrase
- `headache AND aspirin` - Both terms required
- `headache OR migraine` - Either term
- `product:aspirin` - Field-specific search
- `head*` - Wildcard search

23.2 Advanced Search Builder

For complex queries:

1. Click **Advanced Search** next to the search bar
2. Add conditions using the builder:
   - Select field
   - Choose operator (contains, equals, before, after, etc.)
   - Enter value
3. Use **AND/OR** to combine conditions
4. Click **Preview** to see result count
5. Click **Search** to execute

 Advanced Search Builder *Figure 23.1: Advanced Search Query Builder*

23.3 Saved Searches

Save frequently used searches:

1. Build your search query
2. Click **Save Search**
3. Enter a name and description
4. Choose to share with team (optional)
5. Access saved searches from the sidebar

 Saved Searches *Figure 23.2: Saved Searches Panel*

---

24. Duplicate Detection

24.1 Automatic Detection

The system automatically checks for potential duplicates:

- When saving a new case
- When importing cases
- On demand via the **Check Duplicates** button

Matching Criteria:

- Patient identifier (exact match)
- Patient initials + DOB (exact)
- Event date (within 7 days)
- Product name (fuzzy match)
- Reaction terms (MedDRA PT level)

24.2 Duplicate Alert

When duplicates are detected, an alert appears showing:

- Similarity score (0-100%)
- Side-by-side comparison of matching fields
- Matching criteria breakdown

 Duplicate Alert *Figure 24.1: Duplicate Detection Alert with Side-by-Side Comparison*

24.3 Resolution Options

Choose how to handle each potential duplicate:

Option	Description
Not a Duplicate	Dismiss the alert; record decision
Mark as Duplicate	Link current case to original; flag for review
Link as Related	Same patient, different events

Option	Description
Merge Cases	Combine into a single case

24.4 Merge Wizard

To merge two cases:

1. Click **Merge Cases**
2. Select the master case (survives)
3. For each field, choose the source (Case A or Case B)
4. Review the merged preview
5. Confirm merge

 Merge Wizard *Figure 24.2: Case Merge Wizard*

Note: Submitted cases cannot be merged directly; create a follow-up instead.

24.5 Duplicate Registry

View all duplicate decisions in **Admin > Duplicate Registry**:

- Filter by resolution status
- Review decision audit trail
- Re-open dismissed duplicates if needed

 Duplicate Registry *Figure 24.3: Duplicate Registry*

---

25. Case Templates

25.1 What Are Templates?

Templates are pre-configured case forms with:

- Pre-filled default values
- Locked fields (cannot be changed)
- Required field overrides

- Common scenarios (vaccine reactions, medication errors, etc.)

25.2 Using Templates

To create a case from a template:

1. Click **New Case from Template**
2. Browse the Template Library
3. Select a template and click **Use Template**
4. Complete the remaining fields
5. Save the case

 Template Library *Figure 25.1: Template Library*

25.3 Creating Templates

To create a new template:

1. Go to **Settings > Templates > New Template**
2. Enter template name and category
3. Fill in default values for fields
4. Mark fields as locked (cannot be changed)
5. Add required field overrides
6. Save the template

Alternative: Create from an existing case:

1. Open the case
2. Click **Save as Template**
3. Configure template settings
4. Save

 Template Creation Form *Figure 25.2: Template Creation Form*

25.4 Template Categories

Templates are organized by category:

- Vaccine Reactions

- Medication Errors
- Device Malfunctions
- Overdose Cases
- Special Populations (Pediatric, Pregnant)
- Product-Specific

25.5 Template Governance

Administrators can:

- Approve templates for global use
- Set department-specific templates
- Deprecate outdated templates
- Track template usage statistics

---

26. Bulk Import

26.1 Supported Formats

The application supports importing cases from:

- CSV files (comma, semicolon, or tab delimited)
- Excel files (.xlsx, .xls)

Limits:

- Maximum file size: 50 MB
- Maximum rows: 10,000 per import

26.2 Import Wizard

The import wizard guides you through four steps:

Step 1: Upload

- Drag and drop your file or click to browse
- Preview the first 10 rows

- System auto-detects delimiter and encoding


Import Wizard - Step 1 *Figure 26.1: Import Wizard - File Upload*

Step 2: Column Mapping

- Map file columns to case fields
- Use auto-detect for common column names
- Skip columns you don't want to import
- Save mappings for reuse


Import Wizard - Step 2 *Figure 26.2: Import Wizard - Column Mapping*

Step 3: Validate

- Review validation results per row
- Errors are shown in red (must fix)
- Warnings are shown in yellow (review)
- Download error report for offline review


Import Wizard - Step 3 *Figure 26.3: Import Wizard - Validation Results*

Step 4: Import

- Choose import options:
  - Import all valid rows
  - Skip rows with errors
  - Create cases as Draft status
- Monitor progress during import
- View summary when complete


Import Wizard - Step 4 *Figure 26.4: Import Wizard - Import Progress*

26.3 Column Mapping Tips

- **Auto-detection**: Common names like "Patient_ID", "DOB", "Drug_Name" are auto-mapped
- **Saved Mappings**: Save your column mapping for repeated imports from the same source
- **Transformations**: The system handles date format conversion automatically
- **MedDRA/WHO Drug**: Use "Auto-code" to automatically code reactions and drugs

26.4 Import History

View all imports in **Admin > Import History**:

- See date, user, file name, row counts
- Download original file
- View created cases
- Re-run import with same mapping

---

27. Validation Rules

27.1 Overview

The validation engine checks cases against configurable rules:

- **Errors**: Must be fixed before submission
- **Warnings**: Review recommended; can acknowledge
- **Info**: Informational messages

27.2 Built-in Rules

Default system rules include:

Rule	Severity	Description
Age Consistency	Error	Age matches DOB and event date
Date Sequence	Error	Start dates before end dates
Death Requires Date	Error	Death outcome needs death date
Serious Criteria	Error	Serious cases need at least one criterion
Event Onset	Warning	Event should occur during treatment
Reporter Contact	Warning	Contact info required for follow-up
MedDRA Required	Warning	MedDRA code recommended for submission
Age Range	Warning	Patient age should be ≤ 150 years

Rule	Severity	Description
Future Date	Error	Event date cannot be in future

27.3 Viewing Validation Results

Validation runs automatically when you:

- Save a case
- Click **Validate** button
- Attempt to submit

Results are displayed in the Validation Panel:

- Errors shown first (red)
- Warnings next (orange)
- Info last (blue)
- Click an item to jump to the field

 Validation Panel *Figure 27.1: Validation Panel*

27.4 Acknowledging Warnings

Warnings don't block submission but should be reviewed:

1. Read each warning message
2. Select warnings you've reviewed
3. Click **Acknowledge Selected**
4. Add notes explaining why the warning is acceptable
5. Acknowledged warnings are tracked in audit trail

27.5 Custom Rules (Administrators)

Administrators can create custom validation rules:

1. Go to **Settings > Validation Rules**
2. Click **New Rule**
3. Configure:

    - Rule code and name
    - Rule type (required, format, range, cross-field, custom)
    - Severity (error, warning, info)
    - Condition (when to apply)
    - Validation expression
    - Error message
4. Test the rule against sample data
5. Activate the rule

Figure 27.2: Custom Validation Rule Configuration

Expression Examples:

- `patient_age <= 150` - Simple comparison
- `event_onset_date <= report_date` - Date comparison
- `is_serious === true ? seriousness_criteria.length > 0 : true` - Conditional

---

28. Keyboard Shortcuts

28.1 General Shortcuts

Action	Windows/Linux	macOS
New Case	`Ctrl+N`	`Cmd+N`
Save	`Ctrl+S`	`Cmd+S`
Validate	`Ctrl+Shift+V`	`Cmd+Shift+V`
Export XML	`Ctrl+E`	`Cmd+E`
Undo	`Ctrl+Z`	`Cmd+Z`
Redo	`Ctrl+Y`	`Cmd+Shift+Z`

28.2 Navigation Shortcuts

Action	Windows/Linux	macOS
Report Section	`Ctrl+1`	`Cmd+1`
Reporter Section	`Ctrl+2`	`Cmd+2`
Sender Section	`Ctrl+3`	`Cmd+3`
Patient Section	`Ctrl+4`	`Cmd+4`
Reactions Section	`Ctrl+5`	`Cmd+5`
Drugs Section	`Ctrl+6`	`Cmd+6`
Narrative Section	`Ctrl+7`	`Cmd+7`

28.3 Form Navigation

Action	Shortcut
Next Field	`Tab`
Previous Field	`Shift+Tab`
Open Dropdown	`Space` or `Enter`
Select Date	`Enter` (in date picker)

---

29. Troubleshooting

29.1 Login Issues

Cannot log in with correct password:

- Ensure Caps Lock is not on
- Check if account is locked (wait 30 minutes or contact admin)
- Try the "Remember username" option to avoid typos

Account locked:

- Wait 30 minutes for automatic unlock
- Contact your administrator for immediate unlock

29.2 Session Expired

Session expired while working:

- Your data is automatically saved before session expiry
- Log back in to continue where you left off
- Consider extending your session when the warning appears

29.3 Application Won't Start

Symptoms: Application fails to launch or crashes immediately.

Solutions:

1. Ensure your system meets minimum requirements
2. Try reinstalling the application
3. Check if antivirus is blocking the application
4. Delete the database file and restart (warning: loses all data)

29.4 Data Not Saving

Symptoms: Changes are lost after closing.

Solutions:

1. Check for disk space on your system drive
2. Ensure you have write permissions to the data directory
3. Click Save manually before closing
4. Check for "unsaved changes" indicator

29.5 Validation Always Fails

Symptoms: Cannot export XML due to persistent errors.

Solutions:

1. Review each error message carefully
2. Ensure all required fields are filled

3. Check date formats are correct
4. Verify at least one reaction and one suspect drug exist

29.6 XML Export Errors

Symptoms: XML generation fails or produces invalid file.

Solutions:

1. Run validation first and fix all errors
2. Ensure narrative doesn't contain special characters that need escaping
3. Check that all dates are in valid format
4. Try exporting to a different location

29.7 Performance Issues

Symptoms: Application is slow or unresponsive.

Solutions:

1. Close other applications to free memory
2. If case list is large, use filters to reduce displayed cases
3. Consider archiving old exported cases
4. Restart the application

29.8 Getting Help

If you continue to experience issues:

1. Check the application logs (Help > View Logs)
2. Note the exact error message
3. Document steps to reproduce the issue
4. Contact your IT support or the application vendor

---

30. Glossary

Term	Definition
ACK	Acknowledgment - FDA confirmation of successful submission
Adverse Event (AE)	Undesirable medical occurrence during drug treatment
Concomitant Drug	Medication taken alongside the suspect drug
Dechallenge	Stopping a drug to see if adverse event resolves
E2B(R3)	ICH standard format for electronic ICSR transmission
ESG	FDA Electronic Submission Gateway
Expedited Report	Report due within 15 days (serious, unexpected events)
FAERS	FDA Adverse Event Reporting System
HCP	Healthcare Professional
ICSR	Individual Case Safety Report
MedDRA	Medical Dictionary for Regulatory Activities (coding system)
NACK	Negative Acknowledgment - FDA rejection of submission
Pharmacovigilance	Science of detecting and preventing adverse drug effects
RBAC	Role-Based Access Control
Rechallenge	Restarting a drug to see if adverse event recurs
Serious AE	Event resulting in death, hospitalization, disability, etc.
Session	Active login period; expires after inactivity
Spontaneous Report	Voluntary report from healthcare provider or consumer
SRP	Safety Reporting Portal
Suspect Drug	Medication believed to have caused the adverse event
USP	Universal Safety Portal (FDA's new submission system)
21 CFR Part 11	FDA regulation for electronic records and signatures
Assignee	User assigned to work on a case
Audit Trail	Chronological record of all system activities
Batch Submission	Multiple ICSRs bundled into a single XML file for submission

Term	Definition
Data Entry Complete	Workflow state indicating data entry is finished
Data Lock Point (DLP)	Date after which no new data is added to a PSR period
Electronic Signature	Digital authentication for regulatory compliance
Expedited Report	Serious and unexpected AE requiring 15-day reporting
Follow-Up Report	Additional information about a previously submitted case
Medical Review	Clinical assessment of an adverse event case
Non-Expedited Report	AE not meeting expedited criteria, reported periodically
Nullification	Report that voids a previously submitted case
PADER	Post-Approval Adverse Drug Experience Report
PBRER	Periodic Benefit-Risk Evaluation Report
PSR	Periodic Safety Report - aggregates non-expedited cases
PSUR	Periodic Safety Update Report
QC Review	Quality control review before submission
Workflow	Defined sequence of states a case progresses through
ATC	Anatomical Therapeutic Chemical classification system for drugs
Auto-Coding	Automatic suggestion of coded terms from dictionaries
Column Mapping	Associating file columns with database fields during import
Duplicate Detection	Automated process to identify potential duplicate cases
Fuzzy Matching	Search technique that finds similar matches despite typos
HLGT	High Level Group Term - MedDRA hierarchy level 2
HLT	High Level Term - MedDRA hierarchy level 3
LLT	Lowest Level Term - MedDRA hierarchy level 5 (most specific)

Term	Definition
MedDRA	Medical Dictionary for Regulatory Activities - standard medical terminology
Multi-axiality	MedDRA concept where a term can belong to multiple SOCs
Primary SOC	Main System Organ Class classification for a MedDRA term
PT	Preferred Term - MedDRA hierarchy level 4 (coding level)
Saved Search	User-defined search query stored for reuse
Similarity Score	Percentage indicating how similar two cases are for duplicate detection
SOC	System Organ Class - MedDRA hierarchy level 1 (highest)
Template	Pre-configured case form with default values
Validation Engine	Configurable rule-based system for data quality checks
Validation Rule	Configurable check for data quality (error, warning, or info)
WHO Drug	World Health Organization Drug Dictionary for medication coding

Document History

Version	Date	Changes
1.0	January 2026	Initial release for Phase 1 MVP
1.1	January 2026	Phase 2: Added FDA ESG NextGen USP submission workflow
2.0	January 2026	Phase 3: Added multi-user authentication, RBAC, session management
2.1	January 2026	Phase 3: Added workflow management, comments/notes, notifications, audit trail, user management documentation

Version	Date	Changes
3.0	January 2026	Phase 4: Added report type classification, product management, follow-up/nullification reports, batch submission, PSR management with dashboard, creation wizard, and scheduling
4.0	January 2026	Phase 5: Added MedDRA dictionary integration, WHO Drug dictionary, advanced search and filtering, duplicate detection, case templates, bulk import wizard, configurable validation engine

Contact & Support

For technical support or feedback, please contact your system administrator or the application support team.

Default Administrator Credentials (change immediately after first login):

- Username: `admin`
- Password: `Admin@123456`

FDA Resources:

- FAERS Electronic Submissions
- E2B(R3) Implementation Guide
- FDA ESG NextGen