

ZZedc Quickstart: 5-Minute Setup

ZZedc Quickstart Guide

This guide provides an overview of ZZedc functionality and basic installation procedures.

Overview

ZZedc is an Electronic Data Capture (EDC) system implemented in R/Shiny for managing clinical trial and research study data. The system supports data collection, validation, quality control, and export functionality through a web-based interface.

Start Here: 3 Simple Steps

Step 1: Install (30 seconds)

```
# Install both packages (zzedc.validation is the validation core)
install.packages("path/to/zzedc.validation_1.0.0.tar.gz", repos = NULL, type = "source")
install.packages("path/to/zzedc_1.0.0.tar.gz", repos = NULL, type = "source")

# Load ZZedc
library(zzedc)
```

Step 2: Launch (10 seconds)

```
# Start the application
launch_zzedc()

# Your browser opens automatically at http://localhost:3838
```

Step 3: Login (20 seconds)

Default test account: - Username: `test` - Password: `test`

You're in! Welcome to your ZZedc system.

Core System Capabilities

Data Collection and Validation

The system implements automated validation rules during data entry:

```
# Validation rules implemented in ZZedc:
validation_rules <- list(
  "Age range validation" = "Verifies age values within acceptable ranges",
  "Date sequence validation" = "Ensures visit dates follow enrollment chronology",
  "Field completeness checks" = "Identifies missing required data",
  "Data type validation" = "Confirms numeric fields contain appropriate values",
```

```
"Custom rule application" = "Implements study-specific validation logic"
)
```

When validation errors are encountered, the system provides immediate feedback to the data entry operator.

Data Management Interface

The Data Explorer component provides functionality for:

- Enrollment tracking with summary statistics
- Structured data tables with filtering and search capabilities
- Identification of incomplete data elements
- Quality metrics and data completeness assessment
- Subset selection and extraction capabilities

Reporting Functions

The system generates three categories of reports:

Report 1: Enrollment Summary

```
# Report 1 displays:
# - Total enrolled subjects
# - Enrollment distribution by site (when applicable)
# - Subject status categorization
# - Enrollment progression over time
```

Report 2: Quality Control Metrics

```
# Report 2 identifies:
# - Missing data patterns by field
# - Validation error distribution
# - Duplicate record detection
# - Protocol deviation documentation
```

Report 3: Descriptive Statistics

```
# Report 3 generates:
# - Demographic summary statistics
# - Baseline characteristic distributions
# - Outcome variable summaries
# - Safety event tabulations
```

Data Export

The system supports data export in multiple formats:

- CSV format for general-purpose statistical software
- SPSS/SAS formats for advanced statistical analysis
- RDS format for native R processing
- Pre-calculated derived variables and analysis datasets

```
# In the Export tab, select format and download
# Data exports include:
# - Raw data with all variables
# - Derived variables and scores
# - Analysis datasets per protocol
# - Regulatory submission formats
```

Example Implementation: Depression Treatment Trial

This section illustrates typical EDC implementation using a depression treatment trial with 50 participants across 2 sites.

Study Setup

1. Create your study

```
study_config <- list(  
  name = "Depression Treatment Trial v1.0",  
  protocol = "DEPR-2024-001",  
  pi = "Dr. Jane Smith",  
  sites = c("University Medical Center", "Community Health Clinic"),  
  target_enrollment = 50  
)
```

2. Add your team

- Dr. Jane Smith (Principal Investigator) — Full access
- Dr. Mark Johnson (Site PI) — Site 1 data only
- Sarah Lee (Data Coordinator) — Data entry only
- Mike Brown (Biostatistician) — Reports only

3. Define your forms

- Demographics (age, gender, race, income)
- Depression severity (PHQ-9 questionnaire, automatically scored)
- Treatment assignment (randomization)
- Weekly visits (baseline, weeks 1, 2, 4, 8, 12)
- Adverse events
- Study completion

Data Collection

Data coordinators enter participant information through the web interface. The system validates entries against defined rules and provides immediate feedback. For example:

Participant 001 data entry:

- Age: 45 (within range)
- PHQ-9 score: 18 (valid)
- Week 1 visit date: within acceptable window
- "Time to feel relief" field: not completed (flagged)
- Status: Saved successfully

Monitoring and Review

System administrators and study personnel access reports showing:
- Enrollment status: 18/50 participants (36% of target)
- Data completeness: Subjects missing Week 2 visit data identified
- Quality issues: 1 protocol deviation documented (visit 3 days outside window)
- Safety events: 2 adverse events reported and classified

Analysis (End of Study)

Statistician exports the data:

```
# One click exports analysis-ready dataset:  
# - 50 subjects across 2 sites  
# - All validated data + computed scores  
# - Ready for statistical software  
# - Includes audit trail for FDA compliance  
  
analysis_data <- read.csv("depression_trial_export.csv")  
head(analysis_data)  
# All variables present, properly formatted, complete
```

System Applicability by Study Scale

Small Studies (10-50 participants, single site)

Suitable for studies with straightforward data requirements:

- Simple forms with basic validation rules
- Routine data review workflows
- Data export in standard formats (CSV)
- Participant enrollment tracking

Medium-Scale Studies (50-500 participants, 2-5 sites)

Appropriate for multi-site studies with complex data collection:

- Complex data structures supporting longitudinal visits
- Multi-site coordination and site-specific reporting
- Automated data quality metrics and monitoring
- Statistical summarization and reporting functionality

Large-Scale Studies (500+ participants, 5+ sites)

Features for enterprise-level clinical trials:

- Regulatory compliance frameworks (GDPR, 21 CFR Part 11)
- Electronic signature capabilities
- Immutable audit trail documentation
- Centralized randomization procedures
- Real-time safety event monitoring
- Interim analysis data access

Security and Regulatory Features

Data Protection Mechanisms

System features supporting research oversight and institutional requirements:

- Secure authentication using password hashing with cryptographic salts
- Comprehensive audit trail with timestamp and user documentation
- Role-based access control restricting user actions to authorized functions
- Data minimization principles limiting collection to specified requirements
- Consent management tracking with version control

Regulatory Compliance Frameworks

The system implements controls relevant to regulatory requirements:

- Electronic signature system supporting 21 CFR Part 11 requirements
- GDPR compliance features including data subject access rights
- Data validation rule implementation and documentation
- Change control documentation tracking modifications
- Database lock mechanisms preventing post-analysis modifications

Operational Considerations

Additional system characteristics:

- Automated database backup and recovery procedures
- Open-source architecture eliminating licensing restrictions
- Local data storage maintaining institutional data control
- Scalable deployment from standalone to enterprise configurations

Advanced Capabilities You'll Discover

Data Quality Monitoring

```
# Automatic nightly QC checks:  
# - Flag missing data patterns  
# - Identify unusual values (outliers)  
# - Check cross-visit consistency  
# - Generate quality reports
```

Multi-Visit Longitudinal Studies

```
# Support for:  
# - Baseline + follow-up visits  
# - Weekly, monthly, or yearly data  
# - Cross-visit validation (e.g., visit dates in order)  
# - Longitudinal outcome calculations
```

Lab Data Integration

```
# Automated lab result upload:  
# - Direct from lab information systems (HL7)  
# - Or manual entry with validation  
# - Automatic range checking vs reference values  
# - Integration with case report forms
```

Custom Validation Rules

```
# Create rules like:  
# "If treatment='Drug A' then dose required"  
# "If adverse event='serious' then hospitalization required"  
# "If visit_date > baseline + 365 days then flag"  
# "If blood_pressure > 180/110 then notify PI"
```

Electronic Signatures

```
# For regulatory submissions:  
# - Multi-factor authentication  
# - Audit trail of all e-signatures  
# - 21 CFR Part 11 compliance  
# - Acceptable to FDA for data lock
```

Implementation Patterns

Pattern 1: Baseline and Follow-up Studies

Application: Pilot studies, feasibility studies, single-site clinical trials Configuration requirements: Basic forms with limited follow-up visits Training needs: Standard user training (0.5 hours)

Pattern 2: Multi-site Clinical Trials

Application: Phase 2/3 trials, multi-institution research Configuration requirements: Complex forms with site-level permissions and monitoring Training needs: Site coordinator training and documentation (2-3 hours)

Pattern 3: Longitudinal Cohort Studies

Application: Long-term follow-up research, prospective studies Configuration requirements: Complex visit schedules with repeated measurements Training needs: Comprehensive staff training and protocols (4 hours)

Pattern 4: Real-time Safety Monitoring

Application: Early-phase trials, safety-focused research Configuration requirements: Rapid adverse event reporting and escalation Training needs: Full team training with protocol establishment (5 hours)

Next Steps

Ready to dive deeper?

1. **Small studies?** → See Small Project Guide
2. **Medium-sized trials?** → See Medium Project Guide
3. **Advanced features?** → See Advanced Features Guide
4. **Real-world example?** → See Multi-site Clinical Trial

Need help?

- **Email:** rgthomas@ucsd.edu
- **GitHub:** <https://github.com/rgt47/zzedc>
- **Documentation:** All vignettes cover specific use cases

Want to see a demo?

The included sample data lets you explore immediately: 1. Login with test/test 2. Navigate to EDC tab 3. Browse existing subjects 4. Check Reports and Data Explorer 5. Export sample data

Getting Started with ZZedc

To familiarize yourself with the system:

1. Install and launch the application
2. Login with test credentials (test/test)
3. Navigate through the interface tabs (Home, EDC, Reports, Data Explorer, Export)
4. Review the demonstration data included with the installation
5. Consult additional vignettes for specific use cases and advanced features

You're ready. One command gets you started:

```
launch_zzedc()
```

Questions? Check the vignettes or email rgthomas@ucsd.edu

Questions about specific features? Check the full documentation: - Setup & Configuration: See Getting Started - Small teams: Small Project Guide - Large teams: Medium Project Guide - Developers: Advanced Features