

Getting Started with ZZedc

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ZZedc is a comprehensive Electronic Data Capture (EDC) system designed for clinical trials and research studies. This guide will help you get up and running quickly.

What is ZZedc?

ZZedc provides:

- **Secure data collection** with user authentication
- **Modern web interface** built with Bootstrap 5
- **Real-time data validation** and quality controls
- **Flexible reporting** and data export capabilities
- **Multi-user support** with role-based access
- **Compliance features** for regulatory requirements

Installation

Install from Package

```
# Install ZZedc package
install.packages("path/to/zzedc_1.0.0.tar.gz", repos = NULL, type = "source")

# Load the package
library(zzedc)
```

System Requirements

- **R version:** 4.0.0 or higher
- **Web browser:** Chrome, Firefox, Safari, or Edge
- **Memory:** Minimum 4GB RAM recommended
- **Storage:** 100MB for application, additional space for data

Quick Start

1. Launch ZZedc

```
# Launch the application
launch_zzedc()

# Or with custom settings
launch_zzedc(
  host = "127.0.0.1",
  port = 3838,
  launch.browser = TRUE
)
```

This will open ZZedc in your default web browser at <http://localhost:3838>.

2. First Login

Default Test Credentials: - Username: `test` - Password: `test`

Other Available Users: - `admin` / `admin123` (Administrator) - `sjohnson` / `password123` (Principal Investigator) - `asmith` / `coord123` (Research Coordinator)

3. Navigate the Interface

The ZZedc interface has five main tabs:

Home Tab

- Welcome dashboard with quick start guide
- System status and notifications
- Links to documentation and support

EDC Tab

- Electronic data capture forms
- Subject enrollment and data entry
- Data validation and quality checks

Reports Tab

- Three levels of reporting:
 - **Report 1:** Basic summary statistics
 - **Report 2:** Quality control reports
 - **Report 3:** Advanced statistical analysis

Data Explorer Tab

- Interactive data visualization
- Filter and subset data
- Export subsets for analysis

Export Tab

- Download data in multiple formats
- Generate analysis-ready datasets
- Create regulatory submission packages

Basic Workflow

Step 1: Set Up Your Study

```
# Study configuration (modify config.yml or use interface)
study_info <- list(
  name = "My Clinical Study",
  protocol = "STUDY-2024-001",
  pi = "Dr. Researcher",
  target_enrollment = 50
)
```

Step 2: User Management

```
# Add study team members (done through interface)
# Navigate to: Settings > User Management

team_roles <- c(
  "Principal Investigator",
  "Research Coordinator",
  "Data Manager",
  "Biostatistician"
)
```

Step 3: Data Entry

1. Navigate to EDC tab
2. Click “Add New Subject”
3. Enter subject information:
 - Subject ID (auto-generated or manual)
 - Demographics
 - Study-specific data points

```
# Example subject data structure
subject_data <- list(
  subject_id = "STUDY001",
  initials = "AB",
  date_of_birth = "1980-05-15",
  gender = "Female",
  enrollment_date = Sys.Date()
)
```

Step 4: Quality Control

Monitor data quality through:

- **Real-time validation:** Errors highlighted immediately
- **Data completeness:** Track missing values
- **Range checks:** Automatic validation against expected ranges
- **Duplicate detection:** Prevent duplicate entries

Step 5: Generate Reports

```
# Basic reporting workflow:
# 1. Navigate to Reports tab
# 2. Select report type
# 3. Choose date range and filters
# 4. Generate and download

# Available report formats:
report_formats <- c("HTML", "PDF", "Word", "Excel")
```

Key Features Overview

Authentication and Security

ZZedc includes robust security features:

```
# Security features
security_features <- list(
  user_authentication = "Database-based with secure password hashing",
  session_management = "Configurable timeout and session tracking",
  audit_trail = "Complete record of all user actions",
  role_based_access = "Granular permissions by user role",
  data_encryption = "Secure data storage and transmission"
)
```

Data Validation

Automatic validation includes:

- **Type checking:** Ensure numeric fields contain numbers
- **Range validation:** Values within expected ranges
- **Date logic:** Chronological consistency
- **Required fields:** Prevent incomplete records
- **Custom rules:** Study-specific validation logic

Modern UI Components

Built with modern web technologies:

```
# UI Features
ui_capabilities <- list(
  responsive_design = "Works on desktop, tablet, and mobile",
  accessibility = "WCAG 2.1 compliant interface",
  modern_styling = "Bootstrap 5 with professional themes",
  interactive_components = "Real-time updates and feedback",
  data_visualization = "Integrated charts and graphs"
)
```

Configuration

Basic Configuration

ZZedc uses a YAML configuration file:

```
default:
  app:
    name: "Your Study Name"
    version: "1.0.0"
    debug: false

  database:
    path: "data/study.db"
    pool_size: 5

  auth:
    session_timeout_minutes: 30
    max_failed_attempts: 3

  ui:
    theme: "flatly"
    primary_color: "#2c3e50"
```

Environment Variables

Set environment variables for sensitive information:

```
# Example environment variables
Sys.setenv(
  ZZEDC_DB_PATH = "/secure/path/to/database.db",
  ZZEDC_SALT = "your-secure-salt-string",
  ZZEDC_ADMIN_EMAIL = "admin@yourinstitution.edu"
)
```

Sample Data and Testing

Working with Sample Data

ZZedc includes sample data for testing:

```
# Generate sample data for testing
create_sample_subjects <- function(n = 10) {
  data.frame(
    subject_id = paste0("SAMP", sprintf("%03d", 1:n)),
    age = sample(18:80, n, replace = TRUE),
    gender = sample(c("Male", "Female"), n, replace = TRUE),
    enrollment_date = seq(as.Date("2024-01-01"), by = "week", length.out = n),
    status = sample(c("Active", "Completed", "Withdrawn"), n, replace = TRUE),
    stringsAsFactors = FALSE
  )
}

sample_data <- create_sample_subjects(20)
head(sample_data)
```

Database Setup

```
# Database initialization (done automatically on first launch)
# Manual setup if needed:

# 1. Create database directory
dir.create("data", showWarnings = FALSE)

# 2. Run setup script (if available)
# source("setup_database.R")

# 3. Verify database connection
# The application will create necessary tables automatically
```

Common Tasks

Adding New Users

```
# User management workflow:
# 1. Admin login to ZZedc
# 2. Navigate to user management
# 3. Click "Add User"
# 4. Specify role and permissions
```

```

user_roles <- list(
  admin = "Full system access",
  pi = "Study oversight and data review",
  coordinator = "Data entry and basic reporting",
  monitor = "Data review and quality control"
)

```

Data Entry Best Practices

```

# Best practices for data entry
best_practices <- list(
  "Use consistent naming conventions",
  "Enter data promptly after collection",
  "Review entries before saving",
  "Document any issues or deviations",
  "Regularly backup data",
  "Train all users on proper procedures"
)

```

Export and Backup

```

# Regular backup workflow:
# 1. Navigate to Export tab
# 2. Select "Full Database Export"
# 3. Choose format (CSV, SPSS, SAS)
# 4. Download and store securely

backup_schedule <- list(
  frequency = "Daily",
  format = "Multiple formats",
  location = "Secure server with access controls",
  retention = "Per institutional policy"
)

```

Troubleshooting

Common Issues

Cannot connect to ZZedc:

```

# Check if R session is running
# Verify port 3838 is available
# Try different port:
launch_zzedc(port = 3839)

```

Login problems:

```

# Verify credentials
# Check if database is accessible
# Reset password if needed (contact administrator)

```

Data not saving:

```

# Check internet connection
# Verify database permissions

```

```
# Look for validation errors
# Try refreshing the browser
```

Getting Help

1. **Check documentation:** Additional vignettes available
2. **Error messages:** Read carefully and check for validation issues
3. **Log files:** Check application logs for detailed error information
4. **Support contacts:**
 - Email: rgthomas47@gmail.com
 - GitHub: <https://github.com/rgt47/zzedc>

Next Steps

Once you're comfortable with the basics:

1. **Customize for your study:** Modify forms and validation rules
2. **Train your team:** Ensure all users understand the workflow
3. **Set up regular procedures:** Data review, backup, quality control
4. **Explore advanced features:** See other vignettes for detailed guides

Additional Resources

- **Small Projects:** See Small Project Guide
- **Medium Projects:** See Medium Project Guide
- **Advanced Features:** See Advanced Features Guide

Quick Reference

Keyboard Shortcuts

- **Ctrl+S:** Save current form
- **Ctrl+N:** New subject entry
- **F5:** Refresh data view
- **Esc:** Cancel current operation

Important URLs

When running locally:

- **Main application:** <http://localhost:3838>
- **Direct tab access:** Add `#tab-name` to URL
- **API endpoints:** <http://localhost:3838/api/> (if available)

File Locations

```
# Important file locations
file_structure <- list(
  database = "data/memory001_study.db",
  config = "config.yml",
  logs = "logs/",
  exports = "exports/",
  backup = "backup/"
)
```

This completes the getting started guide. You're now ready to begin using ZZedc for your clinical research!