

ADHD_TRIAL_WORKFLOW

September 15, 2025 at 09:19 AM

ADHD Clinical Trial - ZZedc Workflow Guide

Trial Overview

Study: Efficacy of Novel ADHD Medication vs. Placebo **Design:** Randomized, double-blind, placebo-controlled trial **Duration:** 12 weeks with 4 assessment visits **Sample Size:** 60 participants (30 per group) **Primary Endpoint:** ADHD Rating Scale improvement at Week 12

Team Roles & Responsibilities

Dr. Sarah Chen - Principal Investigator

- **Role:** Study oversight, protocol compliance, data review
- **Technical Level:** Basic computer skills
- **ZZedc Access:** Full administrative access, reports review
- **Responsibilities:**
 - Final approval of study setup
 - Weekly data quality reviews
 - Regulatory compliance oversight
 - Safety monitoring

Alex Rodriguez - Graduate Student (Biostatistics)

- **Role:** Technical lead, database administrator
- **Technical Level:** Advanced R programming, database management
- **ZZedc Access:** Full system administration
- **Responsibilities:**
 - Initial system setup and configuration
 - Google Sheets creation and management
 - Data quality assurance
 - Statistical analysis preparation

Maria Santos - Psychometrist

- **Role:** Patient recruitment, data collection, data entry
 - **Technical Level:** Moderate computer skills, clinical assessment expertise
 - **ZZedc Access:** Data entry and patient management
 - **Responsibilities:**
 - Patient screening and enrollment
 - Clinical assessments and data collection
 - Daily data entry into ZZedc
 - Basic data verification
-

Phase 1: Initial Setup (Week -2)

Alex's Tasks - Technical Setup

Step 1: ZZedc Installation and Configuration

```
# 1. Set up ZZedc environment
setwd("/Users/alex/ADHD_Trial/")
source("run_enhanced_app.R") # Launch enhanced ZZedc
```

Step 2: Create Google Sheets Configuration Create Authentication Sheet: **ADHD_Trial_Auth**

Tab: users

| username | password | full_name | email | role | site_id | active |
|--------------|------------|----------------|---------------------------|-------|---------|--------|
| drschen | adhd2024! | Dr. Sarah Chen | schen@university.edu | Admin | 1 | 1 |
| alex_r | biostat123 | Alex Rodriguez | arodriguez@university.edu | Admin | 1 | 1 |
| maria_s | psych456 | Maria Santos | msantos@university.edu | Admin | 1 | 1 |
| backup_admir | backup789 | Backup Admin | backup@university.edu | Admin | 0 | 0 |

Tab: roles

| role | description | permissions |
|-------------|--|-------------|
| Admin | Full system access | all |
| PI | Principal Investigator - can view all data and reports | read_write |
| Coordinator | Research Coordinator - data entry and patient management | read_write |
| Analyst | Data analyst - reports only | read_only |

Tab: sites

| site_id | site_name | site_code | active |
|---------|------------------------------|-----------|--------|
| 1 | University Psychology Clinic | UPC | 1 |

Create Data Dictionary Sheet: ADHD_Trial_DataDict

Tab: forms_overview

| workingname | fullname | visits |
|-----------------------|---------------------------------|-----------------------------|
| screening | Screening & Enrollment | screening |
| demographics | Demographics | baseline |
| medical_history | Medical History | baseline |
| adhd_rating | ADHD Rating Scale | baseline,week4,week8,week12 |
| conners_adult | Conners Adult ADHD Rating Scale | baseline,week4,week8,week12 |
| side_effects | Side Effects Checklist | week4,week8,week12 |
| vital_signs | Vital Signs | baseline,week4,week8,week12 |
| medication_compliance | Medication Compliance | week4,week8,week12 |
| adverse_events | Adverse Events | baseline,week4,week8,week12 |
| study_completion | Study Completion | week12 |

Tab: form_screening

| field | prompt | type | layout | req | values | cond | valid | validmsg |
|----------------------------|-----------------------|------|---------|-----|-----------------------|---------------------------|-------|---|
| subject_id | Subject ID | C | text | 1 | | length(subject_id) == 7 | | Subject ID must be exactly 7 characters |
| screening_date | Screening Date | D | date | 1 | | screening_date <= today() | | Screening date cannot be in future |
| age | Age (years) | N | numeric | 1 | | age >= 18 && age <= 65 | | Age must be 18-65 years |
| gender | Gender | L | radio | 1 | Male:Female:Other | | | |
| inclusion_meths | ADHD criteria? | L | radio | 1 | Yes:No | | | |
| inclusion_age | Age 18-65? | L | radio | 1 | Yes:No | | | |
| inclusion_consented | Consent signed? | L | radio | 1 | Yes:No | | | |
| exclusion_pregnant | Pregnant? | L | radio | 1 | Yes:No | gender=='Female' | | |
| exclusion_takingmedication | Excluded medications? | L | radio | 1 | Yes:No | | | |
| exclusion_history | History of psychosis? | L | radio | 1 | Yes:No | | | |
| eligible | Overall Eligibility | L | radio | 1 | Eligible:Not Eligible | | | |

| field | prompt | type | layout | req | values | cond | valid | validmsg |
|---------------------|---------------------|-------|----------|-----|----------------|------------------------|----------|----------|
| randomization_group | Randomization Group | radio | radio | 0 | Active:Placebo | Eligible == 'Eligible' | Eligible | |
| notes | Screening Notes | C | textarea | 0 | | | | |

Tab: form_demographics

| field | prompt | type | layout | req | values | cond | valid | validmsg |
|----------------|--------------------|--------|---------|-----|--|-----------------------------------|------------|-------------------------|
| subject_id | Subject ID | C | text | 1 | | length(subject_id) == 7 | Subject ID | ID must be 7 characters |
| visit_date | Visit Date | D | date | 1 | | | | |
| race | Race/Ethnicity | select | select | 1 | White:Black or African American: Asian:Hispanic/Latino:Native American: Other:Prefer not to answer | | | |
| education | Years of Education | N | numeric | 1 | | education >= 6 && education <= 25 | Education | must be 6-25 years |
| employment | Employment Status | select | select | 1 | Full-time:Part-time:Student:Unemployed:Disabled:Retired | | | |
| marital_status | Marital Status | L | select | 1 | Single:Married:Divorced:Widowed:Separated | | | |

| field | prompt | type | layout | req | values | cond | valid | validmsg |
|-----------------------|-------------------------|------|--------|-----|--|---------------------------------------|--------------------------|--------------|
| householdIncome | Household Income | L | select | 0 | <\$25k:\$25k-\$50k:\$50k-\$75k:\$75k-\$100k:>\$100k:Prefer not to answer | | | |
| insuranceType | Insurance Type | L | select | 0 | Private:Medicare:Medicaid:Uninsured:Other | | | |
| emergencyContactName | Emergency Contact Name | text | | 1 | | | | |
| emergencyContactPhone | Emergency Contact Phone | text | | 1 | | length(emergency_contact_phone) >= 10 | enter valid phone number | Phone number |

Tab: form_adhd_rating

| field | prompt | type | layout | req | values | cond | valid | validmsg |
|----------------|--|------|--------|-----|-----------------------------|----------------------------|---------------------------------|----------|
| subject_id | Subject ID | C | text | 1 | | length(subject_id) == 7 | Subject ID must be 7 characters | |
| visit_code | Visit Date | L | select | 1 | baseline:week4:week8:week12 | | | |
| assessmentDate | Assessment Date | D | date | 1 | | | | |
| adhd_1 | Often fails to give close attention to details | N | radio | 1 | 0:1:2:3 | adhd_1 >= 0 && adhd_1 <= 3 | Must select 0-3 | |

| field | prompt | type | layout | req | values | cond | valid | validmsg |
|--------|--|------|--------|-----|---------|----------------------------|--------|-----------------|
| adhd_2 | Often has difficulty sustaining attention | N | radio | 1 | 0:1:2:3 | adhd_2 >= 0 && adhd_2 <= 3 | adhd_2 | Must select 0-3 |
| adhd_3 | Often does not seem to listen when spoken to | N | radio | 1 | 0:1:2:3 | adhd_3 >= 0 && adhd_3 <= 3 | adhd_3 | Must select 0-3 |
| adhd_4 | Often does not follow through on instructions | N | radio | 1 | 0:1:2:3 | adhd_4 >= 0 && adhd_4 <= 3 | adhd_4 | Must select 0-3 |
| adhd_5 | Often has difficulty organizing tasks | N | radio | 1 | 0:1:2:3 | adhd_5 >= 0 && adhd_5 <= 3 | adhd_5 | Must select 0-3 |
| adhd_6 | Often avoids tasks requiring sustained attention | N | radio | 1 | 0:1:2:3 | adhd_6 >= 0 && adhd_6 <= 3 | adhd_6 | Must select 0-3 |

| field | prompt | type | layout | req | values | cond | valid | validmsg |
|------------------------|---|---------|--------|-----|---------|---|------------------------|-----------------|
| adhd_7 | Often loses things necessary for activities | N | radio | 1 | 0:1:2:3 | adhd_7 >= 0 && adhd_7 <= 3 | adhd_7 | Must select 0-3 |
| adhd_8 | Often easily distracted by extraneous stimuli | N | radio | 1 | 0:1:2:3 | adhd_8 >= 0 && adhd_8 <= 3 | adhd_8 | Must select 0-3 |
| adhd_9 | Often forgetful in daily activities | N | radio | 1 | 0:1:2:3 | adhd_9 >= 0 && adhd_9 <= 3 | adhd_9 | Must select 0-3 |
| adhd_inattention_total | Sub-scale Total | numeric | 0 | | | adhd_inattention_total >= 0 && adhd_inattention_total <= 27 | adhd_inattention_total | must be 0-27 |
| adhd_10 | Often fidgets with hands or feet | N | radio | 1 | 0:1:2:3 | adhd_10 >= 0 && adhd_10 <= 3 | adhd_10 | Must select 0-3 |
| adhd_11 | Often leaves seat inappropriately | N | radio | 1 | 0:1:2:3 | adhd_11 >= 0 && adhd_11 <= 3 | adhd_11 | Must select 0-3 |

| field | prompt | type | layout | req | values | cond | valid | validmsg |
|---------|---|------|--------|-----|---------|-------------------------|--------------|-----------------|
| adhd_12 | Often runs about or climbs excessively | N | radio | 1 | 0:1:2:3 | adhd_12 && adhd_12 <= 3 | adhd_12 >= 0 | Must select 0-3 |
| adhd_13 | Often has difficulty with quiet activities | N | radio | 1 | 0:1:2:3 | adhd_13 && adhd_13 <= 3 | adhd_13 >= 0 | Must select 0-3 |
| adhd_14 | Often on the go or acts as if driven by motor | N | radio | 1 | 0:1:2:3 | adhd_14 && adhd_14 <= 3 | adhd_14 >= 0 | Must select 0-3 |
| adhd_15 | Often talks excessively | N | radio | 1 | 0:1:2:3 | adhd_15 && adhd_15 <= 3 | adhd_15 >= 0 | Must select 0-3 |
| adhd_16 | Often blurts out answers before questions completed | N | radio | 1 | 0:1:2:3 | adhd_16 && adhd_16 <= 3 | adhd_16 >= 0 | Must select 0-3 |

| field | prompt | type | layout | req | values | cond | valid | validmsg |
|------------|--|-------------------|---------|-----|---------|------|------------|--|
| adhd_17 | Often has difficulty waiting turn | N | radio | 1 | 0:1:2:3 | | adhd_17 | Must >= 0 && adhd_17 <= 3 |
| adhd_18 | Often inter-rupts or in-trudes on others | N | radio | 1 | 0:1:2:3 | | adhd_18 | Must >= 0 && adhd_18 <= 3 |
| adhd_hyp | Hypnotic total Sub-scale Total | Hyperactive total | numeric | 0 | | | adhd_hyp | Total must be && 0-27 adhd_hyperactive_total <= 27 |
| adhd_total | Total score ADHD Rating Scale Score | N | numeric | 0 | | | adhd_total | Total must be && 0-54 adhd_total_score <= 54 |

Tab: form_side_effects

| field | prompt | type | layout | req | values | cond | valid | validmsg |
|-------------|--------------------|------|--------|-----|---------------------------|------|--------------------|------------------------------|
| subject_id | Subject ID | C | text | 1 | | | length(subject_id) | == 7 ID must be 7 characters |
| visit_code | Visit | L | select | 1 | week4:week8:week12 | | | |
| assessment | Assessment Date | D | date | 1 | | | | |
| se_appetite | Decreased appetite | L | radio | 0 | None:Mild:Moderate:Severe | | | |

| field | prompt | type | layout | req | values | cond | valid | validmsg |
|-----------------------|---------------------------|------|----------|-----|---------------------------|------|-------|----------|
| se_insomnia | Sleep problems/insomnia | L | radio | 0 | None:Mild:Moderate:Severe | | | |
| se_headache | Headache | L | radio | 0 | None:Mild:Moderate:Severe | | | |
| se_nausea | Nausea | L | radio | 0 | None:Mild:Moderate:Severe | | | |
| se_dizziness | Dizziness | L | radio | 0 | None:Mild:Moderate:Severe | | | |
| se_dry_mouth | Breath mouth | L | radio | 0 | None:Mild:Moderate:Severe | | | |
| se_constipation | Constipation | L | radio | 0 | None:Mild:Moderate:Severe | | | |
| se_mood_changes | Mood changes/irritability | L | radio | 0 | None:Mild:Moderate:Severe | | | |
| se_anxiety | Increased anxiety | L | radio | 0 | None:Mild:Moderate:Severe | | | |
| se_heart_rate | Increased heart rate | L | radio | 0 | None:Mild:Moderate:Severe | | | |
| se_other_effects | Other side effects | C | textarea | 0 | | | | |
| se_any_severe_effects | Any severe side effects? | L | radio | 1 | Yes>No | | | |

Step 3: Configure ZZedc System

```
# Run Google Sheets setup
source("setup_from_gsheets.R")
setup_zzedc_from_gsheets_complete(
  auth_sheet_name = "ADHD_Trial_Auth",
  dd_sheet_name = "ADHD_Trial_DataDict",
  project_name = "ADHD_Clinical_Trial"
)
```

Step 4: System Testing

```
# Launch the configured system
source("launch_ADHD_Clinical_Trial.R")
```

```
# Test with each user account:  
# Username: alex_r, Password: biostat123  
# Username: drschen, Password: adhd2024!  
# Username: maria_s, Password: psych456
```

Phase 2: Training & Validation (Week -1)

Team Training Session

For Dr. Chen (PI) - 30 minutes

1. System Overview

- Navigate to http://localhost:3838
- Login with username: drschen, password: adhd2024!
- Tour of interface: Home, Forms, Reports tabs

2. Reports Review

- Basic Reports: Subject enrollment, completion rates
- Quality Reports: Data completeness, protocol deviations
- Statistical Reports: Descriptive statistics, efficacy trends

3. Safety Monitoring

- Navigate to “Adverse Events” form
- Review side effects data
- Export procedures for safety reports

For Maria (Psychometrist) - 60 minutes

1. Data Entry Training

- Login with username: maria_s, password: psych456
- Complete practice screening form
- Practice ADHD Rating Scale entry
- Learn data validation messages

2. Patient Management Workflow

- Subject ID format: ADHD001, ADHD002, etc.
- Visit scheduling and tracking
- Required vs. optional fields

3. Quality Control

- Review entered data before submission
- Use “Forms Overview” to track completion
- Handle validation errors

4. Practice Exercises

- Enter 3 mock subjects with complete data
- Practice different visit types
- Test error scenarios

For Alex (Technical Lead) - 45 minutes

1. Administration Features

- User management and permissions
- Database backup procedures
- System monitoring

2. Data Quality Management

- Run quality control reports
- Export data for analysis
- Handle technical issues

3. Troubleshooting Common Issues

- Password resets
 - Form validation problems
 - Database connectivity
-

Phase 3: Study Execution (Weeks 1-12)

Daily Workflow - Maria (Psychometrist)

Morning Setup (15 minutes)

1. System Check

- Navigate to <http://localhost:3838>
- Login with credentials
- Review today's scheduled visits

2. Patient Schedule Review

- Check "Forms Overview" for pending assessments
- Prepare assessment materials
- Verify visit windows

Patient Visits (per patient) Screening Visit (45 minutes) 1. **Pre-Visit** - Verify patient identity - Confirm informed consent - Assign Subject ID (next available: ADHD####)

2. Data Entry - Screening Form

Navigation: Forms → Screening & Enrollment

Required Fields:

- Subject ID: ADHD### (next sequential number)
- Screening Date: Today's date
- Age: Patient's age in years
- Gender: Male/Female/Other
- All inclusion/exclusion criteria (Yes/No)
- Notes: Any relevant observations

3. Randomization (if eligible)

- System will prompt for randomization group
- Record: Active or Placebo (double-blind maintained)
- Schedule baseline visit within 7 days

Baseline Visit (90 minutes) 1. **Demographics Form** Navigation: Forms → Demographics Complete all required fields:
- Subject ID, Visit Date - Race, Education, Employment - Emergency contact information

2. Medical History Form

Navigation: Forms → Medical History

Document:

- Prior ADHD medications
- Comorbid conditions
- Current medications

3. ADHD Rating Scale

Navigation: Forms → ADHD Rating Scale

Instructions:

- Read each item aloud to patient
- Record 0=Never, 1=Sometimes, 2=Often, 3=Very Often
- Complete all 18 items
- System will auto-calculate subscale totals

4. Vital Signs

Navigation: Forms → Vital Signs

Measure and record:

- Height (cm), Weight (kg)
- Blood pressure (systolic/diastolic)
- Heart rate (bpm)

Follow-up Visits (Week 4, 8, 12) - 60 minutes each 1. **ADHD Rating Scale** (repeat baseline procedure) 2. **Side Effects Checklist** Navigation: Forms → Side Effects Checklist Review each potential side effect: - Rate severity:

None/Mild/Moderate/Severe - Document any new symptoms - Flag any severe side effects for immediate PI review
3. **Medication Compliance** 4. **Vital Signs**
5. **Adverse Events** (if any)

End-of-Day Procedures (30 minutes)

1. Data Review

- Navigate to “Forms Overview”
- Verify all forms completed for today’s visits
- Check for validation errors (red flags)

2. Quality Check

- Review entered data for accuracy
- Complete any missing fields
- Add notes for any unusual findings

3. Communication

- Flag urgent issues for Dr. Chen
- Prepare summary for weekly team meeting

Weekly Workflow - Dr. Chen (PI)

Every Monday (30 minutes)

1. Safety Review

Navigation: Reports → Quality Reports

Review:

- Any severe adverse events
- Side effects trends
- Protocol deviations

2. Enrollment Progress

Navigation: Reports → Basic Reports

Monitor:

- Total subjects screened
- Total subjects randomized
- Completion rates by visit

3. Data Quality

- Review quality control reports
- Follow up on any data queries
- Approve/reject any protocol deviations

Bi-weekly Workflow - Alex (Technical Lead)

Every Other Wednesday (60 minutes)

1. System Maintenance

```
# Database backup
file.copy("data/ADHD_Clinical_Trial_gsheets.db",
          paste0("backups/adhd_backup_", Sys.Date(), ".db"))

# System verification
source("test_gsheets_setup.R")
run_all_tests()
```

2. Data Analysis Preparation

```
# Export data for analysis
source("export.R") # Navigate to Export tab in app
# Export to CSV for statistical analysis
```

3. Quality Assurance

- Run data completeness reports
 - Check for outliers or data entry errors
 - Generate recruitment and retention reports
-

Phase 4: Data Management & Analysis (Week 13+)

Database Lock Preparation - Alex

Final Data Review (Week 13)

1. Data Completeness Check

```
# Generate final completeness report
# Navigate to Reports → Quality Reports
# Export missing data report
```

2. Query Resolution

- Review all data validation flags
- Resolve outstanding queries with Maria
- Document all protocol deviations

3. Database Lock

```

# Create final locked database
file.copy("data/ADHD_Clinical_Trial_gsheets.db",
          "data/ADHD_Trial_LOCKED_FINAL.db")

# Generate data dictionary for analysis
# Export complete dataset

```

Statistical Analysis Preparation

1. Data Export

```

# Export all forms to CSV
# Navigation: Export Data → Select All Forms → CSV Format

```

2. Analysis Dataset Creation

- Merge forms by Subject ID and Visit
 - Calculate derived variables (ADHD subscale scores)
 - Create analysis-ready datasets
-

Quality Control Procedures

Daily QC Checks - Maria

- All required fields completed
- Visit dates within protocol windows
- ADHD rating scale items all answered
- Side effects properly documented
- Subject ID format consistent (ADHD###)

Weekly QC Reviews - Dr. Chen

- Safety data reviewed for trends
- Protocol deviations documented
- Enrollment targets on track
- Data quality metrics reviewed

System QC Checks - Alex

- Database backups completed
- User access logs reviewed
- System performance monitored

- Data validation rules working correctly
-

Emergency Procedures

Severe Adverse Event Protocol

1. Immediate Actions (Maria)

- Ensure participant safety
- Document in “Adverse Events” form immediately
- Set severity to “Severe”
- Add detailed narrative

2. Notification (Within 2 hours)

- Email Dr. Chen immediately
- Include Subject ID and event description
- Dr. Chen reviews within 4 hours

3. Reporting (Within 24 hours)

- Dr. Chen determines reportability
- Export adverse event data from system
- Submit required regulatory reports

System Technical Issues

1. Cannot Access ZZedc

- Contact Alex immediately
- Use paper backup forms if needed
- Enter data retroactively once system restored

2. Data Entry Errors

- Contact Alex for data correction
 - Document error and correction in notes
 - Never manually edit database files
-

Success Metrics

Operational Metrics

- **Screening Rate:** Target 2-3 subjects/week
- **Randomization Rate:** Target 75% of screened subjects
- **Retention Rate:** Target >90% completion
- **Data Completeness:** Target >95% complete data

Quality Metrics

- **Data Query Rate:** Target <5% of data points
- **Protocol Deviations:** Target <10% of subjects
- **On-time Visits:** Target >85% within visit windows
- **System Uptime:** Target >99% availability

Timeline Milestones

- **Week 4:** 15 subjects randomized
 - **Week 8:** 40 subjects randomized
 - **Week 12:** 60 subjects randomized (enrollment complete)
 - **Week 16:** All subjects complete Week 12 visit
 - **Week 18:** Database lock and analysis begins
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Appendices

Appendix A: Contact Information

- **Dr. Sarah Chen (PI):** schen@university.edu, 555-0101
- **Alex Rodriguez (Technical):** arodriguez@university.edu, 555-0102
- **Maria Santos (Psychometrist):** msantos@university.edu, 555-0103
- **IT Support:** itsupport@university.edu, 555-0199

Appendix B: System URLs

- **Production System:** <http://localhost:3838>
- **Backup System:** <http://backup-server:3838>
- **Google Sheets:** [Links to authentication and data dictionary sheets]

Appendix C: Training Materials

- ZZedc User Guide: ZZEDC_USER_GUIDE.md
- Google Sheets Setup: GSHEETS_SETUP_GUIDE.md
- ADHD Rating Scale Manual: ADHD_Rating_Scale_Manual.pdf
- Protocol Training Slides: ADHD_Protocol_Training.pptx

This workflow ensures efficient, accurate, and compliant data collection for the ADHD clinical trial using the integrated Google Sheets ZZedc system.