

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

🔍 [MICROSCOPE] 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
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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	PI	1	1
alex_r	biostat123	Alex Rodriguez	arodriguez@university.edu	Admin	1	1
maria_s	psych456	Maria Santos	msantos@university.edu	Clinical	1	1
backup_admin	backup789	Backup Admin	backup@university.edu	Admin	1	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_criteria	Meets ADHD criteria?	L	radio	1	Yes:No			
inclusion_age	Age 18-65?	L	radio	1	Yes:No			
inclusion_informed	Informed consent signed?	L	radio	1	Yes:No			
exclusion_pregnancy	Pregnant?	L	radio	1	Yes:No	gender=='Female'		
exclusion_medications	Medication 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	Randomization Group	C	radio	0	Active:Placebo	eligible==	'Eligible'	
notes	Screening C 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 must be 7 characters
visit_date	Visit Date	D	date	1				
race	Race/Ethnicity	C	select	1	White:Black or African American:Asian:Hispanic/Latino:Native American:Other:Prefer not to answer			
education_years	Years of Education	N	numeric	1			education_years >= 6 && education_years <= 25	Education must be 6-25 years
employment_status	Employment Status	C	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
household_income	Annual Household Income	L	select	0	<\$25k:\$25k-\$50k:\$50k-\$75k:\$75k-\$100k:>\$100k:Prefer not to answer			
insurance_type	Insurance Type	L	select	0	Private:Medicare:Medicaid:Uninsured:Other			
emergency_contact_name	Emergency Contact Name		text	1				
emergency_contact_phone	Emergency Contact Phone		text	1			length(emergency_contact_phone) >= 10	Please enter valid 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	L	select	1	baseline:week4:week8:week12			
assessment_date	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	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	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	Must select 0-3
adhd_5	Often has difficulty organizing tasks	N	radio	1	0:1:2:3		adhd_5 >= 0 && adhd_5 <= 3	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	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	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	Must select 0-3
adhd_9	Often forgetful in daily activities	N	radio	1	0:1:2:3		adhd_9 >= 0 && adhd_9 <= 3	Must select 0-3
adhd_inattention_total	Sub-scale Total	numeric		0			adhd_inattention_total >= 0 && adhd_inattention_total <= 27	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	Must select 0-3
adhd_11	Often leaves seat inappropriately	N	radio	1	0:1:2:3		adhd_11 >= 0 && adhd_11 <= 3	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 >= 0 && adhd_12 <= 3	Must select 0-3
adhd_13	Often has difficulty with quiet activities	N	radio	1	0:1:2:3		adhd_13 >= 0 && adhd_13 <= 3	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 >= 0 && adhd_14 <= 3	Must select 0-3
adhd_15	Often talks excessively	N	radio	1	0:1:2:3		adhd_15 >= 0 && adhd_15 <= 3	Must select 0-3
adhd_16	Often blurts out answers before questions completed	N	radio	1	0:1:2:3		adhd_16 >= 0 && adhd_16 <= 3	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 >= 0 && adhd_17 <= 3	Must select 0-3
adhd_18	Often interrupts or intrudes on others	N	radio	1	0:1:2:3		adhd_18 >= 0 && adhd_18 <= 3	Must select 0-3
adhd_hyperactive_total	Hyperactive Sub-scale Total	N	numeric	0			adhd_hyperactive_total >= 0 && adhd_hyperactive_total <= 27	Total must be 0-27
adhd_total_score	Total ADHD Rating Scale Score	N	numeric	0			adhd_total_score >= 0 && adhd_total_score <= 54	Total must be 0-54

Tab: form_side_effects

field	prompt	type	layout	req	values	cond	valid	validmsg
subject_id	Subject ID	C	text	1			length(subject_id) == 7	Subject ID must be 7 characters
visit_code	Visit	L	select	1	week4:week8:week12			
assessment_date	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	Dry 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_side_effects	Other side effects	C	textarea	0				
se_any_severe_side_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.