



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

*The CDISC vision is to inform patient care & safety
through higher quality medical research.*

A decorative graphic consisting of several overlapping, wavy lines in shades of blue and green that flow from the left side of the page towards the right. These lines terminate in a thick, horizontal bar with a diagonal hatched pattern in blue and green.

Strength *through Collaboration*

TAUG-Schizophrenia v1.0

Public Review Webinar

February 25, 2015

Steve Kopko and Amy Palmer, CDISC



Strength through Collaboration

Introduction to Schizophrenia

- Schizophrenia is a mental disorder characterized by a distorted perception of reality.
- Symptoms of schizophrenia include:
 - Positive symptoms
 - Negative symptoms
 - Cognitive symptoms
- Currently there is no cure for schizophrenia. Treatment may include antipsychotic medications and psychosocial support.

Schizophrenia Data Elements

- Developed by Duke Translational Medicine Institute (DTMI)
 - Data elements abstracted from data collection forms submitted with New Drug Applications for clinical studies
 - Vetted by a Clinical Expert Review Committee and professional societies
- In September 2013, these artifacts were balloted through HL7 at the Informative level
- There were 85 data elements for Schizophrenia, and 94 data elements for Major Depressive Disorder (MDD)
 - Both TAs share 62 common data elements

Learning Objectives

- Overview of Schizophrenia Trial Designs
- Diagnosing Schizophrenia
- Disease History and Relevant Medical History
- Diagnostic Tools and Rating Scales
- Relapse and Remission
- Other items of Interest in Schizophrenia Trials



**Therapeutic Area Data Standards
User Guide for Schizophrenia
Version 1.0 (Draft)**

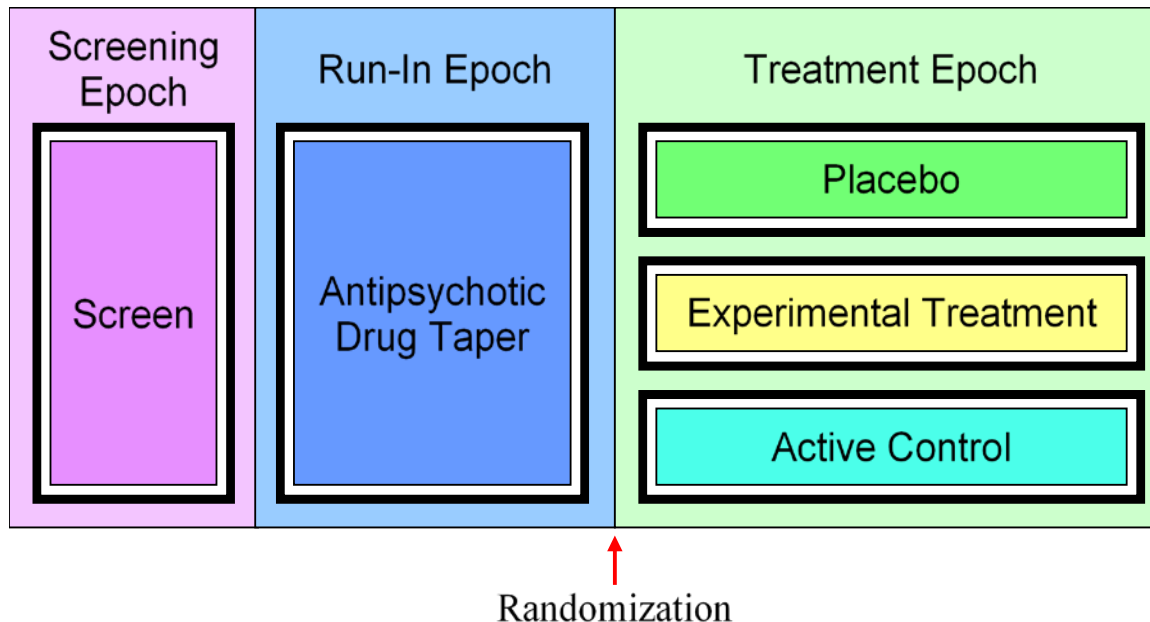
**Prepared by the
CFAST Schizophrenia Standards Team**



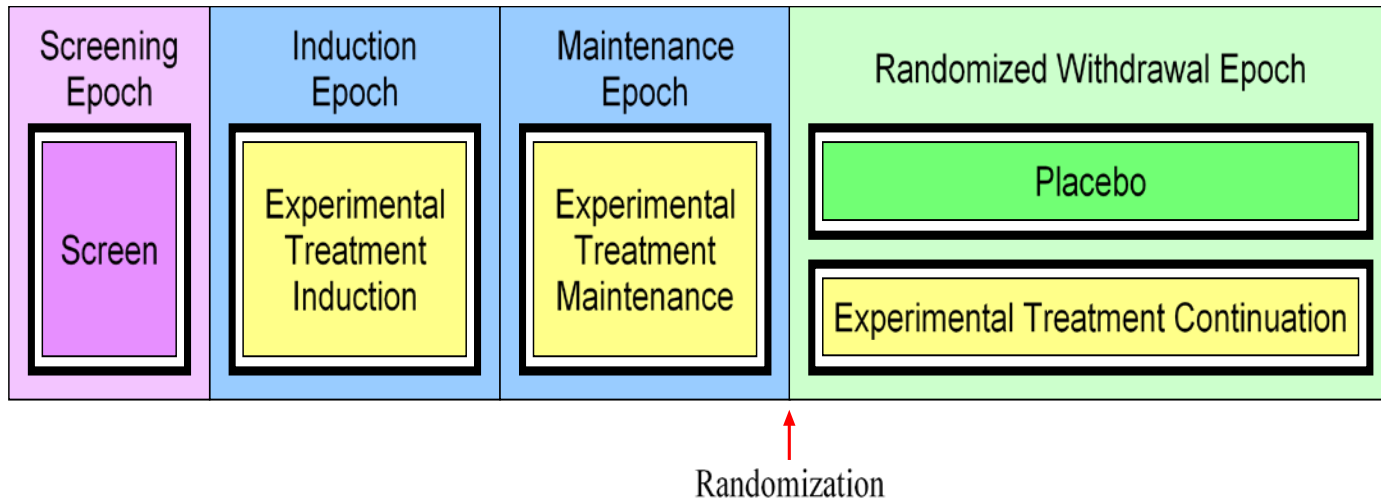
Overview of Schizophrenia Trial Designs

- Three main types of trial designs:
 - Acute Schizophrenia Trials in Patients with Active Psychosis
 - Randomized Withdrawal Trials to Assess Maintenance of Response
 - Adjunctive Treatment Trials for Either Prominent Negative Symptoms or Cognitive Symptoms of Schizophrenia

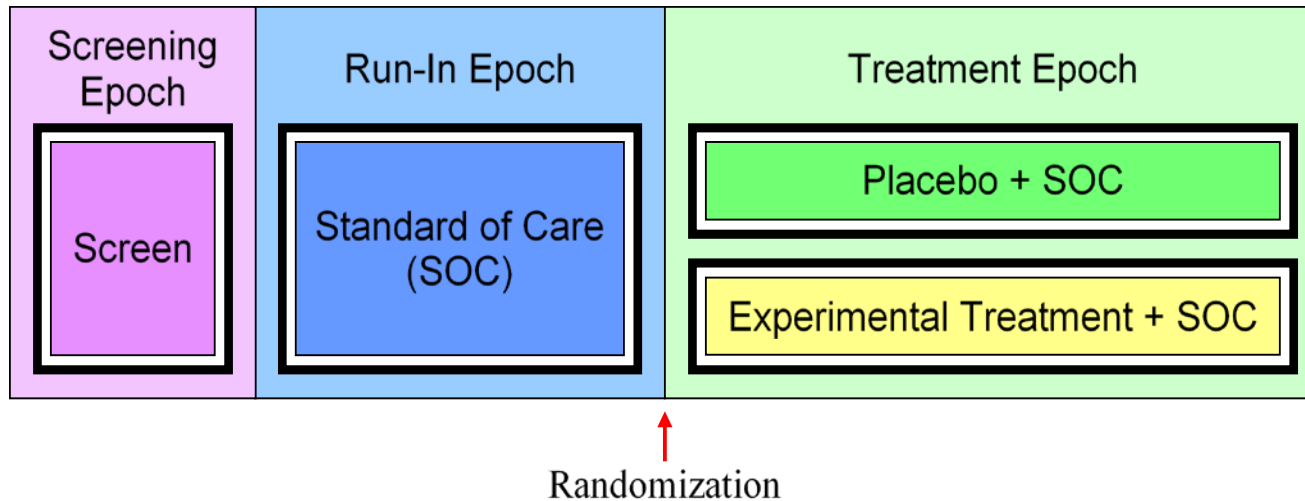
Phase 2 or 3 Acute Schizophrenia Trial in Patients with Active Psychotic Symptoms



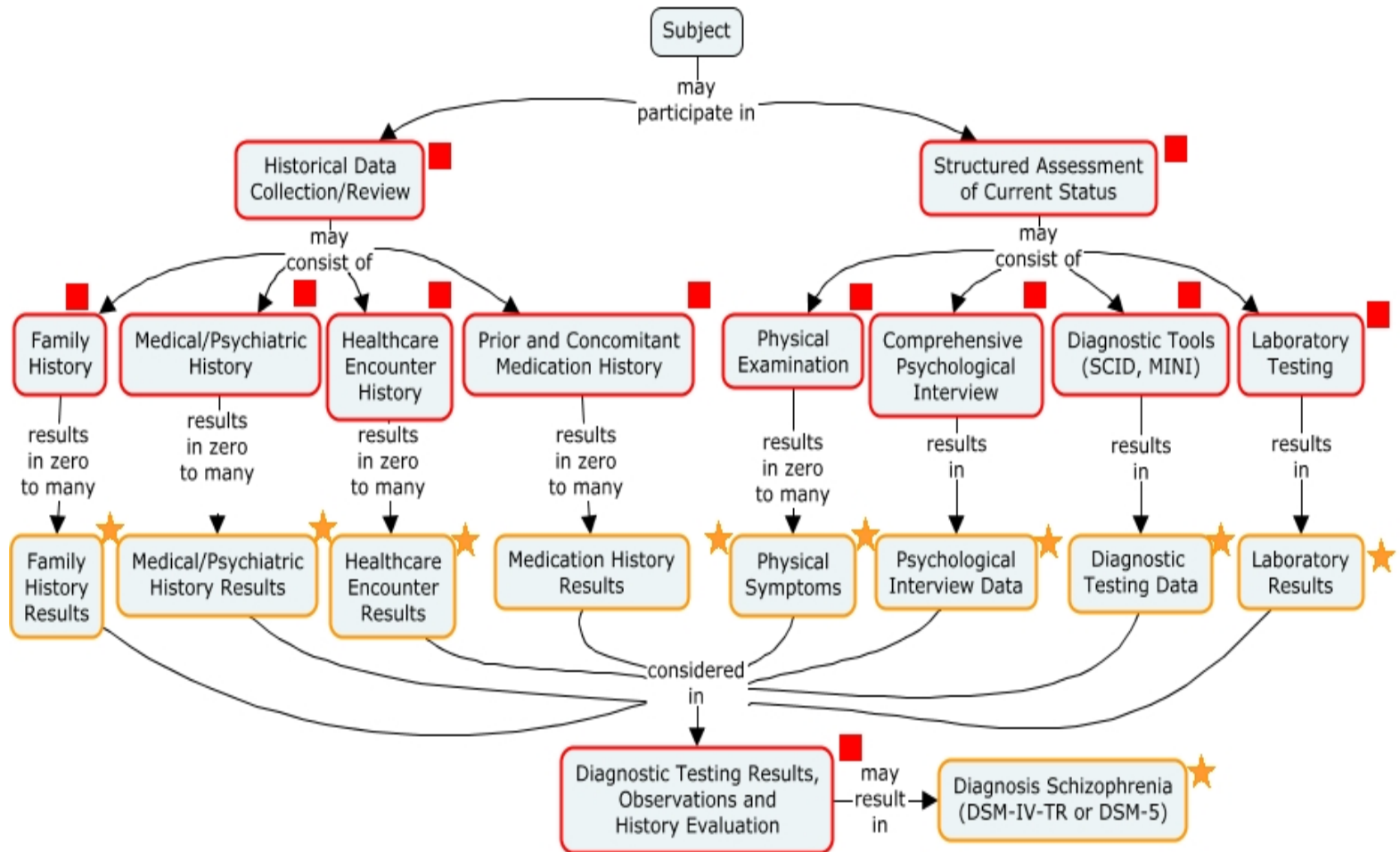
Relapse Prevention: Randomized Withdrawal Design to Assess Maintenance of Response



Adjunctive Phase 3 Predominant-Negative-Symptom Schizophrenia Trial Design



Diagnosing Schizophrenia



Diagnosing Schizophrenia: DSM-IV-TR versus DSM-5

- Diagnosis is made by a physician using either Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) released in 2000 or the DSM-5 released in 2013
- Diagnosis requires at least two of the following symptoms present over a period of at-least one month
 - Delusion, hallucinations, disorganized speech, catatonic or grossly disorganized behavior, or negative symptoms
 - In DSM-5 at least one of two required symptoms should be delusions, hallucinations, or disorganized speech (positive symptoms)
- A schizophrenia diagnosis is typically confirmed with the use of a structured assessment tool such as the Structured Clinical Interview for DSM Disorders (SCID) or the Mini International Neuropsychiatric Interview (MINI)

Schizophrenia Diagnosis Example

- *Example 1*

Illustrates a schizophrenia diagnosis using the DSM-IV-TR and the DSM-5 dictionaries. The DSM-IV-TR lists the subtypes of schizophrenia and this is captured in the MHTERM along with the schizophrenia diagnosis. DSM-5 has dropped the subtypes and the MHTERM is schizophrenia. The MHEVTYP distinguishes between symptoms and diagnosis.

Schizophrenia Diagnosis Example

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHGRPID	MHTERM	MHDECOD	MHCAT	MHEVTYP	MHSTDTC	MHENDTC
1	ABC123	MH	001-001	1		APPENDICITIS	Appendicitis	GENERAL		2006-05-04	2006-05-04
2	ABC123	MH	001-001	2	1	ANXIETY	Anxiety	SCHIZOPHRENIA	SYMPTOMS	2003	
3	ABC123	MH	001-001	3	1	AGITATION	Agitation	SCHIZOPHRENIA	SYMPTOMS	2003-11	2004-02-14
4	ABC123	MH	001-001	4	1	DISORGANIZED SCHIZOPHRENIA	Disorganized schizophrenia	SCHIZOPHRENIA	DIAGNOSIS	2004-01	
5	ABC123	MH	123-456	1		CATATONIC SCHIZOPHRENIA	Catatonic schizophrenia	SCHIZOPHRENIA	DIAGNOSIS	2008-06-06	
6	ABC123	MH	9999-789	1		SCHIZOPHRENIA	Schizophrenia	SCHIZOPHRENIA	DIAGNOSIS	2014-08-05	

suppmh.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC123	MH	001-001	MHSEQ	4	DSMAXIS	DSM-IV-TR Axis	I	CRF	
2	ABC123	MH	001-001	MHSEQ	4	DSMCODE	DSM-IV-TR Code	295.10	CRF	
3	ABC123	MH	001-001	MHSEQ	4	DIAGMETH	Diagnostic Method	SCID-RV	CRF	
4	ABC123	MH	123-456	MHSEQ	1	DSMAXIS	DSM-IV-TR Axis	I	CRF	
5	ABC123	MH	123-456	MHSEQ	1	DSMCODE	DSM-IV-TR Code	295.20	CRF	
6	ABC123	MH	123-456	MHSEQ	1	DIAGMETH	Diagnostic Method	MINI	CRF	
7	ABC123	MH	9999-789	MHSEQ	1	DSMCODE	DSM-5 Code	295.90	CRF	
8	ABC123	MH	9999-789	MHSEQ	1	DIAGMETH	Diagnostic Method	SCID-RV	CRF	

Disease History and Relevant Medical History

- Age at diagnosis, age at first episode, date of most recent exacerbation, number of exacerbations and hospitalizations in the past 24 months
- Other clinically relevant diagnoses
- Family history of schizophrenia
- Tardive dyskinesia (TD) and neuroleptic malignant syndrome (NMS)

Diagnostic Tools and Rating Scales

- Diagnostic Tools
 - Diagnostic assessments are used to confirm a diagnosis of schizophrenia
 - SCID (Structured Clinical Interview for DSM Disorders)
 - MINI (Mini International Neuropsychiatric Interview)
- Rating Scales
 - Clinical trials for schizophrenia rely heavily rating scales and functional tests to assess the efficacy and safety of drugs in the treatment of schizophrenia
 - PANSS (Positive and Negative Syndrome Scale)
 - BPRS (Brief Psychiatric Rating Scale)
 - NSA-16 (Negative Symptom Assessment)
 - MATRICS Consensus Cognitive Battery
 - CGI (Clinical Global Impression)

Relapse and Remission

- Relapse and Remission are of interest in the Randomized Withdrawal Design to Assess Maintenance of Response Studies
 - Criteria for both are protocol-specific
 - Relapse is met during the double-blind portion
 - » Subjects are considered to have completed the study once protocol-defined relapse criteria are met
 - Remission can be assessed during the open-label stabilization phase
 - » May be assessed using a rating scale (PANSS, BPRS-A)

Schizophrenia Relapse Example

- *Example 1*

The subject in the double-blind phase of a Randomized Withdrawal Design to Assess Maintenance of Response Study meets the protocol-specific definition for relapse, which for the purpose of this example includes self-injurious behavior. The event record for self-injurious behavior is not shown below. The patient leaves the study at the time of relapse. Since the subject met the protocol-specific definition of relapse, they are considered a completer, and the “Relapse Indicator” is “Y” (SUPPDS). The self-injurious behavior was reported by the subject, identified in SUPPDS as “self”.

Schizophrenia Relapse Example

ds.xpt

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSDTC	DSSTDTC
1	STUDY01	DS	007-011	1	SELF-INJURIOUS BEHAVIOR	COMPLETED	DISPOSITION EVENT	RANDOMIZED WITHDRAWAL	2010-01-22	2010-01-15

suppds.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	STUDY01	DS	007-011	DSSEQ	1	RLPSIND	Relapse Indicator	Y	CRF	
2	STUDY01	DS	007-011	DSSEQ	1	INFOSRC	Information Source	SELF	CRF	

Schizophrenia – Other Items Represented in the User Guide

- Assessment of psychotic episodes
- Representing subject discontinuations
- Disease state using the Disease Milestones approach
- Concomitant medications of special interest
 - Antipsychotic drug taper
 - Adjunctive therapy

Domains Represented in TAUG-Schizophrenia v1.0

Domains from SDTMIG	Section
Interventions	
CM – Concomitant Medications	Routine Data
EX – Exposure	Disease Assessments and Routine Data
Events	
CE – Clinical Events	Disease Assessments
DS – Disposition	Disease Assessments
HO – Healthcare Encounters	Subject and Disease Characteristics and Disease Assessments
MH – Medical History	Subject and Disease Characteristics
Findings	
CC – Clinical Classifications*	Disease Assessments
LB – Laboratory Test Results	Routine Data
QS – Questionnaires	Disease Assessments
SC – Subject Characteristics	Subject and Disease Characteristics
SS – Subject Status	Disease Assessments
Findings About Events or Interventions	
FA – Findings About	Subject and Disease Characteristics and Disease Assessments
Disease Milestones	
TM - Trial Disease Milestones*	Disease Assessments
SM - Subject Disease Milestones*	Disease Assessments
Trial Design	
TA – Trial Arms	Trial Design
TE – Trial Elements	Trial Design
TI - Trial Inclusion/Exclusion Criteria	Trial Design
TS – Trial Summary	Trial Design
TV – Trial Visits	Trial Design

* Domain was not published in SDTMIG 3.2 and is not final.

New Variables Represented in TAUG-Schizophrenia v1.0

2 Model Fundamentals

2.2 The General Observation Classes

2.2.5 Timing Variables for All Classes

Table 2.2.5: All Observation Classes — Timing Variables

Variable Name	Variable Label	Type	Description
MIDS	Disease Milestone Instance Name	Char	The name of a specific instance of a Disease Milestone Type (MIDSTYPE) described in the Trial Disease Milestones dataset. This should be unique within a subject. Used only in conjunction with RELMIDS and MIDSDTC.
RELMIDS	Temporal Relation to Milestone Instance	Char	The temporal relationship of the observation to the Disease Milestone Instance Name in MIDS. Examples: IMMEDIATELY BEFORE, AT TIME OF, AFTER.
MIDSDTC	Disease Milestone Instance Date/Time	Char	The start date/time of the Disease Milestone Instance Name in MIDS, in ISO8601 format.

Variable order should be as follows:

MIDS, RELMIDS, MIDSDTC	In order, after --ENTPT
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2.2.11 The Domain-Specific Variables Table

The concept of domain-specific variables is being introduced in SDTM v1.5. These variables are for use in a single domain and will be identified in the appropriate implementation guide. The variable names include the specific domain prefix. Table 2.2.11 lists the proposed domain specific variables.

Table 2.2.11: Domain-Specific Variables

Domain	Variable Name	Variable Label	Type	Description
MH	MHEVTYP	Medical History Event Type	Char	Specifies the aspect of the medical condition or event by which MHSTDTC is defined. Examples: DIAGNOSIS, SYMPTOMS, RELAPSE, INFECTION

Variable order should be as follows:

MHEVTYP	After MHTERM
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Clinical Outcome Assessments

Developed for TAUG-Schizophrenia v1.0

Clinical Outcome Assessments (COA) and Classifications		
Full Name and Abbreviation	Domain	Status of Copyright Permission
Psychiatric Symptom Rating Scales		
Positive and Negative Symptom Scale (PANSS)	CC	Permission Granted
Clinical Global Impressions - Severity and Improvement (CGI)	QS	Public Domain
Negative Symptom Assessment Scale 4 and 16 (NSA-4 and NSA-16)	CC	Permission Granted
Brief Assessment of Cognition in Schizophrenia (BACS)	FT	Permission Granted
Extrapyramidal Symptom Rating Scale (abbreviated version) (ESRSa)	CC	Permission Granted
Simpson-Angus Rating Scale (SAS)	CC	Public Domain
Quality of Life Rating Scales		
Quality of Life Scale (Heinrich-Carpenter Quality of Life Scale)	TBD	Public Domain

Example COA Supplement - ESRs-A

CDISC SDTM ESRs-A Clinical Classifications Supplement (Version 1.0)



Extrapyramidal Symptom Rating Scale- Abbreviated (ESRSA)

Clinical Classifications Supplement to the Study Data Tabulation Model Implementation Guide For Human Clinical Trials

Prepared by
CDISC Clinical Outcome Assessment Sub-team

Notes to Readers

This supplement is intended to be used with other CDISC User Guides for specific Therapeutic/Disease Areas and follows the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical trials.

Example COA Annotated CRF - ESRSA-A

CC=Clinical Classifications

CCCAT=ESRSA

Extrapyramidal Symptom Rating Scale-Abbreviated

Scoring Sheet-Long Form

**CCSTRESC/
CCSTRESN**

CCORRES

Parkinsonism

CCSCAT=PARKINSONISM

**Rigidity
Upper limbs**

CCTESTCD=ESRSA101

- | | | |
|----------|-------------|--|
| 0 | No rigidity | |
| 1 | Minimal | <i>Very mild, barely perceptible</i> |
| 2 | Mild | <i>Some resistance to passive movements</i> |
| 3 | Moderate | <i>Definite resistance to passive movements, still easy to move limb, full range motion achieved</i> |
| 4 | Severe | <i>Marked resistance to passive movements, difficulty to move limb with full range of motion</i> |
| 5 | Extreme | <i>Lead pipe rigidity, limb nearly frozen; motion achieved with difficulty</i> |

Lower limbs

CCTESTCD=ESRSA102

- | | | |
|---|-------------|--|
| 0 | No rigidity | |
| 1 | Minimal | <i>Very mild, barely perceptible</i> |
| 2 | Mild | <i>Some resistance to passive movements</i> |
| 3 | Moderate | <i>Definite resistance to passive movements, still easy to move limb, full range motion achieved</i> |
| 4 | Severe | <i>Marked resistance to passive movements, difficulty to move limb with full range of motion</i> |
| 5 | Extreme | <i>Lead pipe rigidity, limb nearly frozen; motion achieved with difficulty</i> |

New Controlled Terminology Proposed in the TAUG-Schizophrenia v1.0

Additions to an existing codelist:				
Codelist Name	New Requested Term	CDISC Synonym	Draft Definition	Examples of how this New Term will be used
METHOD	PHONE CALL		Subject status follow-up methods on disposition.	Schizophrenia TAUG
	CERTIFIED LETTER			

New Controlled Terminology Proposed in the TAUG-Schizophrenia v1.0

New Codelist Name: Subject Characteristics Test Code/Name

New Codelist Description:

Test Code	Test Name	Draft Definition	Permissible Values
NUMLAW	Number Of Law Enforcement Arrests	Number of times the patient has been arrested. May be asked directly of the patient or their proxy or be obtained from clinical documents.	Numeric
HXSUINDC	History Of Suicide Attempt Indicator	Indicates that the patient has made one or more medically serious suicide attempt(s) or two or more non-medically serious suicide attempts (an attempt requiring medical attention is considered a serious attempt) at any time in the past.	No Yes Response
HXVLINDC	History Of Violent Behavior Indicator	Indicates that an individual has demonstrated aggressive behavior that could have foreseeably resulted in significant harm to others at any time in the past.	No Yes Response

New Controlled Terminology Proposed in the TAUG-Schizophrenia v1.0

New Codelist Name: Findings About Test Code/Name			
New Codelist Description:			
Test Code	Test Name	Draft Definition	Permissible Values
SUBJCONT	Subject Contact	Individual subject contact attempts to obtain information.	NO ANSWER PHONE DISCONNECTED UNDELIVERABLE
AGEEPSD1	Age At First Psychotic Episode	Age at first treatment for any psychiatric illness	Numeric
NUMEP	Number of Episodes/Exacerbations	Number of episodes in the 24 moths preceding the assessment. Can be asked directly or calculated from onset and end dates of episodes if a comprehensive lists is collected.	Numeric
AGETRT1	Age At First Treatment	Age at first treatment for a specific psychiatric illness	Numeric
CTNAINDC	Catatonia Indicator	Indicates that symptoms meeting the diagnostic criteria for catatonia, i.e., three or more of Stupor, Catalepsy, Waxy flexibility, Mutism, Negativism, Posturing, Mannerism, Stereotypy, Agitation, Grimacing, Echolalia, Echopraxia, are co-occurring with another mental disorder. Note, the name of the co-occurring other mental disorder is recorded, e.g., catatonia associated with major depressive disorder. SOURCE: DSM5	No Yes Response
LCSSYMP	Longitudinal Course of Schizophrenic Symptoms	SCID-based categorization of the character of a patient's symptoms over time. This specifier is only valid after one or more years of a disorder. Source: DSM-IV-TR	1-Episodic, With Interepisode Residual Symptoms, With Prominent Negative Symptoms 2-Episodic With Interepisode Residual Symptoms 3-Episodic With no Interepisode Residual Symptoms 4-Continuous, With Prominent Negative Symptoms 5-Continuous 6-Single Episode, With Prominent Negative Symptoms 7-Single Episode, in Partial Remission 8-Single Episode, in Full Remission 9-Other or Unspecified Pattern.
PSHONUM	Psychiatric Number of Hospitalizations	Number of inpatient psychiatric hospitalizations in the patient's lifetime excluding study required confinements and present hospitalization if currently hospitalized. This information may be asked directly of patients or obtained from clinical documentation.	Numeric

New Controlled Terminology Proposed in the TAUG-Schizophrenia v1.0

New Codelist Name: Findings About Test Code/Name

New Codelist Description:

Test Code	Test Name	Draft Definition	Permissible Values
AGEHOSP1	Age At First Psychiatric Hospitalization	Age at first hospitalization for Schizophrenia. May be asked directly of patients or their proxies or be obtained directly from clinical documentation.	Numeric
DNCLINDC	Day Or Night Clinic Stays Indicator	Indicates use of a day or night clinic in the past 24 months. This information may be asked directly of the patient or their proxy or obtained from clinical documentation.	No Yes Response
TRTSETT	Most Recent Treatment Setting	Setting in which the patient is currently being treated, or was treated just prior to evaluation.	None Psychiatric treatment as outpatient Partial hospitalization (day or night hospital, halfway house, etc.) Inpatient hospitalization
ACUTSTRS	Most Severe Acute Stressor	The most severe acute stressor sated by the patient that occurred in the past month.	text
CHRNSTS	Most Severe Chronic Stressor	The most severe CHRONIC stressor stated by the patient as present during the past 6 months or longer.	text

New Controlled Terminology Proposed in the TAUG-Schizophrenia v1.0

Schizophrenias Supplemental Qualifiers				
QNAM	QLABEL	Applicable Domain	Definition	Permissible Values
DSMAXIS	DSM-IV-TR Axis	MH	Axis of the DSM-IV-TR diagnosis. Derived based on the DSM IV-TR code.	I, II
DSMCODE	DSM-IV-TR Code	MH	DSM-IV-TR Diagnosis code.	DSM-IV-TR full five digits required
DIAGMETH	Diagnostic Method	MH	Name of the structured interview or instrument used to make or confirm a psychiatric diagnosis.	SCID-CV, SCDI-RV, CIDI, MINI International Neuropsychiatric Interview, SADS, KSADS and Kiddie SADS-PL, KID-SCID, other
DSMCODE	DSM-5 Code	MH	DSM-5 Diagnosis code.	DSM-5 full five digits required
MHAGE	Age at Event	MH	Age at first Episode of disease or disorder. May be derived from date of birth and start date of first episode, asked directly of patients or their proxies or be obtained directly from clinical documentation. We will use our definition as an alternative to the caDSR definition: "Age at diagnosis may be derived or asked directly of the patient or patient proxy."	Numeric YEARS
CLINSIG	Clinically Significant	MH	Indicates that an associated diagnosis is clinically relevant to the situation under consideration.	No Yes response
HOINDC	Indication	HO	Reason for the hospitalization.	MAJOR DEPRESSIVE DISORDER PARANOID SCHIZOPHRENIA PSYCHOTIC EPISODE SUICIDAL IDEATION
FSTEPIND	First Episode Indicator	CE	Indicates that the documented episode is the patient's lifetime first episode of a given disease or disorder. May be asked directly of patients or their proxies or be obtained directly from clinical documentation.	No Yes response
EPSYMPSM	Episode Symptom Similarity	CE	Clinician assessment of whether or not the current symptoms differ in character to those from the previous episode	Symptoms similar to those experienced in the previous and past episodes, Symptoms similar to the previous episode but the symptoms have not been present in past episodes, Symptoms different from the previous episode but have been present in one or more past episodes, Symptoms are significantly different from any previous condition

New Controlled Terminology Proposed in the TAUG-Schizophrenia v1.0

Schizophrenias Supplemental Qualifiers				
QNAM	QLABEL	Applicable Domain	Definition	Permissible Values
CONEPISD	Continuation Of Previous Episode Indicator	CE	Clinician assessed indicator of whether the episode is a new episode (new definitive symptoms) or whether the condition is ongoing (Improvement or stabilization followed by worsening of symptoms) from the previous assessment	No Yes response
SEVCOMP	Episode Severity Comparison	CE	Clinician assessment of symptom severity compared with the previous episode	less severe than the previous episode, similar in severity to the previous episode, more severe than the previous episode
SPDCOMP	Speed of Episode Comparison	CE	Timing of onset of schizophrenic episode. May be asked directly of patients or their proxies or be obtained directly from clinical documentation.	Gradual (1 to several months), Sudden (less than 4 weeks), Unknown
VLEPINDC	Violent Episode Behavior Indicator	CE	Indicates that at the time of assessment, an individual demonstrates homicidal or violent behavior not resulting in his/her hospitalization as of the assessment.	No Yes response
RLPSIND	Relapse Indicator	DS	Indicates that the subject experienced a relapse in the double blind phase of a maintenance study using a randomized withdrawal design. A patient no longer in remission is in relapse. This derived data element is calculated according to a protocol stated definition	No Yes response
INFOSRC	Information Source	DS	Description indicating from where the data values were obtained.	1) Self or proxy, 2) Clinical Documentation, 3) Both.
RLPSJDGE	Investigator Judgment of Relapse	CE	Investigator's judgment that a subject has experienced relapse in the double blind phase of a maintenance study using a randomized withdrawal design. This is a clinical assessment rather than an application of a protocol specified definition and may be corroborated by CGI or other validated measurement.	No Yes response

Schizophrenia – Public Review

- 30-day public review upcoming
 - Published on the CDISC website Wednesday, February 25th 2015
 - Closing date for comments **March 27th 2015**
- Download the document using Adobe Reader (<http://get.adobe.com/reader/>)
- Submit comments using the CDISC public commenting tool located on the CDISC website located here:
 - <http://portal.cdisc.org/CT/default.aspx>
- Instructions on using the comment tracker tool
 - <http://portal.cdisc.org/CT/Documents/How%20to%20Use%20the%20CDISC%20Public%20Comment%20Tracker.docx>

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Schizophrenia – Public Review Webinar

