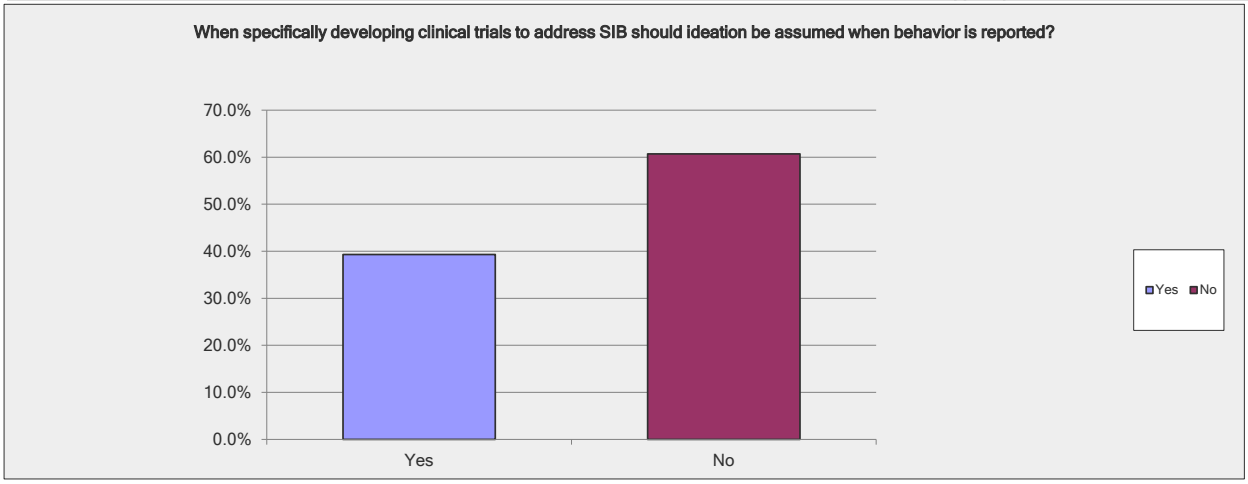
SIB Consensus Pre-meeting Survey: Analysis of SIB Data

Recipients	128
Responded	98
Unresponded	30
% Responded	76%

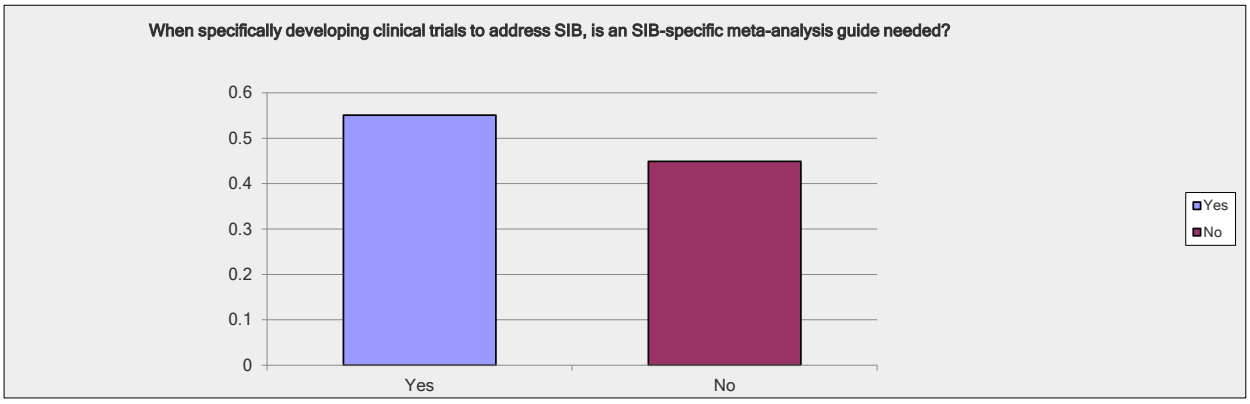
Q1.When specifically developing clinical trials to address SIB should ideation be assumed when behavior is reported?

Answer Options	Response Percent	Response Count
Yes	39.3%	35
No	60.7%	54
	answered question	89
	skipped question	9



Q2.When specifically developing clinical trials to address SIB, is an SIB-specific meta-analysis guide needed?

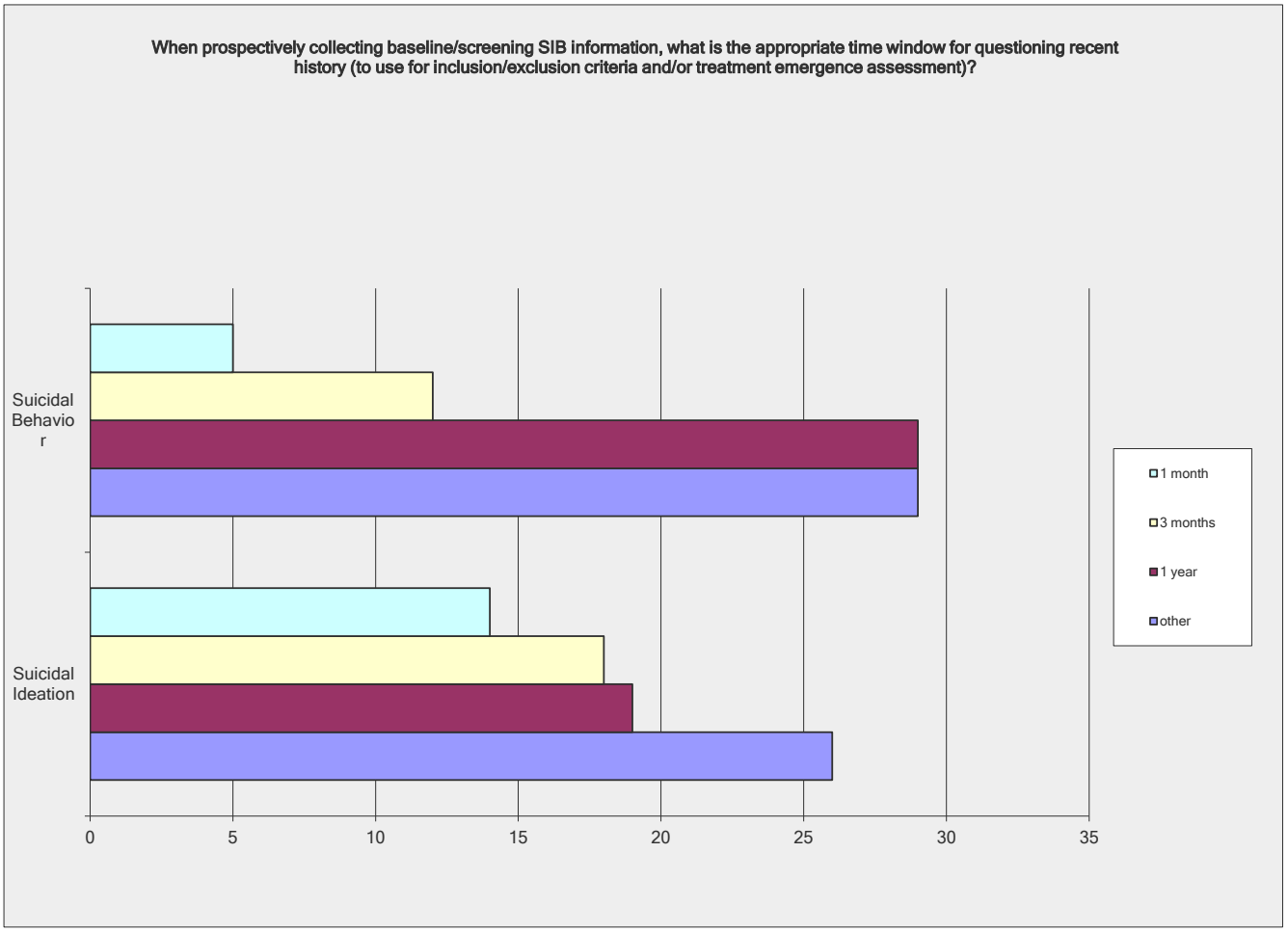
Answer Options	Response Percent	Response Count
Yes	54.5%	42
No	45.5%	35
	answered question	77
	skipped question	21



SIB Consensus Pre-meeting Survey: Analysis of SIB Data

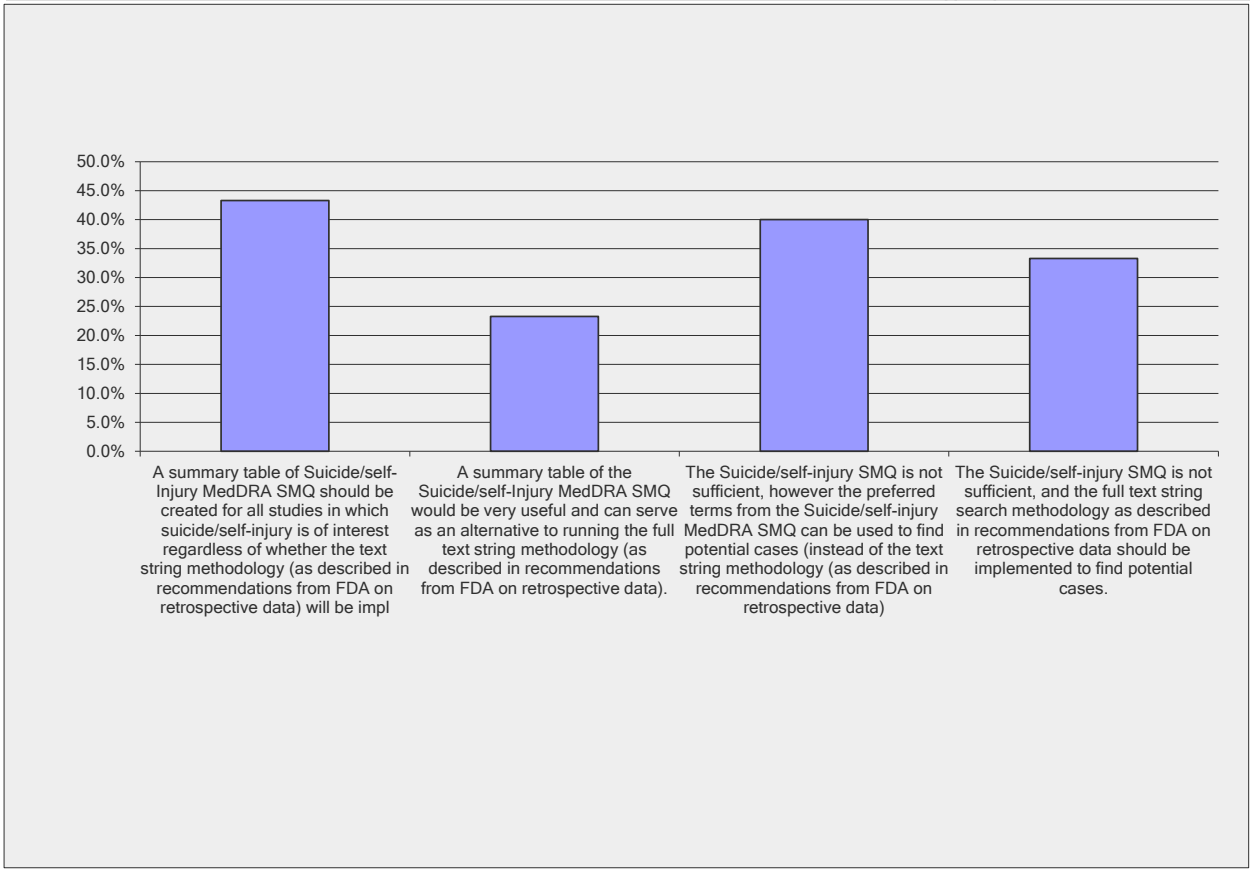
Q3. When prospectively collecting baseline/screening SIB information, what is the appropriate time window for questioning recent history (to use for inclusion/exclusion criteria and/or treatment emergence assessment)?

Answer Options	1 month	3 months	1 year	other	Response Count
Suicidal Ideation	14	18	19	26	77
Suicidal Behavior	5	12	29	29	75
Other					47
				answered question	77
				skipped question	21



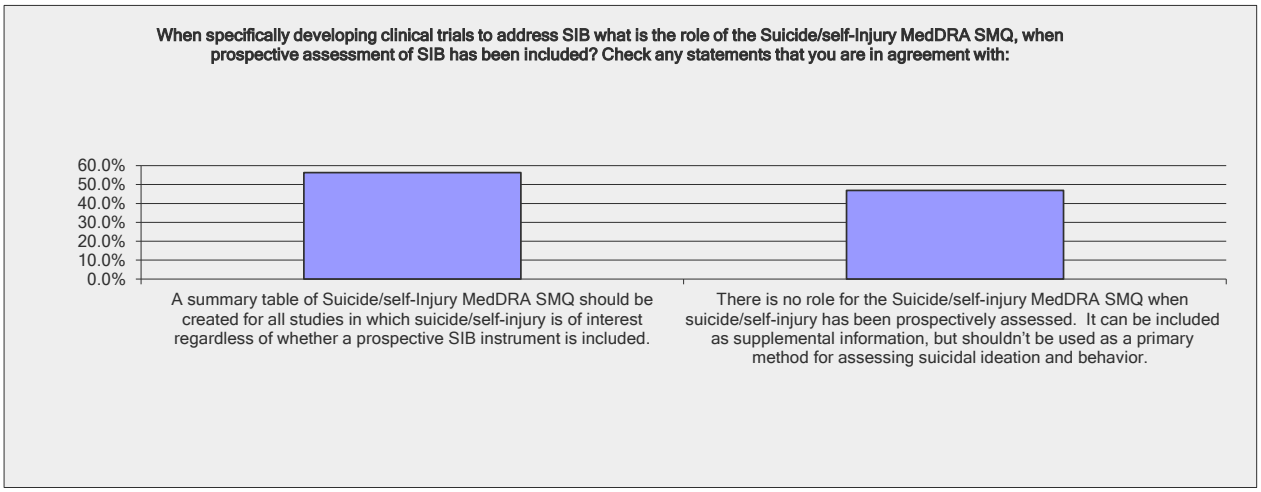
Q4.When specifically developing clinical trials to address SIB, what is the role of the Suicide/self-injury MedDRA standardized MedDRA query (SMQ), when prospective assessment of SIB has not been included? Check any statements that you are in agreement with:

Answer Options	Response Percent	Response Count
A summary table of Suicide/self-Injury MedDRA SMQ should be created for all studies in which suicide/self-injury is of interest regardless of whether the text string methodology (as described in recommendations from FDA on retrospective data) will be implemented.	43.3%	26
A summary table of the Suicide/self-Injury MedDRA SMQ would be very useful and can serve as an alternative to running the full text string methodology (as described in recommendations from FDA on retrospective data).	23.3%	14
The Suicide/self-injury SMQ is not sufficient, however the preferred terms from the Suicide/self-injury MedDRA SMQ can be used to find potential cases (instead of the text string methodology (as described in recommendations from FDA on retrospective data), but adjudication to the C-CASA categories would still be required.	40.0%	24
The Suicide/self-injury SMQ is not sufficient, and the full text string search methodology as described in recommendations from FDA on retrospective data should be implemented to find potential cases.	33.3%	20
answered question		60
skipped question		38



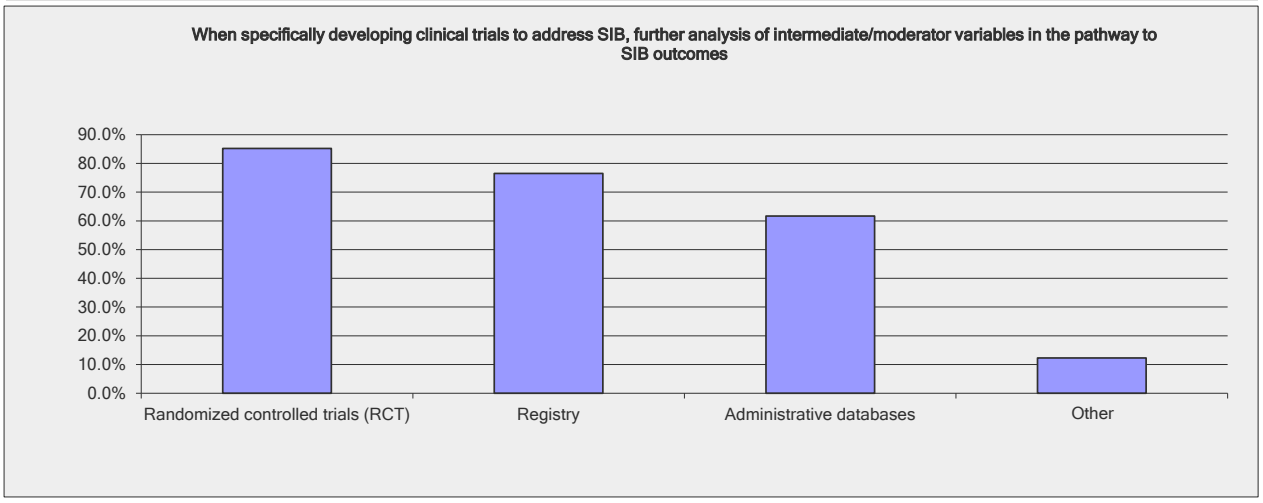
Q5.When specifically developing clinical trials to address SIB what is the role of the Suicide/self-Injury MedDRA SMQ, when prospective assessment of SIB has been included? Check any statements that you are in agreement with:

Answer Options	Response Percent	Response Count
A summary table of Suicide/self-Injury MedDRA SMQ should be created for all studies in which suicide/self-injury is of interest regardless of whether a prospective SIB instrument is included.	56.3%	36
There is no role for the Suicide/self-injury MedDRA SMQ when suicide/self-injury has been prospectively assessed. It can be included as supplemental information, but shouldn't be used as a primary method for assessing suicidal ideation and behavior.	46.9%	30
	answered question	64
	skipped question	34



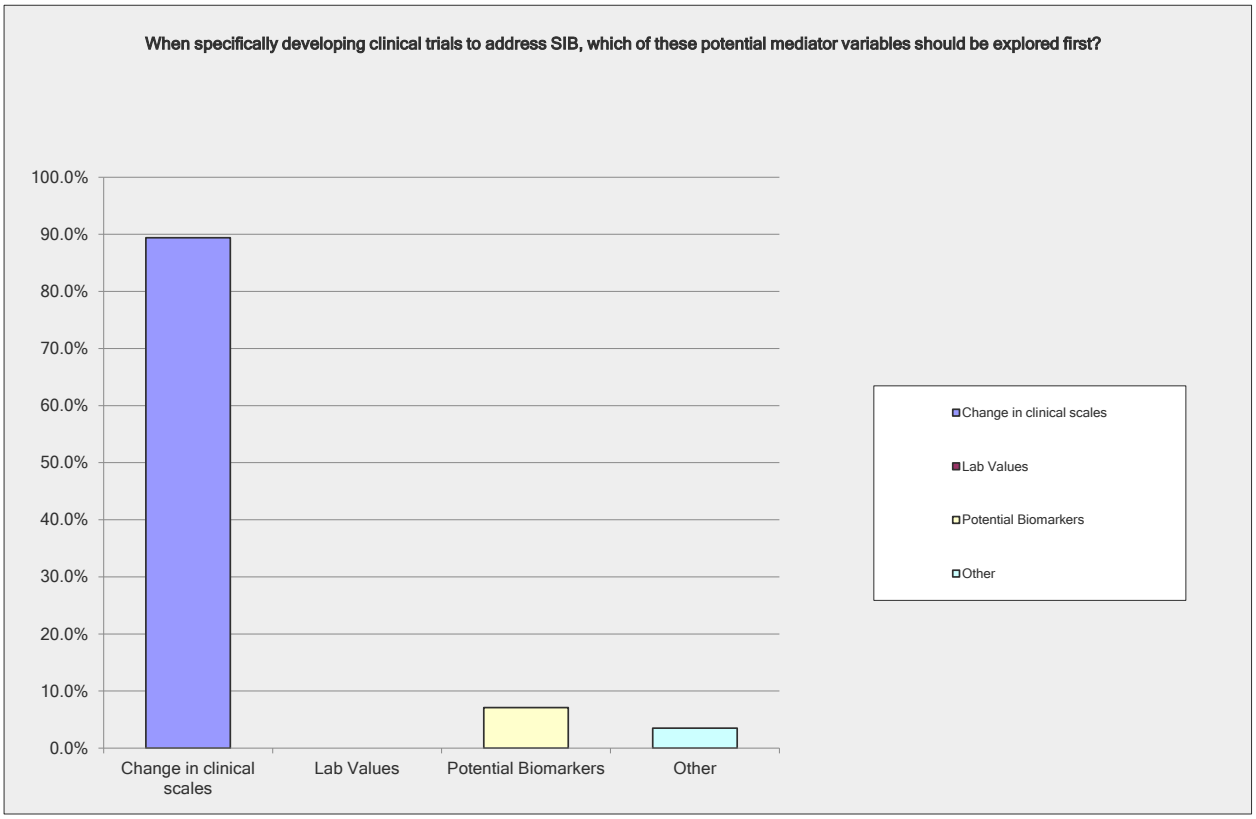
Q6.When specifically developing clinical trials to address SIB, further analysis of intermediate/moderator variables in the pathway to SIB outcomes should be better understood in order to reduce safety hazard for patients. Which of the following routinely collected and available data should be explored further (post hoc) to identify potential treatment mediators of SIB outcomes? Check all that apply.

Answer Options	Response Percent	Response Count
Randomized controlled trials (RCT)	85.2%	69
Registry	76.5%	62
Administrative databases	61.7%	50
Other	12.3%	10
	answered question	81
	skipped question	17



Q7.When specifically developing clinical trials to address SIB, which of these potential mediator variables should be explored first?

Answer Options	Response Percent	Response Count
Change in clinical scales	89.4%	76
Lab Values	0.0%	0
Potential Biomarkers	7.1%	6
Other	3.5%	3
answered question		85
skipped question		13



Q8.When specifically developing clinical trials to address SIB, it is important to study the most relevant data elements to SIB mediators. Name up to 3 relevant data elements to SIB mediators that should be further studied.

Answer Options	Response Count
	48
answered question	48
skipped question	50

Number	Response Text
1	social context, techniques for clinical assessment, possibility of surrogate ideation that inferences suicide risk. (i am not fully clear on that this question is looking for)
2	Lethality and lethal means (current and historic) Drug and alcohol abuse (current and historic) TBD Assessment of impulsivity (current and historic)
3	no comment
4	Age, psychiatric diagnoses (comorbidity) and life-stressors
5	Level of depression, Level of hopelessness, suicidal ideation, psychosis, Level of impulsivity, Availability of a firearm
6	Employment status, social support
7	anxiety, insomnia, hopelessness
8	Aggression, impulsivity, hopelessness
9	depends on how trial aims to reduce SIB; via reduced anhedonia? reduced agitation?
10	clinical scales (SIB or other symptom based scales) biomarkers (eg neuroimaging, cortisol, others) assessment of psychosocial stressors/potential triggers (e-diary, activities of daily living measures, other tools)
11	depression rating, anxiety rating, hopelessness rating
12	Childhood maltreatment, Family history, Past suicidality
13	hopelessness, manic symptoms
14	scales, laboratory values, relevant adverse events including restlessness, insomnia, psychosis
15	Clinical scales: psychotic symptom severity impulsivity/aggression severity Biomarkers: cytokine/chemokine measures; measures of serotonergic function
16	Family crises/support, trauma to person (physical injury, victim of crime, emotional abuse), financial stressors
17	depression symptom score, anxiety symptom score, insomnia
18	change in mood scales
19	Past history, concomitant psychiatric disease, recent distressor
20	comorbidity, biomarkers
21	It depends on the trial
22	Adverse events, clinical scales or scale items measuring SIB, medical history (eg substance abuse, psychiatric history)
23	Anxiety, depression, and substance use status
24	Biomarkers Baseline health status: BMI etc., Depression and anxiety ratings
25	age, gender, previous suicide attempt
26	hopelessness impulsivity psycho-social support
27	Resilience
28	Consistent variable types are essential for analysis with minimal qualitative data points.
29	Pain, Age, Chronic Illness burden
30	Prior attempts Stressors Precipitating events
31	comorbid diagnosis, marital status, recent loss
32	PTSD including childhood sexual abuse, developmental disorders, and depression including Bp depression.
33	Mood (e.g. dperession) Psy history (MDEs, past SI, past attemps)
34	Pharmacological treatment Psychotherapy Psychoeducation
35	biomarkers
36	Rating scales, genetIt's, stress hormones
37	Depression Symptoms Cognitive Symptoms Quality of Life especially daily activites
38	Symptom changes including hopelessness; aggression/impulsivity
39	SIB life-time history, with particular reference to the progressive increase over time of severity of suicidal ideation as well as the frequency of occurrence and type of suicidal behaviour; Clinical measures of impulsivity; Clinical measures of hopelessness.
40	Current co-morbid psych diagnoses Lifetime co-morbid psych diagnosis Current Primary diagnosis
41	I am not convinced that this is likely to be a productive approach in clinical trials to address SIB. The important endpoints are SI, suicidal attempts, death by suicide, etc. These are likely to be the primary endpoints in any indication for SIB that regulatory agencies will be concerned about.
42	perceived burden on others, perceived belongingness, insomnia
43	Concomitant psychopathology Substance use/intoxication
44	Marital or partner status, social support Number of prior treatment trials Medical/psychiatric comorbidity burden
45	family history
46	hopelessness, impulsivity, akathesia
47	Depression, experienced stress, past history of SIB
48	impulsivity, mood state, dissociation

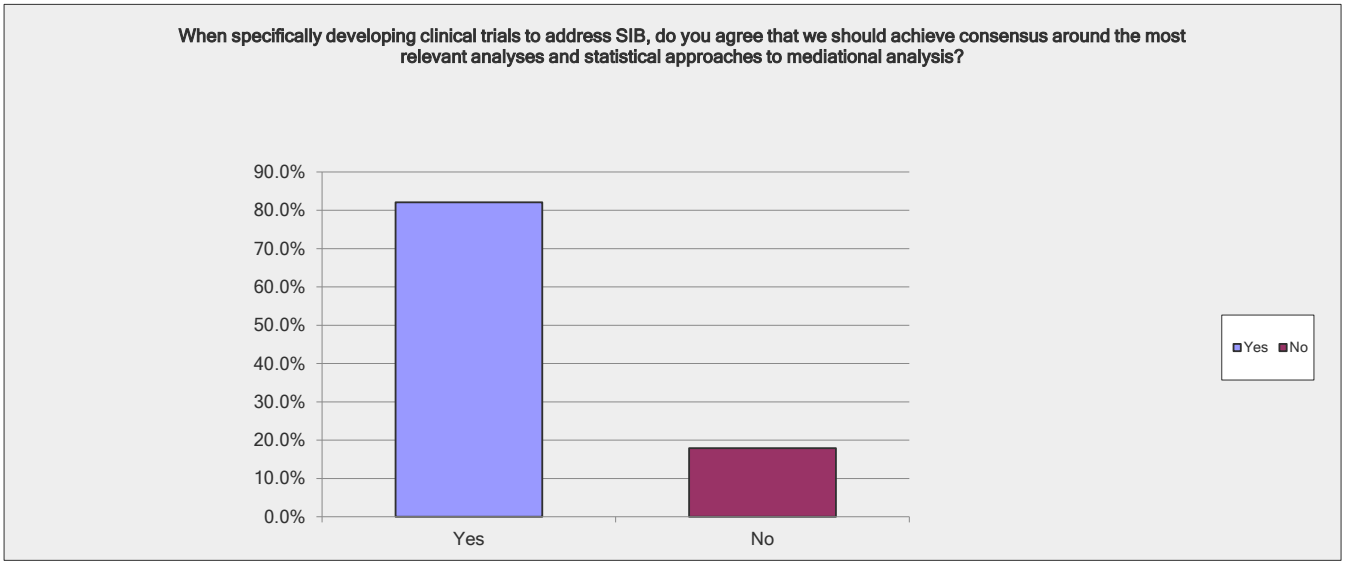
Q9.When specifically developing clinical trials to address SIB, harmonization of selected data fields to SIB mediators across different types of studies and databases (RCT, registry, administrative data bases) will need to be achieved. Name 1 or 2 steps that you would take to progress towards harmonization?

Answer Options	Response Count
	39
answered question	39
skipped question	59

Number	Response Text
1	dont know
2	Create the best instrument that is "fit for purpose" for the intended user with the expectation that utility of the instrument will be best measured by improvements in the public health.
3	Using established data sharing repositories; Requiring common elements of data collection across trials
4	no comment
5	common definitions and recordings of elements that are critical to care and potentially to SIB so the clinical burden is minimal
6	collaborate with NIMH RDoC approach
7	common lexicon/terminology for text data types
8	use of an agreed set of variables to be measured in all types of studies
9	Determine if any individuals span 2 or more of these data bases to determine relationship between different measures used in different venues for SIB
10	Use norm-based scoring (T-scores)
11	systematic collection of AE utilizing rating scales or questionnaires that may precede emergence of SIB that could be utilized across different data bases
12	Really requires international collaborative consensus including all stakeholders
13	use of same rating scales for mediators across studies
14	Standardize data collection for relevant studies.
15	I would first construct clear definitions for terms which does not result in type II or type I errors and create a training program to ensure anyone collecting the data thoroughly understood the terms.
16	operationalizing most important variables
17	define a set of common data elements specifically for SIB.
18	N/A
19	Use open non competitive fora Trans diagnostic approach
20	Leverage CDISC
21	Meta-analyses of SIB trials to investigate the validity of selected mediators Communicate recommendations for SIB study designs to the research community (e.g. ISCTM consensus guidelines)
22	Agreement as to what these are with some attempt made to actually perform statistical analysis to determine how well these actually perform.
23	collection of identifying information that can link data across studies (SS birthdate etc) Create data sharing agreement for use of SIB-related data to ensure feasibility
24	Not sure
25	Very clear definitions for ideation and behavior measures.
26	1. Stratification of all data 2. Group by background, diseases, age, or other factors 3. Analysis of groups separately 4. Meta-anaoysis of groups based on stratification 5. Descriptive overview based on 3. and 4.
27	I don't know
28	Create uniform assessment registry
29	I will need some more time to think about this.
30	Examine existing datasets to: identify if harmonization of any data elements already exists; develop crosswalks between existing similar data elements; propose which elements still need to be harmonized
31	Reach consensus on a clinical model/theory which explain suicidal ideation and behaviour; and sequentially select of a limited number of relevant SIB mediators; define unambigous terminology; select clinical tools/instrument to describe/evaluate selected key mediators.
32	Review of data by primary diagnosis Review of data by co-morbid diagnoses
33	I have no idea what this question is about.
34	standardized variable names/values item level data entry
35	Establishment of standard definitions for target behaviors (e.g., suicide attempt, gesture, lethality, degree of confidence in reliability of information)
36	consensus description based on existing longitudinal data sets?
37	obtain a list of data fields already available from each source and develop a methodology that allows for overlapping fields to be merged
38	provide operationalized definitions and locate items on specific instruments within those definitions. Definitely do not mandate that everyone must use the same instrument as choice of instrument depends on the nature of the study and the outcomes of interest
39	standardization of data fields expected standardization of content expected

Q10.When specifically developing clinical trials to address SIB, do you agree that we should achieve consensus around the most relevant analyses and statistical approaches to mediational analysis?

Answer Options	Response Percent	Response Count
Yes	82.1%	69
No	17.9%	15
answered question		84
skipped question		14



Q11.List 1 or 2 suggestions on advancing collaboration across government, academic and industry research centers to understand more proximal mediators of SIB outcomes in order to improve care and reduce safety hazards for patients .

Answer Options	Response Count
	46
answered question	46
skipped question	52

Number	Response Text
1	identification of clusters geographically to understand ideas of contagion. Inclusion of epidemiologists in SIB to guide population based understanding. partner with a delivery system with geographic connectivity to assess impact beyond the single patient.
2	Let's first decide on the population of individuals who are most likely to be responsive to and to benefit from interventions that follow from these instruments. Let's then decide to identify and test dimensional hypotheses of pain vs control, and those mediators of pain and impulsivity. Let's consider starting with substance abuse, lethal means, PTSD, and intrusive ego-dystonic thought as possible mediators.
3	Establishing data sharing repositories, attending suicide research meetings
4	no comment
5	Publically funded epidemiological studies or "big-data" analysis of administrative databses
6	Better "Gold Standard" instruments
7	Industry should agree as a group and sell it to govt and academia
8	collaborate with NIMH RDoC approach consider what current data bases can be mined
9	develop e-technology that allows integrated capture of healthcare information and integrated database to track proximal mediators (which can subsequently inform clinical intervention approaches)
10	having an agreed set of variables to measure, and an agreed framework for analyzing the findings
11	Shared gov't industry funding of studies Shared de identified data base
12	broad cross-sectional surveys analyzed with SEM
13	Since the FDA recieves data from pharmaceutical companies would it be possible to utilize aggregated data from various studies to study SIB mediators?
14	Standardized reporting algorithm both clinically and statistically.
15	A network of all the above stakeholders needs to be established and funded.
16	Propose working group with publication of suggested analytic methods with purpose/advantages/disadvantages of each
17	developing validated instrument and using them consistently across studies
18	Standardized nomenclature and classification system Standardized terms and definitions for proximal mediators
19	Comprehensive epidemiology studies of SIB.
20	Create datasets that allow patient input on if a particular mediator is either a protective or a 'risk' factor for a particular patient. In addition, we need to look at patterns of these items being either either a protective or 'risk' factor in each separate suicidality disorder.
21	common data elements
22	Develop a national database for which any sponsor can contribute their data (similar to the TBI initiatives, eg, IMPACT)
23	Use open fora to discuss
24	Free research access to all trial data bases after original generator of the trial has completed first round of analyses Create a separate NIMH sponsored data base of SIB trials for free access for r researchers who have contributed to the data base
25	specific symposium focused on this with various parties invited; open and not limited to ISCTM members
26	Require data sharing for SIB-related information Create standard patient identification rubric
27	Explore specific conditions that might be vulnerable
28	Clear definitions of subgroups and risk factors to be identified.
29	Open and transperant discussion regardless government, academic or industry. ISCTM group work is quite valuable. Frequent F2F meetings could accelerate collaboration, though all involved people are very busy.
30	I don't know
31	Clarify funding mechanisms and intellectual property
32	work/grants to do research in genetically more homogenous high risk-ultra high risk populations for elucidation of genetic and epigenetic risk and its transmission
33	Collaboration would be advanced if there is a consensus on one instrument with excellent measurement properties that can be used across all indications. Maybe having subcategories that can be relevant per indication.
34	Engage key stakeholders around a focused project, such as developing recommendations for data harmonization. Include the National Action Alliance for Suicide Prevention.
35	Increase awareness in the public and within the medical and scientific communities that death by suicide is a preventable outcome.
36	Consensus meeting in North America with relevant stakeholders; discussion in Europe with relevant umbrella organisation e.g. WHO
37	Holding ISCTM Consensus meetings attended by representatives from the FDA and EU regulatory agencies, as well as other important stakeholders.
38	1. well, working through organizations such as ISCTM is a good one. 2. ASENT is another organization to do this, and is focused on translational research in neuroscience.
39	EHRs could give reminders about suicide risk when information related to it is entered.
40	Large observational studies Integration of suicide hotline data through standardized data colleciton
41	I think it would be useful to organize one or more conferences on some regular schedule (e.g., annually) to bring these diverse constituencies together and establish a process for generating ideas and initiatives for partnerships, e.g. precompetitive consortia along the lines of ADNI (albeit initially on a smaller scale)
42	This is a tenuous comparison, but a MATRICS-like effort to define common relevant domains and methods.
43	use available data from completed projects such as STOP to inform what sort of medication related side-effects can need to be monitored to reduce SIB
44	Advisory boards including members from each group as well as stakeholders
45	having studies that show impact should help with more universal implementation
46	The FDA can conduct a meta-analysis of their existing data from submissions. Need to involve FDA in producing the analysis and sharing with industry.

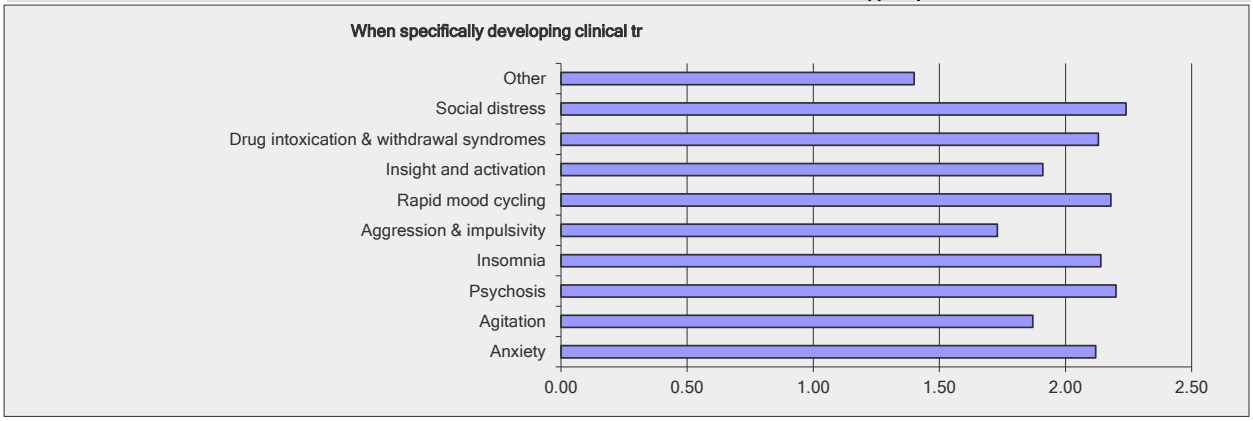
Q12.What information is needed in order to fully describe critical periods for suicidal behavior as it relates to dose titration, dose maintenance, drug withdrawal?

Answer Options	Response Count
	46
answered question	**46**
skipped question	**52**

Number	Response Text
1	dont know
2	Frequency, severity, duration, recurrence.
3	no comment
4	Time of first dose, time since last dose and dose
5	Frequent assessments - weekly
6	Life events, stress - this will be difficult - individual differences in responses to stressors
7	do not understand the question sorry
8	natural history of time course of risk
9	what are all other treatments being offered possible precipitating psychosocial events medication adherence
10	can e-technology track patient's behaviors daily throughout titration and withdrawal periods especially? daily prompt question - "how are you feeling today?" or "have you had any distressing thoughts or feelings today?'; during maintenance, in addition to the standard monitoring periodic checks, could there be a means for patients to trigger an entry if they experience distressing thoughts/feelings or a change in how they feel
11	sufficiently frequent assessments of SIB so that tight correlations can be derived from the data
12	Pharmacokinetics
13	more frequent evaluation, ie, collect what you can on handheld device
14	Time to change in lab values, rating scale thresholds
15	Technologic real-time real-time reports by study participanrs
16	dose response relation time to first thoughts etc
17	Day/time of last dose, adherence to dosing
18	prospective studies of patients at risk
19	Standardized methods for patient documentation of - affect, mood, sleep, eating patterns, physical symptoms (e.g., headaches), cognitive changes, cognitions (e.g., ideations, intent), anxiety levels, cravings, agitation, etc.
20	Dosing intervals and dose changes.
21	A classification system for suicidality phenomena, suicidality events, and suicidality disorders is needed to more fully describe such critical periods for suicidal behavior. Only when these three concepts are investigated separately can we rely on any conclusions from the data.
22	suicidal ideation suicide intent
23	a combination of data from various trial designs, such as RCT, open-label extensions with controlled withdrawal periods.
24	PK characteristics; titration scheme, time to steady state, ...
25	Data from previous literature
26	Tmax and half life of the drug
27	longitudinally collected scale and large population
28	This will be disease specific, also patient population specific and well as drug class or molecule specific.
29	Pharmacology of the drugs Mental history of subject Recent social history of subject
30	full dosing information including co-administration of other drugs. withdrawal associated suicidality may be largely underestimated due to reporting bias.
31	Retrospective information identify area to study prospectively.
32	MOA and impact on behavior and mood
33	Any deviations from treatment regimen.
34	Everything? Background, medical history, social condition, distress, isolation, and current condition. Sorry, I wonder if I do not understand the purpose of this question.
35	Drug withdrawal and discharge from hospital
36	Clinical and demographic characteristics, rating scales, history
37	information on the population that goes into such a trial should be more complete, as typically it is not there...it is way before any of 'critical periods'
38	If subject was enrolled in prior trials, progression through those trials can help determine critical periods. However, analysis can be done with prior datasets to make this determination.
39	Findings from longitudinal studies on the time-course of suicidal ideation and behaviour, and associated relevant risk factors following an important SIB event (i.e. suicide attempt, hospitalisation to prevent suicidal behaviour, etc) are critical to design acute management and maintenance trials to evaluate therapeutic intervention.
40	Pt social circumstance, FH of suicide / suicidality, past history of suicide/suicidality
41	This question is not clear. Suicidal behavior is often a chronic condition which unfolds and develops over the lifetime of a patient. Different aspects of suicidal thinking and behavior may have different developmental trajectories (ie, SI vs SB vs non-suicidal SI vs morbid thoughts,etc). The type of information this question asks about can only be provided by long-term studies of the phenomenology and natural history of suicidal thinking and impulses, coupled with a program of treatment studies targeting different developmental phases of the condition (once described, assuming it is a "condition" or disorder with a natural history and typical developmental progression that can be explored in clinical trials). What exactly is the relevance of this question to the analysis of SIB data collected in clinical studies?
42	episode length.
43	Systematic and frequent longitudinal assessment across these critical stages in assessment and treatment.
44	one needs to monitor all this prospectively for different classes of medication without assuming that the same issues would be relevant for all medications
45	most recent or current treatment and inpatient or ED discharge; mood, life events, SIB
46	more frequent assessment

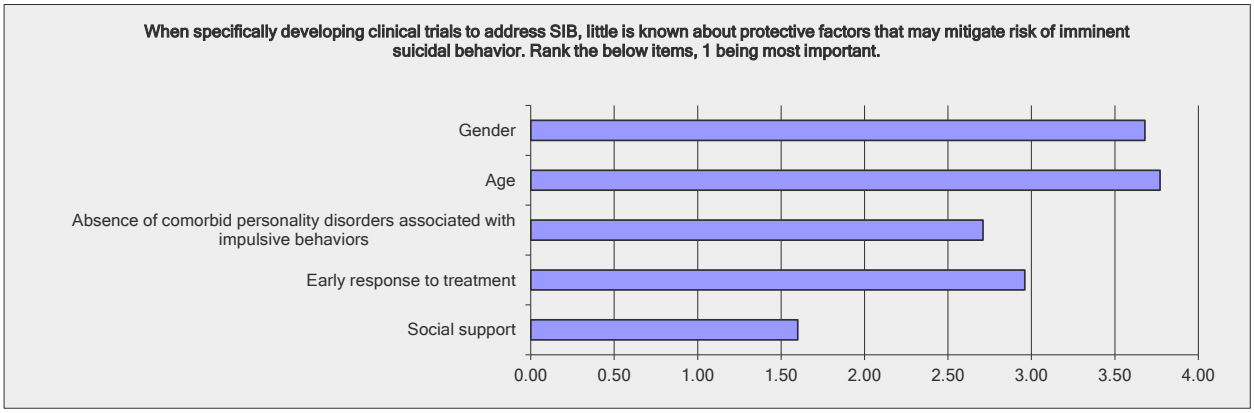
Q13.When specifically developing clinical trials to address SIB, little is known of the predictors of imminent suicidal behavior in the short term (dynamic rapidly changing short term risk factors over days or hours). Rank the top 3 items in the following list that you would consider most important.

Answer Options	Most Important	2nd Most Important	3rd Most Important	Rating Average	Response Count
Anxiety	8	7	11	2.12	26
Agitation	17	9	12	1.87	38
Psychosis	5	10	10	2.20	25
Insomnia	2	2	3	2.14	7
Aggression & impulsivity	24	22	9	1.73	55
Rapid mood cycling	6	11	11	2.18	28
Insight and activation	5	2	4	1.91	11
Drug intoxication & withdrawal syndromes	5	11	8	2.13	24
Social distress	7	11	15	2.24	33
Other	8	0	2	1.40	10
				answered question	87
				skipped question	11



Q14.When specifically developing clinical trials to address SIB, little is known about protective factors that may mitigate risk of imminent suicidal behavior. Rank the below items, 1 being most important.

Answer Options	1	2	3	4	5
Social support	54	16	9	4	1
Early response to treatment	12	20	25	9	16
Absence of comorbid personality disorders associated with	11	29	27	12	7
Age	3	9	13	35	21
Gender	7	13	11	19	32
					answered question
					skipped question



Q15.When specifically developing clinical trials to address SIB, what information is needed in order to assess the relationship of drug exposure to suicide behavior in the context of randomized controlled trials?

Answer Options	Response Count
	50
answered question	**50**
skipped question	**48**

Number	Response Text
1	dont know
2	PK, clinical assessments and accurate assessments of patient adherence to medication
3	Comparison of drug group to placebo group on suicidal behavior across the entire duration of the study
4	Pharmacokinetics and brain penetrance as secondary to time and maintenance of positive and negative pharmacodynamic effect, including follow-up beyond peak predicted ameliatory effect to include potential effects of secondary dysphoria/ withdrawal/ painful dissociation that could be indicative of an extended and undesired pro-suicidal PD effect.
5	pre-treatment history relationships to other treatment emergent adverse events
6	Drug blood levels at the time of SIB
7	Timing, context
8	dose , duration, concmmitatant meds,
9	Subject selection criteria; nature of randomized and concomitant treatments; factors biasing for or against retention of high risk subjects
10	better measurement of the mechanism of the drug target; better measurement of drug adherence
11	treatment response, duration of treatment, treatment adherence and compliance, preceding/concurrent symptoms/adverse events, comorbidities, concomitant medication (including any recent changes), psychosocial stressors, prior medication experience/other medical history
12	accurate assessment of SIB pretreatment placebo comparison cell
13	precise measurement of behavior, enough repeated measures of exposure and behaviors, enough behavioral events, and a sufficient range (low-high) of drug exposures
14	Pharmacokinetics
15	Very carefully done studies
16	Dose of drug across different age groups
17	Defining a plausible mechanism
18	genetic polymorphism
19	time/date of most recent dose, plasma PK if available
20	prospective collection of relevant data...
21	Pre-existing symptoms; prior suicidal history; prior response to drugs (including adverse reactions); prior exposure to others who engaged in suicidal behaviors; existing psychiatric disorders (and symptoms); family history of psychiatric illnesses and suicidal behaviors; history of substance abuse; history of impulsivity; history of violence; history of compliance to treatments; physical illnesses; use of other medications
22	Specifically collect timing of SIB relative to dosing.
23	We need patient input and appropriate look-back timeframes for screen / baseline data collection for comparison for each individual patient. In addition, we need to look for similar patterns across patients. To do this, the clinical trial needs to look at each phenotype or even each genotype of suicidality at a time to determine any pattern in the subgroups of subjects that experienced a change in their suicidality in response to treatment.
24	within or between groups?
25	This is very difficult as most SB will not be in the context of a setting where PK levels can be drawn. If possible, blood levels of the drug (eg PK) and SB assessments with the patient at the time of PK sample. However, the limitation is whether the patient will be able to be completely open regarding SB behavior/plans during the assessment(s)
26	PK profile, implementation of therapeutic drug monitoring
27	Quantity and frequency of substance use
28	Biological measurement of drugs in serum or other body tissue
29	For acute intervention trials: Temporal relationship of SIB and intervention For risk reduction/prevention trials: These trials need an extenened period of observational time as SIB occurs infrequently; large sample size is required for the same reason
30	appropriate study eligibility criteria, validated scale, longitudinal assessment, sufficient sample size, definition of clinically relevant treatment difference.
31	Good history and tracking of drugs and doses would help.
32	Prior drug exposure, Prior mental heath diagnoses, Family history of mental health
33	various clinical data. it is not possible to summarize everything relevant here
34	Good SIB assessment such as C-SSRS or better, eC-SSRS plus clinical assessment.
35	Frequent visits
36	Context under which SIB developed (eg, were there other stressors. etc.)
37	Change of SIB beforre and after drug exposure individualy and statistical analysis of comparison between IP and PLC as groups
38	The time relationship between drug exposure and change in suicidality ratings, in the presence of a control group to rule out non-specific changes with time.
39	adherence to treatment
40	Concentration of drug and length of exposure
41	the population that goes into the trial must be genetically characterized, the trial should be done in genetically high risk population
42	Reliable information from validated surrogate measures of suicidal behavior.
43	Context of previous suicide / suicidality and how compares with current situation; current events potentially associated with suicidal intent
44	sleep assessment, cortisol levels, psychological factors including hopelessness, psychosis, depression.
45	plasma drug levels concurrent to clinical assessments of suicide behavior -- and isn't this obvious?
46	Need to know suicide history, likely need to know a person's capacity to intentionally inflict pain on self. I would advocate for measuring more psychologically oriented variables (e.g., burden, belongingness).
47	Relative time courses of changes in different symptom domains with drug exposure, e.g. effects on anxiety, hopefulness/hopelessness, sleep, motor activity, impulsivity, etc.
48	Baseline SIB information before the medicine was started is important
49	Lifetime and baseline SIB. depression, psychosis, substance use and prior experience with potential adverse events
50	pk