Purpose of QuitSure Clinical Trial

The present clinical trial is being conducted to assess the impact of the (a) QuitSure program on short-term and long-term smoking cessation.
(b) To determine the level of engagement with the QuitSure smartphone app and
(c) To assess the feasibility of the QuitSure program

Right name to be used while conducting the trial in order to remove bias
Quitsmoking Clinical Trial.

Why is the name being used as Quitsmoking clinical trial and not QuitSure Clinical trial?

There are two groups of individuals (intervention and control group). The control group will not receive the QuitSure app program whereas they will receive doctor's (investigators) and his/her team's follow up which the intervention group will not receive. In both the cases individuals of one group should not feel that they are being deprived of the treatment or intervention modality of the other arm. The overall motto of the trial is to assess efficacy of smoking cessation through digital therapeutics and comparing the results with the conventional therapies with doctor's advice. Therefore, we can avoid this conception that we are focusing on intervention group only (which is not true). Both the arms are important for us and we can avoid such bias by calling the program as QuitSmoking Clinical Trial.

How to demarcate a regular or non-regular smoker

People who Smoke at least 1 cigarette per day on average and has smoked at least 100 cigarettes till date. That broadly means that for last 100 days a person has been smoking at the rate of one cigarette or bidi or any form of smoked tobacco for last 100 days regularly. If a person smokes occasionally and total consumed smoked tobacco in numbers does not quantify to 100 in last 100 days we will not qualify the person as a regular smoker and thus he/ she will not be included in the trial.

Why is it necessary to have regular smokers enrolled into the study?

We need to have participants who have sufficient dependence on Nicotine and also sufficient exposure to Nicotine.

(a) Should currently smoke 01 (one) or more cigarettes per day on an average: indicating sufficient dependence on nicotine.
(b) And have smoked at least 100 cigarettes (indicating sufficient exposure of the body to nicotine) on a regular basis.

How do a participant access QuitSure app?

QuitSure app is available for installation through play-store on Android and through App store on IoS platform. A participant in the intervention group is required to install the app and follow the instructions given in the app. The easy user interfaces and training materials will be guiding the participant on its own. Since the aim of the trial is to assess the feasibility of the trail, the investigator team will restrict itself to the installation of the app and registration of the participants on the spot. Following that the participants will not get any direct assistance in technical operations of the app. User feedback is also a valuable tool to assess the difficulty or ease of the following the app (QuitSure).

The process of registration will require the following things to be done:

A. A probable participant enters the clinic and comes to the reception.
B. At reception the receptionist or attendant registers the individual's basic information without asking any leading question about the status of smoking and other details and sends the individual to the doctor, who is the principal/ co-investigator (whose clinic it is) of the trail.

First level screening: At the doctor's desk

C. The doctor takes the history and finds whether he is a regular smoker or not. The doctor does not give instruction or advice to stop smoking at the consultation desk right at the moment but explains about the ill effects of smoking.
D. Then he explains that he/ she and the centre is part of a smoking cessation clinical trial.

E. The doctors clearly explain about the trial as per the contents of the consent form in English language. A participant needs to understand written and verbal communications in English only.

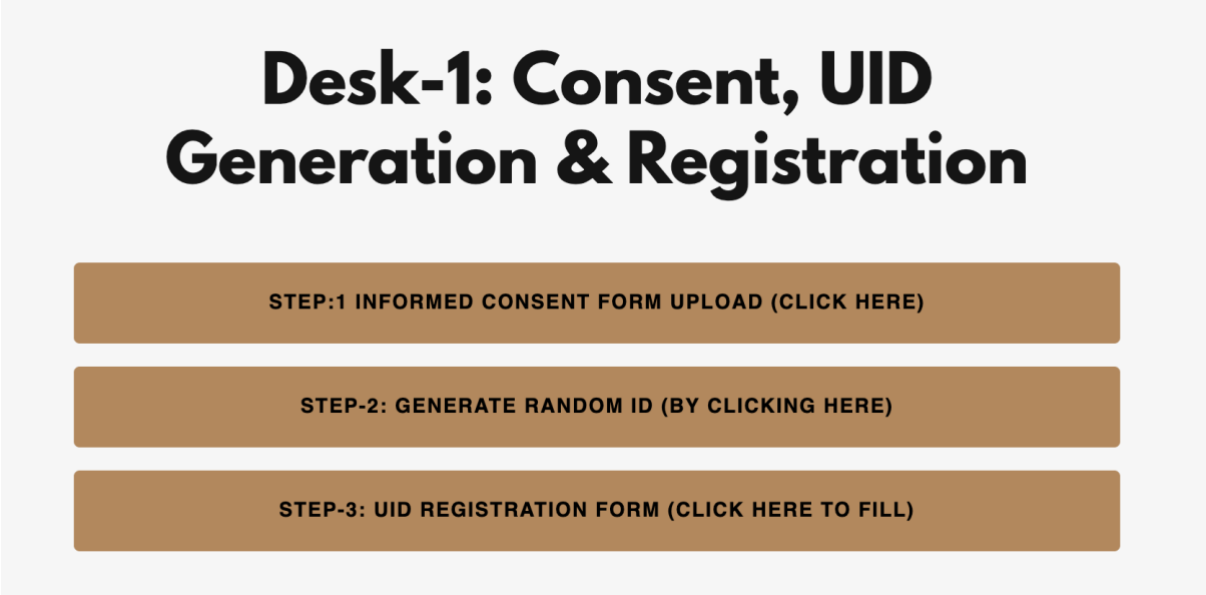
F. Once the participant gives consent he/ she will be in the screening list of the study (the inclusion and exclusion criteria will be applied in the next step). The investigator has to keep printed copies of the consent forms. All due signatures are to be endorsed onto the consent form. The investigator/ researcher, and the PI of the centre are supposed to endorse their name and signature physically on each consent form with date.

G. After the consent is taken the doctor, without knowing to which group/ arm the participant will be in, routes the patient to the interviewer at reception labelled as **'Desk-1.'**

NB:- ***consent has to be taken even before examining the participant's eligibility criteria by subjecting him/ her to multiple questionnaire followed by salivary cotinine test. In such a case, if we screen N number of participants, and x number of participants are excluded then (N-x) will be the actual participants into the trial.***

Second level screening

Desk-1: Consent, UID Generation & Registration



Step-1

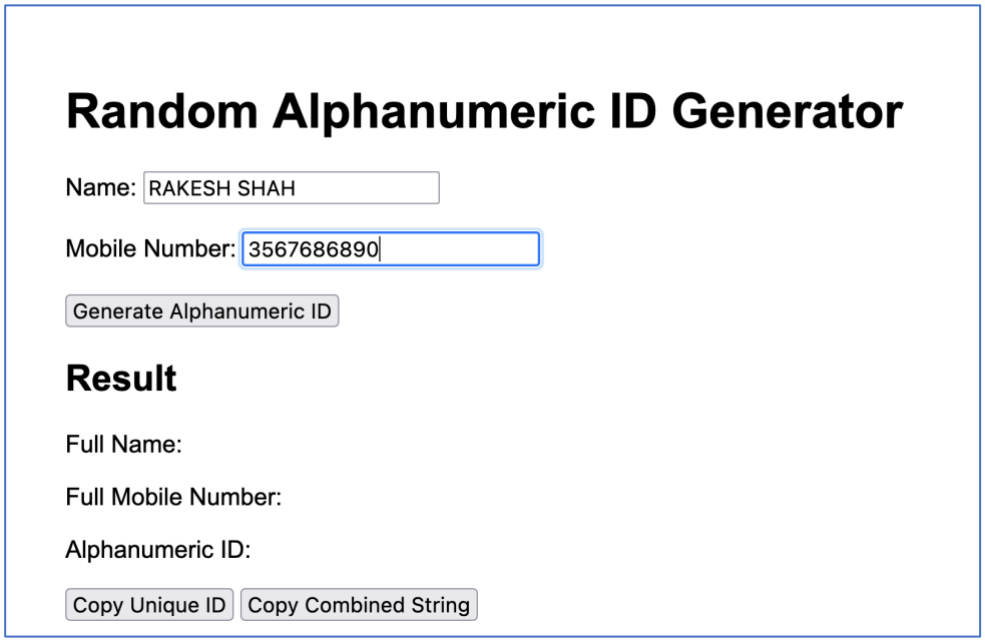
H. To upload the consent form this page of the website has to be used: https://quitsmokingclinicaltrial.in/registration

I. When clicked on Step-1 the link will take you to the Google form to upload the consent form pdf along with filling of some other details.

J. Once the consent upload form is electronically filled, with the upload of the consent form (pdf), a copy of the response is automatically shared to the investigator's email.

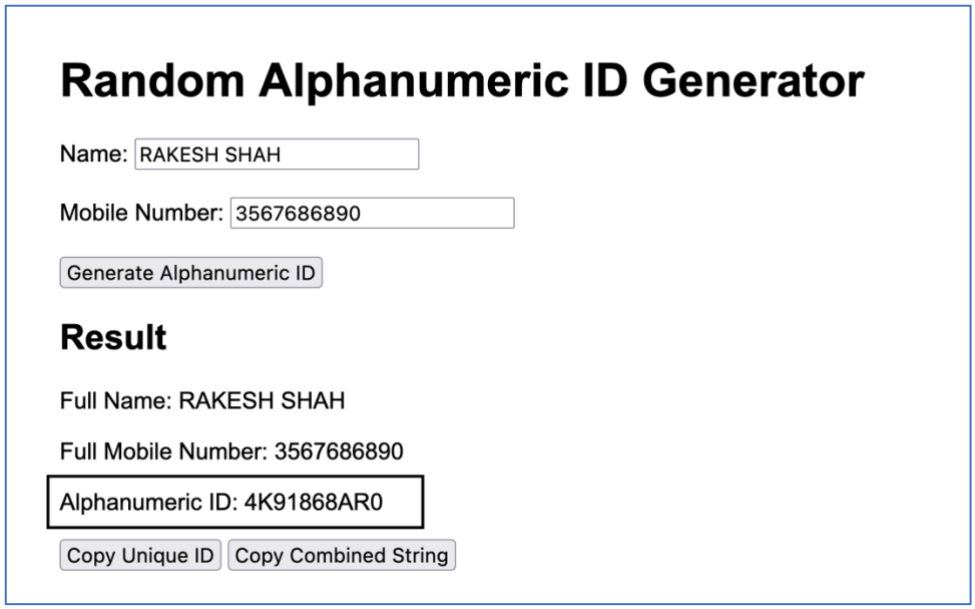
Step-2

K. Generate Unique ID: Click this to go to a section on the website where you need to put the following details to generate the UID of the patient.



L. AFTER ENTERING FULL NAME AND MOBILE NUMBER CLICK ON Generate Alphanumeric ID tab.

M. The Alphanumeric ID will be displayed like below:

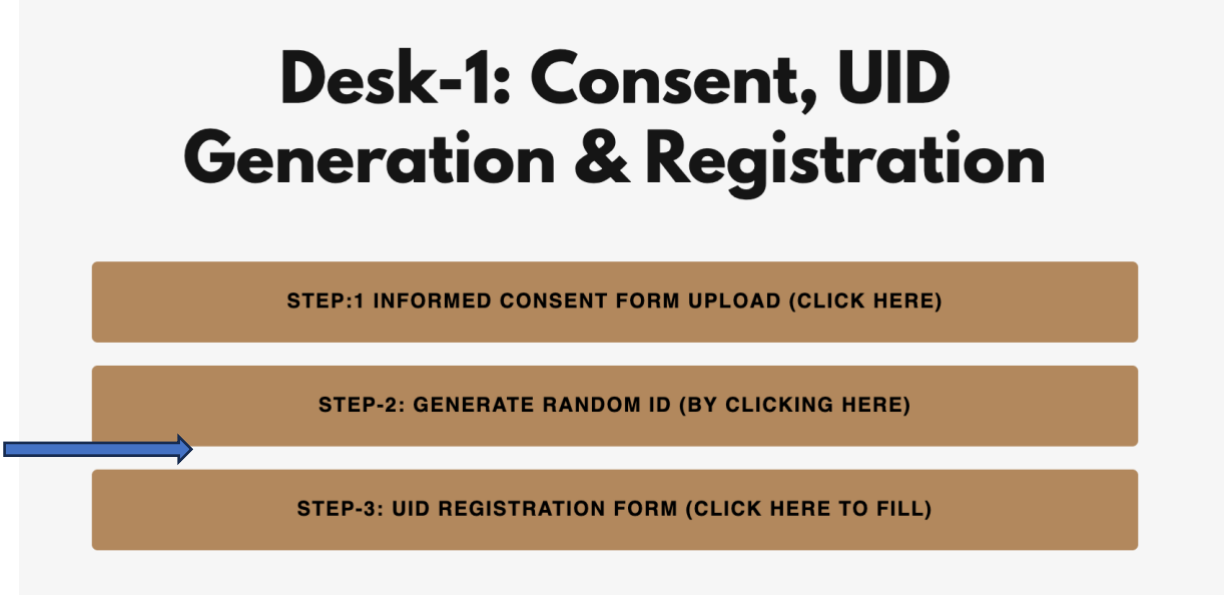


N. The investigator on desk-1 notes down this UID on a chit and gives it to the participant.

O. Then the investigator clicks on 'Copy Unique ID' tab to copy the ID on the clipboard.

Step-3

P. The investigator on desk-1 then clicks the tab: STEP-3: UID REGISTRATION FORM



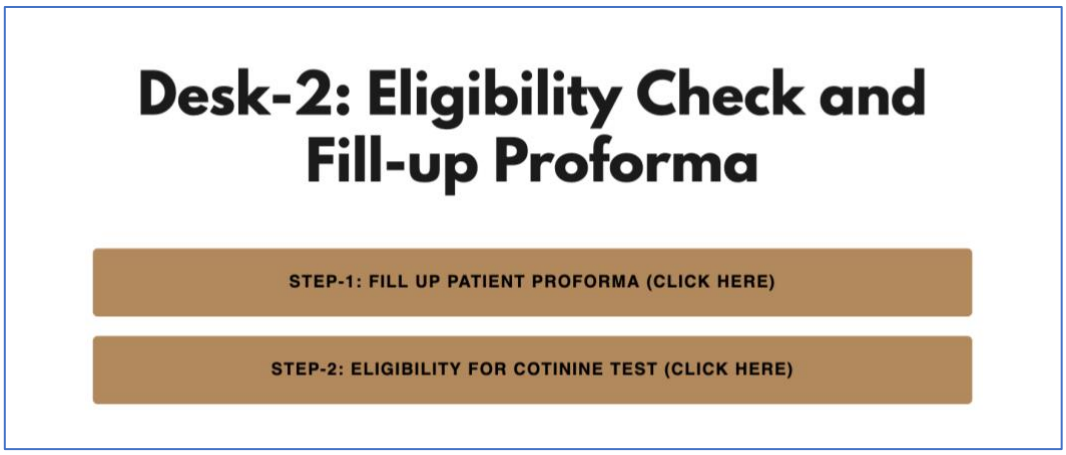
Q. Henceforth, the participant is known by his/ her random number.

R. The interviewer who registers and generates random number does not know which group the participant will be enrolled.

Third level screening

Desk-2

S. After the UID is given to the participant, the participant moves to Desk-2 where the following things need to be performed.



Step-1

On clicking the Step-1 tab, a google form opens up and the proforma is filled with the UID as identification number. Nowhere from now patient name will appear. Only the UID based registration of data has to be followed.

Step-2

Eligibility of cotinine tests is nothing but fulfilling the inclusion and exclusion criteria. The Google form is set like a Quiz. An eligible person should score 12/12 (no less than 12 is allowed as eligibility criteria). With the score of 12/12 a person is sent to Desk-3 for the conduct of Salivary Cotinine test.

Final level screening

Desk-3

T. Once all the eligibility criteria are fulfilled except the biochemical confirmation, the participant is not enrolled yet.
U. At this stage a salivary cotinine test is performed.
V. If salivary cotinine test is positive and all other eligibility criteria score is 12/12 then this final enrolment form is filled.

W. After submit button is pressed the participant is finally enrolled.

X. To upload the enrolment status the following button is pressed to upload the status.