'QuitSure Clinical Trial':

- Investigators' Training Module

Day 1 Visit:

Interaction with the doctor: ask whether willing to participate into the trial, regular smoking history confirmed. Route to desk-1-Desk 2-Desk 3

Desk-1: Consent, UID Generation & Registration.

Desk-2:Eligibility Check and Fill-up Proforma.

Desk-3: Salivary Cotinine Test and final enrolment.

Consent

- ▶ Without informed consent a participant will not be enrolled.

- ▶ All centres will keep sufficient consent forms in hard copies.

- ▶ Consent will be taken on hard copies.

- ▶ Then signed by the participant, investigator and the PI.

- ▶ Then the same will be uploaded with the following google form link:

- ▶ https://forms.gle/7fPD598kbgxazKSb9

- ▶ Convert the images taken into a single pdf and upload.

UID Generation

▶ UID is generated by the website itself

▶ If having the code.

▶ Click on the 2nd tab

▶ After clicking this you will be

Automatically directed to the

'Tools' page, where you can enter the following det... generated (next slide).

Desk-1: Consent, UID Generation & Registration

STEP:1 INFORMED CONSENT FORM UPLOAD (CLICK HERE)

STEP-2: GENERATE RANDOM ID (BY CLICKING HERE)

STEP-3: UID REGISTRATION FORM (CLICK HERE TO FILL)

UID Generator

Random Alphanumeric ID Generator

Name: [_____]

Mobile Number: [_____]

[Generate Alphanumeric ID]

Result

Full Name:

Full Mobile Number:

Alphanumeric ID:

[Copy Unique ID] [Copy Combined String]

Just copy Unique ID and it remains copied on the clipboard

After generation of UID

▶ **CLICK ON COPY UNIQUE ID TO THE CLIPBOARD**

UID Generator

Random Alphanumeric ID Generator

Name: SOUMYA NAGARAJAN

Mobile Number: 9393939393

Generate Alphanumeric ID

Result

Full Name: SOUMYA NAGARAJAN

Full Mobile Number: 9393939393

Alphanumeric ID: 3U9S39773O

Copy Unique ID   Copy Combined String

Link or Register UID with Participant Details

Desk-1: Consent, UID Generation & Registration

STEP:1 INFORMED CONSENT FORM UPLOAD (CLICK HERE)

STEP-2: GENERATE RANDOM ID (BY CLICKING HERE)

STEP-3: UID REGISTRATION FORM (CLICK HERE TO FILL)

The Aim is to enroll only those who give consent. The consent form is to be signed and uploaded on the google form. Then random ID generation is code-based and combines patient's name, mobile number and a random number combination.

Paste the UID at the respective section

Enter the Alphanumeric random Unique ID generated by the website. *

The id is generated through the website by an authorized person only. The alphanumeric random id is the unique id of the patient. The id once generated will not be identical with the same given input of the same participant. Therefore, This ID should be written on a chit of paper and entered into this section for registration. After the unique id is generated participant will be enrolled with the unique id only.

Short answer text

Name of the Participant *

Short answer text

After filling all the fields submit the form

The data goes to secured drive location & inaccessible to all researchers except the admin

De-identification→ Proforma fill up

▶ Deidentification by using a UID instead of name and mobile no.

▶ After de-identification the proforma is filled by clicking the button:

Desk-2: Eligibility Check and Fill-up Proforma

STEP-1: FILL UP PATIENT PROFORMA (CLICK HERE)

STEP-2: ELIGIBILITY FOR COTININE TEST (CLICK HERE)

Eligibility for Cotinine Test

▶ Inclusion and Exclusion Criteria except the Cotinine test have been documented as a quiz having 12 full marks. A participant qualifies for the Cotinine Test if he/ she scores 12/12.

▶ If the score is 12/12 and Cotinine Test is 'positive' then he/ she is enrolled into the trial as a participant.

▶ Until then the participants are screened not enrolled.

▶ The next step is to document this enrollement.

Final Enrolment Form

Desk-3: Salivary Cotinine Test and final enrollment

HOW TO CONDUCT SALIVARY COTININE TEST

FINAL ENROLMENT FORM

Enrolment of the participants is as per UID and not by name. It is done by a researcher who is not aware of the name and other details of the patient (Blinding).

UID based Random Group allocation

Randomized group allocation

Alphanumeric ID Analyzer

Enter Alphanumeric ID (10 bits): [_____] Analyze

Alphanumeric ID Analyzer

Enter Alphanumeric ID (10 bits): [ANF1265B8T] Analyze

Result (c): Group Y

The intervention area will have interview for two groups separately: Group X (intervention arm) and Group Y (Control arm). The alphanumeric ID analyzer uses UID of the participant and with a complex algorithm allocates him/ her to either Group X or Group Y.

Intervention Area

Group Y: Receives advices for quitting smoking and ill effects of smoking. A follow up team from the centre will call the participant on daily basis and explain the ill effects of smoking and tobacco abuse.

Group X: Receives QuitSure app and not the doctor's advice separately. The investigator at the centre helps the participant to download the app on Android or IoS phone.

The registration of the participant will be based on UID.

Intervention period: 6-10 days

A participant will be given 6-10 days time to go through the app (Group X) or Doctor's advice (Group Y).

During the app usage a participant can directly call the team of researchers/ investigators. However, there will be no additional intervention given to IG.
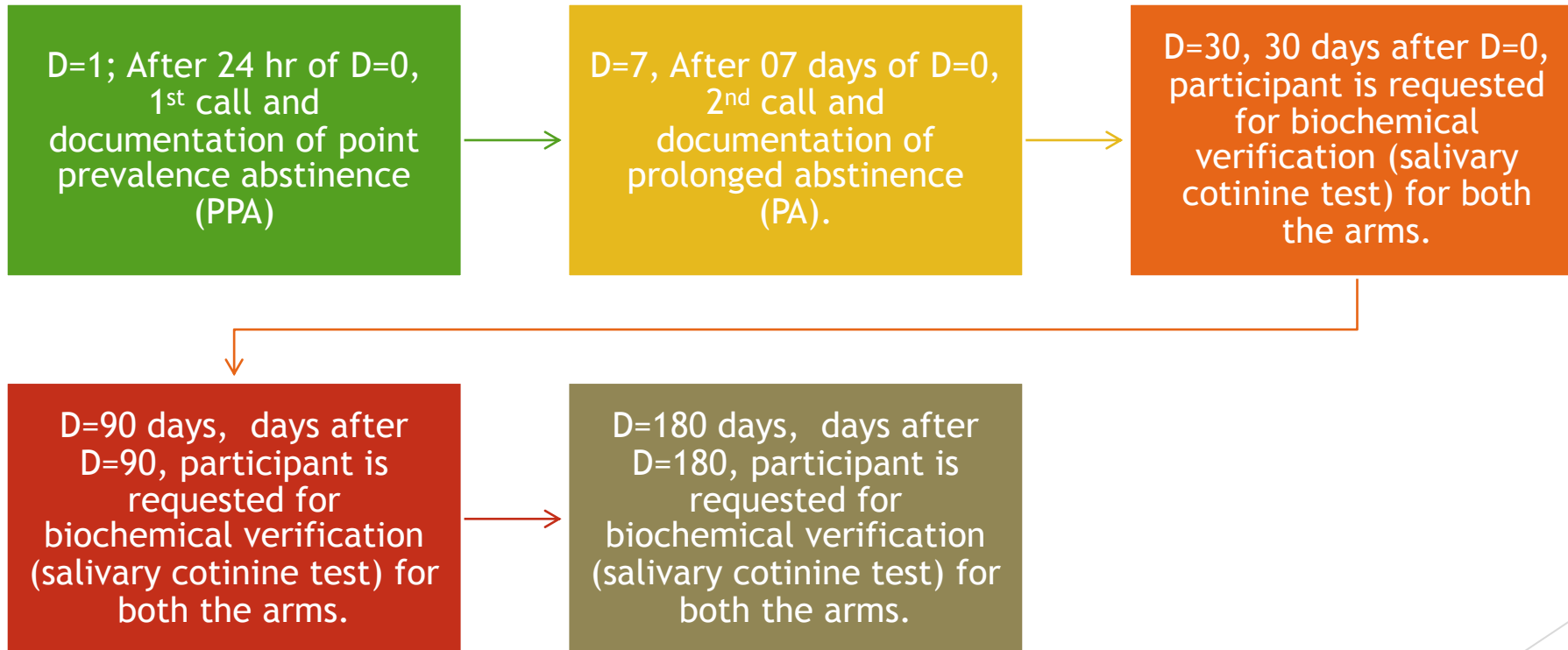

The CG will receive doctor's assistance by telephonic counseling.

Self reporting of quitting

▶ The participants will be given 6-10 days time to use the app, in between 6 and 10th day anytime the participant can call the team and self report.

▶ In case the participant does not self-report researcher team will call the participant and ask about the status.

▶ IG and CG will call their own participants and document if there is any incident of quitting.

▶ The day of quitting is documented as D=0

Follow up calls

D=1; After 24 hr of D=0, 1st call and documentation of point prevalence abstinence (PPA)

→

D=7, After 07 days of D=0, 2nd call and documentation of prolonged abstinence (PA).

→

D=30, 30 days after D=0, participant is requested for biochemical verification (salivary cotinine test) for both the arms.

D=90 days, days after D=90, participant is requested for biochemical verification (salivary cotinine test) for both the arms.

→

D=180 days, days after D=180, participant is requested for biochemical verification (salivary cotinine test) for both the arms.

Form 6: 1st Follow-up D1

Form 7: 2nd Follow-Up D7

Form 8: 3rd Follow-Up D30

Form 9: 4th Follow-Up D90

Form 10: 5th Follow-Up D180

Forms for Follow up calls

Additional Forms

Proforma:
https://forms.gle/q8c2sEJg78fVqDbx9

Consent form:

https://img1.wsimg.com/blobby/go/e8dcfc43-c826-44cd-9208-3697fb5d006b/downloads/consent%20form-1.pdf?ver=1694469606739