

ACRIN: Studies to Evaluate the Impact Of NLST Screening on Smoking Behaviors and Participant Quality Of Life

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Smoking Studies

Research Activities

- The trial is jointly administered by American College of Radiology Imaging Network (ACRIN) and the National Cancer Institute's Lung Screening Study. The 23 ACRIN sites screened 18,840 study participants.
 - At study entry, all ACRIN participants completed a detailed questionnaire providing information on their smoking history and, in the case of current smokers, their intent to quit.
 - Every 6 months ACRIN participants were asked to complete questionnaires

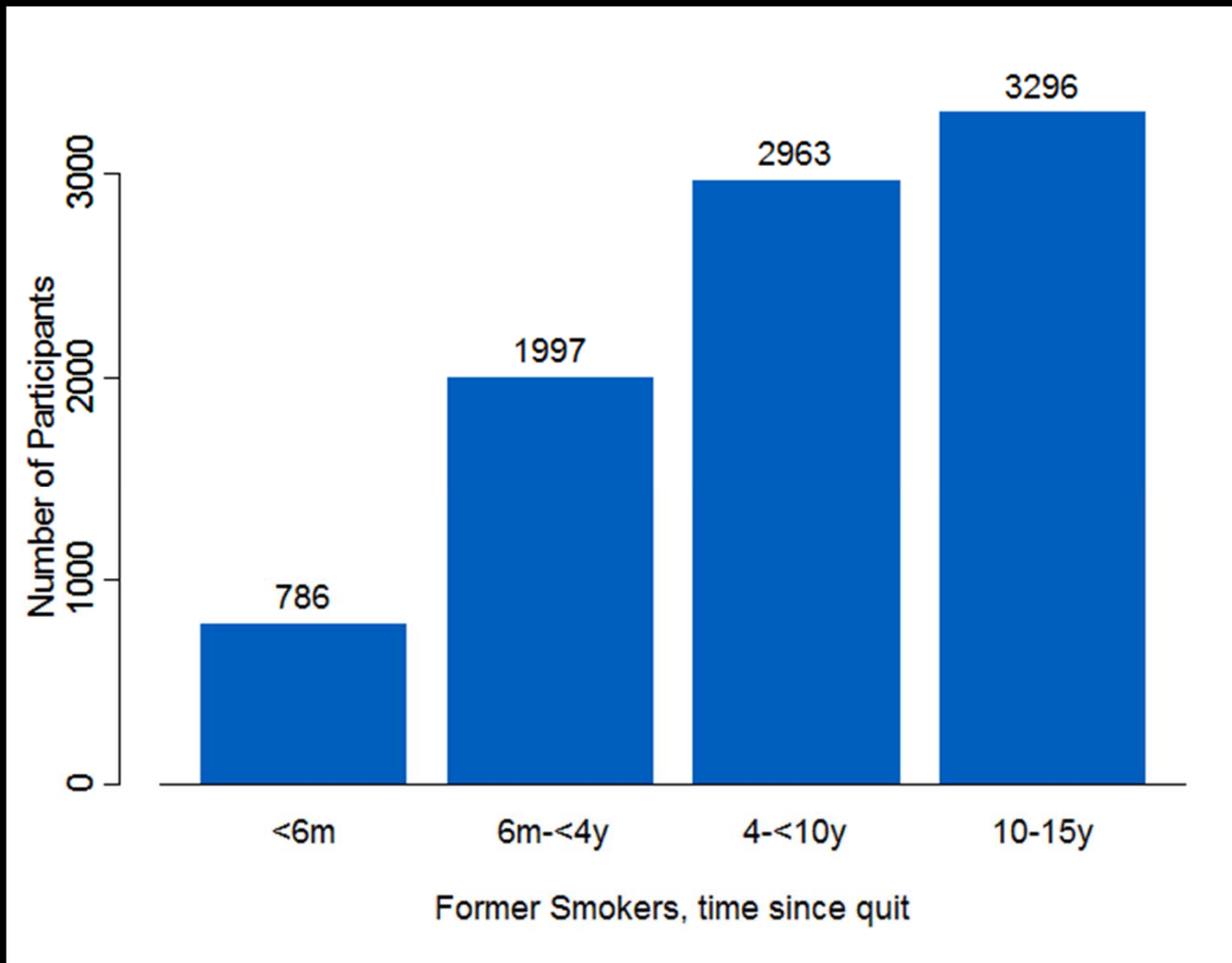
Baseline Smoking Information

- Measures associated with strength of addiction, including
 - physical responses at smoking initiation (dizziness, rush or buzz),
 - age first smoked,
 - age at start of daily smoking,
 - most cigarettes regularly smoked per day,
 - ability to refrain from smoking in inappropriate situations (e.g., church) and when ill,
 - time to first cigarette upon waking,
 - quit history ((Number of quit attempts in last 6 months and Duration of longest quit attempt)
- Fagerstrom Readiness to Quit Ladder

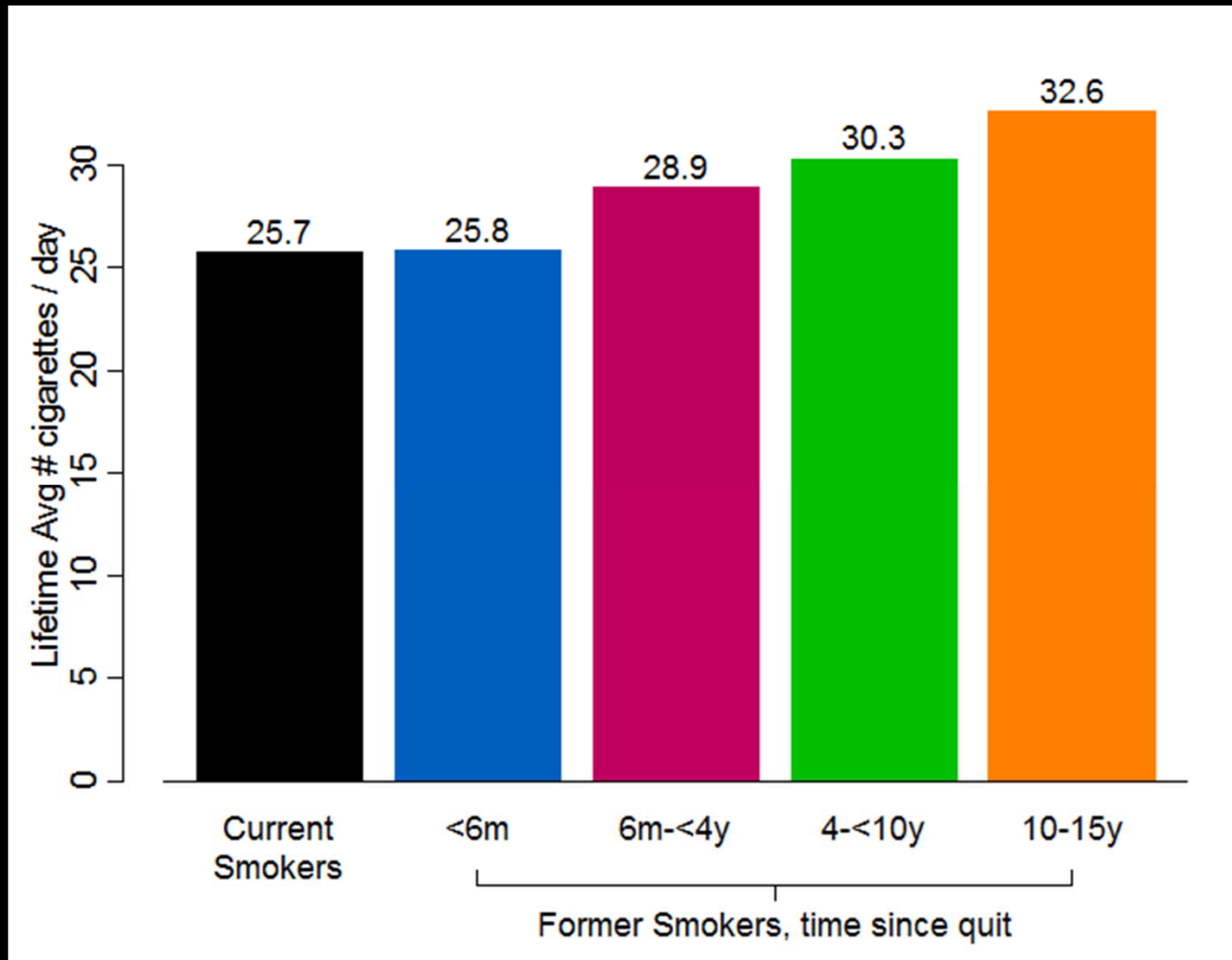
Follow-up Smoking Questions

- Asked participants for smoking behaviors in the past 6 months, including:
 - Did the participants smoke during the past 6 months?
 - Did the participants smoke at the time of completing the questionnaire?
 - How many cigarettes per day were they smoking?
 - Did the primary care provider recommend smoking cessation interventions?
 - Did the participant make any quit attempts?
- Fagerstrom Readiness to Quit Ladder

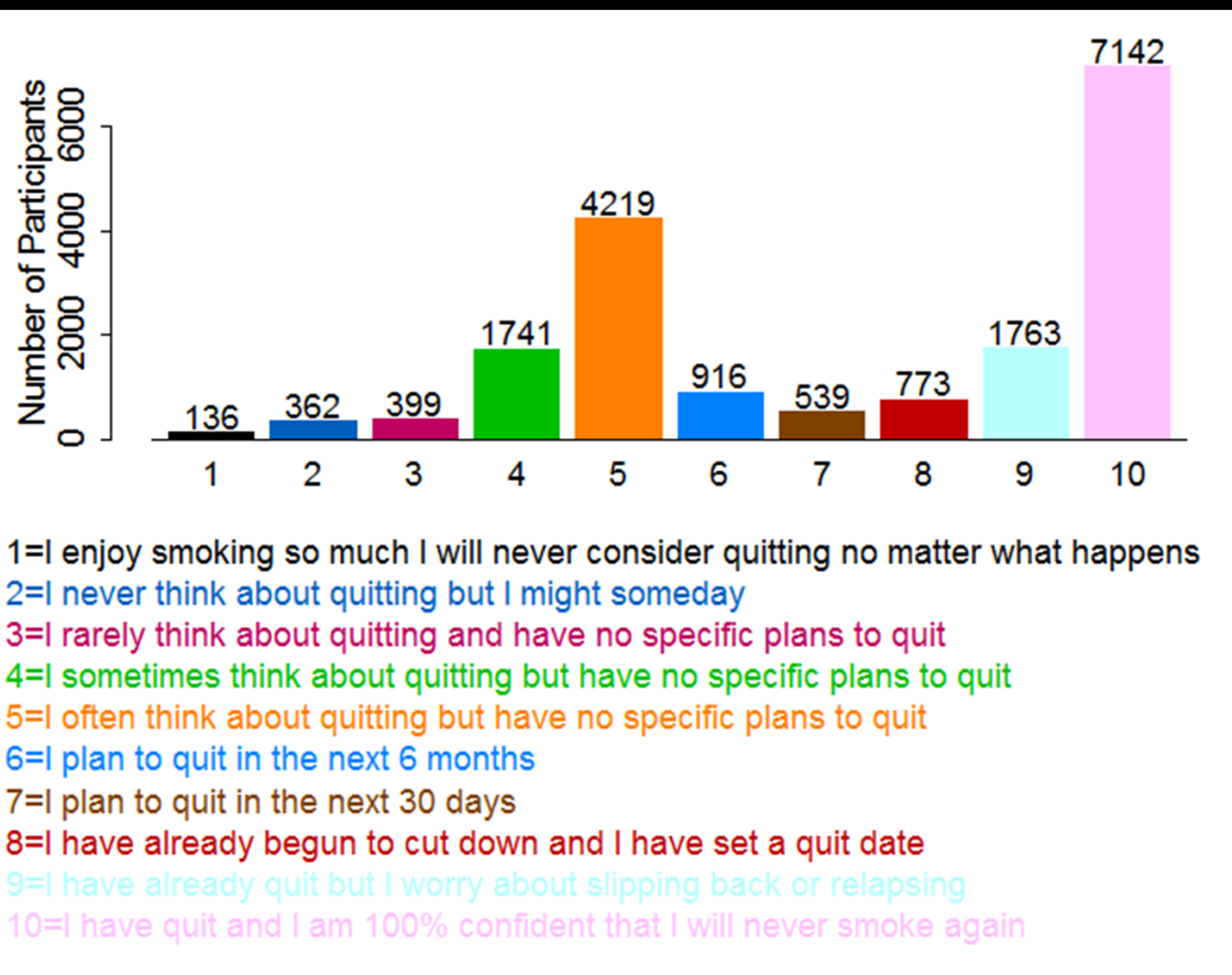
Number of former smokers by time since quit



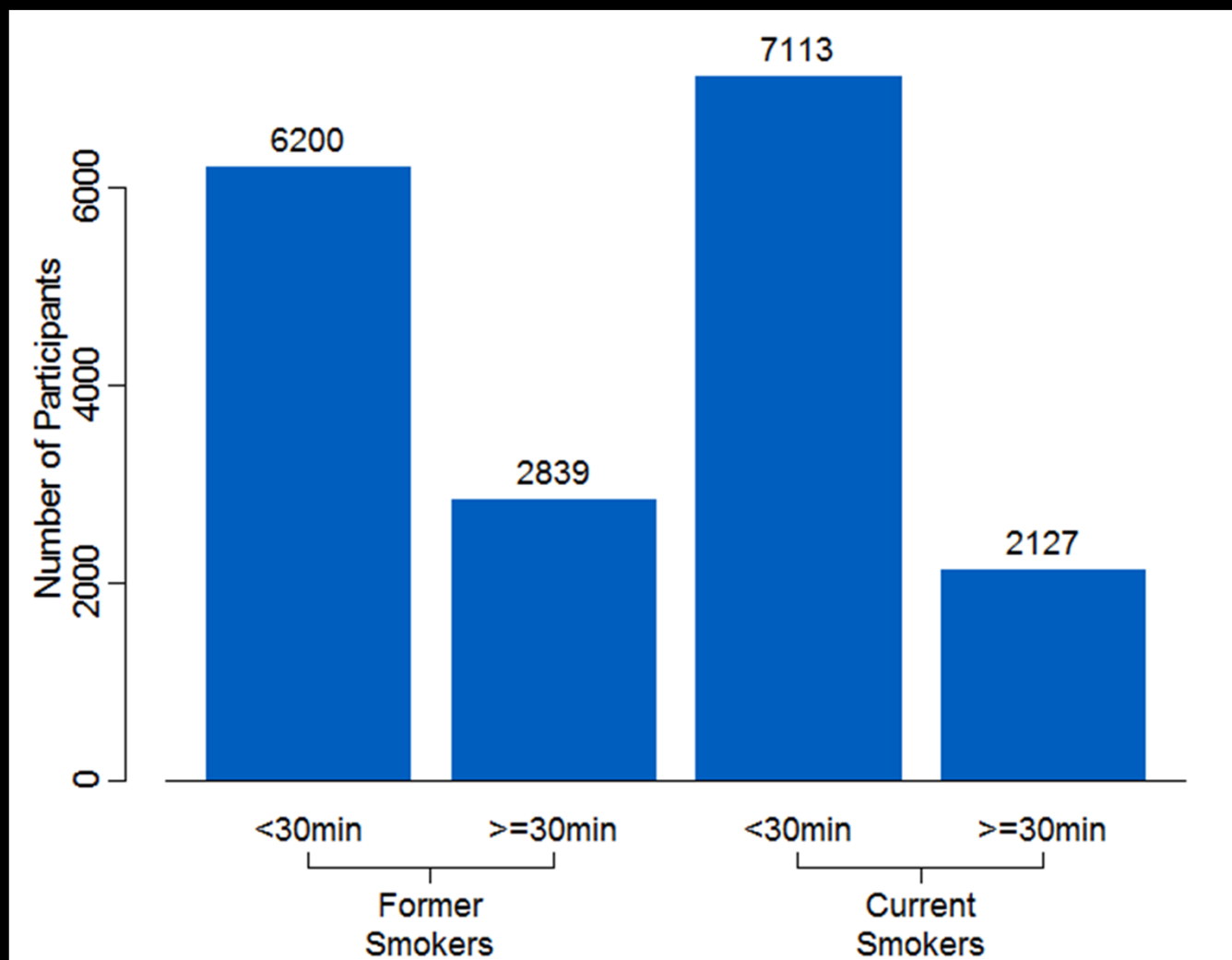
Average lifetime number of cigarettes smoked per day by smoking history



Study participant reported intention to quit smoking at baseline visit



Time to First Morning Cigarette



Quality of Life and Risk Perception Studies

Value of Quality of Life Measures

- QoL measures can be used as predictors of outcomes or behavior
- QoL measures may be used as prognostic factors
- QoL measures may be incorporated into cost-effectiveness models
- It is also possible to derive health utilities from standard health status measures

- Three studies conducted in the ACRIN arm of NLST
 - The impact of screening itself on Quality of Life
 - The impact of a positive test on Quality of Life and Anxiety
 - Lung cancer risk perception and its association with smoking cessation behaviors in a small subsample of participants

Quality of Life Is Measurement

- Used standardized questionnaires
- These questionnaires have been tested and validated
 - SF-36 to measure general health status
 - Sub-scores for specialized domains, such as physical functioning, psychological well-being, and the 5-question Mental Health Index
 - EuroQol EQ-5D and the SF-6D to measure for utilities
 - Spielberger State-Trait Anxiety Index to measure state anxiety

Short Form 36

- 36 questions are used to derive eight profiles of functional health and well-being.
 - Physical health is measured by:
 - Physical Functioning (PF),
 - Role-Physical (RP),
 - Bodily Pain (BP), and
 - General Health (GH) scales.
 - Mental Health is described by:
 - Vitality (VT),
 - Social Functioning (SF)
 - Role-Emotional (RE), and
 - Mental Health (MH) scales.

Short Form 36

- Eight health dimensions are used to derive the summary Measures.
 - PCS: Physical Component Score summarizes the physical health scales,
 - MCS: Mental Component Score summarizes the mental health scales.
- These component scores use the
 - 1998 standardized scores for the general U.S. population for each of the SF-36 subscales and the
 - 1990 factor scale coefficients are incorporated into these summary measures.

Spielberger State Trait Anxiety Index- Form Y-1, State Anxiety

- 20 question measure of state anxiety in study participants.
- The STAI-Y-1 measures state anxiety (an emotional state that is changeable in response to external conditions). High scores indicate a high level of state anxiety.
- Measured on a scale of 20 to 80. Average value for US Stai is 35. Depressed patients often have scores as much as 20 points higher.

Quality of Life Sites

- Quality of Life Sites (16 of ACRIN's 23 sites)
 - Beth Israel Deaconess Medical Center
 - Brigham & Women's Hospital-Harvard Medical School
 - Brown University
 - Dartmouth-Hitchcock Medical Center
 - Jewish Hospital Heart and Lung Institute
 - Johns Hopkins University School of Medicine
 - Mayo Clinic; Jacksonville, FL
 - Mayo Clinic; Rochester, Minnesota
 - MD Anderson Cancer Center
 - Moffitt Cancer Center; University of South Florida
 - St. Elizabeth's Hospital, Youngstown, OH
 - University of California, Los Angeles
 - University of California, San Diego
 - University of Medicine and Dentistry at New Jersey
 - University of Michigan
 - Wake Forest University

Baseline for QoL

- All participants completed the SF-36 and EuroQol EQ-5D as part of their initial series of questionnaires.
- Then a sub-set were selected to receive additional questionnaires at a later date

To determine the impact of screening itself on health status and to determine whether this impact differs across study arms

All participants at Quality of Life Sites complete SF-36 and EuroQol EQ-5D at baseline



Random sample of 1100 participants from the CT arm and 1100 participants from the CXR arm recruited at QoL sites are selected for QoL



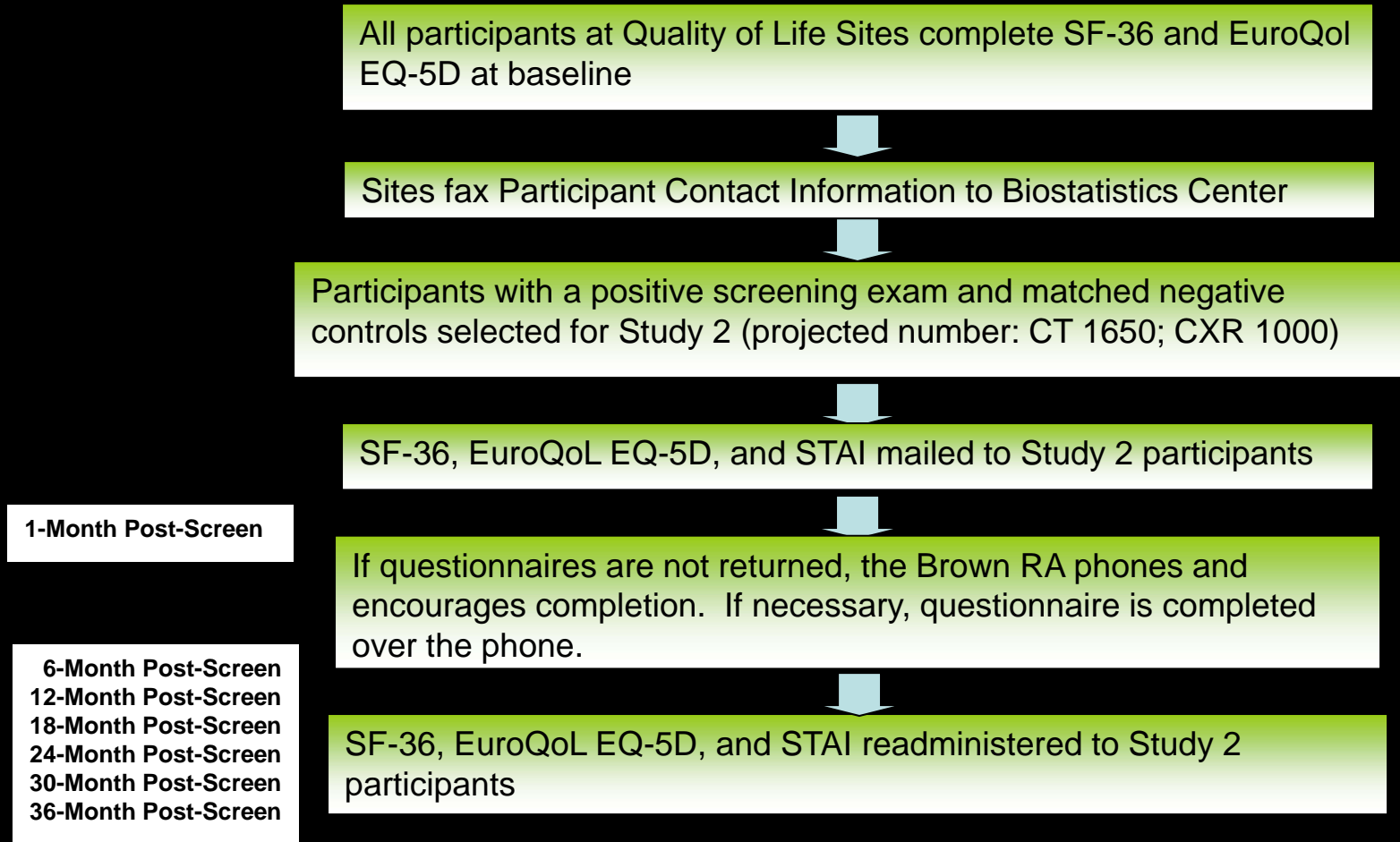
Site is notified that participant has been selected for QoL



Sites administer SF-36 and EuroQol EQ-5D to participants

T1, T2 Screening Visit

To determine in what way a positive test affects health status and anxiety and whether these effects differ across screening arm



Actual Accrual: CT Arm: 2007
CXR Arm: 902

Index positive screening examination may have occurred at T0, T1, or T2