

**Study Title:** Evaluating the effectiveness of low-dose CT based lung cancer screening among high-risk individuals and availability and impact of lung cancer care pathways

**NCT number:** Not Available

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**Project Title (Please provide a title for your project. This title will be used as the referencing name for this request moving forward on all BMS Foundation documents):**

Evaluating the effectiveness of low-dose CT based lung cancer screening among high-risk individuals and availability and impact of lung cancer care pathways.

**Request Start Date:** 01.09.2025

**Request End Date:** 31.08.2028

**Brief Description of Applying Organization (Please describe the applying organization, mission, history of relevant work/experience to improve global public health, and how the organization has demonstrated the ability to execute the proposed project) (2500 Character):**

The All India Institute of Medical Sciences (AIIMS), New Delhi, is India's premier medical institution, renowned for its excellence in medical education, research, and patient care. As an autonomous institute under the Ministry of Health and Family Welfare, Government of India, AIIMS has been at the forefront of advancing public health through groundbreaking clinical research and capacity building. Its mission is to provide exemplary medical care to all, foster innovation in medical science, and develop sustainable health solutions that address India's and the global community's most pressing healthcare challenges. With a strong commitment to equity, AIIMS is dedicated to addressing the burden of non-communicable diseases (NCDs), including cancer, by generating context-specific evidence, training healthcare professionals, and supporting policy translation.

Over the years, AIIMS has established itself as a leading center for oncological research, particularly in the domain of lung cancer, which is emerging as a major public health threat in India. The Institute has a robust track record of conducting multi-centric studies, collaborating with national cancer networks, and contributing to government policies and guidelines. It has been a nodal center for implementing cancer screening programs and evaluating their effectiveness in diverse Indian populations, which presents unique demographic, environmental, and lifestyle-related risk factors.

AIIMS has also demonstrated institutional readiness and capability in managing large-scale public health research initiatives through its extensive network of collaborations with tertiary care centers, community-based health systems, and academic partners across India. For the proposed project evaluating the utility of Low-Dose Computed Tomography (LDCT) for lung cancer screening in the Indian population, AIIMS is uniquely positioned to lead due to its clinical and research infrastructure, skilled multidisciplinary teams, and a history of impactful work in lung health and cancer control. The project aligns with AIIMS' broader goal of strengthening early detection strategies for cancer, understanding health system gaps, and optimizing care pathways for high-risk populations in India.

**Partners (Please list all collaborating partners, if relevant, and specific roles and responsibilities for each partner. If any memorandums of understanding (MOUs) have been signed, please attach in the “Attachments” section at the end of the application) (32500 character):**

The primary implementing institution, All India Institute of Medical Sciences (AIIMS), New Delhi, will serve as the central coordinating body. AIIMS New Delhi will provide overall scientific leadership, project management, data coordination, ethical oversight, and capacity building. The Department of Radiation Oncology, will lead the clinical and imaging protocol standardization, training of healthcare providers, and central data analysis.

We will select other peripheral AIIMS, JIPMER, and the Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh that will serve as regional implementation centers. These tertiary institutions, with well-established oncology and radiology departments, will be responsible for identifying and enrolling high-risk individuals, conducting LDCT scans as per the standardized protocols, and contributing data to the centralized repository. They will also support regional stakeholder engagement and community sensitization efforts to improve awareness and participation in lung cancer screening. We will also map existing diagnostic and treatment care pathways for lung cancer within their respective regions to evaluate system-level readiness for early lung cancer detection and management.

Memorandums of Understanding (MOUs) will be signed with the collaborating institutions to formalize partnerships, define roles and responsibilities, and ensure smooth inter-institutional coordination. The collaboration among these partners ensures a multi-disciplinary, multi-regional, and system-integrated approach to evaluating LDCT for lung cancer screening in India, thereby maximizing the project’s impact and scalability for national implementation.

**Executive Summary (Provide a one-sentence summary of the project concept) (32500 character):**

This multi-centric project aims to evaluate the positive predictive value of Low-Dose Computed Tomography (LDCT) for early detection of lung cancer in high-risk populations in India while simultaneously assessing the availability and effectiveness of existing care pathways for lung cancer diagnosis and management across the country.

**Program Summary (Provide an overview of the project. Include the proposed intervention, the care gap/health disparity that is being addressed, the project’s target population (target geography, disease burden, needs of the target population, and number of patients you expect to serve through this project) (2000 character):**

The GLOBOCAN 2022 report for India, suggests lung cancer as the second most frequent cancer in males, with a case count at 58,970 forming 8.5% of the entire cancer burden for males in India. Upon including females, lung cancer still figures in the top five (ranked 4th) most frequent cancers in the country with 81,748 cases which is 5.8% of the entire case load of cancer in India. LDCT is the only test to screen for lung cancer recommended by various

associations including USPSTF for the high-risk smokers in 50-80 years. There is no conclusive data on the efficacy of LDCT in screening lung cancer in the Indian population and the care pathways which might exist for individuals so diagnosed.

There is a severe lack of evidence in accounting for the utility of LDCT in screening lung cancer in India, which is largely formed by underpowered retrospective results. This study will employ a prospective, cohort design in order to evaluate the efficacy of LDCT screening for lung cancer in a high-risk Indian population.

The subject will receive a relevant and prompt Multidisciplinary team (MDT) referral if any LDCT scan is found to raise suspicions for cancer. The effective management of lung cancer relies heavily on timely diagnosis, streamlined care pathways and coordinated multidisciplinary treatment approaches. This project also aims to systematically evaluate the existence or absence of formalized care pathways for lung cancer patients within the Indian healthcare system, as part of a broader initiative assessing LDCT screening utility. The project will explore the current referral systems, diagnostic workflows, multidisciplinary team involvement, treatment initiation processes, and follow-up mechanisms in diverse healthcare settings participating in the study. By mapping these pathways, the study will identify key bottlenecks, gaps, and regional disparities affecting patient journeys from suspicion or diagnosis through treatment and survivorship.

### **Hypothesis/ Research question (PICO format)**

Low-dose CT scan screening can provide early detection of lung cancer in a high-risk population.

P: Participants at high-risk of lung cancer, I: Low-dose CT scan screening, O: Early detection of lung cancer

### **Study Objectives**

1. To determine the screen positive rate of LDCT in a high-risk Indian population in a multi-centric manner.
2. To investigate the presence and impact of a care pathways for patients screened for lung cancer.

### **Expected outcome/ Deliverables from the project i.e., what will be known at the end, if the project achieves all the stated objectives**

1. Screen positive rate of LDCT in a high-risk Indian population
2. Impact of a care pathways for patients screened for lung cancer.

### **Methodology**

**Goal 1:** To determine the screen positive rate for LDCT in the early detection of lung cancer in a high-risk Indian population in a multi-centric manner.

This three-year multi-centric study aims to determine the screen positive rate of Low-Dose Computed Tomography (LDCT) for early detection of lung cancer in a high-risk Indian population. The study will enroll a total of approximately 1,716 participants, with 156 patients recruited from each of nine peripheral centers alongside 312 from the lead center, Dr. BR Ambedkar Institute Rotary Cancer Hospital, totalling ten participating sites. These centers, primarily Institutes of National Importance (INIs), provide robust logistical, linguistic, and infrastructural support, enabling inclusion of participants from diverse rural, urban, and semi-urban backgrounds across different language and literacy profiles.

Participants who meet inclusion criteria including adults aged 50 to 80 years with a significant smoking history will undergo baseline Low-Dose Computed Tomography (LDCT) screening. Consenting individuals with a history of smoking at least 20 pack-years, either current smokers or those who quit within the last 15 years, will be considered high-risk based on USPSTF guidelines and included in the study. Individuals classified as never-smokers, defined as those who smoked fewer than 100 cigarettes in their lifetime and individuals currently receiving treatment for active cancer, will be excluded. Participants will undergo comprehensive baseline lung health assessments including clinical examination and questionnaire administration, followed by an LDCT scan. Participants with positive LDCT findings will be referred immediately to a multidisciplinary team (MDT) for further management.

If the baseline LDCT is indeterminate, the participant will undergo a Nodule Follow-Up CT (NFU CT). A positive NFU CT will prompt MDT referral. In cases where the NFU CT remains indeterminate, a second NFU CT will be performed. A positive result at this stage will also result in MDT referral, while a negative result will lead to re-assessment during the next scheduled screening round. This stepwise approach ensures close monitoring while minimizing unnecessary interventions.

Sample size estimation, based on a one-tailed hypothesis with a small effect size ( $d_z=0.2$ ), alpha of 0.05, and 80% power, requires 156 subjects per center to detect meaningful outcomes. Statistical analyses will begin with evaluation of sample adequacy using the Kaiser-Meyer-Olkin (KMO) test and Bartlett's test of sphericity. Items with low or ambiguous factor loadings will be reviewed for possible removal or modification. The internal consistency of study instruments will be assessed using Cronbach's alpha, targeting values above 0.70. Test-retest reliability will be examined in a subset of participants over a two-week interval using intraclass correlation coefficients (ICC). Known-group validity will be analyzed by comparing scores across subgroups defined by treatment types, cancer stages, and time since treatment. All analyses will be performed using SPSS version 26 and R software, with statistical significance set at  $p < 0.05$ .

**Goal 2:** To investigate the presence and impact of care pathways for patients screened for lung cancer.

Individuals identified as screen-positive or with indeterminate results requiring follow-up will be referred to multidisciplinary teams (MDTs) for diagnosis and treatment. These referrals will initiate a care pathways process. Each diagnosed case will be followed over a two-year period to assess the navigation of care, treatment initiation, continuity, and outcomes. Data on the time to diagnosis, type and level of healthcare facility accessed, delays in receiving care, and treatment adequacy will be captured through interviews, clinical records, and patient-reported experiences.

The study will particularly focus on identifying barriers in care-seeking, geographic disparities, and institutional gaps in structured care delivery. This implementation will provide a comprehensive understanding of existing lung cancer care frameworks and generate actionable insights for strengthening timely, coordinated, and equitable care pathways for lung cancer patients across India.

**Staff training:** All clinical and support staff will receive adequate training and evaluated for and adjusted for calibration in terms of questionnaire administration, clinical examination, LDCT interpretation and referral practice. The objective here, will be to create a sensitized, educated and trained workforce to continue identifying individuals at high-risk for lung cancer and be qualified to further train other healthcare workers in the domain.

The MDT will include the following healthcare professionals: pulmonologist, thoracic surgeon, radiation oncologist, medical oncologist, radiologist, pathologist, palliative care specialist and nursing staff. AIIMS New Delhi has staff from all these specialties housed in a common cancer centre and will play a leadership role in guiding the other institutes in establishing a similar team within their existing organizational framework. Specialised telemedicine services may also be considered in order to augment existing services at the other participating institutes. With eight core members in the MDT and nine other participating institutes, it can be estimated that about eighty professionals can be trained or upskilled by means of this project.

**Key Project Activities and Timeline (Please describe the key activities and proposed project timeline) (32500 character):**

Timeline of the project	Year 1				Year 2				Year 3			
Quarters	1	2	3	4	1	2	3	4	1	2	3	4
IRB approval, Site Setup, Hiring, and training of staff	X	X										
Subjects' enrolment, and data collection		X	X	X								
Annual scans and follow up					X	X	X	X	X	X	X	X

Care Pathways Evaluation and Patient Outcome Tracking		X	X	X	X	X	X	X	X	X	X	X
Analysis and Final Report				X				X				X

1. **IRB approval, hiring, and training of staffs (1 – 6 months):** Necessary approvals from institutional ethics committees will be obtained, followed by site setup, recruitment and training of research staffs. We will conduct the comprehensive training for all clinical, research staff and support staff involve in the study. They will be briefed on study protocols, questionnaire administration, clinical examination techniques, LDCT interpretation, referral practices, and data management. There will be special emphasis on standardise procedures across all 10 centre and calibrating staff for uniform data collection.
2. **Subject Enrollment and data collection and (4 – 12 months):** We will recruit the participants based on inclusion and exclusion criteria. A patient information sheet will be given to all participants informing study title, objective, methodology and potential benefits & harm of the study. The written consent will be taken from each participant who agreed to participate in the study based on inclusion and exclusion criteria. After the enrolment, baseline assessment will be done including clinical examination, collection of samples, and performing LDCT scan.
3. **Annual Scans and Follow-up (13-36 months):** We will conduct annual LDCT scan of study participants at mentioned intervals. For participants with suspicious findings, we will facilitate prompt MDT referrals for further assessment. We will follow-up all screen positive cases to observe clinical outcomes and care-seeking behavior
4. **Care Pathways Evaluation and Patient Outcome Tracking (4 -36 months):** We will monitor and document the care pathway for all the participants specially for screen positive cases. Those with suspicious for lung cancer will be referred to MDT and subsequent diagnostic procedures will be conducted along with available treatment modalities. Participants will be asked to adherence to follow-up recommendations.
5. **Analysis and Final Report (12, 24, 26 month):** We will analyse the collected data using appropriate statistical methods. We will evaluate the positive predictive value of LDCT and assess the presence, effectiveness, and gaps in care pathways for lung cancer patients. An interim report will be prepared at the end of each year. Final report will be prepared at the end of the study.

**Innovation (Explain the key innovative elements that differentiate this project's approach from how healthcare is currently delivered. How will this project drive innovative solutions to address unmet needs?) (32500 character):**

This study will be the first one from India exploring the use of Low-Dose Computed Tomography (LDCT) for lung cancer screening along with simultaneously assessing the effectiveness of screening and mapping the continuum of care experienced by high-risk individuals. In a situation, where most lung cancer cases are diagnosed at advanced stages with poor outcomes, this study will adopt a proactive and prospective strategy rooted in early detection and structured follow-up. The dual-objective framework of this study, screen positivity rate with LDCT among high-risk individuals in the Indian context and examining the real-world care pathways that will provide an integrated lens to assess both diagnostic efficiency and health system responsiveness.

The project is uniquely designed to capture real-time data on how patients, once screened, move through the healthcare system. By enrolling participants across ten geographically and demographically diverse centers including both peripheral and tertiary institutions, this study will ensure a representative sample that reflects India's heterogeneous healthcare landscape. The inclusion of underserved populations from rural and semi-urban regions will be a critical innovation, addressing the widespread disparities in access, awareness, and infrastructure that currently hinder equitable cancer care in India. This study design will allow for a comprehensive assessment of treatment initiation, delays, continuity of care, and patient outcomes across multiple stages of the care continuum.

This project will harness structured questionnaires to document patient experiences, care-seeking behaviors, and perceived barriers, thereby introducing patient-centered metrics into a system that traditionally underrepresents user perspectives.

In contrast to the current model of lung cancer care, where referrals, diagnostics, and treatment are often disjointed and uncoordinated, this project will use the Multidisciplinary Teams (MDTs) for all screen-positive cases. The MDT approach, although well-established in high-income settings, is yet to be systematically implemented and evaluated in the Indian cancer care framework. This study will not only deploy the MDT model but also evaluate its feasibility, timeliness, and impact in resource-constrained environments, offering a scalable strategy to strengthen care integration and decision-making.

Although LDCT has shown to reduce lung cancer mortality in large international trials, its utility in India remains underexplored due to unique risk profiles, healthcare system limitations, and differing patterns of exposure to tobacco and environmental pollutants. The generation of context-specific evidence on LDCT's predictive value, alongside insights into the current state of lung cancer care pathways, will represent a significant innovation that can reshape national screening policies and health planning.

This project will also contribute to innovation in health policy development by creating a roadmap for implementing organized lung cancer screening programs in low- and middle-income countries (LMICs). The evidence generated will serve as a foundation for drafting national guidelines and designing interventions that bridge the diagnostic and care delivery.

**Model of Care (Describe the model of care in detail. How will the proposed model of care be integrated into the overall healthcare system? How will you ensure that program participants are linked to care and receive appropriate follow-up?) (10,000 character):**

The proposed model of care for this project will adopt a proactive, patient-centered, and system-integrated approach to early detection of lung cancer and care in India. It will be designed to bridge the existing gap between early detection and timely, structured treatment, thereby addressing one of the vital challenges in India's cancer care continuum - delayed diagnosis and lack of multidisciplinary care. This model will embed systematic lung cancer screening using Low-Dose Computed Tomography (LDCT), ensuring a seamless transition from screening to diagnosis, referral, and treatment while simultaneously mapping the existing care pathways and identifying gaps.

The model will start with the identification of high-risk individuals, defined as those aged 50 to 80 years with a history of 20 pack-years of smoking, either current or having quit within the past 15 years. These individuals are enrolled at ten diverse centers across India, including nine peripheral centers and one tertiary care referral center, ensuring a wide geographic and socio-demographic representation. Participants will undergo a comprehensive baseline lung health check-up that includes clinical assessments, spirometry, anthropometry, and structured questionnaires. LDCT screening is conducted at baseline, and participants are categorized based on findings into screen-negative, screen-positive, or indeterminate. Those with indeterminate scans undergo Nodule Follow-Up CT (NFU CT) scans at defined intervals for further risk stratification. The model will ensure that individuals with positive LDCT or NFU CT findings are promptly referred to Multidisciplinary Teams (MDTs), consisting of pulmonologists, radiologists, oncologists, thoracic surgeons, and palliative care specialists, for confirmatory diagnosis, staging, and individualized management plans.

Healthcare workers at the peripheral centers will be trained in risk assessment, participant enrollment, and follow-up processes. Regular capacity-building workshops will be conducted to sensitize and equip these workers and local clinicians with updated knowledge on LDCT screening criteria, referral mechanisms, and supportive care pathways. Participants diagnosed with lung cancer will be linked to the cancer care facility for comprehensive treatment.

This model will leverage India's existing health system capabilities while addressing system-level gaps in screening, diagnosis, and treatment through data-driven and patient-informed interventions.

Will your project seek to? (Select all that apply.)

- 1. Facilitate patient, family and community education and empowerment**
- 2. Strengthen health systems and capacity**
- 3. Improve patient outcomes**
- 4. Integrate and sustain progress**

5. None

**Please describe how your project/intervention plans to improve patient outcomes (32500 character)**

This project will directly improve patient outcomes through early detection and structured integration of care pathways for individuals at high risk of lung cancer. Lung cancer remains a leading cause of cancer-related deaths in India due to late diagnosis, lack of awareness, fragmented care, and poor access to early detection tools. By introducing a systematic lung cancer screening program using Low-Dose Computed Tomography (LDCT) in a high-risk population and by assessing the availability and functionality of care pathways post-diagnosis, will aim to fill major gaps in the cancer care continuum.

This study will be the first multi-centric, prospective initiative in India to generate robust evidence on the effectiveness of LDCT in early diagnosis while simultaneously tracking patient navigation through the healthcare system. Early diagnosis will facilitate access to curative treatments like surgery, chemotherapy, and radiotherapy, which are often ineffective when the disease is diagnosed late. Early-stage lung cancers have significantly better survival rates than advanced-stage disease, and even modest increases in early detection can translate into large public health benefits. The structured follow-up mechanisms embedded in this project will help reduce the currently observed patient drop-offs after diagnosis, which are often caused by systemic fragmentation, lack of navigation services, or financial and logistical barriers.

This project will improve patient outcomes by developing and validating referral protocols that ensure participants are navigated efficiently through the care continuum. This study will also contribute to improved health equity. Lung cancer screening and follow-up services are currently accessible only in a few tertiary centers in India.

**Please describe how your project/intervention plans to strengthen health systems and build capacity to better diagnose and treat your target therapeutic area (32500 character)**

This project will significantly strengthen the Indian healthcare system's capacity to diagnose, refer, and treat lung cancer more effectively and equitably. The project will reinforce system-wide capacity through several interlinked mechanisms, beginning with the establishment of a structured, multi-centric lung cancer screening protocol using LDCT Chest. By introducing this model, the project will create local diagnostic capabilities at peripheral institutions that currently lack comprehensive lung cancer screening programs. Radiologists, technicians, and clinicians at these sites will be trained to conduct, interpret, and act upon LDCT scans based on internationally validated protocols adapted for the Indian context.

In addition to diagnostic strengthening, the project will establish and test referral and treatment pathways across the ten participating centers. The project will also engage in detailed mapping of existing care pathways for lung cancer and will also evaluate the diagnosis and treatment through MDT approach. This project will engage in health communication and community education to raise awareness about lung cancer symptoms, the benefits of early detection, and available services.

**Please describe how your project/intervention plans to facilitate patient, family and community education and empowerment (32500 character)**

This project will have an important component focused on facilitating patient, family, and community education and empowerment. Recognizing that knowledge gaps, cultural stigma, and fear of diagnosis often contribute to late presentation and poor outcomes in lung cancer, the project will embed community-centric educational strategies to promote awareness, improve health literacy, and empower individuals and families to make informed health decisions.

Education and empowerment will start at the level of identifying high-risk individuals. Community health workers will be trained to engage this population through interpersonal outreach, informational sessions, and one-on-one conversations in local languages. The emphasis will be on explaining the significance of early detection of lung cancer using low-dose CT screening, dispelling myths about lung cancer being untreatable or only associated with smoking, and encouraging participation in health check-ups even in the absence of symptoms.

The project will deploy culturally tailored information, education, and communication (IEC) materials that reflect the linguistic, educational, and sociocultural diversity of the participating regions. Pamphlets, posters, short videos, and audio announcements will be developed to deliver messages on the signs and symptoms of lung cancer, the benefits and safety of LDCT, and the importance of timely follow-up after a positive finding. These resources will be disseminated at primary health centers, tobacco cessation clinics, and through village-level campaigns.

Individuals who are identified as screen-positive or indeterminate will receive structured counseling at the time of referral. Counseling will include clear explanations of their scan results, the implications of a positive or indeterminate finding, the need for follow-up investigations or specialist referrals, and support systems available to them.

Family involvement will be actively encouraged, particularly in decision-making processes and treatment follow-up. The project will recognize the crucial role families play in seeking, supporting, and sustaining care. Family members will be oriented on how to support the patient, manage logistical barriers such as travel and cost, and deal with psychosocial stressors. Community-level sensitization will also address prevailing attitudes that normalize

late diagnosis due to fatalism or resource constraints, thereby fostering a more proactive and prevention-oriented mindset among caregivers and community members.

The initiative will also facilitate linkage with tobacco cessation services as part of a holistic risk-reduction strategy. Participants who are current smokers will be counselled on cessation benefits and connected with available cessation programs at the participating institutions.

**Sustainability (How is your project positioned to maintain progress upon grant conclusion? Does this have the potential to be replicated and/or scaled if successful? Describe your project's ambition to affect health policy, if applicable.) (32500 character):**

The project's strategic implementation in ten geographically and demographically diverse centers, including nine peripheral Institutes of National Importance, ensures that the findings reflect the realities of rural, semi-urban, and urban India. This diversity in representation will allow the creation of a flexible, context-responsive screening framework that can be replicated in other states and districts. The recruitment of 1,716 high-risk individuals and three annual scan will generate longitudinal data on diagnostic accuracy, patient outcomes, referral success, and gaps in the current continuum of care. This comprehensive dataset will serve as a valuable resource to inform state-level cancer control planning and national lung health strategies.

If LDCT screening proves to be feasible, acceptable, and diagnostically valuable in the Indian context, the project will advocate for its phased inclusion as a pilot program under NP-NCD or as part of a future vertical lung health initiative modelled after successful programs for oral, cervical and breast cancer screening. Cost-effectiveness data and real-world feasibility results will be compiled to guide the formulation of screening guidelines suited to India's resource settings.

This project will not a stand-alone effort, but rather a strategic demonstration model designed to influence the structural, behavioral, and policy-level determinants of lung cancer care in India.

**Monitoring and Evaluation Plan (What key indicators will be used to measure program success? How do you plan to track the progress of your program?) (32500 character)**

For the first objective, which aims to evaluate the screen positivity rate of LDCT among high risk smokers, the key indicators will be number of high-risk individuals screened using LDCT, the number and percentage of individuals with positive findings, the number and percentage of individuals with confirmed lung cancer diagnosis following a positive LDCT, and the stage at diagnosis. These indicators will provide direct insight into the PPV of LDCT in the Indian context. In addition, the timeliness of diagnostic follow-up, biopsy confirmation rates, nodule size distribution, and histopathological outcomes will be monitored to determine screening accuracy and diagnostic pathways. Data will be disaggregated by age, sex, smoking status, geographic site, and socioeconomic indicators to assess any disparities in screening yield or follow-up.

For the second objective, which focuses on investigating the care pathways post-screening, the project will track whether participants with positive LDCT findings were successfully referred to a multidisciplinary team (MDT), whether diagnostic workup and treatment plans were implemented, and the type of care received (e.g., surgical intervention, chemotherapy, radiotherapy, palliative care). Indicators such as referral success rate, time to treatment initiation, continuity of care, dropout rate from care, and documented barriers to access will be systematically recorded. Over the two-year period post first screening, we will be able to document treatment adherence, disease progression, survival rates, and patient-reported outcomes including symptom relief, satisfaction with care, and perceived quality of communication with providers.

**Monitoring and Evaluation Plan Files (Please attach supplemental materials related to the project's monitoring and evaluation activities here. Examples include a logic model [Click here for Example](#), key indicators, and data collection and monitoring plan [Click here for Template](#)):**

The monitoring and evaluation strategy for this project is designed to systematically assess the effectiveness, efficiency, and impact of low-dose computed tomography (LDCT) in the early detection of lung cancer and to map existing care pathways across India.

#### Logic Model

The logic model provides a clear visual representation of the project's inputs, activities, outputs, outcomes, and long-term impact. Inputs include LDCT infrastructure, trained clinical personnel, and partnerships with ten tertiary and peripheral centers. Activities involve community engagement, risk-based participant recruitment, baseline and follow-up LDCT scans, multidisciplinary team (MDT) referrals, and follow-up for treatment adherence. Outputs include number of participants screened, cases diagnosed, MDT referrals made, and treatment initiated. Short- to medium-term outcomes include earlier stage detection, reduced time to diagnosis, improved access to treatment, and greater understanding of care delivery gaps. The long-term impact targets include better survival outcomes and evidence generation to inform national lung cancer screening and management policy.

To monitor progress and assess success, the following quantitative and qualitative indicators will be tracked:

- Number of individuals screened with LDCT
- Proportion of positive LDCT scans
- Proportion of positive LDCT scans with confirmed diagnosis
- Stage of disease at diagnosis
- Time intervals between screening, diagnosis, and treatment initiation
- Proportion of patients completing MDT referral and initiating treatment

- Care-seeking behavior following diagnosis
- Patient-reported barriers to care and system navigation
- Loss to follow-up rates over the 2-year monitoring period
- Proportion of patients following a structured care pathway

A centralized digital data management system will be used across all sites to standardize data entry, ensure data integrity, and enable real-time tracking of participant progress. Each enrolled individual will be assigned a unique study ID. Data points will include demographic and risk factor profiles, clinical assessments, imaging results, MDT referrals, treatment details, and follow-up status. Structured case report forms (CRFs) will be used at baseline and during follow-up visits, complemented by patient surveys and interviews to capture qualitative insights.

Monthly internal reviews will be conducted to evaluate data completeness and identify gaps. Quarterly monitoring reports will be generated and shared with study partners. Training and capacity building for data managers and site coordinators will be a key feature to ensure quality data collection and protocol fidelity.

**Dissemination Plan (Provide a detailed description of the dissemination plan for effective uptake and sharing of lessons learnt from this project. Include any of the following: peer-reviewed publication plan, conference presentation or participation, dissemination of lessons learned on relevant national and international platforms, and media outreach plan) (32500 plan):**

The dissemination plan for this project will be structured to ensure broad and impactful sharing of findings related to the utility of low-dose computed tomography (LDCT) in lung cancer screening and investigate the care pathways available to lung cancer patients across India. The plan encompasses multiple channels to engage diverse stakeholders including healthcare providers, policymakers, researchers, patient advocacy groups, and the general public.

The primary dissemination pathway will involve publication of results in high-impact peer-reviewed journals specializing in oncology, pulmonology, radiology, and public health. Manuscripts will be prepared detailing utility of LDCT in early lung cancer detection in the Indian context and investigation of care pathways along with identified gaps. Publications will emphasize evidence-based recommendations for integrating LDCT screening within national cancer control strategies and healthcare delivery models.

Conference participation will be integral, with findings presented at leading national and international forums such as the annual congress of ASCO, ESMO, IASLC WCLC, and other relevant oncology and radiology symposia. These presentations will foster dialogue among

clinicians, researchers, and policymakers, facilitating translation of research into practice and stimulating further research collaborations.

Workshops and seminars will be organized for healthcare providers at participating centers and regional hospitals to build awareness and capacity in lung cancer screening and management pathways.

Community engagement and media outreach will play a vital role in increasing public awareness about lung cancer risk factors, the importance of early detection, and available care options. Collaborations with patient advocacy groups will ensure that survivor experiences and barriers to care are highlighted, fostering patient-centered policy and program development.