Informed Consent Form

Version Number: V2.0

Version Date: April 05, 2026

Informed Consent Form(Interventional Study)

Department: Department of Thoracic Surgery

Principal Investigator: Zhong Wenzhao

Project Title: Evaluation of the Effectiveness and Safety of a Locally Deployed AI Model in Multidisciplinary Team (MDT) Decision-Making for Non-Small Cell Lung Cancer: A Prospective, Controlled Clinical Trial

Patient Information Sheet

Dear Ms./Mr.:

We are about to conduct a study titled "Evaluation of the Effectiveness and Safety of a Locally Deployed AI Model in Multidisciplinary Team (MDT) Decision-Making for Non-Small Cell Lung Cancer: A Prospective, Controlled Clinical Trial," and we invite you to participate in this study. This study has been reviewed and approved by the Ethics Committee of Guangdong Provincial People's Hospital.

Before you decide whether to participate in this study, please read this informed consent form as carefully as possible. It will help you understand the study, why it is being conducted, the procedures and duration, as well as the potential benefits, risks, and discomforts that may arise from participating. If you wish, you may discuss it with your relatives or friends, or ask the doctor to provide further explanations to help you make a decision. If you are currently participating in another study, please inform the research staff.

1. Study Background and Purpose

1.1 Disease Burden and Current Treatment Status

Lung cancer has the highest incidence and mortality rates among all malignant tumors worldwide, with non-small cell lung cancer (NSCLC) accounting for approximately 85% of all lung cancer cases. For patients with stage II-IV NSCLC, treatment strategies are complex and diverse, involving the single or combined use of surgery, chemotherapy, radiotherapy, targeted therapy, immunotherapy, and other modalities. The traditional single-department diagnostic and treatment model is no longer sufficient to meet the clinical needs of these patients.

The Multidisciplinary Team (MDT) model integrates experts from multiple disciplines, including thoracic surgery, medical oncology, radiation oncology, radiology, pathology, and respiratory medicine, to collaboratively develop individualized, optimized, and continuous diagnostic and treatment plans for patients. Numerous studies have shown that the MDT model can significantly improve diagnostic accuracy, treatment adherence, survival rates, and quality of life for cancer patients. Therefore, authoritative domestic and international guidelines (e.g., NCCN Guidelines, CSCO Guidelines) strongly recommend MDT discussions for NSCLC patients.

Although the MDT model is conceptually advanced, it faces many limitations in its practical implementation and dissemination, which significantly restrict its effectiveness. First, traditional MDT processes are often inefficient and consume substantial resources. Coordinating senior experts from multiple disciplines for simultaneous meetings is logistically challenging and time-consuming. In-depth discussion of a single case often requires 10-20 minutes, making it difficult for MDT meetings to cover all patients who need discussion, thereby becoming a scarce medical resource. Second, there is variability in the quality and standardization of care. The quality of MDT decisions heavily depends on the individual knowledge, experience, and clinical practice of the participating experts. Significant discrepancies in the understanding and application of guidelines may exist between hospitals in different regions or at different levels, and even among different experts within the same hospital. This leads to "heterogeneity" or "inequity" in lung cancer care, preventing patients from receiving standardized, high-quality care across different medical institutions. Third, there is information overload and escalating decision-making complexity. With the advent of the "precision medicine" era, treatment decisions for NSCLC require the integration of an increasing amount of complex information, including detailed imaging features, pathological subtypes, PD-L1 expression levels, mutation status of numerous driver genes (e.g., EGFR, ALK, ROS1, MET, RET), and the patient's performance status (PS score) and comorbidities. Faced with such a vast amount of information to integrate, there is a risk of missing critical details or failing to adhere to the latest guideline recommendations.

Artificial intelligence, particularly machine learning and natural language processing technologies, is increasingly being applied in medicine, demonstrating significant potential in image recognition, data integration, and decision support. AI models can rapidly process large volumes of data, integrating and analyzing all structured and unstructured patient information within seconds. They perform logical reasoning based on the latest versions of authoritative international and domestic clinical guidelines,

ensuring the standardization and timeliness of decisions. Additionally, they can provide an objective, standardized decision-making reference, helping to mitigate inconsistencies arising from variations in expert experience or fatigue.

Based on these clinical needs and technological possibilities, we have developed a locally deployed AI-assisted decision-making model. This model, trained through deep learning on a large corpus of high-quality clinical guidelines, literature, and de-identified real-world data, aims to emulate a highly skilled, standardized, and tireless MDT expert team, generating treatment recommendations for NSCLC patients that align with guideline recommendations.

Currently, there is a lack of high-quality studies evaluating the role of AI models within the overall MDT decision-making process. Therefore, this study aims to conduct a rigorously designed prospective trial to perform a head-to-head comparison between the locally deployed AI model and traditional human MDT decision-making, scientifically addressing the following key questions: Can the locally deployed AI model achieve a level of decision-making comparable to, or even higher than, that of a human expert team? Can it be efficiently integrated into clinical workflows as a reliable "intelligent assistant" for physicians, ultimately improving the standardization, homogenization, and efficiency of lung cancer care?

1.2 Study Objectives

Primary Objectives: To evaluate the consistency between the plan generated by the locally deployed AI model (Treatment Plan 2) and the plan from the traditional MDT discussion (Treatment Plan 1). To evaluate the consistency between the clinician's final decision after reviewing the AI model's opinion (Treatment Plan 3) and the initial traditional MDT plan (Treatment Plan 1), i.e., the clinician's decision modification rate.

Secondary Objectives: To evaluate the impact of using the locally deployed AI model on MDT discussion efficiency (time from data collection to the end of discussion). To survey MDT physician satisfaction with the discussion process and outcomes after integrating the AI model's opinion. To preliminarily observe and compare long-term survival outcomes (Disease-Free Survival, DFS; Progression-Free Survival, PFS; Overall Survival, OS) in patients treated based on the final MDT plan (Treatment Plan 3).

1.3 Study Sites and Expected Number of Participants

The total number of participants/volunteers to be enrolled in this study is 300. Information for each patient will be assigned to both the AI local deployment group and the real-world MDT group.

2. Study Content and Procedures

If you agree to participate in this study, you will be asked to cooperate with the research staff on the following matters:

Routine MDT Discussion: All your medical information will be submitted, as usual, to the hospital's MDT expert team for discussion. The experts will develop a Treatment Plan 1.

AI Local Model Analysis: Concurrently, your medical information, with personal identifiers removed (anonymized), will also be entered into the locally deployed AI model, which will independently generate a Treatment Plan 2.

Physician Determines Final Plan: Your attending physician will simultaneously review Treatment Plan 1 (expert team plan) and Treatment Plan 2 (model plan), and considering your specific circumstances, will ultimately determine the most suitable Treatment Plan 3 for you, which will be used for your actual treatment.

Follow-up: You will receive treatment and undergo regular follow-up examinations according to Treatment Plan 3. We will collect information on your treatment outcomes and health status for research analysis. These follow-up examinations are routine procedures necessary for your disease management.

Important Note: This study will not use any investigational drugs or add any invasive procedures for research purposes. The final treatment plan is always determined by your attending physician.

During the study, we need to collect relevant data information from you, specifically including: age, sex, baseline confirmed stage, pathology reports, laboratory test reports, imaging data, genetic testing reports, treatment plans, medication dosages, etc. This information will be collected once. The relevant data information will only be used for the purposes of this project. The specimens collected this time will be used for current or future medical research.

After the results are obtained, we will follow up on your subsequent treatment. Follow-up time points will be every six months after treatment, lasting for 2 years.

3. Potential Benefits of the Study

You may receive an additional, valuable treatment perspective from the analysis of the locally deployed AI model, which could help your doctor formulate a more optimized, individualized treatment plan for you.

You will contribute to medical advancement. Your research data will help improve the diagnosis and treatment of future lung cancer patients.

4. Statement on Potential Lack of Benefit

Please be aware that participating in this study does not guarantee that you will achieve a better treatment outcome. The AI model is still in the research stage, and its recommendations may not be applicable to all patients. Some patients may not benefit from the model. Your primary contribution as a participant is providing data for medical research, rather than directly receiving a therapeutic advantage.

5. Potential Risks, Discomforts, and Inconveniences of This Project

Privacy Risk: We will collect and use your medical information. We commit to strictly maintaining the confidentiality of your personal information. All data will be anonymized (i.e., direct identifiers such as your name and ID number will be removed). When the study results are published, no personally identifiable information will be disclosed.

Decision-Making Risk: This is a decision-support study. The final treatment plan will be determined by your experienced attending physician within the MDT framework, ensuring a standard of care no less than routine clinical practice. However, as the AI model is still in the research stage, the recommendations it generates may be inaccurate or not fully aligned with the latest clinical guidelines, carrying a theoretical risk of misdiagnosis or recommendation of an unsuitable treatment plan. While the physician will use their clinical judgment to make the final decision, the AI's recommendations could still influence the decision-making process.

Data Evaluation Risk: The analysis results from the AI model have not yet undergone large-scale clinical validation. Its output may contain biases or errors, and there is currently no routine clinical evaluation process for immediate review of the AI's recommendations. Therefore, its recommendations are for reference only and should not replace the professional judgment of the physician.

The entire research process is subject to oversight by the relevant departments of Guangdong Provincial People's Hospital. If you have any questions during the study, you may consult with the research physician.

6. Privacy Protection

Your medical records (including research case report forms, laboratory and examination reports, etc.) will be kept at the hospital according to regulations. Your participation in the study and all your personal data collected during the study will be kept confidential. The results of the study, when reported, will not reveal your personal identity. Authorized representatives of the higher-level

health/regulatory authorities, the hospital's Ethics Committee, the study investigators, and the sponsor may be allowed to access your medical records to verify the clinical study procedures and/or data. We will strictly protect the privacy of your personal medical information within the scope of current laws.

7. Participant Rights

Your participation is entirely voluntary.

Voluntary Participation: You may refuse to participate in this study without affecting your relationship with your doctor or any medical care and rights you are entitled to.

Withdrawal at Any Time: You have the right to withdraw from this study at any time, for any reason, without any negative impact on your future treatment.

Full Information: You have the right to ask questions at any time during the study and request clear explanations from the research staff.

8. Costs

There are no costs associated with this study.

Finally, thank you for reading the above information. If you decide to participate in this study, please inform your doctor, who will arrange all study-related matters. Please keep this document. You may inquire about relevant information at any time. If you have any questions regarding the study, please contact your supervising physician. The supervising physician's contact number is 19068991913. If you have any questions regarding your rights in this study, please contact the center's Ethics Committee at 020-83525975.

Participant's Statement

I have carefully read this informed consent form. I have had the opportunity to ask questions, and all my questions have been answered. I understand that participation in this study is voluntary. I can choose not to participate, or I can withdraw at any time by notifying the researcher, without facing discrimination or retaliation, and without any impact on my medical care or rights.

If I require other diagnostic/treatment procedures, if I do not follow the study plan, or for other reasonable reasons, the researcher may terminate my continued participation in this clinical study.

I voluntarily agree to participate in this clinical study. I will receive a signed original copy of the informed consent form (including the Patient Information Sheet and Signature Page).

Participant's Signature: _____

Date: _____ Year _____ Month _____ Day

Contact Number: _____

Signature of Legally Authorized Representative [if applicable]: _____

Relationship to Participant: _____

Contact Number: _____

Date: _____ Year _____ Month _____ Day

Investigator's Statement

I have accurately explained the content of the informed consent form to the participant and answered the participant's questions. The participant voluntarily agrees to participate in this clinical study.

Investigator's Signature: _____

Date: _____ Year _____ Month _____ Day

Contact Number: _____