Research Title: Research on Construction and Verification of Multimodal Medical Imaging Large Model

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Research Protocol

1. Research Background

With the continuous accumulation of medical imaging, electronic medical records (EMRs), and multimodal clinical data, how to efficiently utilize multi-source medical information to achieve precise diagnosis and intelligent decision-making has become a core direction in the development of medical artificial intelligence (AI). Although traditional unimodal algorithms (e.g., models based solely on CT, MRI, or ultrasound images) have achieved certain results in specific tasks, their inability to model semantic correlations among imaging, text, and laboratory data often leads to insufficient stability and limited interpretability of diagnostic outcomes, making it difficult to meet the comprehensive decision-making needs of complex clinical scenarios.

In recent years, multimodal large models have demonstrated remarkable cross-modal understanding and knowledge transfer capabilities in natural image processing and general vision-language tasks, providing a new technical paradigm for medical AI. However, the direct application of such models in medical scenarios still faces multiple challenges: First, there are significant differences between the medical semantic system and general language models, making it difficult to accurately characterize disease features and imaging details. Second, complex lesion morphology and uneven sample distribution in medical data increase the difficulty of model generalization. Third, clinical data involves privacy-sensitive information, making data security and ethical compliance prerequisites for research.

Research on medical multimodal large models aims to comprehensively utilize multi-source heterogeneous data, including medical imaging (e.g., CT, MRI, X-ray), EMRs, and laboratory reports, to establish a unified semantic representation and reasoning mechanism, enabling end-to-end intelligent analysis covering disease identification, lesion localization, report generation, and disease prognosis prediction. This research direction not only helps improve the efficiency and accuracy of clinical diagnosis but also provides clinicians with interpretable and traceable auxiliary decision support, boasting broad clinical application prospects.

Based on the hospital's abundant clinical data resources and the research team's algorithm development foundation, this study intends to construct a multimodal large model system for medical imaging diagnosis, realizing a closed-loop intelligent analysis process from multimodal information fusion to diagnostic report generation.

During the research implementation, strict adherence to medical ethical standards will be maintained to fully protect patients' right to informed consent, privacy, and data security. To ensure the scientificity and compliance of the research design, this project must pass ethical review prior to official launch, in accordance with relevant regulations such as the Declaration of Helsinki, International Ethical Guidelines for Biomedical Research Involving Human Subjects, and Ethical Review Measures for Life Science and Medical Research Involving Humans, thus ensuring the organic unity of scientific research and ethical principles and laying a compliant foundation for subsequent clinical validation and application promotion.

2. Research Objectives

This study aims to construct a multimodal medical large model centered on medical imaging, integrating textual reports and structured laboratory data, to achieve unified modeling of multiple tasks including disease diagnosis, lesion segmentation and localization, report generation, and pathological correlation analysis. Through deep learning and validation on real-world clinical data,

this study seeks to connect the entire workflow from data collection and model construction to intelligent diagnosis, promoting the clinical translation and trustworthy application of AI in medical diagnosis.

To achieve this objective, the study plans to conduct exploration and research in the following three aspects:

Construction of a multimodal data fusion and semantic alignment

By integrating multi-source heterogeneous data such as imaging, text, and laboratory tests, a unified feature representation space will be established to realize cross-modal semantic alignment and correlation modeling. A multimodal model capable of simultaneously performing tasks including disease classification, lesion segmentation and localization, and imaging report generation will be designed, achieving a comprehensive upgrade of medical imaging intelligent analysis from "recognition" to "interpretation" and supporting the comprehensive diagnosis of multiple diseases.

Construction and pre-training of multimodal large models

Based on clinical multimodal data, a large model architecture with unified perception and generation capabilities will be designed, and research on pre-training and instruction tuning will be carried out to equip the model with general transfer capabilities for tasks ranging from disease identification and lesion analysis to report generation.

Validation of model generalization performance

The generalization performance of the model in multi-disease and multimodal scenarios will be verified to provide interpretable decision-making basis for clinical auxiliary diagnosis.

Through the above research, it is intended to construct a foundational medical multimodal model with general understanding, diagnostic capabilities, and generalization ability, expecting to promote the intelligent application of medical data, improve the efficiency and accuracy of disease diagnosis, and provide clinicians with a trustworthy intelligent diagnostic auxiliary system.

3. Research Design and Methods

Prospective Validation of a Multimodal Imaging Large Model

(I) Study Design Type and Methodology

This study is a single-center prospective observational study, aiming to conduct prospective validation and optimization of the established medical multimodal large model based on real-time collected clinical multimodal data (imaging, medical records, laboratory tests, reports, etc.). No additional interventions will be imposed on patients' diagnosis and treatment processes during the study; relevant data will only be collected synchronously during routine clinical examinations and diagnostic procedures, making it a non-interventional, minimal-risk prospective study.

During the study period, all newly diagnosed cases meeting the inclusion criteria will be consecutively enrolled. The research team will conduct prospective inference and performance validation of the multimodal medical large model based on imaging findings, EMR text, and laboratory test data, systematically evaluating the model's performance in tasks such as disease diagnosis, lesion localization, and report generation. Study results will be compared with clinicians' actual diagnostic conclusions and pathological gold standards to verify the model's generalization ability and clinical applicability in real-world scenarios.

The overall study protocol includes the following phases:

1. **Case recruitment and data collection:** Patients undergoing imaging examinations in the hospital will be consecutively recruited according to pre-defined inclusion criteria. Study data are derived from routine clinical workflows, covering imaging data, EMRs, laboratory results, and radiology reports. All data will undergo de-identification and quality control before being entered into the study database, with only the minimum necessary information retained.
2. **Model application and inference:** The research team will deploy the multimodal model in the hospital's secure computing environment. For each enrolled patient, the model will automatically generate disease predictions, lesion localization results, and diagnostic reports based on their imaging data and corresponding clinical text.
3. **Clinical comparison and result documentation:** The model outputs will be subject to double-blind evaluation by radiologists and clinicians from relevant departments, compared with the final pathological or clinically confirmed results, and the accuracy, consistency, and interpretability of model predictions will be documented.
4. **Model iteration and continuous validation:** On the premise of ensuring ethical and privacy compliance, the research team will use newly collected data for continuous model fine-tuning and validation, analyzing its stability and robustness across different disease types, devices, and operational conditions.

(II) Study Duration

The study duration is 12 months, officially commencing from the date of approval by the hospital's Institutional Review Board (IRB). The project is scheduled to start on November 15, 2026, and complete all case enrollment, data analysis, and result summarization by November 15, 2027, forming a comprehensive clinical prospective validation report.

(III) Patient Inclusion, Exclusion, and Withdrawal Criteria

Inclusion Criteria

1. Adult patients aged ≥ 18 years;
2. Undergoing imaging examinations (CT, MRI, ultrasound, etc.) in the hospital during the study period;
3. Examination items corresponding to the disease types or systems focused on by the study (hepatobiliary and pancreatic system);
4. Possessing at least complete imaging data and radiology diagnostic reports, with relevant medical record information as supplementary modalities;
5. Patients or their legal representatives signing an informed consent form, agreeing to the use of their de-identified data for scientific research model validation;
6. Case data passing quality review, with good imaging quality and standardized text records.

Exclusion Criteria

1. Patients refusing to sign the informed consent form;
2. Imaging data unassessable due to severe motion artifacts, incomplete scanning, or equipment malfunctions;
3. Severe lack of clinical data or inability to match with imaging data;
4. Special pathological cases or post-operative cases (e.g., extensive resection, significant structural changes after radiotherapy) that affect the consistency of model analysis;
5. Data samples with privacy protection or legal risks.

Withdrawal Criteria

1. Discovery of non-compliance with inclusion criteria or fulfillment of exclusion criteria after enrollment;

2. Failure of data de-identification or file corruption;
3. Patients or their legal representatives withdrawing consent during the study period;
4. Occurrence of data security incidents or ethical risks, leading to exclusion as determined by the IRB after review.

(IV) Detailed Research Protocol

Research Data Sources

Data for this study are derived from patients undergoing routine clinical examinations in the hospital during the study period. Data collection is accomplished relying on the hospital's existing information systems, without imposing additional burdens on patients or interfering with diagnosis and treatment processes. All data are real-world multimodal information generated in routine clinical practice, mainly including:

- Medical imaging data from the Department of Radiology, covering original images and reconstructed sequences such as CT, MRI, and ultrasound, as well as manual annotations, masks, or structured descriptions, which serve as reference standards for model validation;
- Radiology diagnostic reports, including examination findings, diagnostic conclusions, and physician recommendations. All images undergo unified format conversion (e.g., DICOM to NIfTI) and quality assessment before being imported into the study database, with sequences containing artifacts or defects excluded;
- Text data from the electronic medical record system, including admission records, discharge summaries, progress notes, and surgical records. Prior to import, text data undergo automated de-identification to remove sensitive information such as names, hospital admission numbers, ID card numbers, and contact information, retaining only key clinical course points relevant to the research objectives;
- Structured laboratory data from the laboratory information system, including quantitative data such as complete blood count, biochemical indicators, tumor markers, and coagulation function, which are aligned with imaging examinations via timestamps to support cross-modal feature fusion and quantitative analysis of disease states in the model.

All research data undergo rigorous de-identification before being imported into the analysis environment, with only the minimum necessary information required for the study retained. Data collection and usage comply with the Personal Information Protection Law, Data Security Law, and the hospital's ethical requirements. All patients sign a written informed consent form prior to enrollment, explicitly agreeing to the use of their de-identified data for scientific research model validation and performance optimization. The entire research process is conducted under the approval and supervision of the IRB.

Study Endpoints and Indicator System

Study endpoints are divided into primary outcome indicators and secondary outcome indicators.

Primary Outcome Indicators

1. Disease diagnosis task: Area Under the Curve (AUC), Sensitivity, Specificity, Accuracy, F1-score;
2. Lesion localization and segmentation task: Dice coefficient, Hausdorff distance;
3. Report generation task: BLEU, ROUGE, CIDEr, etc.

Secondary Outcome Indicators

1. Clinical consistency: Consistency between model-generated reports and physicians' final reports in terms of key conclusions;
2. Generalization ability: Stability of the model across different devices, disease types,

and populations;

3. Clinical efficiency indicators: Average model inference time, report generation speed, percentage reduction in physician review time;

4. Expert subjective ratings: Scale-based evaluation of the readability and clinical value of model-generated reports by physicians.

Sample Size Estimation Process

The sample size for the prospective validation of this study is determined based on statistical power analysis. Assuming the model achieves an accuracy of approximately 85% in the disease diagnosis task, compared with an 80% accuracy rate of manual diagnosis, with an expected detectable performance difference of 5%, a significance level (α) set at 0.05, and a test power (β) set at 0.2, approximately 500–600 cases per group are required according to the binomial distribution sample size calculation formula, with a total of 1000–2000 newly enrolled cases needed to meet statistical significance requirements.

Considering potential loss to follow-up or data disqualification during the prospective study, the final plan is to collect complete multimodal data (including imaging, reports, and laboratory results) from approximately 2000 patients for model validation and performance analysis. This sample size ensures the accurate evaluation of the model's stability, generalization ability, and consistency with expert diagnosis in real-world clinical scenarios at a 95% confidence level.

Statistical Analysis Procedures

This study adopts intention-to-treat (ITT) analysis as the primary analytical strategy, conducting systematic statistical analysis on data from all enrolled cases. First, descriptive statistics are performed to summarize the baseline characteristics of patients, including age, gender, disease type, and imaging equipment source. Continuous variables are presented as mean ± standard deviation or median depending on their distribution type, while categorical variables are expressed as frequencies. Inter-group differences are analyzed using appropriate statistical methods based on data characteristics: the t-test is used for normally distributed data, and the Mann–Whitney U test is used for non-normally distributed data.

In the analysis of primary outcome indicators, this study focuses on evaluating the model's performance in three core tasks: disease diagnosis, lesion localization, and report generation. For the disease diagnosis task, clinical final diagnosis or pathological results are used as the gold standard to calculate AUC, Sensitivity, Specificity, Accuracy, and F1-score, and receiver operating characteristic (ROC) curves are plotted to comprehensively assess the model's classification ability. For the lesion localization and segmentation task, expert annotations are used as references to calculate the Dice coefficient and Hausdorff distance, measuring the model's performance in lesion recognition range and boundary precision. For the report generation task, model-generated reports are compared with radiologists' reports at the text level, and natural language generation metrics such as BLEU, ROUGE, and CIDEr are used to evaluate language quality and semantic consistency.

In the analysis of secondary outcome indicators, the overall benefits of the model are evaluated from the perspective of clinical usability. Clinical consistency is measured by physician double-blind ratings and Cohen’s Kappa coefficient, assessing the consistency between model-generated reports and physicians' final reports in key diagnostic conclusions. Generalization ability is evaluated by stratifying and analyzing performance indicators across different disease types, devices, and populations to assess the model's stability in multiple scenarios. Clinical efficiency indicators are compared using the t-test or Mann–Whitney U test. Expert subjective ratings are obtained using a 5-point Likert scale, where radiology experts evaluate the readability,

clinical value, and ease of use of the model-generated reports.

4. Sample Size Calculation

This study encompasses multiple stages including retrospective model development and prospective clinical validation. Each stage has distinct objectives, leading to differences in the basis and methods of sample size estimation. This section elaborates on the basis, parameter sources, and methods for sample size calculation in each part, and clearly presents the key calculation formulas.

Retrospective Study Phase

We adopt the LLaVA-Med model as the base model and employ the Low-Rank Adaptation (LoRA) parameter-efficient fine-tuning strategy, with the task scenario focusing on medical image-text bimodal report generation and disease diagnosis. Since LLaVA-Med has already completed pre-training on large-scale image-text alignment data and possesses strong cross-modal alignment capabilities, the fine-tuning objective of this study mainly focuses on medical domain knowledge adaptation and enhancement of task-specific generation capabilities. In this context, most of the model's visual encoder and language backbone are kept frozen, with only the cross-modal interaction module and LoRA low-rank parameters updated, thereby significantly reducing the required data scale.

Comprehensively considering factors such as model parameter scale, number of modalities, task complexity, domain transfer span, and freezing ratio, and substituting the original pre-training scale of LLaVA-Med into empirical formulas, the effective fine-tuning sample size required for this study is estimated to be approximately 10,000–20,000 pairs of high-quality image-text samples. This sample size not only ensures stable semantic alignment and knowledge transfer between medical imaging and clinical text in the model but also balances the efficiency and resource controllability of LoRA fine-tuning.

Prospective Study Phase

The sample size for the prospective validation of this study is determined based on statistical power analysis. Assuming the model achieves an accuracy of approximately 85% in the disease diagnosis task, compared with an 80% accuracy rate of manual diagnosis, with an expected detectable performance difference of 5%, a significance level (α) set at 0.05, and a test power (β) set at 0.2, approximately 500–600 cases per group are required according to the binomial distribution sample size calculation formula, with a total of 1000–2000 newly enrolled cases needed to meet statistical significance requirements.

Considering potential loss to follow-up or data disqualification during the prospective study, the final plan is to collect complete multimodal data (including imaging, reports, and laboratory results) from approximately 2000 patients for model validation and performance analysis. This sample size ensures the accurate evaluation of the model's stability, generalization ability, and consistency with expert diagnosis in real-world clinical scenarios at a 95% confidence level.

5. Data Management and Confidentiality

All records related to the identities of subjects shall be kept confidential, and such information shall not be disclosed to the public except as permitted by applicable laws and/or regulations.

6. Informed Consent

Written informed consent must be obtained from subjects before implementing any research procedures. Patients shall be informed of the specific details of the study, as detailed in the Informed Consent Form. The specific process for obtaining informed consent includes: on the

premise that patients fully understand the study design and research objectives, the informed consent form shall be signed by the patients themselves and/or their authorized family members.

7. Adverse Event Reporting

(1) Definitions

- Adverse Event (AE): Any unfavorable medical occurrence (e.g., patient anxiety resulting from AI misinterpretation).
- Serious Adverse Event (SAE): An event that results in prolonged hospitalization, is life-threatening, causes death, or requires medical intervention.

(2) Reporting Procedures

- Investigators shall report AEs to the Principal Investigator (PI) within 24 hours → report to the IRB within 72 hours;
- SAEs shall be reported to the Hospital Medical Administration Office simultaneously.

(3) Handling Measures

Immediately discontinue the use of AI for the affected patient, initiate clinical remedial measures, and withdraw the patient from the study if necessary. SAEs must be reported via the hospital's internal Non-punitive Adverse Event and Near-miss Reporting System.

Signature of Project Leader:

Date: ____ Year ____ Month ____ Day

AF42 Informed Consent Form for Human Subject Research

The Second Affiliated Hospital of Zhejiang University School of Medicine

Dear Patient,

We invite you to participate in a clinical study entitled "Development and Validation of a Multimodal Imaging Large Model". Before you decide whether to take part in this study, please read the following information carefully. It will help you understand the nature, purpose, procedures, and duration of the study, as well as the potential benefits, risks, and inconveniences that may arise from your participation.

Below is an introduction to the study:

I. Research Background and Objectives

With the continuous accumulation of medical imaging, electronic medical records (EMRs), and multimodal clinical data, how to efficiently leverage multi-source medical information to achieve precise diagnosis and intelligent decision-making has become a core direction in the development of medical artificial intelligence (AI). Although traditional unimodal algorithms (e.g., models based solely on CT, MRI, or ultrasound images) have yielded certain results in specific tasks, their inability to model semantic correlations among imaging, text, and laboratory data often leads to insufficient stability and limited interpretability of diagnostic outcomes, making it difficult to meet the comprehensive decision-making needs of complex clinical scenarios.

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analysis covering disease identification, lesion localization, report generation, and disease prognosis prediction. This research direction not only helps improve the efficiency and accuracy of clinical diagnosis but also provides clinicians with interpretable and traceable auxiliary decision support, boasting broad clinical application prospects.

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This study aims to develop a multimodal medical large model centered on medical imaging, integrating textual reports and structured laboratory data, to achieve unified modeling of multiple tasks including disease diagnosis, lesion segmentation and localization, report generation, and pathological correlation analysis. Through deep learning and validation on real-world clinical data, this study seeks to connect the entire workflow from data collection and model construction to intelligent diagnosis, promoting the clinical translation and trustworthy application of AI in medical diagnosis.

To achieve this objective, the study plans to conduct exploration and research in the following three aspects:

1. **Construction of a Multimodal Data Fusion and Semantic Alignment Framework**: By integrating multi-source heterogeneous data such as imaging, text, and laboratory tests, a unified feature representation space will be established to realize cross-modal semantic alignment and correlation modeling. A multimodal model capable of simultaneously performing tasks including disease classification, lesion segmentation and localization, and imaging report generation will be designed, achieving a comprehensive upgrade of medical imaging intelligent analysis from "recognition" to "interpretation" and supporting the comprehensive diagnosis of multiple diseases.
2. **Construction and Pre-training of Multimodal Large Models**: Based on clinical multimodal data, a large model architecture with unified perception and generation capabilities will be designed, and research on pre-training and instruction tuning will be carried out to equip the model with general transfer capabilities for tasks ranging from disease identification and lesion analysis to report generation.
3. **Validation of Model Generalization Performance**: The generalization performance of the model in multi-disease and multimodal scenarios will be verified to provide interpretable

decision-making basis for clinical auxiliary diagnosis.

Through the above research, it is intended to construct a foundational medical multimodal model with general understanding, diagnostic capabilities, and generalization ability, expecting to promote the intelligent application of medical data, improve the efficiency and accuracy of disease diagnosis, and provide clinicians with a trustworthy intelligent diagnostic auxiliary system.

II. Specific Procedures and Workflow

This study is a single-center prospective observational study, aiming to conduct prospective validation and optimization of the established medical multimodal large model based on real-time collected clinical multimodal data (imaging, medical records, laboratory tests, reports, etc.). No additional interventions will be imposed on patients' diagnosis and treatment processes during the study; relevant data will only be collected synchronously during routine clinical examinations and diagnostic procedures, making it a non-interventional, minimal-risk prospective study.

The overall study protocol includes the following phases:

1. **Case Recruitment and Data Collection**: Patients undergoing imaging examinations in the hospital will be consecutively recruited according to pre-defined inclusion criteria. Study data are derived from routine clinical workflows, covering imaging data, EMRs, laboratory results, and radiology reports. All data will undergo de-identification and quality control before being entered into the study database, with only the minimum necessary information retained.
2. **Model Application and Inference**: The research team will deploy the multimodal model in the hospital's secure computing environment. For each enrolled patient, the model will automatically generate disease predictions, lesion localization results, and diagnostic reports based on their imaging data and corresponding clinical text.
3. **Clinical Comparison and Result Documentation**: The model outputs will be subject to double-blind evaluation by radiologists and clinicians from relevant departments, compared with the final pathological or clinically confirmed results, and the accuracy, consistency, and interpretability of model predictions will be documented.
4. **Model Iteration and Continuous Validation**: On the premise of ensuring ethical and privacy compliance, the research team will use newly collected data for continuous model fine-tuning and validation, analyzing its stability and robustness across different disease types, devices, and operational conditions.

Study Duration: The study will last for 12 months. It is scheduled to start on **November 15, 2026**,

and complete all case enrollment, data analysis, and result summarization by **November 15, 2027**, forming a comprehensive clinical prospective validation report.

III. What You Will Be Required to Do if You Participate in the Study

You will need to consent to the use of your medical imaging data, medical reports, and laboratory test reports generated during your hospitalization.

IV. Potential Benefits of Participating in This Study

Your participation in this study may bring no direct benefits to you personally.

V. Potential Adverse Reactions, Risks, and Risk Prevention Measures

This is a non-interventional study. It will not involve any additional procedures or tests for the research participants, and generally, there are no expected adverse reactions or risks.

VI. Statement on Costs

Your participation in this study will incur no additional costs to you.

VII. Compensation for Study Participation, Including Compensation for Injuries

As this is a non-interventional study that does not impose additional costs on participants, there will be no compensation or injury-related indemnity provided.

VIII. Alternative Options

If you choose not to participate in this study, there are no alternative study-related procedures, and your routine clinical treatment will not be affected in any way.

IX. Confidentiality of Your Personal Information

Your medical records (including study case reports and laboratory test results) will be stored in the hospital in accordance with relevant regulations. Only authorized personnel, including researchers, the Institutional Review Board (IRB), monitors, auditors, and regulatory authorities, will have access to your medical records. Unauthorized personnel unrelated to the study will not be permitted to access your records. Your personal identity will not be disclosed in any public reports of the study results. We will make every effort to protect the privacy of your personal medical information to the fullest extent permitted by law.

X. Termination of Study Participation

Your decision to participate in this study is entirely voluntary. You may refuse to participate or withdraw from the study at any time without providing a reason. This decision will not affect your relationship with your treating physicians, nor will it negatively impact your medical treatment or any other benefits you are entitled to.

XI. Institutional Review Board

This study has been submitted to and approved by the Institutional Review Board for Human Subject Research of The Second Affiliated Hospital of Zhejiang University School of Medicine, following a comprehensive review including an assessment of risks to study participants. **For inquiries regarding ethical issues and participant rights during the study, you may contact the board at the following telephone number (during daytime hours only):0571-87783759； (Chief Duty Officer) during nighttime hours:1375711836;Email Address:HREC2013@126.com**

I confirm that I have read and understood the informed consent form for this study, voluntarily consent to the research-related procedures involved in this study, and agree to the use of my medical data for the publication of study results. Signature of Subject:_____ Contact Information: Date:_____

Signature of Representative:_____Relationship to the Subject:_____Contact Information:_____ Date:_____

(if applicable)

Witness (if applicable)：_____Contact Information:_____ Date:_____

I confirm that I have explained the details of this study to the patient, including their rights as well as potential benefits and risks, and have provided them with a signed copy of the informed consent form.

Signature of Investigator: _____

Contact Information: _____(Mobile) Date:_____